

ALERE INC.
Form 10-K/A
April 29, 2011

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-K/A
(Amendment No. 1)

**ANNUAL REPORT PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF
1934**

For the fiscal year ended December 31, 2010.

Commission file number 000-16789

ALERE INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware (State or other jurisdiction of incorporation or organization)	04-3565120 (I.R.S. Employer Identification No.)
51 Sawyer Road, Suite 200, Waltham, Massachusetts (Address of principal executive offices)	02453 (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, \$0.001 per share par value	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 ☐

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 ☐

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 ☒ 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 ☒ 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. ☐

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 ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐
(Do not check if a 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 ☒

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, 2010 (the last business day of the registrant's most recently completed second fiscal quarter) was \$1,901,649,455.

As of April 20, 2011, the registrant had 85,485,171 shares of common stock, par value \$0.001 per share, outstanding.

ALERE INC.

FORM 10-K

For The Fiscal Year Ended December 31, 2010

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EXPLANATORY NOTE

The primary purpose of this Amendment No. 1 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (the Original Report) is to amend Part III, Items 10 through 14 of the Original Report, which was filed with the U.S. Securities and Exchange Commission on March 1, 2011, to include information previously omitted from the Original Report in reliance on General Instruction G to Form 10-K, which provides that registrants may incorporate by reference certain information from a definitive proxy statement filed with the SEC within 120 days after the end of the fiscal year.

We are also amending Part IV, Item 15 of the Original Report to include certain exhibits required to be filed with this Amendment No. 1 and to file one other exhibit.

We have made no other significant changes to the Original Report. In order to preserve the nature and character of the disclosures set forth in the Original Report, this report speaks as of the date of the filing of the Original Report, March 1, 2011, and we have not updated the disclosures in this report to speak as of a later date.

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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 13 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, women's health, infectious disease, oncology and toxicology. 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 become more effective.

Our company, then 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 from Inverness Medical Innovations, Inc. 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 major 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. As discussed in Note 23 of the Notes to Consolidated Financial Statements, in January 2010, we completed the divestiture of our entire vitamins and nutritional supplements business segment and the results of this former business segment are classified as discontinued operations.

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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 market. We distinguish the point-of-care and patient self-testing 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 consists primarily of small and medium size laboratories and testing locations, such as physician office laboratories, specialized mobile clinics, emergency rooms and some rapid-response laboratories in larger medical centers.

In the market for rapid diagnostic products, the ability to deliver faster, accurate results at reasonable 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, less expensive, self-contained diagnostic kits. As the speed and accuracy of such products improve, we believe that these products will play an increasingly important role in achieving early diagnosis, timely intervention and therapy monitoring outside of acute medicine 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, women's health, infectious disease, oncology and toxicology. While we currently sell these products under numerous brands, as discussed below, we have begun a process of consolidating many of our brands under the Alere name.

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 Triage, Cholestech LDX and INRatio products, all acquired through acquisitions in 2007, have established us as a leader in this market. The 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. The Triage cardiovascular tests include the following:

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 syndrome and heart failure. We also offer a version of the Triage BNP Test for use on Beckman Coulter lab analyzers.

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.

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, risk stratification of patients with acute coronary syndromes and risk stratification of patients with heart failure. This panel combines

troponin I, CK-MB, myoglobin and BNP to provide rapid, accurate results in whole blood and plasma.

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

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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.

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.

Triage NGAL. An immunoassay for use in the rapid, quantitative determination of neutrophil gelatinase-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. Triage NGAL is not available for sale in the United States.

Our 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 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 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 Cholestech LDX System's ease of use and accuracy. This waiver allows the Cholestech LDX System to be marketed to physician offices, rather than hospitals or larger laboratories.

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. Today we sell an improved version of the system, the Alere INRatio2 System, which targets the patient self-testing market through enhanced ease of use. Patient self-testing has gained significant momentum since March 2008 when Centers for Medicare & Medicaid Services expanded coverage of home INR monitoring to include chronic atrial fibrillation and venous thromboembolism patients on warfarin.

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 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 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.

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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.

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 fertility/ovulation testing and bone therapy (osteoporosis) monitoring. 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 or their unborn or newborn babies. We also market a portfolio of tests for sexually-transmitted diseases. Our women's health products are currently sold under our Acceava, Clearview, Sure-Step, Inverness Medical TestPack and Osteomark brands.

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, strep throat, HIV, herpes simplex virus (HSV-2), hepatitis C (HCV), malaria, pneumonia, C.difficile, infectious mononucleosis, lyme disease, chlamydia, H.pylori, RSV, rubella and other infectious diseases. Our tests for infectious disease are currently sold under brand names which include Acceava, Alere, BinaxNOW, Clearview, Determine, TestPack, DoubleCheckGold, Panbio, Standard Diagnostics and TECHLAB. We have also started commercializing the Alere CD4 Analyzer in several countries in Africa. The Alere CD4 Analyzer is the first point-of-care platform which measures absolute CD4 counts in HIV patients with results in 20 minutes, using single-use, disposable fingerstick cartridges.

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 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. While we believe that these factors will continue to impact sales of certain of our infectious disease products, there can be no assurance that our future sales of these products will necessarily follow historical patterns.

Oncology. Among chronic disease categories, we are focused on oncology diagnostics as an area of significant future opportunity. The Matritech NMP22 BladderChek Test is the only in-office test approved by the FDA as an aid in the diagnosis of bladder cancer. The 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 NMP22 Test Kit, a quantitative ELISA also designed to detect elevated levels of NMP22 protein.

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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.

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 is linked globally to the spread of HIV/AIDS through contaminated needles. Drug abuse is one of the most costly 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 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, 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. 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.

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 Triage, iScreen, Concateno and SureStep. The TOX Drug Screen panel sold for use with our 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 up to six different drugs in under five minutes and two drugs in under 90 seconds.

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, or Alere Toxicology, and Redwood Laboratories, or Redwood. Alere Toxicology's laboratories are certified by the U.S. Substance Abuse and Mental Health Services Administration, or SAMHSA. Through 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 services, or the monitoring and documentation of adherence to prescription drug treatment plans through diagnostic testing.

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

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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 and patients 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 1,800 healthcare professionals who share a passion for patient and customer care.

Our key health management programs are:

Care. 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 clinicians 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.

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. As mentioned above, home INR monitoring has grown increasingly popular since the Centers for Medicare & Medicaid Services expanded coverage to include home INR monitoring of chronic atrial fibrillation and venous thromboembolism patients on warfarin. 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.

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 first and second trimester genetic testing, as well as 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

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telephonic and home-based nursing services that support physician and patient goals. 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 in the United States. As a result, first and fourth quarter revenues each year tend to be lower than second and third quarter revenues.

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. 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 debilitating disease.

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 Free & Clear 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. Free & Clear's evidence-based programs address the four key modifiable health risks that contribute to chronic disease: tobacco use, poor nutrition, physical inactivity and stress.

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 and its regulations, or HIPAA. 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.

Apollo serves as the hub for participants to access their medical information, personal health record and appropriate health programs and offers the following key enhancements:

- personalized platform that acts as a virtual coach, presenting content based on data collected on the participant and delivering personal health support in a way that is designed to feel satisfying to the participant when they need it the most;

- a meaningful, engaging experience with content and activities presented based on the participant's preferences, activities and personal health data; and

- a deep, rich library of multi-media resources designed to address individual learning styles that can be generated dynamically by the system or located through a search by the participant.

Providing access to the broad-based resources of the Apollo portal demonstrates a commitment to the enhanced health of an organization's population.

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

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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, Switzerland, the Netherlands, Belgium, France, Austria, 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 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.

Manufacturing

Our primary manufacturing facilities are located San Diego, California; Scarborough, Maine; 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 Triage system, our 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 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 Stirling, Scotland. We also conduct research and development at various of our other facilities, including facilities in the United States, Australia, China, Germany, Israel, South Korea, and the United

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Kingdom. Our research and development programs currently focus on the development of cardiology, women's health, infectious disease, oncology and toxicology products and on health management programs.

Global Operations

We are a global company with major manufacturing facilities in the United States, China, Japan, 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, France, Germany, Hong Kong, India, Israel, Italy, Japan, the Netherlands, New Zealand, South Africa, South Korea, Spain, 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. During 2010 and 2009, respectively, approximately 64% and 69% of our net revenue was generated from the United States, approximately 17% and 17% of our net revenue was generated from Europe, and approximately 19% and 14% of our net revenue was generated from customers located elsewhere.

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, oncology and toxicology. Competition for rapid diagnostic products is intense and is primarily based on price, quality, breadth of product line and distribution capabilities. Some 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. Some automated immunoassay systems may also be considered to compete with our products 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 Triage and 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 who produce automated immunoassay systems. We expect these large companies to continue to compete vigorously to maintain their dominance of the cardiology testing market. Although we offer our Triage BNP test for use on Beckman Coulter Immunoassay Systems, our other primary cardiology products are not currently designed for automated batch testing. Our Triage products face strong competition from Abbott's i-Stat hand-held system and our Cholestech LDX system also faces direct competition from Abaxis Medical Diagnostics, which markets its point-of-care blood laboratory systems to physician office laboratories. 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 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 NMP-22 BladderChek Test is currently the only in-office test approved by the FDA as an aid

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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 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, boutique 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 disease. Our ELISA tests compete against the large diagnostics companies 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 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.

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 of 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, state governments and self-insured employers. Some of these entities, health plans and self-insured employers in particular, 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 however that our ability to improve clinical and financial outcomes and our technology platforms, most notably our new Apollo system, will enable us to compete effectively.

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

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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, 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 in terms of field of use or transferability and may require royalty payments.

The medical products 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. Many of these trademarks have been registered with the United States Patent and Trademark Office or internationally, as appropriate.

The medical products 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 abilities 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 13 through 28 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

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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 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.

Certain of the 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.

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 Health Information Technology for Economic and Clinical Health, or 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 13 through 28 of this report.

Employees

As of January 31, 2011, we had approximately 11,900 employees, including temporary and contract employees, of which approximately 6,500 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.

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 healthcare 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

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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