ALERE INC.
Form 10-K
February 29, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTIONS 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2011.

Commission file number 000-16789

ALERE INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3565120**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
51 Sawyer Road, Suite 200, Waltham, Massachusetts	**02453**
(Address of principal executive offices)	(Zip Code)

(781) 647-3900

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934 (the Exchange Act):

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $0.001 per share par value	New York Stock Exchange
Series B Convertible Perpetual Preferred Stock, $0.001 per share par value	New York Stock Exchange
9.00% Senior Subordinated Notes Due 2016	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Exchange Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act of 1933. Yes ¨ No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ¨ No þ

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ 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 registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

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

Large accelerated filer þ	Accelerated filer ¨	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The aggregate market value of the voting common stock held by non-affiliates of the registrant based on the closing price of the registrant s stock on the New York Stock Exchange on June 30, 2011 (the last business day of the registrant s most recently completed second fiscal quarter) was $2,329,078,581.

As of February 24, 2012, the registrant had 80,289,863 shares of common stock, par value $0.001 per share, outstanding.

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ALERE INC.

FORM 10-K

For The Fiscal Year Ended December 31, 2011

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PART I

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Readers can identify these statements by forward-looking words such as may, could, should, would, intend, will, expect, anticipate, believe, estimate, continue or similar words. Readers should carefully review statements that contain these words because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other forward-looking information. We caution investors that all such forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from any projected results or expectations that we discuss in this report. You should therefore carefully review the risk factors and uncertainties discussed in Item 1A entitled Risk Factors, which begins on page 16 of this report, as well as those factors identified from time to time in our periodic filings with the Securities and Exchange Commission. We undertake no obligation to update any forward-looking statements.

Unless the context requires otherwise, references in this Annual Report on Form 10-K to we, us, our, or our company refer to Alere Inc. and its subsidiaries.

ITEM 1. BUSINESS

GENERAL

Alere Inc. enables individuals to take charge of improving their health and quality of life at home, under medical supervision, by developing new capabilities in near-patient diagnosis, monitoring and health management. Our global leading products and services, as well as our new product development efforts, focus on cardiology, infectious disease, toxicology, diabetes, oncology and women s health. We are confident that our ability to offer rapid diagnostic tools combined with value-added healthcare services will improve care for patients, lower costs to payers and help healthcare providers deliver improved clinical outcomes.

Our company, formerly known as Inverness Medical Innovations, Inc., was formed to acquire the women s health and professional diagnostics businesses of its predecessor, Inverness Medical Technology, Inc., through a split-off and merger transaction, which occurred in November 2001. Since that time, we have grown our businesses through strategic acquisitions, tactical use of our intellectual property portfolio and through organic growth. In July 2010, our company changed its name to Alere Inc. Our common stock is listed on the New York Stock Exchange under the symbol ALR.

Our principal executive offices are located at 51 Sawyer Road, Suite 200, Waltham, Massachusetts 02453 and our telephone number is (781) 647-3900. Our website is www.alere.com, and we make available through the investor center of this site, free of charge, our Annual Reports 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, as amended, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the Securities and Exchange Commission, or the SEC. We also make our code of ethics and certain other governance documents and policies available through our website. We intend to make required disclosures of amendments to our code of ethics, or waivers of a provision of our code of ethics, on the Corporate Governance page of our website s investor center.

Segments

Our reportable operating segments are professional diagnostics, health management and consumer diagnostics. Financial information about our reportable segments is provided in Note 17 of the Notes to Consolidated Financial Statements which are included elsewhere in this report.

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Products and Services

Professional Diagnostics. Professional diagnostics are generally designed to assist medical professionals in both preventative and interventional medicine, and include testing and monitoring performed in hospitals, laboratories and doctors offices and, increasingly, patient self-testing, which we define as testing or monitoring performed at home under the supervision of a medical professional. Professional diagnostic products provide for qualitative or quantitative analysis of patient samples for evidence of a specific medical condition, disease state or toxicological state or to measure response to therapy. Within professional diagnostics, we focus on point-of-care, rapid diagnostic testing and health monitoring and the developing patient self-testing and patient-self management markets. We distinguish these markets from clinical diagnostic markets consisting of large, centralized laboratories offering a wide range of highly-automated laboratory services in hospital or related settings. The point-of-care market for rapid diagnostic products includes all areas where a patient is assessed or diagnosed, including hospitals, laboratories, physician offices, specialized mobile clinics, emergency rooms, rapid-response laboratories and patient health screening locations.

In the market for rapid diagnostic products, the ability to deliver faster, accurate results at competitive prices generally drives demand. This means that, while there is certainly demand for faster, more efficient automated equipment from large hospitals and major reference testing laboratories, there is also growing demand by point-of-care facilities and smaller laboratories for fast, high-quality, cost-effective and potentially life-saving, self-contained diagnostic kits. As the speed and accuracy of these products improve, we believe that these products will play an increasingly important role in achieving earlier diagnosis, timely intervention and therapy monitoring outside acute medical environments, especially where supplemented by the support and management services that we also provide.

Our current professional diagnostic products include point-of-care and laboratory tests sold within our focus areas of cardiology, infectious disease, toxicology, diabetes, oncology and women s health. While we currently sell these products under numerous brands, as discussed below, we have begun a process of rebranding many of our products under the Alere trademark.

Cardiology. Cardiovascular disease encompasses a spectrum of conditions and illnesses, including high blood pressure, high cholesterol, metabolic syndrome, coronary artery disease, heart attack, heart failure and stroke. It is estimated that 80 million Americans alone have one or more types of cardiovascular disease. The worldwide cardiology diagnostic market, including the markets for heart failure diagnostics, coronary artery disease risk assessment, coagulation testing and acute coronary syndrome, exceeds $1.5 billion. Our Alere Triage, Alere Cholestech LDX and Alere INRatio products, all acquired through acquisitions in 2007, have established us as a leader in this market. The Alere Triage system consists of a portable fluorometer that interprets consumable test devices for cardiovascular conditions, as well as the detection of certain drugs of abuse. Alere Triage cardiovascular tests include the following:

Alere Triage BNP Test. An immunoassay that measures B-type Natriuretic Peptide (BNP) in whole blood or plasma, used as an aid in the diagnosis and assessment of severity of heart failure. The test is also used for the risk stratification of patients with acute coronary syndromes and heart failure. We also offer a version of the Alere Triage BNP Test for use on Beckman Coulter lab analyzers.

Alere Triage NT-proBNP. An immunoassay for the rapid quantitative determination of N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) in anti-coagulated whole blood and plasma specimens. The test is used as an aid in the diagnosis of congestive heart failure, the risk stratification of patients with acute coronary syndromes and heart failure, and the assessment of increased risk of cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease. Alere Triage NT-proBNP is CE marked, but is not available for sale in the United States.

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Alere Triage Cardiac Panel. An immunoassay for the quantitative determination of creatine kinase-MB (CK-MB), myoglobin and troponin I in whole blood or plasma, used as an aid in the diagnosis of acute myocardial infarction.

Alere Triage CardioProfilER Panel. An immunoassay for use as an aid in the diagnosis of acute myocardial infarction, the diagnosis and assessment of severity of congestive heart failure and the risk stratification of patients with acute coronary syndromes and heart failure. This panel combines troponin I, CK-MB, myoglobin and BNP to provide rapid, accurate results in whole blood and plasma.

Alere Triage Profiler Shortness of Breath (S.O.B.) Panel. An immunoassay for use as an aid in the diagnosis of myocardial infarction, the diagnosis and assessment of severity of congestive heart failure, the assessment and evaluation of patients suspected of having disseminated intravascular coagulation and thromboembolic events, including pulmonary embolism and deep vein thrombosis, and the risk stratification of patients with acute coronary syndromes. This panel combines troponin I, CK-MB, myoglobin, BNP and D-dimer to provide rapid, accurate results in whole blood and plasma.

Alere Triage Cardio3. An immunoassay for the rapid quantitative determination of CK-MB, troponin I and BNP in whole blood and plasma specimens. The Alere Triage Cardio3 Panel is used as an aid in the diagnosis of myocardial infarction, the diagnosis and assessment of severity of congestive heart failure and the risk stratification of patients with acute coronary syndromes and heart failure. Alere Triage Cardio3 is CE marked, but is not available for sale in the United States.

Alere Triage Cardio2. An immunoassay for the rapid quantitative determination of troponin I and BNP in whole blood and plasma specimens. The Alere Triage Cardio2 Panel is used as an aid in the diagnosis of myocardial infarction, the diagnosis and assessment of severity of congestive heart failure, the risk stratification of patients with acute coronary syndromes and heart failure. Alere Triage Cardio2 is CE marked, but is not available for sale in the United States.

Alere Triage Troponin I. An immunoassay for the quantitative determination of troponin I in whole blood and plasma specimens. The test is used as an aid in the diagnosis of myocardial infarction. Alere Triage Troponin I is CE marked, but is not available for sale in the United States.

Alere Triage D-Dimer Test. An immunoassay for use as an aid in the assessment and evaluation of patients suspected of having disseminated intravascular coagulation or thromboembolic events, including pulmonary embolism and deep vein thrombosis.

Alere Triage NGAL. An immunoassay for use in the rapid, quantitative determination of neutrophil gelantinase-associated lipocalin (NGAL) in anticoagulated whole blood or plasma specimens. Studies have shown a link between elevated NGAL levels and the later occurrence of elevated creatinine indicative of prior acute kidney injury. Alere Triage NGAL is CE marked, but is not available for sale in the United States.

Our Alere Cholestech LDX System is a point-of-care monitor of blood cholesterol and related lipids which is used to test patients at risk of, or suffering from, heart disease and related conditions. The Alere Cholestech LDX System makes it possible to provide a complete lipid profile with tests for total cholesterol, high-density lipoprotein cholesterol (HDL) and low-density lipoprotein cholesterol (LDL), triglycerides, and glucose, as well as tests for alanine aminotransferase (ALT) and aspartate aminotransferase (AST) (for liver enzyme monitoring), and high sensitivity C-reactive protein, or hs-CRP. The system can also provide coronary heart disease risk assessment from the patient s results as measured on the lipid profile cassette. The Alere Cholestech LDX System provides results in five minutes per test cassette (seven minutes for hs-CRP) and is CLIA-waived, meaning the United States Food and Drug Administration, or FDA, has waived the more stringent requirements for laboratory testing applicable to moderate or high complexity laboratories based on the Alere

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Cholestech LDX System s ease of use and accuracy. This waiver allows the Alere Cholestech LDX System to be marketed to physician offices and clinics, rather than hospitals or larger laboratories, and to be used in health screening by medical professionals.

Our Alere INRatio System is an easy-to-use, hand-held blood coagulation monitoring system for use by patients and healthcare professionals in the management of warfarin, a commonly prescribed medication used to prevent blood clots. The Alere INRatio System measures PT/INR, which is the patient s blood clotting time reported pursuant to an internationally normalized ratio, to help ensure that patients at risk of blood clot formation are maintained within the therapeutic range with the proper dosage of oral anticoagulant therapy. The Alere INRatio System is 510(k) cleared by the FDA for use by healthcare professionals, as well as for patient self-testing, and is also CE marked in Europe. The system is targeted to both the professional, or point-of-care, market, as well as the patient self-testing market. We also sell an improved version of the system, the Alere INRatio2 System, which targets the patient self-testing market through enhanced ease of use.

We also distribute the epoc® Blood Analysis System for blood gas and electrolyte testing pursuant to an agreement with Epocal, Inc., or Epocal. The epoc (enterprise point-of-care) platform is a point-of-care analysis system which provides wireless bedside blood gas and electrolyte measurement testing solutions and complements our Alere Triage products in cardiology and emergency room settings. Utilizing easy to use, low-cost disposable Smart-Cards, the epoc System produces laboratory-quality results in critical and acute care settings in about 30 seconds. The epoc System received FDA 510(k) clearance in 2006 for marketing in the U.S. and is also CE marked in Europe.

During 2010, we launched the Alere Heart Check System in Europe. The Alere Heart Check System provides a quantitative reading of BNP in 10 minutes using a fingerstick sample (12 microliters) with substantially equivalent performance to lab instruments. Initially being marketed as a point-of-care device, the Alere Heart Check System is ultimately designed for home use and is intended to enable doctors to remotely monitor BNP levels of congestive heart failure patients and adjust their therapy accordingly.

We also sell disposable, lateral flow rapid diagnostic tests for d-dimer and troponin I under our Clearview brand. These tests offer efficiency, as well as ease of use and accuracy, to clinics, hospitals and laboratories around the world.

Infectious Disease. We believe that the demand for infectious disease diagnostic products is growing faster than many other segments of the immunoassay market due to the increasing incidence and awareness of certain diseases or groups of diseases, including viral hepatitis, respiratory syncytial virus (RSV), influenza, pneumonia, tuberculosis, human immunodeficiency virus (HIV) / acquired immunodeficiency syndrome (AIDS), enteric disease, herpes and other sexually-transmitted diseases. To meet this demand, we have continued to expand our product offerings and now offer one of the world s largest infectious disease test menus. We develop and market a wide variety of point-of-care tests for influenza A/B, RSV, strep throat, pneumonia, C. difficile, infectious mononucleosis, HIV, herpes simplex virus (HSV-2), hepatitis C (HCV), hepatitis B (HBV), malaria, lyme disease, chlamydia, H.pylori, rubella and other infectious diseases. Our tests for infectious disease are currently sold under brand names that include Alere, Alere Determine, Acceava, BinaxNOW, Clearview, DoubleCheckGold, Panbio, Standard Diagnostics, TECHLAB and TestPack. We are also expanding commercialization of the Alere CD4 Analyzer in several countries in Africa, Asia and Europe, as well as in North and South America. The Alere CD4 Analyzer is the first point-of-care CD4 platform which measures absolute CD4 counts. A CD4 count is a measure of the number of helper T cells per cubic millimeter of blood used to analyze the prognosis of patients with HIV. The Alere CD4 Analyzer provides results in 20 minutes or less, using single-use, disposable fingerstick cartridges. CD4 results delivered quickly and at the point of care can improve antiretroviral therapy-related patient retention and improve access to treatment.

In addition to point-of-care products, we also offer a line of indirect fluorescent antibody, or IFA, assays for over 20 viral, bacterial and autoimmune diseases, a full line of serology diagnostic products

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covering a broad range of disease categories and over 70 enzyme-linked immunosorbent assays, or ELISA tests, for a wide variety of infectious and autoimmune diseases, as well as a full line of automated instrumentation for processing ELISA tests. We are the exclusive U.S. distributor of the AtheNA Multi-Lyte® Test System, a multiplexed, fluorescent bead-based system designed to simultaneously perform multiple assays from a single sample using just one well. It offers a simple and streamlined alternative to IFA and ELISA testing, providing improved clinical sensitivity and comparable clinical specificity in a labor-saving, automation-friendly format. Our IFA, serology and ELISA products, which generally serve the clinical diagnostics laboratory markets, are generally marketed under our Wampole brand.

Demand for certain infectious disease tests, such as influenza A/B, or flu, is significantly affected by the seasonal nature of the cold and flu season. As a result, we typically experience higher sales of our flu tests in the first and fourth quarters. Sales of our flu products also vary widely from year to year based in large part on the severity, duration and timing of the onset of the cold and flu season.

Toxicology. Drug abuse is a major global health problem, as well as a social and economic burden. In addition to being a primary cause of lost workforce productivity, family conflict and drug-related crime, drug abuse of illicit and prescription drugs is linked globally to the spread of HIV/AIDS, hepatitis and other blood-borne pathogens through the use of contaminated needles. This misuse of drugs and drug addiction are among the costliest health problems in the United States, and increasingly abroad. As a result, employers, law enforcement officials, healthcare professionals and others expend considerable effort to ensure that their employees, patients and other constituents are free of substance abuse and misuse. This critical need creates a significant market for simple and reliable laboratory-based, point-of-care and rapid toxicology tests to detect both the most commonly abused substances and an ever-evolving set of esoteric and regional toxins. Additionally, physicians are increasingly utilizing drug testing to identify and address signs of prescription drug misuse, whether illicit or by prescription, and more broadly, to improve outcomes in addiction medicine. Urine and oral-based screening and confirmation tests for drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely-accepted method for toxicology screening at the point of care.

We offer one of the most comprehensive lines of drugs of abuse tests, reagent systems and laboratory testing options available today. Our products include tests to detect alcohol, as well as various device platforms for the detection of the following illicit and prescription drugs of abuse: amphetamines/methamphetamines, cocaine, opiates, phencyclidine, tetrahydrocannabinol, acetaminophen, barbiturates, benzodiazepines, methadone, propoxyphene and tricyclic antidepressants, using urine and, for some applications, saliva, hair and other body fluids.

Our rapid toxicology tests are sold primarily under the brands Alere Triage, Alere iScreen, Concateno and SureStep. The Alere Triage TOX Drug Screen panel sold for use with our Alere Triage MeterPro system detects the presence of many of the illicit and prescription drugs listed above at the point of care in approximately 15 minutes. It is widely used in hospital and clinical testing as a laboratory instrument to aid in the detection of drug abuse. Our Drug Detection System, or DDS, is an enhanced, on-site saliva drug detection system utilized in roadside testing which displays results for the presence of two drugs in less than 90 seconds and six different drugs in less than five minutes.

We also offer comprehensive laboratory-based testing services throughout Europe under the name Concateno and in the United States under the names Alere Toxicology Services, Inc., or Alere Toxicology, and Redwood Toxicology Laboratory, Inc., or Redwood. Two of Alere Toxicology s laboratories are certified to the highest standard by the U.S. Substance Abuse and Mental Health Services Administration, or SAMHSA. In addition, we are expanding our offerings in the growing market for pain management and addiction medicine services, or the monitoring and documentation of adherence to prescription drug treatment or drug abstinence plans through complex laboratory testing. In 2011 we acquired Avee Laboratories Inc. to further develop our efforts in this area. Finally, through

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Redwood, we offer comprehensive, low-cost laboratory testing services to multiple domestic clients, including law enforcement agencies, penal systems, insurers and employers in the United States. In addition, we are expanding our offerings in the growing market for pain management and addiction medicine services, or the monitoring and documentation of adherence to prescription drug treatment or drug abstinence plans through complex laboratory testing.

Diabetes. During the fourth quarter of 2011, we acquired Axis-Shield plc and Arriva Medical, LLC, or Arriva. The point-of-care products of Axis-Shield include the Afinion Analyzer System and the NycoCard System. The Afinion Analyzer System makes it possible to easily and rapidly determine the level of glycated hemoglobin, or HbA1c, in a patient s blood at the physician s office during the visit, which can provide information regarding the patient s average blood sugar levels over a period of time. This system will simplify monitoring of any type of diabetes, facilitating treatment management and prevention of complications. By providing timely information regarding a patient s blood sugar levels over time, it may also increase the patient s motivation to comply with treatment and lifestyle changes to optimize prognosis. The NycoCard System, which is a widely distributed, low-cost product suited to countries with developing healthcare systems, includes tests for CRP, HbA1c and U-Albumin. The test for U-Albumin is used for early identification of renal disease in patients with diabetes or hypertension. Physicians test for elevated levels of CRP in a patient s bloodstream to detect signs of inflammation or tissue damage, which can be associated with a wide variety of chronic and acute conditions. With our acquisition of Arriva, we are now a major, national mail order supplier of diabetic testing supplies, including blood glucose monitors, test strips, lancets, lancing devices, and control solution, as well as other related medical supplies in the United States. These products are usually covered by Medicare, Medicaid and other third-party payers.

Oncology. Among chronic disease categories, we are focused on oncology diagnostics as an area of significant future opportunity. The Alere NMP22 BladderChek Test is the only in-office test approved by the FDA as an aid in the diagnosis of bladder cancer. The Alere NMP22 BladderChek Test is a non-invasive assay, performed on a single urine sample that detects elevated levels of NMP22 protein. The test can be performed in a physician s office with results delivered during the patient visit, allowing a rapid, accurate and cost-effective means of aiding the detection of bladder cancer in patients at risk, when used in conjunction with standard diagnostic procedures. We also offer the Alere NMP22 Test Kit, a quantitative ELISA test designed to detect elevated levels of NMP22 protein.

Our Clearview FOB and Ultra FOB rapid tests aid in the early detection of colorectal cancer, the third most common type of cancer in men and women. Also, as a result of our November 2010 acquisition of AdnaGen AG, or AdnaGen, a German company specializing in the development of cancer diagnostics through the detection and analysis of circulating tumor cells, we now sell the AdnaTest ColonCancer and AdnaTest BreastCancer products, which are CE-certified for the detection of circulating tumor cells.

Women s Health. Since women s health and general sexual health issues are a global health concern, this area remains a priority for us. In the professional marketplace, we are a global leader in pregnancy and fertility/ovulation testing. Our professional pregnancy tests are generally urine-based, CLIA-waived rapid tests in dipstick or cassette format.

Our professional women s health products also target diseases or conditions, such as pre-eclampsia, rubella, pre-term labor and premature rupture of membrane, which pose unique threats to mothers, fetuses or newborn babies. Additionally, we offer bone therapy (osteoporosis monitoring). We also market a portfolio of tests for sexually-transmitted diseases. Our women s health products are currently sold under our Alere, Acceava, Clearview, Osteomark, Sure-Step and TestPack brands.

Health Management. Our health management business strives to empower participants in our programs and physicians so they can work together towards better health. We believe that by utilizing

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existing professional diagnostic devices and new devices under development to enhance the delivery of health management and by improving the quality of medical data available to healthcare providers, we can further facilitate cost containment and outcome-driven decision making. We also provide services supporting home INR testing. Currently, our health management business is principally conducted in the United States, but we have plans to expand further internationally.

Our expert-designed health management programs:

- embrace the entire lifespan, from pre-cradle to end-of-life, and targeted health states, from wellness to prevention to total health management of the individual for those having various chronic illnesses;
- target high-cost chronic conditions with programs designed to improve outcomes and reduce expenditures;
- provide health coaches who engage and motivate participants during teachable moments;
- help participants improve their health by supporting their individual health goals;
- help payers, physicians, patients and accountable care organizations connect more efficiently through the exchange of health information;
- bring greater clarity to healthcare with empowering technologies that lead to better outcomes; and
- offer the expertise of more than 2,000 healthcare professionals who share a passion for patient and customer care.

Our key health management programs are:

Disease and Case Management. The Alere Disease Management (Chronic Care) Program provides technology-enabled, evidence-based solutions for managing chronic and high-cost conditions, improving clinical outcomes and reducing healthcare costs. The Alere Disease Management Program assists individuals with chronic diseases or conditions to better manage their care by increasing their knowledge about their illnesses, potential complications and the importance of medication and treatment plan compliance. Our highly-trained nurses proactively contact participants to monitor their progress and ensure they are following the plan of care set by their physician. They work with participants to identify potential gaps in care, which occur when individuals are not treated in accordance with national standards of care, or best practices, or when an individual fails to comply with his or her treatment plan.

We offer a personal health support model of care. This model differs from providers of traditional, total population health models in several ways, including how individuals are selected, as well as a more disciplined approach to defining who can benefit from what kinds of touches and how these specific interactions are best accomplished. A second key differentiator is the use of the Alere DayLink Monitor for persons participating in higher risk health management programs. The DayLink Monitor records a participant s weight and/or blood glucose, as well as answers to questions regarding their symptoms. This information is gathered daily and sent to our clinicians for review. The Alere Disease Management Program currently assists individuals with the following chronic diseases or conditions: asthma, coronary artery disease, chronic obstructive pulmonary disease, diabetes, heart failure, pain, weight management and depression. In addition, we also offer Complex Care Management for participants who require more attention and care than a traditional disease management program provides. What distinguishes our two programs is that Complex Care provides on-site care, and the Disease Management (Chronic Care) Program involves telephone contact with Alere clinicians. Our accountable care offerings are designed to provide wellness, decision support, care coordination, care management and case management services to health care providers who agree to be accountable for the quality, cost, and overall care of beneficiaries who are enrolled in such programs.

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Women s & Children s Health. Our Women s and Children s Health division delivers a wide spectrum of obstetrical care services, ranging from a risk assessment to identify women at risk for pregnancy complications to a neonatal program for early infant care management. In between are home-based obstetrical programs to manage and monitor pregnant women who have medical or pregnancy-related problems that could harm the health of the mother or baby. We deliver telephonic and home-based nursing services that support improved clinical outcomes. We have developed and refined these services over the years to accommodate physician plans of care. We focus on assessment of patient data and providing education. Our high-risk pregnancy management program revenues tend to be seasonal. Revenues tend to decrease with the onset of the holiday season starting with Thanksgiving. As a result, first and fourth quarter revenues each year tend to be lower than second and third quarter revenues.

Wellness. Wellness Solutions is a suite of integrated wellness programs and resources designed to help organizations reduce health risks and improve the health and productivity of their employees and health plan members, while reducing healthcare-related costs. Wellness programs include screening for risk factors associated with diabetes, cardiovascular heart disease, hypertension and obesity; screening for high-risk pregnancies; assessments of health risks for broad populations; programs that promote better health by encouraging sustainable changes in behavior and health coaching. Our Alere Wellbeing business specializes in web-based learning and phone-based cognitive behavioral coaching to help employers, health plans and state governments improve the overall health and productivity of their covered populations. Alere Wellbeing s evidence-based programs address the four key modifiable health risks that contribute to chronic disease: tobacco use, nutrition, physical inactivity and stress.

Patient Self-Testing Services. We also offer services designed to support anticoagulation management for patients at risk for stroke and other clotting disorders who can benefit from home INR monitoring. Our Alere Home Monitoring business assists patients in acquiring home INR monitors, including our Alere INRatio2 monitors, and seeking Medicare reimbursement and insurance coverage, while providing physicians with a comprehensive solution for incorporating home INR monitoring into their practice. Our CoagNow program includes our Face-2-Face patient training model, which utilizes experienced nurse educators, patient scheduling, collection and reporting of home testing results to the physician and CoagClinic, our sophisticated web-based application that provides healthcare professionals with real-time access to patient information.

Oncology. The Alere Oncology Program is the longest-running cancer management program (since 1994) in the U.S. The Alere Oncology Program manages adults diagnosed with any cancer that requires treatment beyond a single surgery and includes services for over 42 different tumor types and over 200 stages of cancer. Since the program s inception, we have managed more than 65,000 participants. Cancer continues to challenge employers and health plans as they search for tools to compassionately manage this condition among their population in the most cost-effective manner. By incorporating best of breed practices and coordinating with physicians and participants, we provide an integrated solution to proactively manage this expensive and increasingly chronic disease.

Technology Solutions. Our technology solutions provide employers and health plans with a powerful portal or front door to our continuum of healthcare services and allow individuals to create a confidential on-line record of their personal healthcare data that is compliant with the requirements of the Health Insurance Portability and Accountability Act, or HIPAA, and its regulations. Our Apollo technology platform, which was launched in January 2010, provides the framework and supporting infrastructure for a series of significant enhancements to Alere s services, including a dynamic, interactive and personalized experience for employees via an enhanced health portal, and was designed to provide us with the ability to integrate data from a variety of sources, including health plans, pharmacy benefit managers, self-reported data and point-of-care devices.

Through our recent acquisition of Wellogic, a provider of software solutions designed to connect the healthcare industry, we now also offer health information exchange solutions, care coordination software solutions and electronic health record, or EHR, technology. These technologies are designed

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so that comprehensive patient information from multiple venues of care is available at the point of care and easily used by healthcare providers who depend on it. We also intend to include these technologies and services in our accountable care offerings, which are designed to provide wellness, decision support, care coordination, care management and case management services to healthcare providers who agree to be accountable for the quality, cost and overall care of beneficiaries who are enrolled in such programs. Our EHR solutions are certified under the Medicare and Medicaid EHR Incentive Programs authorized under the Health Information Technology for Economic and Clinical Health Act, or HITECH, to allow clients to qualify for incentive payments as they demonstrate meaningful use of EHR technology.

Consumer Diagnostics. In 2007, we and affiliates of The Procter & Gamble Company, or P&G, commenced a 50/50 joint venture for the development, manufacturing, marketing and sale of existing and to-be-developed consumer diagnostic products, outside the cardiology, diabetes and oral care fields. As part of this arrangement, we transferred essentially all of the assets of our consumer diagnostics business, other than our manufacturing and core intellectual property assets, to the joint venture, and P&G acquired its interest in the joint venture. Accordingly, substantially all of the consumer diagnostics business conducted by us prior to the joint venture, including all of our products targeting the worldwide over-the-counter pregnancy and fertility/ovulation test market, are now sold by the joint venture, which is an unconsolidated entity operating primarily under the name SPD Swiss Precision Diagnostics GmbH, or SPD.

As part of the SPD joint venture, we entered into a finished product purchase agreement, pursuant to which we currently manufacture and sell to SPD substantially all of the consumer diagnostic products which it sells. We also entered into certain transition and long-term services agreements with SPD, pursuant to which we provide certain operational support services to the joint venture. Our consumer diagnostics segment recognizes the revenue and costs arising from these arrangements.

Our other current consumer diagnostic products consist of our market-leading First Check brand of over-the-counter drug tests for at-home testing for up to seven illicit drugs and five prescription drugs, as well as First Check brand over-the-counter tests for cholesterol monitoring and colon cancer screening. Taking advantage of our leadership in the field of women s health, we also sell Balance Activ Vaginal Gel directly to consumers and health care professionals for the effective treatment of bacterial vaginosis without antibiotics.

Methods of Distribution and Customers

In the United States, Canada, the United Kingdom, Ireland, Germany, Italy, Spain, Portugal, Switzerland, the Netherlands, Belgium, France, Austria, Sweden, Norway, Denmark, Finland, Israel, India, Japan, China, South Korea, Taiwan, Australia, New Zealand, South Africa, Brazil, Argentina and Colombia, we distribute our professional diagnostic products to hospitals, reference laboratories, physician offices and other point-of-care settings through our own sales forces and distribution networks. In these countries, as well as in all other major world markets, we also utilize third-party distributors to sell our products. Our Alere Home Monitoring business facilitates the distribution of our Alere INRatio PT/INR coagulation monitors by contacting targeted customers and facilitating the Medicare reimbursement process for physicians and for patients monitoring at home.

We market our health management programs primarily to health plans (both commercial and governmental) and self-insured employers and, to a lesser extent, to government and governmental programs, pharmaceutical companies and physicians, through our employee sales force and channel partners.

We market and sell our First Check consumer drug testing products in the United States through retail drug stores, drug wholesalers, groceries and mass merchandisers. These products compete intensively with other brand name drug testing products based on price, performance and brand awareness.

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Manufacturing

Our primary manufacturing facilities are located in San Diego, California; Scarborough, Maine; Dundee, Scotland; Oslo, Norway; Hangzhou and Shanghai, China; Matsudo, Japan; and Yongin, South Korea. We also manufacture products at a number of other facilities in the United States, Australia, Germany, India, Israel, South Africa, Spain and the United Kingdom.

Our primary manufacturing facilities are ISO certified and registered with the FDA. We manufacture substantially all of our consumable diagnostic products at these facilities. We also manufacture the consumable diagnostic devices containing the diagnostic chemistry or other proprietary diagnostic technology, which are used in conjunction with our diagnostic or monitoring systems, including our Alere Triage system, our Alere Cholestech LDX monitoring devices, our Alere INRatio monitoring devices and the digital pregnancy and ovulation prediction tests and fertility monitors that we supply to the SPD joint venture. We contract with third parties to supply the electronic reader portion of these diagnostic or monitoring systems and to supply various other products that we sell, including our Alere Triage BNP Test for use on Beckman Coulter systems, a majority of our IFA tests and our TECHLAB products.

Research and Development

Our primary research and development centers are in San Diego, California; Scarborough, Maine; Jena, Germany and Cambridge, Stirling and Dundee, United Kingdom. We also conduct research and development at some of our other facilities, including facilities in the United States, Australia, China, Israel, Japan and South Korea. Our research and development programs focus on the development of cardiology, women s health, infectious diseases, diabetes, oncology and toxicology products together with health management programs, as well as connectivity and information and data management solutions related to our diagnostic products and our health management programs. Information about research and development expenses for the last three fiscal years is provided on page F-4 of the consolidated financial statements.

Global Operations

We are a global company with major manufacturing facilities in the United States, China, Japan, Norway, Scotland, South Korea and significant research and development operations in the United States, Germany and the United Kingdom. Our distribution network supporting our professional diagnostics business includes offices in the United States, Argentina, Australia, Austria, Belgium, Brazil, Canada, China, Colombia, Denmark, Finland, France, Germany, Hong Kong, India, Israel, Italy, Japan, the Netherlands, New Zealand, Norway, Portugal, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan and the United Kingdom.

Our professional diagnostic products are sold throughout the world. Our health management programs are offered almost exclusively in the United States but we now operate health management units in Australia, Germany and the United Kingdom. During 2011 and 2010, respectively, we generated approximately 61% and 64% of our net revenue from the United States, approximately 17% and 17% from Europe and approximately 22% and 19% from other locations.

For further financial information about geographic areas, see Note 17 of the Notes to Consolidated Financial Statements which are included elsewhere in this report.

Competition

Professional Diagnostics. Our professional diagnostics products are primarily point-of-care rapid diagnostic testing products focused within the areas of cardiology, women s health, infectious disease, diabetes, oncology and toxicology. Competition for rapid diagnostic products is intense and is primarily based on price, quality, breadth of product line, technology and distribution capabilities. Some

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competitors in the market for professional rapid diagnostic products, such as Becton Dickinson, are large companies with substantial resources, while numerous smaller, yet aggressive companies also compete with us. No competitor, small or large, offers a portfolio of professional rapid diagnostic products as broad as ours and, as a result, our competitors differ significantly within each of our areas of focus. Automated immunoassay systems also compete with our products, depending on government regulations or when labor shortages force laboratories to automate or when the costs of such systems are lower. Such systems are provided by Abbott, Siemens, Beckman Coulter, Johnson & Johnson, Roche and other large diagnostic companies.

In cardiology, the majority of diagnostic immunoassays utilized by physicians and other healthcare providers are performed by independent clinical reference laboratories and hospital-based laboratories using automated analyzers for batch testing. As a result, the primary competitors for our Alere Triage and Alere Cholestech LDX point-of-care testing systems, which consist of rapid diagnostic devices interpreted by portable electronic readers, are the large diagnostic companies identified above that produce automated immunoassay systems. We expect these large companies to continue to compete vigorously to maintain their significant market share of the cardiology testing market. Although we offer our Alere Triage BNP test for use on Beckman Coulter Immunoassay Systems, our other primary cardiology products are not currently designed for automated batch testing. Our Alere Triage products face strong competition from Abbott s i-Stat hand-held system, and our Alere Cholestech LDX system also faces direct competition from Abaxis Medical Diagnostics, which markets its point-of-care blood laboratory systems to physician office laboratories and from Polymer Technology Systems CardioChek test. The primary competitors for our Alere INRatio PT/INR monitoring system are Roche and International Technidyne Corporation, which recently merged with Nexus Dx, who together currently account for approximately 75% of the domestic sales of PT/INR point-of-care and patient self-testing devices.

Becton Dickinson, Quidel and Meridian Bioscience are the largest competitors for our rapid diagnostic tests targeted at women s health and infectious disease. Our HIV products, in particular, also compete with tests offered by OraSure Technologies. Newer technologies utilizing amplification techniques for analyzing molecular DNA gene sequences, from companies such as Abbott, Becton Dickinson, Roche, Cepheid and Gen-Probe, are making in-roads into the infectious disease market.

In oncology, our Alere NMP-22 diagnostic products aid in diagnosing and monitoring bladder cancer patients, in conjunction with standard diagnostic procedures, and are based on our proprietary nuclear matrix protein technology. Our Alere NMP-22 BladderChek Test is currently the only in-office test approved by the FDA as an aid in the diagnosis of bladder cancer. However, competition in the development and marketing of cancer diagnostics and therapeutics, using a variety of other technologies, is intense. Competing diagnostic products based on other technologies may be introduced by other companies and could adversely affect our competitive position. In a larger sense, our tests also compete with more invasive or expensive procedures, such as surgery, bone scans, magnetic resonance imaging and other in vivo imaging techniques. In the market for urine-based diagnostic tests, our Alere NMP-22 tests also compete with existing cellular-based tests, such as the microscopic examination of suspicious cells, and UroVysion, which is a fluorescent in-situ hybridization test.

In toxicology, the competitors for our drugs of abuse tests include many of the large diagnostics companies named above, which manufacture instrumented drug tests, reagents or instruments sold in a variety of formats to customers in the worldwide employment, transportation, government and clinical sectors. Additionally, in many markets in which the barriers to entry are low due to less stringent regulations, we compete with dozens of privately-held, small and emerging low-cost manufacturers of lateral flow point-of-care drug tests. Our worldwide drug testing laboratory services compete with hundreds of multi-national and regional clinical, toxicology and forensic laboratories.

We also sell ELISA and multiplex immunoassay diagnostic testing products, as well as serology, IFA and microbiology tests, all primarily targeted at infectious and autoimmune diseases. Our ELISA

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tests compete against large diagnostics companies similar to those named above, which manufacture state-of-the-art automated immunoassay systems and a wide array of diagnostic products designed for processing on those systems. Other competitors, including INOVA Diagnostics, DiaSorin, Qiagen and Diamedx, are smaller companies that compete based on quality and service. In the United States and Canada, we focus on matching the instrumentation and product testing requirements of our customers by offering a wide selection of diagnostic products and test equipment. The markets for our serology, IFA and microbiology products are mature and competition is based primarily on price and customer service. Our main competitors in serology and microbiology testing include Remel and Biokit. Our main competitors in IFA testing are Bio-Rad Laboratories, INOVA Diagnostics, Immuno Concepts, Trinity Biotech, Meridian Biosciences and DiaSorin. However, products in these categories also compete to a large extent against rapid membrane and ELISA products, which are often easier to perform and read and can be more precise.

In the field of diabetes, the competitors for the Afinion Analyzer System and NycoCard System includes Siemens, Bio-Rad Laboratories and Tosoh Corporation. Arriva competes with mail order suppliers, as well as local retail pharmacies, such as Walgreens and CVS. The largest mail-order specialty competitors include Liberty Medical, CCS Medical, Simplex Medical, AmMed Direct, United States Medical Supply and Sanare.

Generally, our professional diagnostic products competitive positions may be based on, among other things, being first to market with a novel product, product performance, accuracy, convenience, cost-effectiveness, the strength of our intellectual property and price, as well as on the effectiveness of our sales force and our marketing and distribution partners. Where we face competition from large diagnostic companies, these competitors have greater resources than we do. In addition, certain competitors may have more favorable competitive positions than we do in markets outside the United States.

We believe that our dedication to research and development and our strong intellectual property portfolio, coupled with our manufacturing expertise, diversified product positioning, global market presence and established distribution networks, provide us with a competitive advantage in the point-of-care markets in which we compete.

Health Management. Competition in the health management market is intense because barriers to entry are low. Other health management service providers include Health Dialog, Healthways and numerous smaller service providers. Our competitors and potential competitors also include health plans, self-insured employers, healthcare providers, pharmaceutical companies, pharmacy benefit management companies, case management companies and other organizations that provide services to health plans, governments, governmental programs and self-insured employers. Some of these entities, particularly health plans and self-insured employers, may be customers or potential customers and may own, acquire or establish health management service providers or capabilities for the purpose of providing health management services in-house. Many of these competitors are considerably larger than we are and have access to greater resources. We believe that our ability to improve clinical and financial outcomes and our technology platforms, most notably our new Apollo system, provide us with certain competitive advantages.

Consumer Diagnostics. Our First Check tests compete against over-the-counter diagnostic tests sold primarily by Phamatech, but also by other smaller competitors. Essentially, all of our remaining consumer diagnostic product sales are to SPD, our joint venture. These products are sold by SPD in retail markets where competition is intense and based primarily on brand recognition and price. Our revenues, as well as our share of the profits from the sale of these products by SPD, are dependent upon SPD s ability to effectively compete in these markets.

Patents and Proprietary Technology; Trademarks

We have built a strong intellectual property portfolio consisting of an increasing number of patents, patent applications and licensed patents which are intended to protect our vision of the technologies,

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products and services of the future. Our intellectual property portfolio consists of patents that we own and, in some cases, patents or other proprietary rights that we license from third parties, which may be limited with respect to term and in terms of field of use or transferability and may require royalty payments.

The medical device industry, including the diagnostic testing industry, historically has been characterized by extensive litigation regarding patents, licenses and other intellectual property rights. Litigation relating to intellectual property rights is also a risk in the health management industry.

We believe that our history of successfully enforcing our intellectual property rights in the United States and abroad demonstrates our resolve in enforcing our intellectual property rights, the strength of our intellectual property portfolio and the competitive advantage that we have in this area. We have incurred substantial costs, both in asserting infringement claims against others and in defending ourselves against patent infringement claims, and we expect to incur substantial litigation costs as we continue to aggressively protect our technology and defend our proprietary rights.

Finally, we believe that certain of our trademarks are valuable assets that are important to the marketing of both our products and services. We have applied for or obtained registration for many of these trademarks with the United States Patent and Trademark Office or comparable foreign agencies.

The medical device industry, including the diagnostic testing industry, and the health management industry place considerable importance on obtaining and enforcing patent and trade secret protection for new technologies, products, services and processes. Trademark protection is an important factor in the success of certain of our product lines and health management programs. Our success therefore depends, in part, on our ability to obtain and enforce the patents and trademark registrations necessary to protect our products, to preserve our trade secrets and to avoid or neutralize threats to our proprietary rights from third parties. We cannot, however, guarantee our success in enforcing or maintaining our patent rights; in obtaining future patents or licensed patents in a timely manner or at all; or as to the breadth or degree of protection that our patents or trademark registrations or other intellectual property rights might afford us. For more information regarding the risks associated with our reliance on intellectual property rights, see the discussion in Item 1A entitled Risk Factors on pages 16 through 33 of this report.

Government Regulation

Our businesses are subject to extensive and frequently changing federal, state, local and foreign laws and regulations. Changes in applicable laws or any failure to comply with existing or future laws, regulations or standards could have a material adverse effect on our results of operations, financial condition, business and prospects. We believe our current arrangements and practices are in material compliance with applicable laws and regulations. There can be no assurance that we are in compliance with all applicable laws and regulations or that we will be able to comply with new laws or regulations.

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably, all of our products sold in the United States are subject to the Federal Food, Drug and Cosmetic Act, or the FDCA, as implemented and enforced by the FDA. All of our diagnostic products sold in the United States require either FDA clearance to market under Section 510(k) of the FDCA, or Pre-market Approval, or PMA, which may require pre-clinical and clinical trials. Foreign countries may require similar or more onerous approvals to manufacture or market these products. The marketing of our consumer diagnostic products is also subject to regulation by the U.S. Federal Trade Commission, or the FTC. In addition, we are required to meet regulatory requirements in countries outside the United States, which can change rapidly with relatively short notice. We must also demonstrate to the FDA that our diagnostic tests intended for home use or for use by laboratories holding a Certificate of

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Waiver under the Clinical Laboratory Improvement Act of 1967 and the Clinical Laboratory Amendments of 1988, or CLIA, including most physician office laboratories, are simple with a low risk of error. Foreign countries may require similar or more onerous approvals to manufacture or market our products.

CLIA extends federal oversight to many clinical laboratories, including certain of our drug testing laboratories in the United States, by requiring that they be certified to meet quality assurance, quality control and personnel standards. Laboratories also must undergo proficiency testing and are subject to inspections. Certain of our drug testing laboratories perform drug testing on employees of federal government contractors and certain other entities and are therefore regulated by the Substance Abuse and Mental Health Services Administration, or SAMHSA, which has established detailed performance and quality standards that laboratories must meet to be approved to perform drug testing on employees of federal government contractors and certain other entities.

The Medical Device User Fee Act, or MDUFA, will expire in September 2012 and requires reauthorization by Congress. Reauthorization is likely to lead to changes in MDUFA in 2012, possibly affecting funding for the FDA, as well as processes such as 510(k) and CLIA waiver that are relevant to our business.

Certain of our clinicians, such as nurses, must comply with individual licensing requirements. All of our clinicians who are subject to licensing requirements are licensed in the state in which they are physically present, such as the location of the call center from which they operate and, if applicable, states in which they visit or interact with patients, to the extent such licensure is required. In the future, multiple state licensing requirements for healthcare professionals who provide services telephonically over state lines may require us to license more of our clinicians in more than one state. New judicial decisions, agency interpretations or federal or state laws or regulations could increase the requirement for multi-state licensing of a greater number of our clinical staff, which would increase our administrative costs.

In 2012, we will assume reporting responsibilities under Section 6002 of 2010 s Affordable Care Act, which is commonly referred to as the Physician Payment Sunshine Act, or the Sunshine Act. We will be required to collect data on and annually report to the Centers for Medicare and Medicaid Services, certain payments or other transfers of value to physicians and teaching hospitals and annually report certain physician ownership and investment interests held by physicians or the immediate family members of physicians.

Certain aspects of our health management business are subject to unique licensing or permit requirements by state and local health agencies. In addition, our health management business is subject to HIPAA and the HITECH Act. We are also required to obtain certification to participate in certain governmental payment programs, such as various state or federal Medicare/Medicaid programs. Some states have established Certificate of Need/Determination of Need, or CON/DON, programs regulating the expansion of healthcare operations. The failure to obtain, renew or maintain any of the required licenses, certifications or CON/DONs could adversely affect our business.

For more information about the governmental regulations to which our business is subject and the risk associated with non-compliance with those regulations, see the risk factors discussed in Item 1A entitled Risk Factors on pages 16 through 33 of this report.

Employees

As of January 31, 2012, we had approximately 14,500 employees, including temporary and contract employees, of which approximately 7,400 employees are located in the United States. In addition, we utilize consultants specializing in areas such as research and development, risk management, regulatory compliance and marketing.

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ITEM 1A. RISK FACTORS

The risks described below may materially impact your investment in our company or may in the future, and, in some cases already do, materially affect us and our business, financial condition and results of operations. You should carefully consider these factors with respect to your investment in our securities.

We face intense competition, and our failure to compete effectively may negatively affect sales of our products and services.

The industries in which we operate, including the medical diagnostic products industry and the health management industry, are rapidly evolving, and developments are expected to continue at a rapid pace. Competition in these industries is intense and expected to increase as new products, services and technologies become available and new competitors enter the market. Our competitors in the United States and abroad are numerous and include, among others, diagnostic testing and medical products companies, universities and other research institutions, health management service providers, healthcare providers and health insurers. Many of our existing or potential competitors have substantially greater research and development capabilities, clinical, manufacturing, regulatory and marketing experience and financial and managerial resources than we do. Our sales and results of operations may be adversely affected by:

- customers perceptions of the comparative quality of our competitors products or services;
- the ability of our competitors to develop products, services and technologies that are more effective than ours or that render ours obsolete;
- our competitors ability to obtain patent protection or other intellectual property rights that would prevent us from offering competing products or services;
- the ability of our competitors to obtain regulatory approval for the commercialization of products or services more rapidly or effectively than we do; and
- competitive pricing by our competitors, particularly in emerging markets.

In addition, as markets for our novel products become saturated with competing products, such as for our meter-based Triage BNP test, the growth rates of sales unit volume and average selling prices for those products may decline, which may adversely impact our product sales, gross margins and overall financial results. This may occur even if we are able to successfully introduce new products in these markets, and achieve market acceptance of those products, in a timely manner.

We may experience difficulties that may delay or prevent our development, introduction or marketing of new or enhanced products or services.

Our success depends on our ability to effectively introduce new and competitive products and services. The development of new or enhanced products or services is a complex, costly and uncertain process and is becoming increasingly complex and uncertain in the United States. Furthermore, developing and manufacturing new products and services requires us to anticipate customers and patients needs and emerging technology trends accurately. We may experience research and development, manufacturing, regulatory, marketing and other difficulties that could delay or prevent our introduction of new or enhanced products and services. The research and development process in the healthcare industry generally takes a significant amount of time from design stage to product launch. This process is conducted in various stages, and each stage presents the risk that we will not achieve our goals. We may have to abandon a product in which we have invested substantial resources. We cannot be certain that:

- any of our products or services under development will prove to be safe and effective in clinical trials;

we will be able to obtain, in a timely manner or at all, necessary regulatory approvals;

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the products and services we develop can be manufactured or provided at acceptable cost and with appropriate quality; or

these products and services, if and when approved, can be successfully marketed.

These factors, as well as manufacturing or distribution problems or other factors beyond our control, could delay the launch of new products or services. Any delay in the development, approval, production, marketing or distribution of a new product or service could materially and adversely affect our competitive position, our branding and our results of operations.

Our financial condition and results of operations may be adversely affected by international business risks.

We generate a significant percentage of our net revenue from outside the United States, and a significant number of our employees, including manufacturing, sales, support, and research and development personnel, are located in foreign countries, including Australia, Brazil, China, Germany, India, Israel, Japan, Norway, South Korea, South Africa, Spain and the United Kingdom. Conducting business outside the United States subjects us to numerous risks, including:

lost revenues as a result of macroeconomic developments, such as the current European budgetary issues, debt crisis and related European financial restructuring efforts, which may cause European governments to reduce spending and cause the value of the Euro to deteriorate, thus reducing the purchasing power of European customers;

decreased liquidity resulting from longer accounts receivable collection cycles typical of foreign countries;

lower productivity resulting from difficulties we encounter in staffing and managing sales, support, and research and development operations across many countries;

lost revenues or unexpected expenses resulting from difficulties associated with enforcing agreements and collecting receivables through foreign legal systems;

lost revenues or unexpected expenses resulting from disputes with third-party distributors of our products or from third parties claiming distribution rights to our products under foreign laws or legal systems;

lost revenues or unexpected expenses resulting from the imposition by foreign governments of trade barriers such as tariffs, quotas, preferential bidding, and import restrictions;

higher cost of sales resulting from import or export licensing requirements;

lost revenues or other adverse effects resulting from acts of war, terrorism, theft or other lawless conduct or otherwise resulting from economic, social or political instability in or affecting foreign countries in which we sell our products or operate;

lost revenues or other adverse effects resulting from international sanctions regimes;

adverse effects resulting from changes in foreign regulatory or other laws affecting sales of our products or our foreign operations;

greater tax liability resulting from international tax laws, including U.S. taxes on foreign subsidiaries;

increased financial accounting and reporting burdens and complexities;

increased costs to comply with changes in legislative or regulatory requirements;

lost revenues or increased expenses resulting from the failure of laws to protect our intellectual property rights; and

lost revenues resulting from delays in obtaining import or export licenses, transportation difficulties and delays resulting from inadequate local infrastructure.

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Our international operations subject us to varied and complex domestic, foreign and international laws and regulations. Compliance with these laws and regulations often involves significant costs or requires changes in our business practices that may reduce revenues and profitability. We could incur additional legal compliance costs associated with our global operations and could become subject to legal penalties if we do not comply with certain regulations. For example, we are subject to the United States Foreign Corrupt Practices Act which, among other restrictions, prohibits U.S. companies and their intermediaries from making payments to foreign officials for the purpose of obtaining or retaining business or otherwise obtaining favorable treatment, as well as anti-bribery and corruption laws of other jurisdictions. In addition, our international activities are subject to compliance with United States economic and trade sanctions, which restrict or otherwise limit our ability to do business in certain designated countries. Our training and compliance program and our other internal control policies and procedures may not always protect us from acts committed by our employees or agents.

Because our business relies heavily on foreign operations and revenues, changes in foreign currency exchange rates and our need to convert currencies may negatively affect our financial condition and results of operations.

Our business relies heavily on our foreign operations. Six of our eight largest manufacturing operations are conducted outside the United States in China, Japan, Norway, Scotland and South Korea, and we also have manufacturing operations in Australia, Germany, India, Israel, South Africa, Spain and the United Kingdom. We have significant research and development operations in Germany and the United Kingdom, and we conduct additional research and development activities outside the United States in Australia, China, Israel, Japan and South Korea. In addition, for the year ended December 31, 2011, approximately 39% of our net revenue was derived from sales outside the United States. Because of the scope of our foreign operations and foreign sales, we face significant exposure to movements in foreign currency exchange rates. Our primary exposures are related to the operations of our European and Asia Pacific subsidiaries and our manufacturing facilities in China, Japan and South Korea. These exposures may change over time as our business practices evolve and could result in increased costs or reduced revenue and could affect our actual cash flow. Changes in the relative values of currencies occur regularly and, in some instances, may have a significant impact on our operating results. We cannot predict with any certainty changes in foreign currency exchange rates or the degree to which we can cost-effectively mitigate these risks.

Healthcare reform legislation could adversely affect our revenue and financial condition.

The Patient Protection and Affordable Care Act of 2010 (as amended by the Health Care and Education Reconciliation Act of 2010), or the ACA, makes comprehensive reforms at the federal and state level affecting the coverage and payment for healthcare services in the United States. In particular, the ACA significantly alters Medicare Advantage reimbursements by setting the federal benchmark payment closer to the payments in the traditional fee-for-service Medicare program. This change could reduce our revenues from the Medicare Advantage plans for which we perform services, although the precise effect on any particular plan, much less the impact on us, is impossible to predict. Effective January 1, 2013, the ACA includes a 2.3% excise tax on the sale of certain medical devices. Legislative provisions impose federal reporting requirements regarding payments or relationships between manufacturers of covered drugs, devices or biological or medical supplies, and physicians, among others.

The ACA requires that providers of health insurance plans maintain specified minimum medical loss ratios. We believe that the majority of our health management services would qualify as quality improving activities , but there have been no regulations specifically classifying our services in such a manner. If our health management services are not classified as quality improving activities under the ACA, health insurance providers will not be permitted to count expenditures on those services toward the calculation of their medical loss ratios, which may adversely impact demand for our health management services and the results of operations of our health management business.

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Additionally, revenues associated with our recently-acquired diabetes business may be impacted by the Durable Medical Equipment, Prosthetics, Orthotics and Supplies, or the DMEPOS, Competitive Bidding Program. Under this program, in certain designated geographical areas, Medicare will no longer reimburse suppliers for certain products and services, including mail-order diabetes testing supplies, based on the Medicare fee schedule amount. Instead, in those areas, the Centers for Medicare and Medicaid Services, or CMS, will provide reimbursement for those products and services based on a competitive bidding process. Only the suppliers selected through the bidding process will be eligible to have their products reimbursed by Medicare. The DMEPOS Competitive Bidding Program could make it more difficult to sell mail-order diabetes testing supplies in affected areas or require us to sell them at a lower price, either of which could have a material adverse effect on our sales and profitability.

Legislative and regulatory bodies are likely to continue to pursue healthcare reform initiatives and may continue to reduce the funding of the Medicare and Medicaid programs, including Medicare Advantage, in an effort to reduce overall healthcare spending. The ultimate impact of all of the reforms in the ACA, and its impact on us, is impossible to predict. If all of the reforms in the legislation are implemented, or if other reforms in the United States or elsewhere are adopted, those reforms may have an adverse effect on our financial condition and results of operations.

If the results of clinical studies required to gain regulatory approval to sell our products are not available when expected, or do not demonstrate the safety and effectiveness of those products, we may be unable to sell those products.

Before we can sell certain of our products, we must conduct clinical studies intended to demonstrate that those products are safe and effective and perform as expected. The results of these clinical studies are used to obtain regulatory approval from government authorities such as the FDA. Clinical studies are experiments involving human patients having the diseases or medical conditions that the product is trying to evaluate or diagnose. Conducting clinical studies is a complex, time-consuming and expensive process. In some cases, we may spend several years completing the necessary clinical studies.

If we fail to adequately manage our clinical studies, those clinical studies and corresponding regulatory approvals may be delayed or we may fail to gain approval for our products altogether. Even if we successfully manage our clinical studies, we may not obtain favorable results and may not obtain regulatory approval. If we are unable to market and sell our new products or are unable to obtain approvals in the timeframe needed to execute our product strategies, our business and results of operations would be materially and adversely affected.

If we are unable to obtain required clearances or approvals for the commercialization of our products in the United States, we would not be able to sell those products in the United States.

Our future performance depends on, among other matters, the timely receipt of necessary regulatory approvals for new products. Regulatory approval can be a lengthy, expensive and uncertain process. In addition, regulatory processes are subject to change, and new or changed regulations can result in increased costs and unanticipated delays.

In the United States, clearance or approval to commercially distribute new medical devices is received from the FDA through clearance of a Premarket Notification, or 510(k), or through approval of a PMA. The FDA may deny 510(k) clearance because, among other reasons, it determines that our product is not substantially equivalent to another U.S. legally marketed device. The FDA may deny a PMA because, among other reasons, it determines that our product is not sufficiently safe or effective. As part of the clearance or approval process, if we intend to sell certain diagnostic tests for home use or for use by laboratories holding a CLIA Certificate of Waiver, including most physician office laboratories, we must generally provide data demonstrating to the FDA s satisfaction that our tests are

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simple with a low risk of error. Failure to obtain FDA clearance or approval would preclude commercialization in the United States, and failure to obtain or maintain CLIA-waived status for any product would preclude us from selling that product for home use or to CLIA-waived laboratories, which could materially and adversely affect our future results of operations.

Modifications or enhancements that could significantly affect safety or effectiveness, or that constitute a major change in the intended use of the device, require new 510(k) or PMA submissions. We have made modifications to some of our products since receipt of initial 510(k) clearance or PMA. With respect to several of these modifications, we filed new 510(k)s describing the modifications and received FDA 510(k) clearance. We have made other modifications to some of our products that we believe do not require the submission of new 510(k)s or PMAs. The FDA may not agree with any of our determinations not to submit a new 510(k) or PMA for any of these modifications made to our products. If the FDA requires us to submit a new 510(k) or PMA for any device modification, we may be prohibited from marketing the modified products until the new submission is cleared or approved by the FDA.

The FDA has proposed changes to the 510(k) process. If the changes to the 510(k) process are adopted as proposed, the time and cost to obtain a 510(k) clearance or PMA could increase significantly.

We are subject to regulatory approval requirements of the foreign countries in which we sell our products, and these requirements may prevent or delay us from marketing our products in those countries.

We are subject to the regulatory approval requirements for each foreign country in which we sell our products. The process for complying with these approval requirements can be lengthy and expensive. Any changes in foreign approval requirements and processes may cause us to incur additional costs or lengthen review times of our products. We may not be able to obtain foreign regulatory approvals on a timely basis, if at all, and any failure to do so may cause us to incur additional costs or prevent us from marketing our products in foreign countries, which may have a material adverse effect on our business, financial condition and results of operations.

Our business is subject to substantial regulatory oversight and our failure to comply with applicable regulations may result in significant costs or, in certain circumstances, the suspension or withdrawal of previously obtained clearances or approvals.

Our businesses are extensively regulated by the FDA and other federal, state and foreign regulatory agencies. These regulations impact many aspects of our operations, including development, manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, physician interaction and record-keeping.

The FDA and foreign regulatory agencies may require post-market testing and surveillance to monitor the performance of approved products or may place conditions on any product approvals that could restrict the commercial applications of those products. The discovery of problems with a product may result in restrictions on the product, including withdrawal of the product from the market. In addition, in some cases we may sell products or provide services which are reliant on the use or commercial availability of products of third parties, including medical devices, equipment or pharmaceuticals, and regulatory restrictions placed upon any such third party products could have a material adverse impact on the sales or commercial viability of our related products or services.

We are subject to routine inspection by the FDA and other agencies for compliance with the Quality System Regulation and Medical Device Reporting requirements in the United States and other applicable regulations worldwide. Our manufacturing facilities and those of our suppliers and distributors also are, or can be, subject to periodic regulatory inspections.

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Under CLIA, some of our drug testing laboratories in the United States are required to be certified to meet quality assurance, quality control and personnel standards. Laboratories also must undergo proficiency testing and are subject to inspections. Our laboratories that perform drug testing on employees of federal government contractors and some other entities are regulated by the United States SAMHSA, which has established detailed performance and quality standards that laboratories must meet in order to perform this work.

Portions of our health management business are subject to unique licensing or permit requirements. For example, we may be required to obtain certification to participate in governmental payment programs, such as state or federal Medicaid/Medicare programs. We may need an operating license in some states, and some states have established Certificate of Need programs regulating the expansion of healthcare operations. In addition, we believe that some of our health management services are educational in nature, do not constitute the practice of medicine or provision of healthcare and, thus, do not require that we maintain federal or state licenses to provide these services. However, it is possible that federal or state laws regarding the provision of virtual or telephonic medicine could be revised or interpreted to include our services, or that other laws may be enacted which require licensure or otherwise relate to our health management services. In that event, we may incur significant costs to comply with such laws and regulations.

We are also subject to laws relating to matters such as privacy, safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with these laws and regulations. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products or injunctions against our distribution of products, termination of our service agreements by our customers, disgorgement of money, operating restrictions and criminal prosecution.

New laws may be enacted, or regulatory agencies may impose new or enhanced standards, that would increase our costs, as well as expose us to risks associated with non-compliance.

We are subject to healthcare fraud and abuse regulations that could result in significant liability, require us to change our business practices and restrict our operations in the future.

We are subject to laws regulating fraud and abuse in the healthcare industry, including anti-kickback and false claims laws. The Federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Many states have also adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for health care items or services reimbursed by any payer, not only the Medicare, Medicaid and Veterans Administration programs. These laws constrain the sales, marketing and other promotional activities of manufacturers of medical devices by limiting the kinds of financial arrangements, including sales programs, with hospitals, physicians, laboratories and other potential purchasers of medical devices and related services.

Other laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, or are for items or services that were not provided as claimed. These laws may also be triggered by failure to return identified overpayments to a payer. Anti-kickback and false claims laws prescribe civil and/or criminal penalties for noncompliance that can be substantial including, in some instances, fines, imprisonment and, within the United States, exclusion from participation in government healthcare programs. Furthermore, since we are reimbursed directly by federal healthcare programs for certain good and services and, given that many of our customers rely on reimbursement from Medicare, Medicaid and other governmental programs to cover a substantial portion of their

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expenditures, our exclusion from such programs as a result of a violation of these laws could have a material adverse effect on our business, results of operations, financial condition and cash flows. The interpretation and enforcement of these laws and regulations are uncertain and subject to rapid change.

Billing and payment for healthcare services are highly regulated, and the failure to comply with applicable laws and regulations can result in civil or criminal sanctions, including exclusion from federal and state healthcare programs.

A portion of our healthcare products and services are paid for by private and governmental third-party payers, such as Medicare and Medicaid. These third-party payers typically have different and complex billing and documentation requirements that we must satisfy in order to receive payment, and they carefully audit and monitor our compliance with these requirements. We must also comply with numerous other laws applicable to billing and payment for healthcare services, including privacy laws. Failure to comply with these requirements may result in non-payment, refunds, exclusion from government healthcare programs, and civil or criminal liabilities, any of which may have a material adverse effect on our revenues and earnings. In addition, failure by third-party payers to properly process our payment claims in a timely manner could delay our receipt of payment for our products and services, which may have a material adverse effect on our cash flows.

The health management industry is rapidly and continually evolving, and any such changes may impact the health management portion of our business.

The health management industry is rapidly and continually evolving due to factors such as changes in federal and state regulations and cost reduction pressures. We cannot predict with certainty the future growth rate or the ultimate size of the market. Our failure to manage any changes in the industry may adversely affect the revenues and results of operations of our health management business. The success of our health management business depends on a number of factors. These factors include:

- our ability to differentiate our health management services from those of competitors;
- the extent and timing of the acceptance of our services as a replacement for, or supplement to, traditional managed-care offerings;
- the effectiveness of our sales and marketing efforts with customers and their participants, employees or constituents;
- our ability to devise new and additional services beneficial to health plans, employers and states and their respective participants, employees or constituents;
- our ability to obtain and retain all necessary licenses, permits and regulatory clearances and approvals related to our services and any products used as part of our services, and to deliver effective, reliable and safe services to our customers and their participants, employees or constituents;
- our ability to achieve, measure and effectively communicate cost savings for our customers through the use of our services; and
- our ability to obtain, retain and renew contracts with customers and potential customers with favorable pricing as competition increases and to the extent that customers attempt to provide health management services themselves.

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Increasing health insurance premiums and co-payments or high deductible health plans may cause individuals to forgo health insurance and avoid medical attention, either of which may reduce demand for our products and services.

Health insurance premiums, co-payments and deductibles have generally increased in recent years. These increases may cause individuals to forgo health insurance, as well as medical attention. This behavior may reduce demand for our point-of-care diagnostic products and also reduce the number of lives managed by our health management programs.

Rising unemployment may negatively impact the collectability of uninsured accounts and patient due accounts and/or reduce total health plan populations.

Some of our health management contracts provide reimbursement to us based on total relevant populations managed by health plans. If unemployment rates rise, our revenues under these contracts may be reduced as managed lives may decrease. One of the primary collection risks of our health management business accounts receivable relates to uninsured patient accounts and patient accounts for which the primary insurance carrier has paid the amounts covered by the applicable insurance policy, but patient responsibility amounts (deductibles and co-payments) remain outstanding. If unemployment rates rise, these uninsured and patient due accounts could increase as a percentage of the health management business accounts receivable. Deterioration in the collectability of these accounts could adversely affect the health management business collection of accounts receivable, cash flows and results of operations. These financial pressures could have an adverse impact on our business.

A portion of our health management fees are contingent upon performance.

Some of our existing health management agreements contain savings or other guarantees, which provide that our revenues, or a portion of them, are contingent upon projected cost savings or other quality performance measures related to our health management programs. There is no guarantee that we will accurately forecast cost savings and clinical outcome improvements under our health management agreements or meet the performance criteria necessary to recognize potential revenues under the agreements. Additionally, untimely, incomplete or inaccurate data from our customers, or flawed analysis of such data, could have a material adverse impact on our ability to recognize revenues.

If our costs of providing health management services increase, we may not be able to pass these cost increases on to our customers.

Many of our health management services are provided pursuant to long-term contracts that we may be unable to re-negotiate. If our costs increase, we may be unable to increase our prices, which would adversely affect our overall profit margin and net income.

Demands of third-party payers, cost reduction pressures among our customers and restrictive reimbursement practices may adversely affect our revenues.

Our ability to negotiate favorable contracts with non-governmental payers, including managed-care plans, significantly affects the revenues and operating results of our health management business. Our customers continue to face cost reduction pressures that may cause them to curtail their use of, or reimbursement for, health management services, to negotiate reduced fees or other concessions or to delay payment. Furthermore, the increasing leverage of organized buying groups among non-governmental payers may reduce market prices for our products and services, thereby reducing our profitability. Reductions in price increases or the amounts received from current customers or lower pricing for our services to new customers could have a material adverse effect on the financial position, cash flows and results of operations of our health management business.

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In addition, the ability of our customers to obtain appropriate reimbursement for products and services from third-party payers is critical to the success of our business because it affects which products customers purchase and the prices they are willing to pay. If we develop a new product but the product is not approved for reimbursement by private and governmental third-party payers, the product may not be successful. Domestic and foreign healthcare reforms may further reduce reimbursement levels and adversely affect demand for and profitability of our products and services. These reforms, along with other cost-containment initiatives, could have a material adverse effect on our business, results of operations and financing condition.

Future reductions in state spending on existing preventative care programs could reduce our net revenues, net income and cash flows.

Due to budgetary shortfalls, many states are considering, or have enacted, cuts to existing preventative care programs. These cuts have included, or may include, elimination or reduction of coverage for some or all of our preventative care programs. For example, in 2011, several states reduced their funding of smoking cessations programs provided by our Alere Wellbeing business. During 2011, approximately 58% of the net revenue of our Alere Wellbeing business was derived from sales to state governments. Continued state budgetary pressures could lead to further reductions in funding for our services which, in turn, could have a material adverse effect on our financial position and operating results.

Our data management and information technology systems are critical to maintaining and growing our business.

Our business, particularly our health management business, is dependent on the effective use of information technology and, consequently, technology failure or obsolescence may negatively impact our business. In addition, data acquisition, data quality control, data privacy, data security and data analysis, which are a cornerstone of our health management programs, are intense and complex processes subject to error. Untimely, incomplete or inaccurate data, flawed analysis of data or our inability to properly integrate, implement, protect and update systems could have a material adverse impact on our business and results of operations. In particular, we are relying on our recently launched healthcare portal, Apollo, to provide the framework and supporting infrastructure for significantly enhanced future health management programs and to provide a competitive advantage. Apollo is a relatively new system and may not provide these expected benefits or meet our needs or the needs of our customers or program participants.

We expect that we will need to continue to improve and further integrate our information technology systems by training and educating our employees with respect to system improvements and integrations on an ongoing basis in order to effectively run our business. If we fail to successfully manage our information technology systems, including Apollo, our business and operating results could be adversely affected.

Our ability to protect our information systems and electronic transmissions of sensitive data from data corruption, cyber-based attacks and security breaches is critical to the success of our business.

We are highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store electronic information, including personal information of our customers. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches, can create system disruptions, shutdowns or unauthorized disclosure of confidential information. In addition, a security breach that leads to disclosure of consumer information (including personally identifiable information) could harm our reputation, compel us to comply with disparate state breach notification laws and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we

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are unable to prevent such security or privacy breaches, our operations could be disrupted, or we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data.

In addition, the interpretation and application of consumer and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our data practices. If so, this could result in government-imposed fines or orders requiring that we change our data practices, which could have an adverse effect on our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices in a manner adverse to our business.

Poor economic conditions may negatively impact our toxicology business.

The high rates of unemployment currently affecting the United States and other countries negatively impact the demand for pre-employment drug testing. Additionally, reduced government funding for drug screening programs negatively impacts the market for our toxicology tests. Finally, a portion of our domestic laboratory testing services is reimbursed by Medicare and private payers and is subject to continued downward price pressure. If any or all of these trends continue or accelerate, they may have a material adverse impact on the results of operations of our toxicology business.

If we deliver products with defects, we may be subject to product recalls or negative publicity, our credibility may be harmed, market acceptance of our products may decrease and we may be exposed to liability.

The manufacturing and marketing of professional and consumer diagnostics involve an inherent risk of product liability claims. For example, a defect in one of our diagnostic products could lead to a false positive or false negative result, affecting the eventual diagnosis. Our product development and production are extremely complex and could expose our products to defects. Manufacturing and design defects could lead to recalls (either voluntary or required by the FDA or other government authorities) and could result in the removal of a product from the market. Defects in our products could also harm our reputation, lead to negative publicity and decrease sales of our products.

In addition, our marketing of monitoring services may cause us to be subjected to various product liability or other claims, including, among others, claims that inaccurate monitoring results lead to injury or death, or, in the case of our toxicology monitoring services, the imposition of criminal sanctions. Any product liability or other claim brought against us, regardless of merit, could be costly to defend and could result in an increase to our insurance premiums. If we are held liable for a claim, that claim could materially damage our business and financial condition.

We may experience manufacturing problems or delays due to, among other reasons, our volume and specialized processes, which could result in decreased revenue or increased costs.

The global supply of our products depends on the uninterrupted efficient operation of our manufacturing facilities. Many of our manufacturing processes are complex and involve sensitive scientific processes, including unique and often proprietary antibodies which cannot be replicated or acquired through alternative sources without undue delay or expense. Other processes present difficult technical challenges to obtain the manufacturing yields necessary to operate profitably. In addition, our manufacturing processes may require complex and specialized equipment which can be expensive to repair or replace with required lead times of up to a year.

The manufacturing of certain of our products is concentrated in one or more of our plants, with limited alternate facilities. Any event that negatively impacts our manufacturing facilities, our manufacturing systems or equipment, or our contract manufacturers or suppliers could delay or

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suspend shipments of products or the release of new products or could result in the delivery of inferior products. Our revenues from the affected products would decline and we could incur losses until such time as we or our contract manufacturers are able to restore our or their production processes or we are able to put in place alternative contract manufacturers or suppliers.

We rely on suppliers for raw materials and other products and services, and fluctuations in the availability and price of such products and services may adversely affect our business or results of operations.

We rely on numerous third parties to supply raw materials and other components for our manufacturing processes. In some cases, these raw materials and components are available only from a sole supplier. We also rely on a number of significant third-party manufacturers to produce some of our professional diagnostics products. Stringent requirements of the FDA and other regulatory authorities regarding the manufacture of our products may prevent us from quickly establishing additional or replacement sources for the raw materials, components or manufacturing services that we use or from doing so without excessive cost. As a result, a reduction or interruption in supply or an inability to secure alternative sources of raw materials, components or manufacturing services could have a material adverse effect on our business, result of operations, financial condition and cash flows.

We may not realize the intended benefits of the relocation of some of our manufacturing facilities to China.

In recent years we have shifted production of several of our products to our manufacturing facilities in China and closed less efficient and more expensive facilities elsewhere. We may shift production of additional products to China and other lower cost facilities. Moving production is difficult and involves significant risk. We may experience delays, inefficiencies and unanticipated costs as a result of problems establishing relationships with local materials suppliers; acquiring new facilities or adapting existing facilities and equipment to the production of new products; hiring, training and retaining personnel; and establishing and maintaining compliance with governmental regulations and industry standards. Any of these factors could have a material negative impact on our financial performance.

We could suffer monetary damages, incur substantial costs or be prevented from using technologies important to our products as a result of pending legal proceedings.

We are involved in various legal proceedings arising out of our business. Because of the nature of our business, we may be subject at any particular time to commercial disputes, product liability claims, negligence claims or various other lawsuits arising in the ordinary course of our business, including infringement and other licensing and intellectual property claims, distributor disputes, employment matters or investor matters. The lawsuits we face generally seek damages, sometimes in substantial amounts, for commercial or personal injuries allegedly suffered and can include claims for punitive or other special damages. An adverse ruling or rulings in one or more such lawsuits could, individually or in the aggregate, substantially harm our sales, operations or financial performance.

The rights we rely upon to protect the intellectual property underlying our products may not be adequate to prevent third parties from using our technology, which would reduce a competitive advantage provided by our patents.

Our success depends in part on our ability to develop or acquire commercially valuable intellectual property rights and to enforce those rights. The degree of present and future protection for our intellectual property is uncertain and may change. The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

- pending patent applications we have filed, or to which we have exclusive rights, may not result in issued patents or may take longer than we expect to result in issued patents;

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patents licensed or issued to us or our customers may not provide a competitive advantage;

other parties may challenge patents or patent applications licensed or issued to us or our customers;

other companies may design around technologies we have patented, licensed or developed; and

all patents have a limited life, meaning at some point valuable patents will expire and we will lose the competitive advantage they provide.

In addition to patents, we rely on a combination of trade secrets, non-disclosure agreements and other contractual provisions and technical measures to protect our intellectual property rights. Nevertheless, these measures may not be adequate to safeguard the technology underlying our products. If these measures do not protect our rights, third parties could access our technology and our competitive advantage in the market would be reduced. In addition, employees, consultants and others who participate in the development of our products may breach their agreements with us regarding our intellectual property, and we may not have adequate remedies for the breach. We also may not be able to effectively protect our intellectual property rights in some foreign countries. For a variety of reasons, we may decide not to file for patent, copyright or trademark protection or prosecute potential infringements of our patents. Our trade secrets may also become known through other means not currently foreseen by us. Despite our efforts to protect our intellectual property, our competitors or customers may independently develop similar or alternative technologies or products that are equal or superior to our technology and products without infringing any of our intellectual property rights, or design around our proprietary technologies.

Claims by others that our products infringe their proprietary rights could adversely affect our ability to sell our products and services and could increase our costs.

Substantial litigation over intellectual property rights exists in the professional and consumer diagnostics industries and in the health management industry. We expect that our products and services could be increasingly subject to third-party infringement claims as the number and functionality of our products grows and as we enter new and different industries and markets. Third parties may have or obtain patents which our products and services or technology may actually or allegedly infringe. Any of these third parties might assert infringement claims against us. Any litigation could result in the expenditure of significant financial resources and the diversion of management s time and resources. In addition, litigation in which we are accused of infringement may result in negative publicity, have an impact on prospective customers, cause product delays, or require us to develop alternative technology, make substantial payments to third parties or enter into royalty or license agreements, which may not be available on acceptable terms, or at all. If a successful claim of infringement were made against us and we could not develop non-infringing technology or license rights to the infringed or similar technology on a timely and cost-effective basis, we may be forced to stop selling current products or abandon new products under development and we could be exposed to legal actions by our customers.

We may need to initiate lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would reduce our ability to compete.

In order to protect or enforce our patent rights, we may initiate litigation or other proceedings against, or enter into negotiations or settlement discussions with, third parties. Litigation may be necessary to:

assert claims of infringement;

enforce licensing terms and conditions;

protect our trade secrets or know-how; or

determine the enforceability, scope and validity of the proprietary rights of ourselves or others.

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We have initiated a number of lawsuits against competitors whom we believe to be selling products that infringe our proprietary rights. These lawsuits and any other lawsuits that we initiate in the future could be expensive, take significant time and divert management s attention from other business concerns. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us.

Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in our industry are subject to change and often uncertain. We may not prevail in any of these suits, and the damages or other remedies awarded, if any, may not be commercially valuable. During the course of these suits, there may be public announcements of the results of hearings, motions and other interim proceedings or developments in the litigation. If securities analysts or investors perceive any of these results to be negative, the trading prices of our securities may decline.

Our future business prospects may be limited if our acquisition strategy is not successful.

As part of our business strategy, we seek to acquire or invest in businesses that offer complementary products, services or technologies to ours. If we are unable to identify and consummate acquisition opportunities, we may not achieve our growth targets. We may lose acquisition opportunities to competitors who offer a higher purchase price or who reach agreement with the target company earlier than we do. We may fail to complete acquisitions for many reasons, including failure to obtain antitrust or other regulatory clearances, failure to obtain requisite shareholder approval and failure to obtain necessary financing, and we may incur significant expenses, including potentially the expense of litigation, pursuing acquisitions, whether or not consummated.

Our business could be materially adversely affected as a result of the risks associated with our acquisition strategy.

Since our inception, we have acquired numerous businesses, including Standard Diagnostics, Inc., or Standard Diagnostics, in 2010 and Axis-Shield plc, or Axis-Shield, in 2011. The ultimate success of our acquisitions depends, in part, on our ability to realize the anticipated synergies, cost savings and growth opportunities from integrating newly-acquired businesses or assets into our existing businesses. However, the acquisition and successful integration of independent businesses or assets is a complex, costly and time-consuming process, and the benefits we realize may not exceed the costs of the acquisition. The risk and difficulties associated with acquiring and integrating companies and other assets include, among others:

- the impact of the acquisition on our financial and strategic position and reputation;
- consolidating manufacturing, research and development operations and health management information technology platforms, where appropriate;
- integrating newly-acquired businesses or product lines into a uniform financial reporting system;
- coordinating sales, distribution and marketing functions and strategies, including the integration of our current health management products and services;
- establishing or expanding manufacturing, sales, distribution and marketing functions in order to accommodate newly-acquired businesses or product lines or rationalizing these functions to take advantage of synergies;
- preserving the important licensing, research and development, manufacturing and supply, distribution, marketing, customer and other relationships of acquired businesses;
- minimizing the diversion of management s attention from ongoing business concerns;

the potential loss of key employees of the acquired business;

coordinating geographically separate operations; and

regulatory and legal issues relating to the integration of legacy and newly-acquired businesses.

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These factors could have a material adverse effect on our business, results of operations or financial condition, and managing multiple acquisitions or investments at the same time could exacerbate these risks. To the extent that we issue equity securities in connection with any acquisition or investment, existing shareholders may experience dilution. Additionally, regardless of the form of consideration we pay, acquisitions and investments could negatively impact our net income and earnings per share.

If goodwill or other intangible assets that we have recorded in connection with our acquisitions of other businesses become impaired, we could have to take significant charges against earnings.

As a result of our acquisitions, we have recorded, and may continue to record, a significant amount of goodwill and other intangible assets. Under current accounting guidelines, we must assess, at least annually and potentially more frequently, whether the value of goodwill and other intangible assets has been impaired. For example, during the fourth quarters of 2011 and 2010, we determined that our goodwill related to our health management business was impaired, resulting in non-cash impairment charges in the amount of approximately $383.6 million and $1.0 billion, respectively. Any further reduction or impairment of the value of goodwill or other intangible assets will result in additional charges against earnings, which could materially reduce our reported results of operations in future periods.

We do not have complete control over the operations of SPD, our 50/50 joint venture with P&G.

Because SPD is a 50/50 joint venture, we do not have complete control over its operations, including business decisions, which may impact SPD s profitability.

Additionally, certain subsidiaries of P&G have the right, at any time upon certain material breaches by us or our subsidiaries of our obligations under the joint venture documents, to acquire all of our interest in SPD at fair market value less any applicable damages.

Our business has substantial indebtedness.

We currently have, and will likely continue to have, a substantial amount of indebtedness. Our indebtedness could, among other things, make it more difficult for us to satisfy our debt obligations, require us to use a large portion of our cash flow from operations to repay and service our debt or otherwise create liquidity problems, limit our flexibility to adjust to market conditions, place us at a competitive disadvantage and expose us to interest rate fluctuations. As of December 31, 2011, we had total debt outstanding of approximately $3.3 billion, which included approximately $2.1 billion in aggregate principal amount of indebtedness outstanding under our secured credit facility, consisting of A term loans in the aggregate principal amount of $917.2 million, B term loans in the aggregate principal amount of $922.7 million and Incremental B-1 term loans in the aggregate principal amount of $250.0 million. Our secured credit facility has various final maturity dates occurring in 2016 and 2017, but if certain of our notes remain outstanding as of defined measurement dates in 2015, our secured credit facility will mature on those dates. At December 31, 2011, we also had an aggregate of approximately $1.1 billion in aggregate principal amount of indebtedness outstanding under our senior and senior subordinated notes, all of which matures in 2016 or 2018, as well as $150.0 million in aggregate principal amount of indebtedness outstanding under our 2007 senior subordinated convertible notes, which matures in 2016.

We expect to obtain the money to pay our expenses and to pay the principal and interest on our indebtedness from cash flow from our operations and potentially from other debt or equity offerings. Accordingly, our ability to meet our obligations depends on our future performance and capital raising

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activities, which will be affected by financial, business, economic and other factors, many of which are beyond our control. If our cash flow and capital resources prove inadequate to allow us to pay the principal and interest on our debt and meet our other obligations, we could face substantial liquidity problems and might be required to dispose of material assets or operations, restructure or refinance our debt and forego attractive business opportunities. We may be unable to do so on acceptable terms. In addition, the terms of our existing or future debt agreements may restrict us from pursuing any of these alternatives.

The agreements governing our indebtedness subject us to various restrictions that may limit our ability to pursue business opportunities.

The agreements governing our indebtedness subject us to various restrictions on our ability to engage in certain activities, including, among other things, our ability to:

- acquire other businesses or make investments;
- raise additional capital;
- incur additional debt;
- pay dividends or make distributions or repurchase or redeem our stock or senior or subordinated debt;
- prepay indebtedness; and
- consolidate, merge or sell all or substantially all of our assets.

These restrictions may limit or restrict our cash flow and our ability to pursue business opportunities or strategies that we would otherwise consider to be in our best interests.

Our secured credit facility contains certain financial and other restrictive covenants that we may not satisfy, and that, if not satisfied, could result in the acceleration of the amounts due under our secured credit facility and the limitation of our ability to borrow additional funds in the future.

The agreements governing our secured credit facility subject us to various financial and other restrictive covenants with which we must comply on an ongoing or periodic basis. These include covenants pertaining to maximum consolidated secured leverage ratios, minimum consolidated interest coverage ratios and limits on capital expenditures. If we violate any of these covenants, we may suffer a material adverse effect. Most notably, our outstanding debt under our secured credit facility could become immediately due and payable, our lenders could proceed against any collateral securing such indebtedness, and our ability to borrow additional funds in the future could be limited or terminated. Alternatively, we could be forced to refinance or renegotiate the terms and conditions of our secured credit facility, including the interest rates, financial and restrictive covenants and security requirements of the secured credit facility, on terms that may be significantly less favorable to us.

A default under any of the agreements governing our indebtedness could result in a default and acceleration of indebtedness under other agreements.

The agreements governing our indebtedness contain cross-default provisions whereby a default under one agreement could result in a default and acceleration of our repayment obligations under other agreements. If a cross-default were to occur, we may not be able to pay our debts or borrow sufficient funds to refinance them. Even if new financing were available, it may not be available on acceptable terms. If some or all of our indebtedness is in default for any reason, our business, financial condition and results of operations could be materially and adversely affected.

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We may not be able to satisfy our debt obligations upon a change of control or fundamental change, which could limit our opportunity to enter into a change of control or fundamental change transaction.

If we undergo a change of control, as provided in our secured credit facility, the senior notes or the senior subordinated notes, or a fundamental change or termination of trading, as provided in the 2007 senior subordinated convertible notes, we may be required to repay or repurchase some or all of such indebtedness. We may not have sufficient financial resources to satisfy all of our repayment and repurchase obligations. Our failure to purchase notes as required under the senior or senior subordinated notes or the 2007 senior subordinated convertible notes would constitute a default under the relevant indentures and under our secured credit facility and could have material adverse consequences for us and our stakeholders.

Our operating results may fluctuate for various reasons and, as a result, period-to-period comparisons of our results of operations will not necessarily be meaningful.

Many factors relating to our business, such as those described elsewhere in this section, make our future operating results uncertain and may cause them to fluctuate from period to period. Because our revenue and operating results are difficult to predict, we believe that period-to-period comparisons of our results of operations are not a good indicator of our future performance. If revenue declines in a quarter, our results of operations will be harmed because many of our expenses are relatively fixed. In particular, research and development, sales and marketing and general and administrative expenses are not significantly affected by variations in revenue. If our quarterly operating results fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop suddenly and significantly.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of amounts that have been accrued.

We are subject to income taxes in both the United States and various foreign jurisdictions, and we may take certain income tax positions on our tax returns that tax authorities may disagree with. We provide reserves for potential payments of tax to various tax authorities related to uncertain tax positions. However, the calculation of our tax liabilities involves the application of complex tax regulations to our global operations in many jurisdictions. Therefore, a dispute with a tax authority may result in a payment that is materially different from our current estimate of the tax liabilities associated with our returns.

Changes in tax laws or tax rulings could materially impact our effective tax rate. There are several proposals to reform U.S. tax rules being considered by U.S. law makers, including proposals that may reduce or eliminate the deferral of U.S. income tax on our unrepatriated earnings, potentially requiring those earnings to be taxed at the U.S. federal income tax rate, reduce or eliminate our ability to claim foreign tax credits, and eliminate various tax deductions until foreign earnings are repatriated to the U.S. Our future reported financial results may be adversely affected by tax rule changes which restrict or eliminate our ability to claim foreign tax credits or deduct expenses attributable to foreign earnings, or otherwise affect the treatment of our unrepatriated earnings.

We may incur losses in excess of our insurance coverage.

Our insurance coverage includes product liability, property, healthcare professional and business interruption policies. Our insurance coverage contains policy limits, specifications and exclusions. We believe that our insurance coverage is consistent with general practices within our industry. Nonetheless, we may incur losses of a type for which we are not covered by insurance or which exceed the limits of liability of our insurance policies. In that event, we could experience a significant loss which could have a material negative impact on our financial condition.

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Our future success depends on our ability to recruit and retain key personnel.

Our future success depends on our continued ability to attract, hire and retain highly qualified personnel, including our executive officers and scientific, technical, sales and marketing employees, and their ability to manage growth successfully. Experienced personnel in our industry are in high demand and competition for their talents is intense. If we are unable to attract and retain key personnel, our business may be harmed. In addition, the loss of any of our key personnel, particularly key research and development personnel, could harm our business and prospects and could impede the achievement of our research and development, operation or strategic objectives.

Future sales of our common stock, including shares issuable upon conversion of our Series B Convertible Perpetual Preferred Stock, or Series B Preferred Stock, or our senior subordinated convertible notes, may adversely affect the market price of our common stock.

Sales of a substantial number of shares of our common stock or other equity securities in the public market could depress the price of our common stock and impair our ability to raise capital through the sale of additional equity securities. The price of our common stock could be affected by possible sales of the substantial number of shares of our common stock potentially issuable upon conversion of our Series B Preferred Stock or our senior subordinated convertible notes and by other hedging or arbitrage trading activity that may develop involving our common stock. If the conditions applicable to the conversion of our Series B Preferred Stock were satisfied, then subject to adjustment, each of the approximately 1.8 million shares of Series B Preferred Stock outstanding as of December 31, 2011 could convert into 5.7703 shares of our common stock, or approximately 10.2 million shares of our common stock. Upon certain extraordinary transactions, depending on the market price of our common stock at that time, the conversion rate could increase such that significantly more shares of common stock could be issued. Our $150.0 million in aggregate principal amount of senior subordinated convertible notes is convertible into shares of our common stock at a conversion price of approximately $43.98 per share, or approximately 3.4 million shares.

The holders of our Series B Preferred Stock are entitled to receive liquidation payments in preference to the holders of our common stock.

As of December 31, 2011, the outstanding shares of our Series B Preferred Stock had an aggregate stated liquidation preference of approximately $709.8 million. Dividends accrue on the shares of Series B Preferred Stock at a rate of 3% per annum, and we have the option to pay these dividends in cash or in shares of common stock or additional shares of Series B Preferred Stock. If we pay these dividends in shares of common stock or additional shares of Series B Preferred Stock, the number of shares of common stock or Series B Preferred Stock issued will be based upon market prices at the time of such payment. Upon a liquidation of our company, the holders of shares of Series B Preferred Stock will be entitled to receive a liquidation payment prior to the payment of any amount with respect to the shares of our common stock. The amount of this preferential liquidation payment is the aggregate stated liquidation preference, plus any accrued and unpaid dividends. Because of the substantial liquidation preference to which the holders of the Series B Preferred Stock are entitled, the amount available to be distributed to the holders of our common stock upon a liquidation of our company could be substantially limited or reduced to zero.

The terms of the Series B Preferred Stock may limit our ability to raise additional capital through subsequent issuances of preferred stock.

For so long as any shares of Series B Preferred Stock remain outstanding, we are not permitted, without the affirmative vote or written consent of the holders of at least two-thirds of the Series B Preferred Stock then outstanding, to authorize or designate any class or series of capital stock having rights on liquidation or as to distributions (including dividends) senior to the Series B Preferred Stock. This restriction could limit our ability to plan for or react to market conditions or meet extraordinary capital needs, which could have a material adverse impact on our business.

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Anti-takeover provisions in our organizational documents and Delaware law may limit the ability of our stockholders to control our policies and effect a change of control of our company and may prevent attempts by our stockholders to replace or remove our current management, which may not be in your best interests.

Provisions of our certificate of incorporation and bylaws may discourage a third party from making a proposal to acquire us, even if some of our stockholders might consider the proposal to be in their best interests, and may prevent attempts by our stockholders to replace or remove our current management. These provisions include the following:

- our certificate of incorporation currently provides for three classes of directors with the term of office of one class expiring each year, commonly referred to as a staggered board. By preventing stockholders from voting on the election of more than one class of directors at any annual meeting of stockholders, this provision may have the effect of keeping the current members of our board of directors in control for a longer period of time than stockholders may desire;

- subject to the rights of the holders of our Series B Preferred Stock, our certificate of incorporation authorizes our board of directors to issue shares of preferred stock without stockholder approval and to establish the preferences and rights of any preferred stock issued, which would allow the board to issue one or more classes or series of preferred stock that could discourage or delay a tender offer or change in control;

In addition, our board of directors may in the future adopt other protective measures, such as a stockholder rights plan, which could delay, deter or prevent a change in control.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters, together with the administrative office for most of our United States consumer operations, is located at 51 Sawyer Road, Waltham, Massachusetts. During 2011 we opened an office in Galway, Ireland from which we oversee and conduct much of our professional diagnostic products business in Europe, and ultimately, outside the United States. We also operate a shared service center in Orlando, Florida, which houses certain critical back-office and sales operations supporting our U.S. professional diagnostics operations. Our health management business is headquartered in Atlanta, Georgia. These key administrative facilities are leased from third parties.

We own approximately 32.6 acres of land in San Diego, California which houses one of our eight primary manufacturing operations, as well as significant administrative and research and development operations for our professional diagnostics business. Our buildings on this property total 336,000 square feet and include 167,000 square feet of manufacturing space for professional diagnostic products.

Our other primary manufacturing operations are in Hangzhou and Shanghai, China; Matsudo, Japan; Yongin, South Korea; Oslo, Norway; Dundee, Scotland and Scarborough, Maine. We manufacture some of our consumer and professional diagnostics products in a manufacturing facility of approximately 410,000 square feet in Hangzhou, China, which we own. The majority of our consumer diagnostic products are manufactured in a facility of approximately 54,000 square feet in Shanghai, China, which we lease. We manufacture our Determine products in a leased space of approximately 35,000 square feet in Matsudo, Japan. Standard Diagnostics manufactures most of its professional diagnostic products in a 63,000 square foot facility in Yongin, South Korea, which we own. Axis-Shield, which we acquired in late 2011, manufactures the majority of our point-of-care products for patients

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with diabetes in a leased space of approximately 47,500 square feet in Oslo, Norway and a leased space of approximately 51,000 square feet in Dundee, Scotland. We manufacture certain professional diagnostic products in a 64,000 square foot facility that we lease in Scarborough, Maine.

We rely increasingly on toxicology laboratories to provide reliable drugs of abuse testing results to customers. We own two SAMHSA certified laboratories located in Gretna, Louisiana and Richmond, Virginia. We also operate laboratories in Santa Rosa, California; Austin, Texas; Tampa, Florida; Clearwater, Florida and Abingdon, England.

Additionally, we have leases or other arrangements for other facilities in various locations worldwide, including smaller manufacturing operations and laboratories, as well as research and developments operations, administrative or sales offices, call centers and warehouses. We believe that adequate space for our manufacturing, testing and other operations will be available as needed.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any pending legal proceedings that we currently believe could have a material adverse impact on our sales, operations or financial performance. Because of the nature of our business, we may be subject at any particular time to lawsuits or other claims arising in the ordinary course of our business, and we expect that this will continue to be the case in the future.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

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

Unregistered Sales of Equity Securities and Use of Proceeds

On October 19, 2011, we issued 839 shares of our common stock upon the net exercise of warrants to purchase 2,400 shares of our common stock, resulting in aggregate non-cash consideration to us of approximately $32,000. On November 11, 2011, we issued 36,794 shares of our common stock upon the exercise of warrants for cash, resulting in aggregate proceeds to us of approximately $625,000. The warrants were issued in private placements relating to various acquisitions. The shares were offered and sold pursuant to the exemption afforded by Section 4(2) of the Securities Act of 1933, as amended.

On November 23, 2011, we issued 806,452 shares of our common stock to certain former members of Arriva Medical, LLC in connection with our acquisition of that company. We relied on the exemption from registration afforded by Section 4(2) of the Securities Act.

Market Information

Our common stock trades on the New York Stock Exchange (NYSE) under the symbol ALR. The following table sets forth the high and low sales prices of our common stock for each quarter during fiscal 2011 and 2010.

	High	Low
Fiscal 2011		
Fourth Quarter	$ 26.62	$ 17.82
Third Quarter	$ 38.53	$ 19.62
Second Quarter	$ 41.18	$ 33.83
First Quarter	$ 40.55	$ 34.75
Fiscal 2010		
Fourth Quarter	$ 36.81	$ 26.61
Third Quarter	$ 31.60	$ 25.36
Second Quarter	$ 40.32	$ 26.06
First Quarter	$ 44.87	$ 38.30

On February 24, 2012, there were 1,955 holders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently intend to retain earnings to support our growth strategy and do not anticipate paying cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, on our common stock will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion. In addition, restrictive covenants under our secured credit facility and the indentures governing the terms of our senior notes and our senior subordinated notes currently prohibit or limit the payment of cash or stock dividends.

Stock Performance Graph

The following line graph compares the cumulative total stockholder return on our common stock from December 29, 2006 through December 30, 2011 with the cumulative total return of a broad equity market index and a published industry index. This graph assumes an investment of $100.00 on

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December 29, 2006 in our common stock, and compares its performance with the NYSE Composite Index and the Dow Jones U.S. Healthcare Index (the Current Indices). We paid no dividends on our common stock during the period covered by the graph. The Current Indices reflect a cumulative total return based upon the reinvestment of dividends of the stocks included in those indices. Measurement points are December 29, 2006 and the last trading day of each subsequent year end through December 30, 2011.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock.

Current Indices

Date	ALR	NYSE Composite Index	Dow Jones U.S. Healthcare Index
12/29/06	$ 100.00		