ALERE INC.
Form 10-K
March 01, 2013
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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, 2012.

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	New York Stock Exchange
Stock, $0.001 per share par value	
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 þ 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 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 common stock held by non-affiliates of the registrant based on the closing price of the registrant s common stock on the New York Stock Exchange on June 29, 2012 (the last business day of the registrant s most recently completed second fiscal quarter) was $1,472,919,947.

As of February 25, 2013, the registrant had 81,201,382 shares of common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive proxy statement to be filed in connection with the registrant s 2013 annual meeting of shareholders are incorporated by reference into Part III of this Form 10-K.

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ALERE INC.

FORM 10-K

For The Fiscal Year Ended December 31, 2012

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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 17 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 greater control of their health at home, under the supervision of their healthcare providers, by combining near-patient diagnostics, health monitoring capabilities, and information technology solutions. A leading global provider of point-of-care diagnostics and services, we have developed a strong commercial presence in cardiology, infectious disease, toxicology, and diabetes. Our products and services help healthcare practitioners make earlier, more effective treatment decisions and improve outcomes for individuals living with chronic disease. Our portfolio also includes a broad array of health information solutions that increase access to critical health data, provide clinical decision support, and facilitate more comprehensive performance reporting and analysis. We believe that the integration of these solutions with our novel diagnostics and monitoring services positions us to enable customers to reduce the healthcare costs associated with managing chronic disease considerably, addressing what may be the greatest burden faced by most health systems around the world today.

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 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.

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Segments

Our reportable operating segments are professional diagnostics, health information solutions 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.

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. While there is certainly demand for faster, more efficient automated equipment from large hospitals and major reference testing laboratories, we believe 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 they 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 we also provide. Our current professional diagnostic products include point-of-care and laboratory tests within the following areas:

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 82 million American adults alone have one or more types of cardiovascular disease. The worldwide cardiology point-of-care diagnostics market, including the markets for heart failure diagnostics, coronary artery disease risk assessment, coagulation testing and acute coronary syndrome, exceeds $2.0 billion. Our Alere Triage, Alere Cholestech LDX and Alere INRatio products, 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 congestive heart failure. The test is used for the risk stratification of patients with acute coronary syndromes and heart failure as well. 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 anticoagulated 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

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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 not available for sale in the United States.

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 Panel. An immunoassay for the rapid quantitative determination of CK-MB, troponin I and BNP in whole blood and plasma specimens. This 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 not available for sale in the United States.

Alere Triage Cardio2 Panel. An immunoassay for the rapid quantitative determination of troponin I and BNP in whole blood and plasma specimens. This 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 Cardio2 is CE marked, but 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 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 not available for sale in the United States.

Alere Triage CardioRenal Panel. An immunoassay for use as an aid in the diagnosis of acute kidney injury and congestive heart failure, and the risk stratification of patients with heart failure and acute coronary syndromes. This panel combines two biomarkers, BNP and NGAL, to provide rapid, accurate quantitative results in whole blood or plasma. Alere Triage CardioRenal Panel 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. The system can also provide coronary heart disease risk assessment from

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the patient s results as measured on the lipid profile cassette. The Alere Cholestech LDX System provides results in five minutes per test cassette 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 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 offer the epoc Blood Analysis System for blood gas, electrolyte and metabolite testing, which is manufactured by our recently acquired Epocal division. The epoc (enterprise point-of-care) platform is a point-of-care analysis system which provides wireless bedside blood gas, electrolyte and metabolite 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.

During 2010, we launched the Alere Heart Check System in Europe. The Alere Heart Check System provides a quantitative reading of BNP in less than 15 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, vector-borne diseases such as malaria and dengue, 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, SD, TECHLAB and Alere TestPack. We are also expanding commercialization of the Alere CD4 Analyzer in several countries in Africa, Asia and Europe, as well as in South America and the Caribbean. The Alere CD4 Analyzer is one of the first point-of-care CD4 platforms which measures absolute CD4 counts. A CD4 count is a measure of the number of T-helper lymphocytes per cubic millimeter of blood, which is used to stage a patient s HIV disease as well as monitor HIV disease progression. The Alere CD4 Analyzer

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provides results in 20 minutes or less, using single-use, disposable fingerstick cartridges. CD4 results delivered quickly and accurately at the point of care can improve patient retention and 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 covering a broad range of disease categories and over 50 enzyme-linked immunosorbent assay, 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, 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 the most commonly abused substances and an ever-evolving set of newly-formulated, synthetic and regional toxins. Additionally, physicians and treatment centers 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. Finally, both domestically and abroad, a substantial market exists for services to help employers and governments manage their workforces compliance with drug, alcohol and/or related fitness-for-duty health policies.

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, and a growing range of designer drugs of abuse. Our products test using urine or, for certain applications, saliva, hair or other body fluids.

Our rapid toxicology tests are sold primarily under the brands Alere Toxicology, Alere Triage, Alere iScreen 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

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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 Alere Toxicology, formerly Concateno, and in the United States under the names Alere Toxicology Services, or Alere Toxicology, and Redwood Toxicology Laboratory, or Redwood. Three 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. 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 2012 we acquired eScreen, a leading provider of automated and efficient workplace drug testing services. We believe this acquisition helps to position Alere s toxicology business as a full-service solution provider to a broad range of domestic and foreign employers in transport, oil and gas, mining and related industries that follow rigorous drug testing policies. We believe that the combination of products, laboratory testing and services that we offer for drugs of abuse enhances our ability to compete in this market.

Diabetes. We offer point-of-care diabetes products, including our Afinion Analyzer System and our 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. In June 2012, we added our CE-marked Lipid Panel, an important tool for cardiovascular disease risk assessment, to the Afinion Analyzer System. The NycoCard System, which is a widely distributed, low-cost product suited to countries with developing healthcare systems, includes tests for CRP and HbA1c. 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. Through our subsidiary Arriva, we are 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 U.S. These products are usually covered by Medicare, Medicaid and other third-party payers.

Oncology. 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, 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 marked for the detection of circulating tumor cells.

Women s Health. In the professional marketplace, we are a global leader in pregnancy testing. Our professional pregnancy tests are generally urine- or serum-based, CLIA-waived rapid tests in dipstick or cassette format.

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

Connected Device Technologies. We understand that fast and accurate diagnostic results alone are not likely to satisfy the future mandates of accountable care. We believe that, to be effective, diagnostic data should be actionable, comprehensive and readily accessible to patients, physicians, and payers. When this data is made available via an integrated electronic health record, or EHR, care can more easily be personalized to meet the needs of each patient, and these patients can become more effectively engaged in their own health improvement. Additionally, when an EHR is paired with robust analytical tools, healthcare providers, payers, and accountable organizations can more easily assess treatment effectiveness and quantify patient outcomes and cost savings. For these reasons, we are developing several chronic care and other health information solutions built around fast, easy, and accurate diagnostics that we expect to ultimately permit the automatic import of health data into a health information exchange, or HIE, which we believe will facilitate the sort of health interactions, analysis, and reporting that will fuel more effective delivery and quality of care.

Through Alere Informatics, a business unit formed through our acquisitions of Medical Automation Systems, or MAS, in October 2011, and Laboratory Data Systems, or LDS, in August 2011, we offer RALS, the point-of-care industry s leading data management solution, which is deployed in nearly 2,000 hospitals nationwide, and RALS-Freedom, known as AegisPOC outside the U.S., the first web-based data management solution designed for critical care settings. Our RALS systems provide bidirectional interfaces that connect a hospital s glucose meters and other point-of-care devices measuring blood gases, prothrombin time, and cardiac parameters to its laboratory and health information systems.

Alere Connect, formerly MedApps, which we acquired in July 2012, develops and sells remote health monitoring solutions designed to deliver streamlined, cost-effective connectivity across patient, care provider and electronic medical records. Alere Connect s comprehensive health information platform and suite of cloud-based software tools enhance care for patients in both wellness and chronic disease management programs. These solutions are intended to help care management and healthcare practitioners to extend their services to a broader patient population, increasing the cost-avoidance benefits and efficiencies associated with remote health monitoring.

Our Alere Connect products include:

HealthPAL: A small, portable hub device for collecting health readings from compatible medical monitors and transmitting them to a user s EHR. HealthPAL provides the proactive benefits of remote health monitoring and is designed to be a cost-effective telehealth solution.

HealthCOM: A web-based application for healthcare professionals to remotely monitor and manage the data collected with HealthPAL. HealthCOM also provides professional administration features to assist healthcare practitioners in managing their patient populations and associated equipment inventory.

These products enable secure data integration with a variety of online electronic health records in a manner that is compliant with the requirements of the Health Insurance Portability and Accountability Act, or HIPAA, and are designed to be easily used by people of all ages and levels of comfort with technology. HealthPAL and HealthCOM also use cloud-based technology to lower implementation costs for providers, while delivering services that scale appropriately. In short, the Alere Connect platform is intended to bridge the gap between diagnostic data and devices and our health information solutions described below.

Health Information Solutions (formerly Health Management)

Our health information solutions are designed to provide physicians with actionable data that allows them to make more effective decisions in real time, deliver quality care, and put the individuals

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they treat on a pathway to better health. Core to our strategy are our proprietary diagnostic platforms and biomarkers that provide rapid results at the point of care for the most costly chronic conditions and our health information technologies, which will ultimately enable diagnostic data to be fed directly into an information exchange that integrates patient-related data in a single EHR. We offer a variety of software-based analytics, clinical decision support tools, and accountable care programs that enable healthcare providers to initiate earlier interventions, personalize treatment plans, lower costs by reducing hospital readmissions, and measure improvements in outcomes at both a patient and population level. With this wide range of scalable solutions, we are able to support healthcare practitioners in the transition to accountable care as well as in meeting the new pay-for-performance guidelines set by the Centers for Medicare & Medicaid Services, or CMS. Our information solutions address the data and care gaps resulting from today s fragmented healthcare environment, but are also modular and can be easily integrated with many existing resources customers may already have in place. Our health information solutions are primarily available in the United States, but we intend to offer them internationally in the future.

Through Alere Accountable Care Solutions, or Alere ACS, formerly known as Alere Wellogic, we deliver health information solutions that help provider organizations meet the CMS Meaningful Use requirements and improve coordination across multiple venues of care. Our principal offering from this group, the Alere Health Information Exchange, or Alere HIE, harmonizes multiple streams of data from disparate sources in a single patient-centered record and promotes the sharing of information among a patient s various healthcare providers, collapsing geographic and technological barriers and enabling care providers to more effectively identify and manage high-risk patients in a broad population. Alere ACS also offers an EHR, known as Consult EHR, which gives healthcare practitioners greater visibility into a patient s overall health status, as opposed to a more limited snapshot , and complies with the requirements of HIPAA. Consult EHR can also be used to manage administrative, billing and other functions more effectively and efficiently. Consult EHR is certified under the Medicare and Medicaid EHR Incentive Programs that have been authorized as part of the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, which allows clients to qualify for incentive payments by demonstrating the meaningful use of EHR technology.

Through Alere Analytics, formerly known as DiagnosisOne, which we acquired in July 2012, we offer a broad array of analytical and clinical decision support tools, which are delivered on our smartPath platform. smartPath leverages our extensive library of evidence-based medical knowledge to enable real-time patient and population assessment, predictive modeling, and risk stratification. It also generates immediate recommendations for care, enabling earlier interventions and helping to reduce avoidable errors and improve overall health outcomes. The smartPath platform compiles, analyzes, and enables reporting on disparate clinical data sets for hospital systems, multi-million-member insurers, government bodies, and several EHR and healthcare IT vendors. It can be easily integrated with various existing hospital and laboratory information systems. Key features of the smartPath platform include:

- combines rules and evidence-based content with actual patient data to quickly create relevant care plans;
- uses the evidence-based knowledge and proprietary analytics to enable improved clinical decision making and efficiency;
- applies continuously available patient- and population-level data in a manner tailored to the user; and
- provides continuous, automated syndromic reporting that enables users to address community health issues.

Also, our Apollo technology platform, which is the supporting infrastructure underlying many of our health improvement programs described below, integrates data from a variety of sources that include health plans, pharmacy benefit managers, point-of-care devices, and patient self-reports in a highly

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dynamic, interactive portal to deliver high quality patient education and engender behavior-changing communication among clinicians and patients.

All of these health information solutions, coupled with our expertise in near-patient diagnostics, enable us to offer a suite of health improvement programs, including accountable care programs, that address the three core objectives of value-driven healthcare:

- improving the patient s care experience by raising levels of quality and satisfaction;
- reducing the per capita costs of healthcare while maintaining a focus on the individual needs of each patient; and
- improving the overall health of managed populations.

Our health improvement programs are designed to address the most prevalent, costly chronic conditions, deploying real-time diagnostics data, robust analytics, and advanced decision support capabilities to identify high-risk individuals and set personalized care plans. They are supported by trained clinicians with expertise in health coaching and behavior change. Our data exchange solutions also help to ensure that clinicians who encounter a patient in the care pathway have real-time visibility into that patient s health information, which helps to reduce fragmentation, create operational efficiencies, and improve care effectiveness. Our programs focused on health improvement and accountable care include:

Disease and Case Management. The Alere Disease Management (Chronic Care) Program provides technology-enabled, evidence-based solutions for managing chronic and high-cost conditions, as well as improving clinical and financial outcomes. The Alere Disease Management Program enables individuals with chronic conditions to better manage their health through education about their illnesses, potential complications, and the importance of therapy compliance. Our highly-trained nurses proactively contact participants to monitor their progress and compliance with the care plans set by their physicians. They also work with participants to identify potential care gaps, which occur when individuals are not treated in accordance with best practices or when they fail to follow their treatment plans.

Our personalized health support model differs from more traditional models in that it applies a more disciplined approach to defining which patients could benefit from particular interactions and the best means of initiating these interactions. A second key differentiator is the use of biometric devices for participants in programs focused on higher-risk conditions. 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.

The Alere Oncology Case Management Program is the longest-running cancer management program (since 1994) in the United States. Our program provides services for adults diagnosed with any cancer that requires treatment beyond a single surgery, and we have developed treatment guidelines to support 42 different tumor types and more than 200 stages of cancer in a compassionate, cost-effective way.

Women s & Children s Health. Our Women s and Children s Health division delivers a wide variety of obstetrical care services that range from risk assessments focused on identifying women who may experience pregnancy complications to a neonatal program that supports early infant care management. We offer home-based obstetrical monitoring for pregnant women with medical or pregnancy-related problems that could put their health or the health of their babies at risk. We also 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 care plans, with a focus on assessing patient data and providing education. Our high-risk pregnancy management program revenues tend to be seasonal, decreasing with the onset of the holiday season starting on Thanksgiving. Consequently, first and fourth quarter revenues each year tend to be lower than second and third quarter revenues.

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Wellness. We offer a suite of integrated wellness programs and resources that are designed to reduce participant health risks and healthcare-related costs. Our wellness programs include screening for risk factors associated with chronic disease, particularly tobacco use, poor nutrition, physical inactivity, and chronic stress. After evaluating these risks, we deploy health coaching, administered telephonically or through web-based applications, to drive sustainable changes in behavior that promote better health.

Patient Self-testing Services. We offer services designed to support anticoagulation management for patients who take warfarin to control their risk for stroke and clotting disorders. Alere Home Monitoring, our patient self-testing business, assists patients in acquiring home INR monitors and with insurance coverage determinations and provides physicians with a comprehensive model that allows them to incorporate patient self-testing into their practices. Our program has been developed to identify candidates who will benefit from self-testing protocols and who will be able to follow them successfully for a sustained period of time. The program is built around a sophisticated, web-based application that delivers patient results and other information to healthcare providers on a real-time basis, facilitating immediate therapy adjustments where appropriate and reducing the risk of serious events.

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. Taking advantage of our leadership in the field of women s health, we also sell Balance Activ Vaginal Gel directly to consumers and healthcare professionals for the effective treatment of bacterial vaginosis without antibiotics.

Methods of Distribution and Customers

We distribute our professional diagnostic products to hospitals, reference laboratories, physician offices and other point-of-care settings through an extensive worldwide distribution network. We have our own sales force in many countries, including most major 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 in the United States by contacting patients who have expressed an interest or have prescriptions from their physicians and facilitating the Medicare reimbursement process for physicians and for patients monitoring at home. Our diabetes testing supplies business provides these products via mail-order to patients in the United States.

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

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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 with other brand name drug testing products based on price, performance and brand awareness.

Manufacturing

Our primary manufacturing facilities are located in San Diego, California; Scarborough, Maine; Hangzhou and Shanghai, China; Matsudo, Japan; Oslo, Norway; Dundee, Scotland; 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 and Dundee, United Kingdom. We also conduct research and development at some of our other facilities, including facilities in the United States, the United Kingdom, China, Israel, Japan and South Korea. Our research and development programs focus on the development of cardiology, infectious disease, toxicology, diabetes, oncology and women s health products together with health information technologies that will facilitate connectivity and information and data management solutions. 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, South Korea and the United Kingdom 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 over 30 countries.

Our professional diagnostic products are sold throughout the world. Our health information solutions are sold almost exclusively in the United States but we now offer our health information solutions in Australia, Germany and the United Kingdom. During both 2012 and 2011, we generated approximately 61% of our net revenue from the United States, approximately 17% from Europe and approximately 22% 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 sold within the areas of cardiology, infectious disease, toxicology, diabetes, oncology and women s health. Competition for rapid diagnostic products is intense and is primarily

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based on price, quality, breadth of product line, technology and distribution capabilities. Some competitors in the market for professional rapid diagnostic products, such as BD, are large companies with substantial resources, while numerous smaller, yet aggressive companies also compete with us. We believe that 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 unit costs of such systems are lower and other indirect costs are not taken into account. 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, as well as our epoc Blood Analysis System, 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, who together currently account for a substantial majority of the domestic sales of PT/INR point-of-care and patient self-testing devices.

BD, Quidel and Meridian Bioscience are the largest competitors for our rapid diagnostic tests targeted at infectious disease and women s health. 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, BD, Roche, Cepheid and Gen-Probe, are making in-roads into the infectious disease market.

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 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, whose tests are often easier to perform and read and can be more precise.

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.

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In the field of diabetes, the competitors for the Afinion Analyzer System and NycoCard System include Siemens, Bio-Rad Laboratories and Tosoh Corporation. Arriva, which is our mail order diabetes testing product supply business, primarily sells products which are covered by Medicare, Medicaid and other third-party payers. Our major competitors for the sale of these products are large retail pharmacies, such as Walmart, Walgreens and CVS, independent pharmacies and a number of mail order suppliers. Competition for reimbursed diabetes testing supplies, which represent the majority of our business, will change significantly as a result of CMS decision, based on a competitive bidding process, to reimburse only 15 selected suppliers willing to accept a fixed reimbursement rate. As a result of the competitive bidding process, CMS has offered Arriva a national mail-order contract.

Our Alere NMP22 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. The Alere NMP22 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 NMP22 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.

Generally, the competitive positions of our professional diagnostic products 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, particularly 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 capabilities, 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 Information Solutions. Competition in the health information space is intense due to low barriers to entry. Athenahealth, Cerner Corporation, Allscripts Healthcare Solutions, Greenway Medical Technologies, and McKesson provide health information exchange, data management, and clinical support solutions that compete directly with our health information solutions. Additionally, Health Dialog, Healthways, Optum Health, Active Health and a number of smaller service providers offer products that compete with our integrated care management solutions. 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 information service providers or capabilities for the purpose of providing health information solutions 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, including our 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

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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 including an increasing number of patents, patent applications, copyrights, trade secrets and licensed intellectual property, which are intended to protect our vision of the technologies, products and services of the future. Our intellectual property portfolio includes patents and other intellectual property that we own and, in some cases, patents or other intellectual property 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 to our health information solutions business, including our health information technologies.

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 and the market for health information solutions, 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 information solutions. 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 17 through 36 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, changes in the interpretation or application of such 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 diagnostic products, and certain of our health information technologies and solutions, sold in

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the United States are subject to the Federal Food, Drug and Cosmetic Act, or the FDCA, as implemented and enforced by the FDA. Our diagnostic products sold in the United States, including any imbedded or stand-alone software which has been classified by the FDA as a Class II medical device, generally require either FDA clearance to market under Section 510(k) of the FDCA, or Premarket Approval, or PMA, which may require pre-clinical and clinical trials. Certain of our health information solutions are classified by the FDA as Medical Device Data Systems, or MDDS, which are software systems distinct from Class II medical device software, that transfer, store, convert and display medical device data. MDDS do not require FDA clearance or approval to be marketed and sold, but are subject to the FDA-mandated quality standards. 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 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 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 our clinicians, such as nurses, must comply with individual licensing requirements. We believe that 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 2013, we will assume reporting responsibilities under Section 6002 of the 2010 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 CMS certain payments or other transfers of value to physicians and teaching hospitals and annually report certain ownership and investment interests held by physicians or their immediate family members.

Many areas of our business, including but not limited to our health improvement, diabetes supply and patient self-testing services are subject to unique licensing or permit requirements by state and local health agencies. In addition, these and other areas of our business are 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 17 through 36 of this report.

Employees

As of January 31, 2013, we had approximately 17,400 employees, including temporary and contract employees, of which approximately 9,200 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 markets in which we operate, including the markets for medical diagnostic products and health information solutions, are rapidly evolving, and developments are expected to continue at a rapid pace. Competition in these markets 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 information solutions 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;
- our ability to manufacture, in a cost-effective way, sufficient quantities of our products to meet customer demand;
- 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 Alere 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 face risks and uncertainties relating to the FDA warning letter and OIG subpoena.

On October 9, 2012, we received a warning letter from the FDA referencing inspectional observations set forth in an FDA Form 483 that we received in June 2012. The observations were the result of an inspection of our San Diego facility conducted earlier during 2012 relating to our Alere Triage products, which resulted in two recalls of certain Alere Triage products and revised release specifications for our Alere Triage meter-based products. On October 30, 2012, we responded to the warning letter and submitted evidence of our completion of most of the actions previously detailed in our July 2012 response to the FDA Form 483. Since then we have worked diligently in an effort to fully address each of the issues the FDA has identified, and we plan to continue to do so.

In May 2012, Alere San Diego, Inc. received a subpoena from the Office of Inspector General of the Department of Health and Human Services, or the OIG, seeking documents relating primarily to the quality control testing and performance characteristics of our Alere Triage cardiac marker devices and the Triage TOX Drug Screen manufactured at Alere San Diego. We are in the process of responding to the OIG subpoena and the investigation is ongoing.

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We cannot assure you that the government will find our efforts to resolve the FDA warning letter or the investigation initiated by the OIG subpoena to be satisfactory. We may be unable to implement corrective actions within a timeframe or in a manner satisfactory to the FDA. Failure to do so can result in enforcement proceedings by the government, which may include potential civil or criminal fines and penalties, including disgorgement of amounts earned on any legally-adulterated products; injunctive relief, which could limit, modify or constrain our ability to manufacture, market and sell our products; and exclusion from participation in government healthcare programs, such as Medicare and Medicaid. We have received inquiries from regulatory authorities outside the United States regarding the Alere Triage recalls in the United States and, in at least one case, remedial or corrective action was required. We cannot predict whether other governments regulatory authorities will require additional remedial or corrective actions in the future. The investigation initiated by the OIG subpoena can result in civil or criminal fines or penalties, increased supervision of our business operations by the OIG, or exclusion from participation in government healthcare programs, such as Medicare and Medicaid. We are unable to predict when these matters will be resolved or what action, if any, the government will take in connection with these matters. The issues arising out of the FDA inspection and OIG subpoena may be expanded to cover other matters. We can also face product liability, third-party payer, shareholder, or other litigation. Any of these risks and uncertainties can adversely affect our revenues, results of operations, cash flows and financial condition.

Also, except for increases in manufacturing costs and decreased profitability for our Alere Triage products, we are unable to predict what impact these matters or ensuing proceedings, if any, will have on our results of operations, cash flows or financial condition. Our related efforts to improve our production and quality control processes in accordance with the revised release specifications for the Alere Triage meter-based products and to increase production to offset lower yields have increased our manufacturing costs, and we expect that our costs will continue to increase as we continue to implement the final release specifications or other similar changes to enhance our quality control processes that we or the FDA may deem necessary. Because our efforts to improve our manufacturing processes at our San Diego facility are ongoing and because we are continuing to seek to implement the remaining changes in accordance with the timelines set forth in our response to the FDA, we cannot predict the continuing impact of the final quality control release specifications on our manufacturing yields. We cannot guarantee that we will be able to manufacture all of the impacted products at cost-effective yield rates under the final release specifications, in which case, we may be required to, or we may opt to, cease production and sale of the impacted products. In any case, we expect that our ability to supply certain Alere Triage products will continue to be limited, which we expect to adversely affect revenues from sales of these products. We are unable to predict the scope or the duration of any product shortage. Our revenues and market share could continue to be adversely affected by customer decisions to switch to competing products due to product shortages or damage to our reputation resulting from these matters.

We may experience difficulties that 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 require 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;

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

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, 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

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

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 anti-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 located in China, Japan, Norway, South Korea and the United Kingdom, and we also have manufacturing operations in Australia, Germany, India, Israel, South Africa and Spain. We have significant research and development operations in Germany and the United Kingdom, and we conduct additional research and development activities in China, Israel, Japan and South Korea. In addition, for the year ended December 31, 2012, 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, which will adversely affect our results of operations. 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 information solutions would qualify as quality improving activities , but there have been no regulations specifically classifying our services in such a manner. If our health information solutions 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

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of their medical loss ratios, which may have a material adverse effect on demand for our health information solutions and the results of operations of our health information solutions business.

Additionally, revenues associated with our recently-acquired diabetes business will be impacted by the Durable Medical Equipment, Prosthetics, Orthotics and Supplies, or the DMEPOS, Competitive Bidding Program. Under this program, 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 the Centers for Medicare and Medicaid Services, or CMS, will provide reimbursement for those products and services based on a competitive bidding process. Our Arriva business has been selected through the bidding process and offered a contract to have its products reimbursed by Medicare. However, the DMEPOS Competitive Bidding Program will require us to sell diabetes supplies subject to Medicare reimbursement at significantly lower prices, which will have a material adverse effect on the profitability of these products.

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 a material 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 510(k), or 510(k), or through a Premarket Approval, or 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

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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 the criteria for our tests are simple with a low risk of error. Failure to obtain FDA clearance or approval would preclude commercialization in the U.S. 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. As long as our San Diego facility remains subject to the FDA Warning Letter that we received in October 2012, that facility will be ineligible to receive PMA approvals. While no PMA submissions are currently pending for that facility and we do not plan any new submissions for that facility in 2013, if we are unable to resolve the Warning Letter in a timely manner, our ability to gain approval for new or enhanced products could be adversely impacted.

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

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applicable regulations worldwide. Our manufacturing facilities and those of our suppliers and distributors also are, or can be, subject to periodic regulatory inspections.

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 information solutions 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 the health improvement programs offered by our health information solutions 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 information solutions. 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. Changes in applicable laws, changes in the interpretation or application of such laws, or any failure to comply with existing or future laws, regulations or standards which could have a material adverse effect on our results of operations, financial condition, business and prospects. Moreover, 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 healthcare 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

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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 goods 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 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 market for health information solutions is rapidly and continually evolving, and any such changes may impact our health information solutions business.

The market for health information solutions 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 this market may adversely affect the revenues and results of operations of our health information solutions business. The success of our health information solutions business, including our health improvement programs, depends on a number of factors. These factors include:

- our ability to differentiate our health information solutions 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 products and 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 information solutions 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 information solutions, including our health improvement programs.

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

Some of the contracts for our health information solutions 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 information solutions 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 information solutions business accounts receivable. Deterioration in the collectability of these accounts could adversely affect the health information solutions 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 information solutions fees are contingent upon performance.

Some of our existing health information solutions 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 information solutions programs. There is no guarantee that we will accurately forecast cost savings and clinical outcome improvements under our health information solutions 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 information solutions increase, we may not be able to pass these cost increases on to our customers.

Many of our health information solutions 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 information solutions business. Our customers continue to face cost reduction pressures that may cause them to curtail their use of, or reimbursement for, health information solutions, 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 information solutions 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 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 2012, nearly half of Alere Wellbeing s state clients partially, or substantially, reduced their funding of smoking cessation programs we provided. During 2012, approximately 62% 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.

In addition, some states may reduce current spending on preventative care programs in order to conserve funds for use in anticipated future programs, which may or may not occur. For example, the Centers for Disease Control and Prevention, or CDC, conducted a successful anti-smoking campaign in 2012. The CDC has announced that it is planning to implement another such campaign in 2013. We believe that, in anticipation of that campaign, many states are reducing spending on tobacco cessation programs so that they will have funds available to spend in conjunction with the CDC s expected campaign. If the CDC cancels, delays or substantially modifies its 2013 campaign, if states do not spend the expected funds in conjunction with that campaign, or if tobacco users are reluctant to respond to the campaign, funding for our services could be negatively impacted, which 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 information solutions 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 information solutions 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 integrated care management system, our health information exchange and our clinical decision-support software to provide the framework and supporting infrastructure for significantly enhanced future health information solutions programs and to provide a competitive advantage. These systems and software are relatively new 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 on an ongoing basis in order to effectively run our business. If we fail to successfully manage our information technology systems, our business and operating results could be adversely affected.

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Our ability to protect our information systems and electronic transmissions of sensitive data from data corruption, cyber-based attacks, security breaches or privacy violations 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 or privacy violation that leads to disclosure of consumer information (including personally identifiable information or protected health 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 are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, 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 our toxicology business operations.

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.

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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 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.

Compliance with the SEC s new conflict minerals rules will increase our costs and adversely affect our results of operations.

We are subject to the SEC s new disclosure requirements for public companies that manufacture, or contract to manufacture, products for which certain minerals and their derivatives, namely tin, tantalum, tungsten and gold, known as conflict minerals, are necessary to the functionality or production of those products. These regulations will require us to determine which of our products contain conflict minerals and, if so, to perform an extensive inquiry into our supply chain, in an effort to determine whether or not such conflict minerals originate from the Democratic Republic of Congo, or DRC, or an adjoining country. We expect to incur additional costs to comply with these disclosure requirements, including costs related to determining the source of any of the relevant minerals used in our products, which will adversely affect our results of operations. Because our supply chain is complex, the due diligence procedures that we implement may not enable us to ascertain the origins of any conflict minerals that we use or determine that these minerals did not originate from the DRC or an adjoining country, which may harm our reputation. We may also face difficulties in satisfying customers who may require that our products be certified as DRC conflict-free, which could harm our relationships with these customers and lead to a loss of revenue. These new requirements could also have the effect of limiting the pool of suppliers from which we source these minerals, and we may be unable to obtain conflict-free minerals at competitive prices, which could increase our costs and adversely affect our manufacturing operations and our profitability.

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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 proprietary technology.

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;
- 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. For example, certain patents related to our lateral flow technology expire in 2014 and 2015.

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 information solutions marketplace. We expect that our products and services could be increasingly subject to third-party infringement claims as the number and functionality of our products grow and as we enter new and different industries and markets. Third

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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 technologies, 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 and other intellectual property 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.

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 can also put 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.

Intellectual property law relating to the fields in which we operate is still evolving and, consequently, patent and other intellectual property positions in our industry are subject to change and often uncertain. We may not prevail in any of these suits or other efforts to protect our technology, 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 products, services or technologies complementary 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 and adversely affected as a result of the risks associated with our acquisition strategy.

Since our inception, we have acquired numerous businesses, including Axis-Shield in 2011 and eScreen in 2012. The ultimate success of our acquisitions depends, in part, on our ability to realize the

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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 information or other 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 information solutions 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.

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 information solutions 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.

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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, 2012, we had total debt outstanding of approximately $3.7 billion, which included approximately $2.3 billion in aggregate principal amount of indebtedness outstanding under our secured credit facility, consisting of A term loans (including Delayed Draw term loans) in the aggregate principal amount of $878.4 million, B term loans in the aggregate principal amount of $913.4 million, Incremental B-1 term loans in the aggregate principal amount of $247.5 million, Incremental B-2 term loans in the aggregate principal amount of $196.7 million and revolving credit loans in the aggregate principal amount of $22.5 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, 2012, we also had an aggregate of approximately $1.2 billion in aggregate principal amount of indebtedness outstanding under our senior and senior subordinated notes, all of which mature in 2016 or 2018, as well as $150.0 million in aggregate principal amount of indebtedness outstanding under our 3% convertible senior subordinated notes, which matures in 2016.

We expect to obtain the money to pay our expenses and 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 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, which we may be unable to do on acceptable terms, and forego attractive business opportunities. 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 or create liens on our assets;
- 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.

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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.

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 3% convertible senior subordinated 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 3% convertible senior subordinated 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.

We may not be able to collect all or a portion of amounts which we have loaned to a third party which has filed for bankruptcy protection.

In December 2012, we made a $40.0 million secured loan to a third party in connection with a potential acquisition. In February 2013, the issuer of the note filed for protection under Chapter 11 of the U.S. Bankruptcy Code. The Bankruptcy Court subsequently granted us continuing, valid, binding, enforceable and perfected first priority liens and security interests in all of the post-petition collateral of the debtor to the same extent, priority and enforceability held on pre-petition collateral, in order to secure any and all obligations of the debtor to us under the note, and other related agreements. We have assessed the note for impairment and determined that the note remains fully realizable and, accordingly, we have not recorded a reserve against the amount receivable as of December 31, 2012. The bankruptcy process is inherently complicated and subject to uncertainties and future changes in circumstances and there can be no certainty as to the outcome of these proceedings and that the note will remain realizable.

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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.

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.

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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 3% convertible senior subordinated 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 3% convertible senior subordinated 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, 2012 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 3% convertible senior subordinated 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, 2012, 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.

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

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best interests, and may prevent attempts by our stockholders to replace or remove our current management. These provisions include the following:

- although we have amended our certificate of incorporation to declassify our board of directors , under Delaware law certain continuing directors have terms ending in 2014 and 2015. By preventing stockholders from voting on the election of all of our directors at our annual meetings of stockholders in 2013 and 2014, the longer terms of these continuing directors 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; and

- 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 our United States consumer operations, is located at 51 Sawyer Road, Suite 200, Waltham, Massachusetts. From our office in Galway, Ireland, we oversee and conduct much of our professional diagnostic products business in Europe. 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 information solutions business is headquartered in Atlanta, Georgia. These key administrative facilities are leased from third parties.

We own approximately 18.8 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 Scarborough, Maine; Hangzhou and Shanghai, China; Matsudo, Japan; Oslo, Norway; Dundee, Scotland and Yongin, South Korea. We manufacture some of our consumer and professional diagnostic products in a manufacturing facility of approximately 448,000 square feet in Hangzhou, China, which we own. The majority of our consumer diagnostic products are manufactured in a facility of approximately 133,000 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 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 increasingly rely on our network of toxicology laboratories to provide reliable drugs-of-abuse test results to customers. We own three SAMHSA certified laboratories in the United States, located in Gretna, Louisiana; Santa Rosa, California and Richmond, Virginia. We also operate toxicology laboratories in Austin, Texas; Clearwater, Florida; London, England and Abingdon, England, and we operate an accredited forensic laboratory in Malvern, England.

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Additionally, we have facilities, which are generally leased, in various locations worldwide, including smaller manufacturing operations and laboratories, as well as research and development 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

Matters Relating to our San Diego Facility

On October 9, 2012, we received a warning letter from the FDA referencing inspectional observations set forth in an FDA Form 483 received in June, 2012. The observations were the result of an inspection of our San Diego facility conducted earlier during 2012 relating to our Alere Triage products, which resulted in two recalls of certain Alere Triage products and revised release specifications for our Alere Triage meter-based products. On October 30, 2012, we responded to the warning letter and submitted evidence of our completion of most of the actions previously detailed in our prior response to the FDA Form 483. We have worked cooperatively with the FDA in an effort to fully address each of the inspectional observations and intend to continue to do so.

In May 2012, we also received a subpoena from the Office of Inspector General of the Department of Health and Human Services, or the OIG, seeking documents relating primarily to the quality control testing and performance characteristics of Alere Triage products. We are cooperating with the OIG and continue to supply documents to the OIG under the subpoena.

We are unable to predict when these matters will be resolved or what further action, if any, the government will take in connection with them. Except for increases in manufacturing costs and decreased profitability for our Alere Triage products, we are unable to predict what impact, if any, these matters or ensuing proceedings, if any, will have on our financial condition, results of operations or cash flows.

Class Action Litigation against Alere Home Monitoring

On January 24, 2013, a class action complaint was filed in the U.S. District Court for the Northern District of California against Alere Home Monitoring, or AHM, asserting claims for damages and other relief under California state law, including under California s Confidentiality of Medical Information Act, relating to an inadvertent disclosure of personally identifiable information of approximately 116,000 patients resulting from the theft of a laptop computer from an employee of AHM. The Office of Civil Rights of the U.S. Department of Health and Human Services was notified of the inadvertent disclosure in accordance with the Breach Notification Rule under the HITECH Act, as were certain state agencies. We believe that AHM has strong defenses to the claims made in the complaint and AHM intends to defend this matter vigorously.

Claims in the Ordinary Course and Other Matters

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. Such lawsuits often seek damages, sometimes in substantial amounts. An adverse ruling in such a lawsuit could have a material adverse impact on our sales, operations or financial performance.

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

During the fourth quarter of 2012, we did not sell any of our equity securities in transactions that were not registered under the Securities Act of 1933, as amended, or 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 2012 and 2011:

	High	Low
Fiscal 2012		
Fourth Quarter	$ 22.10	$ 17.20
Third Quarter	$ 20.54	$ 17.13
Second Quarter	$ 26.50	$ 17.62
First Quarter	$ 27.22	$ 21.51
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

On February 25, 2013, there were 1,598 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 31, 2007 through December 31, 2012 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 December 31, 2007 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 31, 2007 and the last trading day of each subsequent year end through December 31, 2012.

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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
12/31/07	$ 100.00	$ 100.00	$ 100.00
12/31/08	$ 33.66	$ 59.11	$ 75.97
12/31/09	$ 73.89	$ 73.77	$ 90.31
12/31/10	$ 65.15	$ 81.76	$ 92.50
12/30/11	$ 41.10	$ 76.76	$ 101.27
12/31/12	$ 32.93	$ 86.69	$ 118.17

The performance graph above shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section. This graph will not be deemed incorporated by reference into any filing under the Securities Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth selected consolidated financial data of our company as of and for each of the years in the five-year period ended December 31, 2012 and should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our Consolidated Financial Statements and notes thereto included elsewhere in this Annual Report on Form 10-K.

On January 15, 2010, we completed the sale of our vitamins and nutritional supplements business. The sale included our entire private label and branded nutritionals businesses and represents the complete divestiture of our entire vitamins and nutritional supplements business segment. The results of the vitamins and nutritional supplements business are included in income (loss) from discontinued operations, net of tax, for all periods presented in the statement of operations data below. The assets and liabilities associated with the vitamins and nutritional supplements business have been reclassified to current classifications as assets held for sale and liabilities related to assets held for sale and, as such, have impacted working capital amounts, which are reflected in the balance sheet data section below, for all balance sheet dates presented.

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For a discussion of certain factors that materially affect the comparability of the selected consolidated financial data or cause the data reflected herein not to be indicative of our future results of operations or financial condition, see Item 1A Risk Factors, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operation and Notes 2(v) and 4 of our Consolidated Financial Statements included elsewhere in this report.

	For the Year Ended December 31,				
	2012	2011	2010	2009	2008
	(in thousands, except per share data)				
Statement of Operations Data:					
Net product sales	$ 1,913,731	$ 1,683,132	$ 1,472,403	$ 1,365,079	$ 1,151,265
Services revenue	876,518	679,922	662,185	528,487	405,462
Net product sales and services revenue	2,790,249	2,363,054	2,134,588	1,893,566	1,556,727
License and royalty revenue	28,576	23,473	20,759	29,075	25,826
Net revenue	2,818,825	2,386,527	2,155,347	1,922,641	1,582,553
Cost of net product sales	932,150	795,424	688,325	619,503	543,317
Cost of services revenue	450,999	338,232	325,286	240,026	177,098
Cost of net product sales and services revenue	1,383,149	1,133,656	1,013,611	859,529	720,415
Cost of license and royalty revenue	7,354	7,036	7,149	8,890	8,620
Cost of net revenue	1,390,503	1,140,692	1,020,760	868,419	729,035
Gross profit	1,428,322	1,245,835	1,134,587	1,054,222	853,518
Operating expenses:					
Research and development	183,001	150,165	133,278	112,848	111,828
Sales and marketing	643,423	565,583	499,124	441,646	381,939
General and administrative	492,766	399,330	446,917	357,033	295,059
Goodwill impairment charge		383,612	1,006,357		
Gain on dispositions, net				(3,355)	
Operating income (loss)	109,132	(252,855)	(951,089)	146,050	64,692
Interest expense, including amortization of original issue discounts and write-off of deferred financing costs and other income (expense), net	(230,603)	86,808	(116,697)	(105,802)	(102,939)
Income (loss) from continuing operations before provision (benefit) for income taxes	(121,471)	(166,047)	(1,067,786)	40,248	(38,247)
Provision (benefit) for income taxes	(30,319)	(24,214)	(29,931)	15,627	(16,644)
Income (loss) from continuing operations before equity earnings of unconsolidated entities, net of tax	(91,152)	(141,833)	(1,037,855)	24,621	(21,603)
Equity earnings of unconsolidated entities, net of tax	13,245	8,524	10,566	7,626	1,050
Income (loss) from continuing operations	(77,907)	(133,309)	(1,027,289)	32,247	(20,553)
Income (loss) from discontinued operations, net of tax			11,397	1,934	(1,048)
Net income (loss)	(77,907)	(133,309)	(1,015,892)	34,181	(21,601)
Less: Net income attributable to non-controlling interests	275	233	1,418	465	167
Net income (loss) attributable to Alere Inc. and Subsidiaries	(78,182)	(133,542)	(1,017,310)	33,716	(21,768)

Preferred stock dividends	(21,293)	(22,049)	(24,235)	(22,972)	(13,989)
Preferred stock repurchase		23,936			
Net income (loss) available to common stockholders(1)	$ (99,475)	$ (131,655)	$ (1,041,545)	$ 10,744	$ (35,757)

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	For the Year Ended December 31,				
	2012	2011	2010	2009	2008
	(in thousands, except per share data)				
Basic and diluted net income (loss) per common share attributable to Alere Inc. and Subsidiaries:					
Income (loss) per common share from continuing operations	$ (1.23)	$ (1.58)	$ (12.47)	$ 0.11	$ (0.45)
Income (loss) per common share from discontinued operations	$	$	$ 0.14	$ 0.02	$ (0.01)
Net income (loss) per common share(1)	$ (1.23)	$ (1.58)	$ (12.33)	$ 0.13	$ (0.46)

	December 31,				
	2012	2011	2010	2009	2008
	(In thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$ 328,346	$ 299,173	$ 401,306	$ 492,773	$ 141,324
Working capital	$ 757,928	$ 669,275	$ 411,399	$ 828,944	$ 470,349
Total assets	$ 7,067,928	$ 6,672,701	$ 6,330,374	$ 6,943,992	$ 5,955,360
Total debt	$ 3,708,508	$ 3,353,495	$ 2,398,985	$ 2,149,324	$ 1,520,534
Other long-term obligations	$ 594,823	$ 534,098	$ 589,822	$ 847,634	$ 809,254
Total stockholders equity	$ 2,180,422	$ 2,229,234	$ 2,575,038	$ 3,527,555	$ 3,278,838

(1) Net income (loss) available to common stockholders and basic and diluted net income (loss) per common share are computed consistent with annual per share calculations described in Notes 2(o) and 12 of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Statements

This Annual Report on Form 10-K, including this Item 7, 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. You can identify these statements by forward-looking words such as may, could, should, would, intend, will, expect, anticipate, believe, estimate, continue or similar words. You should read statements that contain these words carefully 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. Forward-looking statements include, without limitation, statements regarding anticipated expansion and growth in certain of our product and service offerings, the impact of our research and development activities, potential new product and technology achievements, the potential for selective acquisitions, including acquisitions of health information solutions businesses outside the United States, our ability to improve our working capital and operating margins, our expectations with respect to Apollo, our integrated health information solutions technology platform, our ability to improve care and lower healthcare costs for both providers and patients, and our funding plans for our future working capital needs and commitments. Actual results or developments could differ materially from those projected in such statements as a result of numerous factors, including, without limitation, those risks and uncertainties set forth in Item 1A entitled Risk Factors, which begins on page 17 of this report, as well as those factors identified from time to time in our filings with the Securities and Exchange Commission. We do not undertake any obligation to update any forward-looking statements. This report and, in particular, the following discussion and analysis of our financial condition and results of operations, should be read in light of those risks and uncertainties and in conjunction with our accompanying consolidated financial statements and notes thereto.

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Overview

We enable individuals to take greater control of their health at home, under the supervision of their healthcare providers, by combining near-patient diagnostics, health monitoring capabilities and information technology solutions. A leading global provider of point-of-care diagnostics and services, we have developed a strong commercial presence in cardiology, infectious disease, toxicology, and diabetes. Our products and services help healthcare practitioners make earlier, more effective treatment decisions and improve outcomes for individuals living with chronic disease.

During 2012, we focused on completing the foundation for this business model, a process which we began during 2011. With our acquisitions of Avee Laboratories in October 2011, eScreen in April 2012 and Branan Medical in December 2012, our toxicology group is now a full-service provider to a broad range of domestic and foreign employers from industries that require rigorous drug testing. We also built a strong presence in diabetes from the ground up. Following our November 2011 acquisitions of Axis Shield and Arriva Medical, which effectively established our diabetes business, we acquired several mail-order, diabetes home-testing product supply businesses. Our diabetes revenues have grown to over $144.0 million in 2012, and including the effect of acquisitions completed in early 2013, we now service more than 250,000 active diabetes customers. We believe that the strong foundation that we have built in diabetes, specifically in our mail-order diabetes testing supply business, provides us with a competitive advantage in dealing with the impact that CMS competitive bidding program, which will significantly reduce current reimbursement rates starting in July 2013, will have on competition and pricing in the market for diabetes testing supplies.

Core to our strategy are health information technologies that enable diagnostic data to be fed directly into an information exchange that integrates the diagnostic data with other patient-related information in a single health record. In the second half of 2011 and in 2012, we focused on acquiring health information technologies that would supplement our internally developed information technologies, including Apollo, and improve our ability to execute our business strategy. Specifically:

- During the second half of 2011, we acquired RALS, the point-of-care industry s leading data management solution, and AegisPOC, the first web-based data management solution designed for critical care settings, which we have since enhanced and renamed RALS Freedom. Our RALS systems provide bidirectional interfaces that connect a hospital s glucose meters and other point-of-care devices measuring blood gases, prothrombin time, and cardiac parameters to its laboratory and health information systems.

- In December 2011, we acquired Wellogic, now Alere Accountable Care Solutions, or Alere ACS. Through Alere ACS, we deliver health information solutions that help provider organizations meet CMS Meaningful Use requirements and improve coordination across multiple venues of care. These solutions include the Alere Health Information Exchange, which harmonizes multiple streams of data from disparate sources in a single patient-centered record, and Consult EHR, which gives healthcare practitioners greater visibility into a patient s health status.

- In July 2012, we acquired MedApps, now Alere Connect. Alere Connect develops and sells remote health monitoring solutions designed to collect health readings from compatible medical monitors and transmit them to a user s electronic health record, as well as web-based applications to help practitioners manage this data. Alere Connect s comprehensive health information platform and suite of cloud-based software tools enhance care for patients in both wellness and chronic disease management programs.

- In July 2012, we also acquired DiagnosisOne, now Alere Analytics. Through Alere Analytics, we offer a broad array of analytical and clinical decision support tools, which are delivered on our smartPath platform.

As a result, we now offer a variety of software-based analytics, clinical decision support tools, and health improvement programs that enable healthcare providers to initiate earlier interventions, personalize treatment plans, lower costs by reducing hospital readmissions, and measure improvements in outcomes at both a patient and population level.

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During 2012, we also continued to build momentum behind our next generation of novel diagnostic platforms that we expect to drive our growth in future years. Our CD4 platform continues to gain traction and has expanded our global footprint as a leading provider of chronic HIV management diagnostics. We are currently developing expansions to this rapid molecular platform to address additional areas such as hepatitis C and tuberculosis. Our second near-patient molecular platform, which is focused on a broad spectrum of infectious disease targets, continues to progress through U.S. clinical trials. We anticipate that the first use of this cartridge-based system will be rapid flu testing, but applications for additional targets such as group A Streptococcus, respiratory syncytial virus, or RSV, and *C. difficile* are planned. With our novel molecular diagnostic platforms launched, or in the late stages of development, we have now begun to refocus our research and development efforts away from long-term projects towards product enhancements and menu expansion for our existing platforms.

2012 Financial Highlights

Net revenue increased by $432.3 million, or 18%, to $2.8 billion in 2012, from $2.4 billion in 2011.

Gross profit increased by $182.5 million, or 15%, to $1.4 billion in 2012, from $1.2 billion in 2011.

For the year ended December 31, 2012, we generated a net loss available to common stockholders of $99.5 million, or $1.23 per basic and diluted common share. For the year ended December 31, 2011, we generated a net loss available to common stockholders of $131.7 million, or $1.58 per basic and diluted common share. The 2011 net loss included a $383.6 million non-cash charge associated with the impairment of goodwill in our health information solutions business segment and reporting unit.

Results of Operations

The following discussions of our results of continuing operations exclude the results related to the vitamins and nutritional supplements business segment, which was previously presented as a separate operating segment prior to its divestiture in January 2010. The vitamins and nutritional supplements business segment has been segregated from continuing operations and is reflected as discontinued operations in our consolidated financial statements. See Income from Discontinued Operations, Net of Tax below. Where discussed, results excluding the impact of foreign currency translation are calculated on the basis of local currency results, using foreign currency exchange rates applicable to the earlier comparative period. We believe presenting information using the same foreign currency exchange rates helps investors isolate the impact of changes in those rates from other trends. Our results of operations were as follows:

Year Ended December 31, 2012 Compared to Year Ended December 31, 2011

Net Product Sales and Services Revenue. Net product sales and services revenue increased by $427.2 million, or 18%, to $2.8 billion in 2012, from $2.4 billion in 2011. Net product sales and services revenue increased primarily as a result of our acquisitions which contributed an aggregate of $447.6 million of the increase. Excluding the impact of foreign currency translation, net product sales and services revenue in 2012 grew by approximately $460.0 million, or 19%, over 2011.

Net Product Sales and Services Revenue by Business Segment. Net product sales and services revenue by business segment for 2012 and 2011 is as follows (in thousands):

	2012	2011	% Increase (Decrease)
Professional diagnostics	$ 2,165,216	$ 1,736,172	25%
Health information solutions	535,422	534,514	%
Consumer diagnostics	89,611	92,368	(3)%
Net product sales and services revenue	$ 2,790,249	$ 2,363,054	18%

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Professional Diagnostics

The following table summarizes our net product sales and services revenue from our professional diagnostics business segment by groups of similar products and services for 2012 and 2011 (in thousands):

	2012	2011	% Increase (Decrease)
Cardiology	$ 503,534	$ 518,746	(3)%
Infectious disease	615,950	564,983	9%
Toxicology	587,261	387,209	52%
Diabetes	144,441	14,960	866%
Other	314,030	250,274	25%
Professional diagnostics net product sales and services revenue	$ 2,165,216	$ 1,736,172	25%

Net product sales and services revenue from our professional diagnostics business segment increased by $429.0 million, or 25%, to $2.2 billion in 2012, from $1.7 billion in 2011. Excluding the impact of foreign currency translation, net product sales and services revenue from our professional diagnostics business segment increased by $462.2 million, or 27%, comparing 2012 to 2011. Net product sales and services revenue increased primarily as a result of acquisitions, which contributed an aggregate of $441.4 million of the non-currency-adjusted increase. Net product sales from our North American flu-related sales decreased approximately $2.5 million, from $46.1 in 2011 to $43.6 million 2012. Net product sales and services revenue from our professional diagnostics business segment were negatively impacted by the FDA recall matters related to our Alere Triage meter-based products. Net product sales of meter-based Triage products in the U.S. totaled $150.3 million in 2012, as compared to $199.2 million in 2011. Excluding the impact of acquisitions, the decrease in flu-related sales during the comparable periods and the impact of the reduction in net product sales from meter-based Triage products in the U.S., the currency-adjusted organic growth for our professional diagnostics net product sales and services revenue was approximately $73.7 million, or 5%, from 2011 to 2012.

Within our professional diagnostics business segment, net product sales and services revenue for our cardiology business decreased by approximately $15.2 million, or 3%, to $503.5 million in 2012, from $518.7 million in 2011, primarily as a result of the FDA recall matters related to our Alere Triage meter-based products. Net product sales of meter-based Triage products in the U.S. totaled $150.3 million in 2012, as compared to $199.2 million in 2011. The decrease in sales of our meter-based Triage products was partially offset by $19.3 million in sales contributed by the acquisition of Axis-Shield. Net product sales and services revenue for our infectious disease business increased by approximately $51.0 million, or 9%, to $616.0 million in 2012, from $565.0 million in 2011, with our acquisition of Axis-Shield contributing $27.4 million of such increase. Net product sales and services revenue for our toxicology business increased by approximately $200.1 million, or 52%, to $587.3 million in 2012, from $387.2 million in 2011, with our recent acquisitions of Avee, eScreen and Amedica Biotech, Inc., or Amedica, contributing approximately $193.9 million of the increase. Our diabetes net product sales and services revenue increased by approximately $129.5 million, or 866%, to $144.4 million in 2012, from $15.0 million in 2011, with our recent acquisitions contributing nearly all of the increase.

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Health Information Solutions

The following table summarizes our net product sales and services revenue from our health information solutions business segment by groups of similar products and services for 2012 and 2011 (in thousands):

	2012	2011	% Increase (Decrease)
Disease and case management	$ 218,378	$ 237,938	(8)%
Women s & children s health	120,259	114,287	5%
Wellness	104,634	104,868	%
Patient self-testing services	92,151	77,421	19%
Health information solutions net product sales and services revenue	$ 535,422	$ 534,514	%

Net product sales and services revenue from our heath information solutions business segment increased by $0.9 million to $535.4 million in 2012, from $534.5 million in 2011. Within our health information solutions business segment, our disease and case management net product sales and services revenue decreased approximately $19.6 million, or 8%, to $218.4 million in 2012, compared to $237.9 million in 2011, principally due to the increasingly competitive environment, including pricing pressures, the impact of health plans insourcing these services, and state budget pressures. Our patient self-testing services net product sales and services revenue increased approximately $14.7 million, or 19%, to $92.2 million in 2012, compared to $77.4 million in 2011, principally driven by an increase in our home coagulation monitoring programs resulting from a larger patient population and a simultaneous reduction in customer attrition rates. Higher census levels as a result of increased physician referrals led to a 5% increase in revenue from our women s and children s health business.

Consumer Diagnostics

Net product sales and services revenue from our consumer diagnostics business segment decreased by $2.8 million, or 3%, to $89.6 million in 2012, from $92.4 million in 2011. Net product sales by SPD were $187.8 million and $209.2 million during 2012 and 2011, respectively, with the impact of foreign currency translation accounting for substantially all of the decrease.

Net Product Sales and Services Revenue by Geographic Location. Net product sales and services revenue by geographic location for 2012 and 2011 is as follows (in thousands):

	2012	2011	% Increase
United States	$ 1,703,929	$ 1,433,372	19%
Europe	477,681	393,285	21%
Elsewhere	608,639	536,397	13%
Net product sales and services revenue	$ 2,790,249	$ 2,363,054	18%

Net product sales and services revenue of $1.7 billion and $1.4 billion generated in the United States was approximately 61% of total net product sales and services revenue for each of the years ended December 31, 2012 and 2011. The growth in net product sales and services revenue in all geographic regions resulted primarily from the various acquisitions and organic growth, as discussed above.

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License and Royalty Revenue. License and royalty revenue represents license and royalty fees from intellectual property license agreements with third parties. License and royalty revenue increased by $5.1 million, or 22%, to $28.6 million in 2012, from $23.5 million in 2011. During 2012, we received an up-front royalty payment of $11.0 million related to a license of certain of our molecular intellectual property. We also received additional license and royalty revenue during 2012 as a result of our acquisition of Axis-Shield, which contributed approximately $3.7 million of the increase. These increases during 2012 were offset by an amendment to our license agreement with Quidel during 2011 whereby the license agreement was converted to a fully paid-up license. As a result of the amendment, we did not record royalty revenue from Quidel during 2012, as opposed to $7.5 million of royalty revenue recorded from Quidel during 2011, and do not anticipate recording royalty revenue from Quidel in the future.

Gross Profit and Margin Percentage. Gross profit increased by $182.5 million, or 15%, to $1.4 billion in 2012, from $1.2 billion in 2011. The increase in gross profit during 2012 was largely attributed to the increase in net product sales and services revenue resulting from acquisitions. Cost of net revenue during 2012 and 2011 included amortization of $4.7 million and $6.0 million, respectively, relating to the write up of inventory to fair value in connection with certain acquisitions. Reducing gross profit for 2012 and 2011 was $3.1 million and $2.9 million, respectively, in restructuring charges.

Cost of net revenue included amortization expense of $72.3 million and $63.2 million for 2012 and 2011, respectively.

Overall gross margin percentage was 51% in 2012, compared to 52% in 2011.

Gross Profit from Net Product Sales and Services Revenue by Business Segment. Gross profit from net product sales and services revenue increased by $177.7 million, or 14%, to $1.4 billion in 2012, from $1.2 billion in 2011. Gross profit from net product sales and services revenue by business segment for 2012 and 2011 is as follows (in thousands):

	2012	2011	% Increase (Decrease)
Professional diagnostics	$ 1,151,325	$ 964,034	19%
Health information solutions	236,470	245,753	(4)%
Consumer diagnostics	19,305	19,611	(2)%
Gross profit from net product sales and services revenue	$ 1,407,100	$ 1,229,398	14%

Professional Diagnostics

Gross profit from our professional diagnostics net product sales and services revenue increased by $187.3 million, or 19%, to $1.2 billion during 2012, from $964.0 million in 2011, principally as a result of gross profit earned on revenue from acquired businesses, as discussed above. Comparing 2012 to 2011, gross profit was negatively impacted by a decrease in our meter-based Triage product sales, as discussed above. The FDA recall relating to our meter-based Triage products also resulted in incremental costs during 2012 principally due to costs of refunds made during the period, replacement products issued at no cost, unfavorable manufacturing variances and the lost margin on the reduced volume of tests sold during 2012. Cost of professional diagnostics net product sales and services revenue during 2012 and 2011 included amortization of $4.7 million and $6.0 million, respectively, relating to the write-up of inventory to fair value in connection with certain acquisitions. Reducing gross profit for both 2012 and 2011 was $2.3 million in restructuring charges.

Cost of professional diagnostics net product sales and services revenue included amortization expense of $64.4 million and $55.1 million for 2012 and 2011, respectively.

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As a percentage of our professional diagnostics net product sales and services revenue, gross profit from our professional diagnostics business was 53% in 2012, compared to 56% in 2011. Increased revenue from our recently acquired toxicology businesses, which contribute lower-than-segment-average gross margins, and a decrease in our meter-based Triage product sales, which contribute higher-than-segment-average gross margins, contributed to the decrease in gross margin for the respective periods.

Health Information Solutions

Gross profit from our health information solutions net product sales and services revenue decreased by $9.3 million, or 4%, to $236.5 million during 2012, from $245.8 million in 2011, primarily as a result of the increasingly competitive environment, including pricing pressures, the impact of health plans insourcing less differentiated services, such as disease and case management, and state budget pressures. Reducing gross profit for 2012 and 2011 was $0.8 million and $0.7 million, respectively, in restructuring charges.

Cost of health information solutions net product sales and services revenue included amortization expense of $6.7 million for both 2012 and 2011, respectively.

As a percentage of our health information solutions net product sales and services revenue, gross profit from our health information solutions business was 44% in 2012, compared to 46% in 2011. The lower margin percentage is primarily the result of the increasingly competitive environment, including pricing pressures, the impact of health plans insourcing less differentiated services, such as disease and case management, and state budget pressures.

Consumer Diagnostics

Gross profit from our consumer diagnostics net product sales and services revenue decreased $0.3 million, or 2%, to $19.3 million during 2012, from $19.6 million in 2011.

Cost of consumer diagnostics net product sales and services revenue included amortization expense of $1.2 million and $1.4 million for 2012 and 2011, respectively.

As a percentage of our consumer diagnostics net product sales and services revenue, gross profit from our consumer diagnostics business was 22% for 2012, compared to 21% in 2011.

Research and Development Expense. Research and development expense increased by $32.8 million, or 22%, to $183.0 million in 2012, from $150.2 million in 2011. Restructuring charges associated with our various restructuring plans to integrate our newly-acquired businesses totaling $1.3 million and $0.4 million were included in research and development expense during 2012 and 2011, respectively. Amortization expense of $26.9 million and $12.6 million was included in research and development expense for 2012 and 2011, respectively. Included in the $26.9 million of amortization expense for 2012 was $19.2 million related to the write off of certain in-process research and development projects recorded in connection with the Axis-Shield acquisition during the fourth quarter of 2011. Included in the $12.6 million of amortization expense for 2011 was $7.2 million related to the write off of certain in-process research and development projects recorded in connection with the Standard Diagnostics acquisition during the first quarter of 2010.

Research and development expense as a percentage of net revenue was 6% for both 2012 and 2011.

Sales and Marketing Expense. Sales and marketing expense increased by $77.8 million, or 14%, to $643.4 million in 2012, from $565.6 million in 2011. The increase in sales and marketing expense primarily relates to additional spending related to newly-acquired businesses. Amortization

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expense of $239.9 million and $220.9 million was included in sales and marketing expense for 2012 and 2011, respectively. Restructuring charges associated with our various restructuring plans to integrate our newly-acquired businesses totaling $2.5 million and $5.0 million were included in sales and marketing expense during 2012 and 2011, respectively.

Sales and marketing expense as a percentage of net revenue was 23% and 24% for 2012 and 2011, respectively.

General and Administrative Expense. General and administrative expense increased by $93.4 million, or 23%, to $492.8 million in 2012, from $399.3 million in 2011. The increase in general and administrative expense primarily relates to additional spending related to newly-acquired businesses. Acquisition-related costs of $9.7 million and $11.5 million were included in general and administrative expense for 2012 and 2011, respectively. Included in general and administrative expense for 2012 and 2011 was $6.6 million and $14.1 million, respectively, of income recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations. Amortization expense of $8.0 million and $11.2 million was included in general and administrative expense for 2012 and 2011, respectively. Restructuring charges associated with our various restructuring plans to integrate our newly-acquired businesses totaling $13.4 million and $20.0 million were included in general and administrative expense during 2012 and 2011, respectively.

General and administrative expense as a percentage of net revenue was 17% for both 2012 and 2011.

Impairment of Goodwill. We conduct our annual goodwill impairment analysis during the fourth quarter of each year. During the fourth quarter of 2011, when conducting Step 1 of the impairment analysis, as prescribed by ASC 350, *Intangibles Goodwill and Other*, or ASC 350, the analysis indicated that the carrying value of the net assets of our health information solutions reporting unit exceeded the estimated fair value of the reporting unit. As a result, we were required to complete Step 2 of the impairment analysis, as prescribed by ASC 350, to determine the amount of the goodwill impairment charge. The Step 2 portion of the analysis indicated that we needed to record a goodwill impairment charge of approximately $383.6 million, which was recorded during the fourth quarter of 2011. Step 1 of the 2012 impairment analysis did not indicate that the carrying value of any of the assets exceeded the fair value of the applicable reporting unit and, accordingly, we did not record any goodwill impairment charges during 2012. Further details of the goodwill impairment analysis are disclosed in Note 2 of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

Interest Expense. Interest expense includes interest charges and the amortization of deferred financing costs and original issue discounts associated with certain debt issuances. Interest expense increased by $36.6 million, or 18%, to $240.6 million in 2012, from $204.0 million in 2011. The increase is principally due to higher interest expense recorded in connection with higher outstanding debt balances and applicable interest rates in 2012, compared to the outstanding debt balances and applicable interest rates in 2011. Interest expense in 2012 includes approximately $23.2 million of expense associated with the repurchase of substantially all of our 7.875% senior notes. Interest expense for 2011 included interest expense and amortization of fees paid for certain debt modifications totaling $32.5 million recorded in connection with the termination of our former secured credit facility and related interest rate swap agreement in 2011.

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Other Income (Expense), Net. Other income (expense), net includes interest income, realized and unrealized foreign exchange gains and losses and other income and expense. The components and the respective amounts of other income (expense), net are summarized as follows (in thousands):

	2012	2011	Increase/ (Decrease)
Interest income	$ 2,028	$ 2,570	$ (542)
Foreign exchange gains (losses), net	(7,876)	(22,870)	14,994
Other	15,805	22,183	(6,378)
Other income (expense), net	$ 9,957	$ 1,883	$ 8,074

The increase in foreign exchange gains (losses), net for 2012, compared to 2011, was primarily the result of a $12.7 million realized foreign currency loss associated with a cash balance established in connection with the Axis-Shield acquisition in 2011 and a $1.9 million realized foreign currency loss associated with the settlement of an acquisition-related contingent consideration obligation during 2011.

Other income of $15.8 million for 2012 included $15.5 million of prior period royalty settlements, which included a $13.5 million final royalty termination payment received from Quidel, a net $4.2 million gain recorded on the disposal of property, plant and equipment and $1.4 million of income associated with legal settlements related to intellectual property litigation. Partially offsetting the impact of these events was the settlement of a prior year dispute with a former distributor totaling approximately $3.9 million.

Other income of $22.2 million for 2011 includes $13.8 million of income associated with an amendment of our license agreement with Quidel, which also includes a settlement of prior period royalties, $5.0 million of income associated with the settlement of a dispute over certain intellectual property rights, a $4.8 million reversal of a prior period legal settlement reserve no longer deemed necessary, partially offset by approximately $1.6 million of losses recorded on disposal of fixed assets.

Gain on Sale of Joint Venture Interest. In connection with the formation of SPD in May 2007, we entered into an option agreement with P&G, pursuant to which P&G had the right, for a period of 60 days commencing on May 17, 2011, to require us to acquire all of P&G s interest in SPD at fair market value. No gain on the proceeds that we received from P&G through the formation of SPD was recognized in our financial statements until P&G s option to require us to purchase its interest in SPD expired. On July 16, 2011, P&G s option to require us to acquire its interest in SPD at fair market value expired. In connection with the expiration of the option, the gain totaling approximately $288.9 million was recognized during the third quarter of 2011.

Benefit for Income Taxes. Benefit for income taxes increased by $6.1 million, to a $30.3 million benefit in 2012, from a $24.2 million benefit in 2011. The effective tax rate in 2012 was 25%, compared to 15% in 2011. The increase in the benefit for income taxes, and the corresponding effective tax rate, from 2011 to 2012 is primarily related to the rate differential on foreign earnings and the recognition of a tax benefit associated with the goodwill impairment charge recorded during 2011.

The primary components of the 2012 benefit for income taxes relate to U.S. federal and state income tax benefits, including favorable adjustments for revaluation on contingent consideration, offset by tax provisions on foreign income, increases in certain valuation allowances, increase in reserve for uncertain tax positions, and increase for other permanent adjustments. The primary components of the 2011 benefit for income taxes relate to U.S. federal and state income tax benefits and the tax benefit on foreign income, offset by losses related to the 2011 goodwill impairment that were not tax benefitted.

Equity Earnings in Unconsolidated Entities, Net of Tax. Equity earnings in unconsolidated entities are reported net of tax and include our share of earnings in entities that we account for under the equity method of accounting. Equity earnings in unconsolidated entities, net of tax, for 2012

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primarily reflect the following: (i) earnings from our 50% interest in SPD in the amount of $10.7 million, (ii) earnings from our 40% interest in Vedalab S.A., or Vedalab, in the amount of $0.4 million and (iii) earnings from our 49% interest in TechLab, Inc., or TechLab, in the amount of $2.3 million. Equity earnings in unconsolidated entities, net of tax, for 2011 primarily reflect the following: (i) earnings from our 50% interest in SPD in the amount of $5.9 million, (ii) earnings from our 40% interest in Vedalab, in the amount of $0.7 million and (iii) earnings from our 49% interest in TechLab, in the amount of $2.0 million.

Net Loss. For 2012, we generated a net loss available to common stockholders of $99.5 million, or $1.23 per basic and diluted common share, compared a net loss available to common stockholders of $131.7 million, or $1.58 per basic and diluted common share for 2011. Net loss available to common stockholders reflects $21.3 million and $22.0 million of preferred stock dividends paid during 2012 and 2011, respectively, and $23.9 million of income associated with the repurchase of preferred stock during 2011. The net loss in 2012 and 2011 resulted from the various factors discussed above. See Note 12 of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for the calculation of net loss per common share.

Year Ended December 31, 2011 Compared to Year Ended December 31, 2010

Net Product Sales and Services Revenue. Net product sales and services revenue increased by $228.5 million, or 11%, to $2.4 billion in 2011 from $2.1 billion in 2010. Net product sales and services revenue increased primarily as a result of our health information solutions and professional diagnostics-related acquisitions which contributed an aggregate of $163.2 million of the non-currency-adjusted increase. Excluding the impact of foreign currency translation, net product sales and services revenue in 2011 grew by approximately $199.9 million, or 9%, over 2010. Contributing to the increase in net product sales and services revenue was an increase in North American flu-related net product sales during 2011, which increased approximately $27.2 million, from $18.8 million in 2010 to $46.1 million in 2011, as a result of a more typical flu season in 2011 than the lower-than-normal flu levels observed in 2010. Net product sales and services revenue in our health information solutions segment was adversely impacted by the increasingly competitive environment, including pricing pressures and the impact of health plans in-sourcing less differentiated services, such as disease management. Also contributing to the decrease was the loss of approximately $13.1 million of revenue related to the discontinuance of the administration of the drug therapy terbutalene, as a result of the FDA s new warning against the use of terbutalene to treat preterm labor in certain situations, which impacted our women s and children s health business. Wellness net product sales and services revenue from our Alere Wellbeing business, formerly known as Free & Clear, has been negatively impacted as a result of the continuation of decreased funding under certain states quitline programs. Additionally, our patient self-testing services business was adversely impacted by a reimbursement policy change from the CMS.

Net Product Sales and Services Revenue by Business Segment. Net product sales and services revenue by business segment for 2011 and 2010 is as follows (in thousands):

	2011	2010	% Increase (Decrease)
Professional diagnostics	$ 1,736,172	$ 1,440,718	21%
Health information solutions	534,514	598,819	(11)%
Consumer diagnostics	92,368	95,051	(3)%
Net product sales and services revenue	$ 2,363,054	$ 2,134,588	11%

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Professional Diagnostics

The following table summarizes our net product sales and services revenue from our professional diagnostics business segment by groups of similar products and services for 2011 and 2010 (in thousands):

	2011	2010	% Increase
Infectious disease	$ 564,983	$ 437,709	29%
Cardiology	518,746	488,497	6%
Toxicology	387,209	300,125	29%
Diabetes	14,960		N/A
Other	250,274	214,387	17%
Professional diagnostics net product sales and services revenue	$ 1,736,172	$ 1,440,718	21%

Net product sales and services revenue from our professional diagnostics business segment increased by $295.5 million, or 21%, to $1.7 billion in 2011, from $1.4 billion in 2010. Excluding the impact of currency translation, net product sales and services revenue from our professional diagnostics business segment increased by $266.9 million, or 19%, comparing 2011 to 2010. Net product sales and services revenue increased primarily as a result of acquisitions which contributed an aggregate of $161.1 million of the non-currency-adjusted increase. Contributing to the increase in net product sales and services revenue was an increase in North American flu-related net product sales during 2011, as compared to 2010. Net product sales from our North American flu sales increased approximately $27.2 million, from $18.8 million in 2010 to $46.1 million in 2011, as a result of a more typical flu season in 2011 than the lower-than-normal flu levels observed in 2010. Excluding the impact of acquisitions and the increase in flu-related sales during the comparable periods, the currency-adjusted organic growth for our professional diagnostics net product sales and services revenue was 6%.

Within our professional diagnostics business segment, net product sales and services revenue for our infectious disease business increased by approximately $127.3 million, or 29%, to $565.0 million in 2011, from $437.7 million in 2010, driven by increased North American flu-related, HIV and malaria net product sales, coupled with the impact of two recent Brazilian acquisitions, which contributed approximately $29.6 million of the increase, and our acquisition of Axis-Shield in November 2011, which contributed approximately $6.5 million of the increase. Net product sales and services revenue for our cardiology business increased by approximately $30.2 million, or 6%, to $518.7 million in 2011, from $488.5 million in 2010, driven particularly by growth outside the U.S., growth in our domestic cholesterol and professional coagulation testing businesses and our acquisition of Axis-Shield, which contributed approximately $4.2 million of the increase, offset by continued softness in domestic BNP net product sales, primarily related to issues with sales on the Beckman Coulter platform. Our toxicology business increased by approximately $87.1 million, or 29%, to $387.2 million in 2011, from $300.1 million in 2010, with our recent acquisitions contributing approximately $74.4 million of the increase. Our diabetes net product sales and services revenue in 2011 relates to two acquisitions completed during the fourth quarter of 2011.

Health Information Solutions

The following table summarizes our net product sales and services revenue from our health information solutions business segment by groups of similar products and services for 2011 and 2010 (in thousands):

	2011	2010	% Increase (Decrease)
Disease and case management	$ 237,938	$ 281,563	(15)%
Women s & children s health	114,287	126,910	(10)%
Wellness	104,868	103,343	1%
Patient self-testing services	77,421	87,003	(11)%
Health information solutions net product sales and services revenue	$ 534,514	$ 598,819	(11)%

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Net product sales and services revenue from our heath information solutions business segment decreased by $64.3 million, or 11%, to $534.5 million in 2011, from $598.8 million in 2010. Net product sales and services revenue in our health information solutions segment was adversely impacted by the increasingly competitive environment, including pricing pressures and the impact of health plans in-sourcing less differentiated services, such as disease and case management. Also contributing to the decrease was the loss of approximately $13.1 million of revenue related to the discontinuance of the administration of the drug therapy terbutalene, as a result of the FDA s new warning against the use of terbutalene to treat preterm labor in certain situations, which impacted our women s and children s health business. Additional revenue loss of approximately $2.8 million resulted from the closure of our GeneCare business located in Chapel Hill, North Carolina during the first quarter of 2011. Wellness net product sales and services revenue from our Alere Wellbeing business has been negatively impacted as a result of the continuation of decreased funding under certain states quitline programs. Additionally, our patient self-testing services business was adversely impacted by a reimbursement change from the CMS.

Consumer Diagnostics

Net product sales and services revenue from our consumer diagnostics business segment decreased by $2.7 million, or 3%, to $92.4 million in 2011, from $95.1 million in 2010. The decrease was primarily driven by a decrease of our non-SPD related revenue totaling approximately $4.4 million, comparing 2011 to 2010. The decrease in our non-SPD related revenue primarily relates to the loss of a distribution contract for certain products in the United Kingdom in late 2010. The decrease in our non-SPD related revenue was partially offset by an increase in our SPD-related revenue, which increased approximately $1.8 million, comparing 2011 to 2010. Net product sales by SPD were $209.2 million and $193.8 million during 2011 and 2010, respectively.

Net Product Sales and Services Revenue by Geographic Location. Net product sales and services revenue by geographic location for 2011 and 2010 is as follows (in thousands):

	2011	2010	% Increase
United States	$ 1,433,372	$ 1,363,145	5%
Europe	393,285	358,865	10%
Elsewhere	536,397	412,578	30%
Net product sales and services revenue	$ 2,363,054	$ 2,134,588	11%

Net product sales and services revenue of $1.4 billion and $1.4 billion generated in the United States were approximately 61% and 64%, respectively, of total net product sales and services revenue for the year ended December 31, 2011 and 2010, respectively. The growth in net product sales and services revenue in all geographic regions resulted primarily from the various acquisitions and organic growth, both discussed above.

License and Royalty Revenue. License and royalty revenue represents license and royalty fees from intellectual property license agreements with third parties. License and royalty revenue increased by $2.7 million, or 13%, to $23.5 million in 2011, from $20.8 million in 2010. The increase in license and royalty revenue during 2011 was largely driven by our acquisition of Axis-Shield, which contributed approximately $1.8 million of the increase.

Gross Profit and Margin Percentage. Gross profit increased by $111.2 million, or 10%, to $1.2 billion in 2011, from $1.1 billion in 2010. The increase in gross profit during 2011 was largely attributed to the increase in net product sales and services revenue resulting from acquisitions, an increase in North American flu-related net product sales and organic growth from our professional diagnostics business segment. Cost of net revenue during 2011 and 2010 included amortization of $6.0 million and $6.6 million, respectively, relating to the write up of inventory to fair value in connection with certain acquisitions. Reducing gross profit for 2011 and 2010 was $2.9 million and $3.9 million in restructuring charges, respectively.

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Cost of net revenue included amortization expense of $63.2 million and $63.0 million for 2011 and 2010, respectively.

Overall gross margin percentage was 52% in 2011, compared to 53% in 2010.

Gross Profit from Net Product Sales and Services Revenue by Business Segment. Gross profit from net product sales and services revenue increased by $108.4 million to $1.2 billion in 2011, from $1.1 billion in 2010. Gross profit from net product sales and services revenue by business segment for 2011 and 2010 is as follows (in thousands):

	2011	2010	% Increase (Decrease)
Professional diagnostics	$ 964,034	$ 801,745	20%
Health information solutions	245,753	297,085	(17)%
Consumer diagnostics	19,611	22,147	(11)%
Gross profit from net product sales and services revenue	$ 1,229,398	$ 1,120,977	10%

Professional Diagnostics

Gross profit from our professional diagnostics net product sales and services revenue increased by $162.3 million, or 20%, to $964.0 million during 2011, from $801.7 million in 2010, primarily as a result of the increase in net product sales and services revenue, as discussed above. Cost of professional diagnostics net product sales and services revenue during 2011 and 2010 included amortization of $6.0 million and $6.6 million, respectively, relating to the write-up of inventory to fair value in connection with certain acquisitions. Reducing gross profit for 2011 and 2010 was $2.3 million and $3.3 million in restructuring charges, respectively.

Cost of professional diagnostics net product sales and services revenue included amortization expense of $55.1 million and $53.7 million for 2011 and 2010, respectively.

As a percentage of our professional diagnostics net product sales and services revenue, gross profit from our professional diagnostics business was 56% in both 2011 and 2010.

Health Information Solutions

Gross profit from our health information solutions net product sales and services revenue decreased by $51.3 million, or 17%, to $245.8 million during 2011, from $297.1 million in 2010, primarily as a result of the decrease in net product sales and services revenue as discussed above. Reducing gross profit for 2011 and 2010 was $0.7 million and $0.6 million in restructuring charges, respectively.

Cost of health information solutions net product sales and services revenue included amortization expense of $6.7 million and $7.7 million for 2011 and 2010, respectively.

As a percentage of our health information solutions net product sales and services revenue, gross profit from our health information solutions business was 46% in 2011, compared to 50% in 2010. The lower margin percentage earned during 2011 is primarily a result of the decrease in net product sales and services revenue, as discussed above.

Consumer Diagnostics

Gross profit from our consumer diagnostics net product sales and services revenue decreased $2.5 million, or 11%, to $19.6 million during 2011, from $22.1 million in 2010. The decrease in gross profit is primarily a result of changes in net product sales and services revenue mix during 2011, as discussed above.

Cost of consumer diagnostics net product sales and services revenue included amortization expense of $1.4 million and $1.5 million for 2011 and 2010, respectively.

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As a percentage of our consumer diagnostics net product sales and services revenue, gross profit from our consumer diagnostics business was 21% for 2011, compared to 23% in 2010. The lower margin percentage earned during 2011 is primarily a result of the change in net product sales and services revenue, as discussed above.

Research and Development Expense. Research and development expense increased by $16.9 million, or 13%, to $150.2 million in 2011, from $133.3 million in 2010. Included in research and development expense in 2011 is $3.9 million of stock-based compensation expense, representing a decrease of approximately $3.2 million from 2010. Restructuring charges associated with our various restructuring plans to integrate our newly-acquired businesses totaling $0.4 million and $0.5 million were included in research and development expense during 2011 and 2010, respectively. Amortization expense of $12.6 million and $4.8 million was included in research and development expense for 2011 and 2010, respectively.

Research and development expense as a percentage of net revenue was 6% for both 2011 and 2010.

Sales and Marketing Expense. Sales and marketing expense increased by $66.5 million, or 13%, to $565.6 million in 2011, from $499.1 million in 2010. The increase in sales and marketing expense primarily relates to additional spending related to newly-acquired businesses along with an increase in our global sales force in support of product launches. Amortization expense of $220.9 million and $212.3 million was included in sales and marketing expense for 2011 and 2010, respectively. Restructuring charges associated with our various restructuring plans to integrate our newly-acquired businesses totaling $5.0 million and $1.5 million were included in sales and marketing expense during 2011 and 2010, respectively.

Sales and marketing expense as a percentage of net revenue was 24% and 23% for 2011 and 2010, respectively.

General and Administrative Expense. General and administrative expense decreased by $47.6 million, or 11%, to $399.3 million in 2011, from $446.9 million in 2010. General and administrative expense in 2010 included $60.1 million of compensation expense recorded in connection with purchasing the remaining shares of a minority shareholder of Standard Diagnostics. Excluding the impact of the $60.1 million of compensation expense recorded in 2010, general and administrative expense increased approximately $12.5 million, or 3%, to $399.3 million in 2011, from $386.8 million in 2010. The increase in the adjusted general and administrative expense primarily relates to additional spending related to newly-acquired businesses. Acquisition-related costs of $11.5 million and $8.2 million were included in general and administrative expense for 2011 and 2010, respectively. Included in general and administrative expense for 2011 and 2010 was $14.1 million of income and $1.8 million of expense, respectively, recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations. Amortization expense of $11.2 million and $18.4 million was included in general and administrative expense for 2011 and 2010, respectively.

General and administrative expense as a percentage of net revenue was 17% and 21% for 2011 and 2010, respectively.

Impairment of Goodwill. We conducted our annual goodwill impairment analysis during the fourth quarter of 2011. When conducting Step 1 of the impairment analysis, as prescribed by ASC 350, *Intangibles Goodwill and Other*, or ASC 350, the analysis indicated that the carrying value of the net assets of our health information solutions reporting unit exceeded the estimated fair value of the reporting unit. As a result, we were required to complete Step 2 of the impairment analysis, as prescribed by ASC 350, to determine the amount of the goodwill impairment charge. The Step 2 portion of the analysis indicated that we needed to record a goodwill impairment charge of approximately $383.6 million, which was recorded during the fourth quarter of 2011. Any further

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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. Further details of the goodwill impairment analysis are disclosed in Note 2 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Interest Expense. Interest expense includes interest charges, and the amortization of deferred financing costs and original issue discounts associated with certain debt issuances. Interest expense increased by $64.5 million, or 46%, to $204.0 million in 2011, from $139.4 million in 2010. This increase was partially due to interest expense of $32.5 million recorded in 2011, in connection with the termination of our former secured credit facility and related interest rate swap agreement, coupled with the amortization of fees paid for certain debt modifications. Contributing to the increase in interest expense recorded in 2011, compared to 2010, was interest expense incurred on our 8.625% senior subordinated notes issued in September 2010, totaling approximately $36.4 million in 2011, compared to $9.9 million in 2010. Additionally, higher outstanding debt balances during 2011, compared to 2010, contributed to the increase in interest expense during the respective periods.

Other Income (Expense), Net. Other income (expense), net includes interest income, realized and unrealized foreign exchange gains and losses and other income and expense. The components and the respective amounts of other income (expense), net are summarized as follows (in thousands):

	2011	2010	Increase/ (Decrease)
Interest income	$ 2,570	$ 1,960	$ 610
Foreign exchange gains (losses), net	(22,870)	9,752	(32,622)
Other	22,183	11,026	11,157
Other income (expense), net	$ 1,883	$ 22,738	$ (20,855)

The decrease in foreign exchange gains (losses), net for 2011, compared to 2010, was primarily the result of a $12.7 million realized foreign currency loss associated with a cash balance established in connection with the Axis-Shield acquisition in 2011, a $1.9 million realized foreign currency loss associated with the settlement of an acquisition-related contingent consideration obligation during 2011, as well as additional net realized and unrealized foreign exchange losses associated with changes in currency exchange rates during the respective periods.

Other income of $22.2 million for 2011 includes $13.8 million of income associated with an amendment of our license agreement with Quidel, which also includes a settlement of prior period royalties, $5.0 million of income associated with the settlement of a dispute over certain intellectual property rights, a $4.8 million reversal of a prior period legal settlement reserve no longer deemed necessary, partially offset by approximately $1.6 million of losses recorded on disposal of fixed assets.

Other income (expense), net for 2010 includes a $4.5 million gain on a sale of marketable securities, a net recovery of $3.3 million related to certain restructuring activities, a $3.1 million net gain associated with legal settlements related to previously disclosed intellectual property litigation relating to our health information solutions businesses and approximately $0.5 million of income associated with a settlement of prior years royalties during 2010, which were partially offset by a charge related to an accounts receivable reserve for a prior year s sale.

Gain on Sale of Joint Venture Interest. In connection with the formation of SPD in May 2007, we entered into an option agreement with P&G, pursuant to which P&G had the right, for a period of 60 days commencing on May 17, 2011, to require us to acquire all of P&G s interest in SPD at fair market value. No gain on the proceeds that we received from P&G through the formation of SPD was recognized in our financial statements until P&G s option to require us to purchase its interest in SPD expired. On July 16, 2011, P&G s option to require us to acquire its interest in SPD at fair market value expired. In connection with the expiration of the option, the gain totaling approximately $288.9 million was recognized during the third quarter of 2011.

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Benefit for Income Taxes. Benefit for income taxes decreased by $5.7 million, to a $24.2 million benefit in 2011, from a $29.9 million benefit in 2010. The effective tax rate in 2011 was 15%, compared to 3% in 2010. The decrease in the benefit for income taxes from 2010 to 2011 is primarily related to the tax provision associated with the taxes on foreign income. The increase in the effective tax rate between the two years primarily results from the rate differential on foreign earnings and state income taxes.

The primary components of the 2011 benefit for income taxes relate to U.S. federal and state income taxes, taxes on foreign income and the recognition of a tax benefit associated with the goodwill impairment charge recorded during 2011. The primary components of the 2010 benefit for income taxes relate to U.S. federal and state income taxes, taxes on foreign income and the recognition of a tax benefit associated with the goodwill impairment charge recorded during 2010.

Equity Earnings in Unconsolidated Entities, Net of Tax. Equity earnings in unconsolidated entities are reported net of tax and include our share of earnings in entities that we account for under the equity method of accounting. Equity earnings in unconsolidated entities, net of tax, for the year ended December 31, 2011 primarily reflect the following: (i) earnings from our 50% interest in SPD in the amount of $5.9 million, (ii) earnings from our 40% interest in Vedalab, in the amount of $0.7 million and (iii) earnings from our 49% interest in TechLab, in the amount of $2.0 million. Equity earnings in unconsolidated entities, net of tax, for the year ended December 31, 2010 reflect the following: (i) earnings from our 50% interest in SPD in the amount of $8.5 million, (ii) earnings from our 40% interest in Vedalab, in the amount of $0.2 million and (iii) earnings from our 49% interest in TechLab, in the amount of $1.9 million.

Income from Discontinued Operations, Net of Tax. The results of the vitamins and nutritional supplements business are included in income from discontinued operations, net of tax, for all periods presented. For the year ended December 31, 2010, the discontinued operations generated net income of approximately $11.4 million, which includes a gain of $18.7 million ($11.6 million, net of tax) on the sale of the vitamins and nutritional supplements business.

Net Loss. For the year ended December 31, 2011, we generated a net loss available to common stockholders of $131.7 million, or $1.58 per common share, compared to a net loss available to common stockholders of $1.0 billion, or $12.33 per common share for the year ended December 31, 2010. Net loss available to common stockholders reflects $22.0 million and $24.2 million of preferred stock dividends paid during the years ended December 31, 2011 and 2010, respectively, and $23.9 million of income associated with the repurchase of preferred stock during the year ended December 31, 2011. The net loss in 2011 and 2010 resulted from the various factors as discussed above. See Note 12 of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for the calculation of loss per common share.

Liquidity and Capital Resources

Based upon our current working capital position, current operating plans and expected business conditions, we expect to fund our short- and long-term working capital needs primarily using existing cash and our operating cash flow, and we expect our working capital position to improve as we improve our future operating margins and grow our business through new product and service offerings and by continuing to leverage our strong intellectual property position. As of December 31, 2012, we had $328.3 million of cash and cash equivalents, of which $80.0 million was held by domestic subsidiaries and $248.3 million was held by foreign entities. We do not plan to repatriate cash held by foreign entities due to adverse tax implications, including incremental U.S. tax liabilities and potential foreign withholding tax liabilities.

We may also utilize our secured credit facility or other new sources of financing to fund a portion of our capital needs and other commitments, including our contractual contingent consideration

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obligations and future acquisitions. As of December 31, 2012, we had outstanding borrowings totaling $22.5 million under the $250.0 million revolving line of credit under our secured credit facility, leaving $227.5 million available to us for additional borrowings. Our ability to access the capital markets may be impacted by the amount of our outstanding debt and equity and the extent to which our assets are encumbered by our outstanding secured debt. The terms and conditions of our outstanding debt instruments also contain covenants which expressly restrict our ability to incur additional indebtedness and conduct other financings. As of December 31, 2012, we had $3.7 billion in outstanding indebtedness comprised of $2.3 billion under our secured credit facility, $450.0 million of 7.25% senior notes due 2018, $1.8 million of 7.875% senior notes due 2016, $400.0 million of 8.625% senior subordinated notes due 2018, $392.9 million of 9% senior subordinated notes due 2016 and $150.0 million of 3% convertible senior subordinated notes due 2016. In February 2013, we redeemed all of the outstanding 7.875% senior notes. See Note 6 of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for further information about our outstanding debt balances.

If the capital and credit markets experience volatility or the availability of funds is limited, we may incur increased costs associated with issuing debt instruments. In addition, it is possible that our ability to access the capital and credit markets could be limited by these or other factors at a time when we would like, or need, to do so, which could have an adverse impact on our ability to refinance maturing debt and/or react to changing economic and business conditions.

Our funding plans for our working capital needs and other commitments may be adversely impacted by unexpected costs associated with integrating the operations of newly-acquired companies, executing our cost-savings strategies and prosecuting and defending our existing lawsuits and/or unforeseen lawsuits against us. We also cannot be certain that our underlying assumed levels of revenues and expenses will be realized. In addition, we intend to continue to make investments in our research and development efforts related to the substantial intellectual property portfolio we own. We may also choose to further expand our research and development efforts and may pursue the acquisition of new products and technologies through licensing arrangements, business acquisitions, or otherwise. We may also choose to make significant investment to pursue legal remedies against potential infringers of our intellectual property rights. If we decide to engage in such activities, or if our operating results fail to meet our expectations, we could be required to seek additional funding through public or private financings or other arrangements. In such event, adequate funds may not be available when needed or may be available only on terms which could have a negative impact on our business and results of operations. In addition, if we raise additional funds by issuing equity or convertible securities, dilution to then- existing stockholders may result.

Cash Flow Summary

	Year Ended December 31,	
	2012	**2011**
Net cash provided by operating activities	$ 319,683	$ 271,253
Net cash used in investing activities	(574,191)	(898,196)
Net cash provided by financing activities	285,745	540,080
Foreign exchange effect on cash and cash equivalents	(2,064)	(15,270)
Net increase (decrease) in cash and cash equivalents	29,173	(102,133)
Cash and cash equivalents, beginning of period	299,173	401,306
Cash and cash equivalents, end of period	$ 328,346	$ 299,173

Summary of Changes in Cash Position

As of December 31, 2012, we had cash and cash equivalents of $328.3 million; a $29.2 million increase from December 31, 2011. Our primary sources of cash during 2012 included $319.7 million

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generated by our operating activities, $443.2 million of net proceeds received in connection with the issuance of our 7.25% senior notes, $198.0 million of net proceeds received in connection with the Incremental B-2 term loans under our secured credit facility, $22.4 million of proceeds received from the sale of property, plant and equipment, $14.9 million from common stock issuances under employee stock option and stock purchase plans, $14.3 million of net proceeds under various revolving credit facilities, $12.7 million return on investment from equity method investments and $3.1 million from the sales of marketable securities. Our primary uses of cash during 2012 related to $424.6 million net cash paid for acquisitions, $311.6 million related to the repayment of long-term debt obligations, $137.4 million of capital expenditures, $56.3 million related to an increase in other assets, $21.3 million for cash dividends paid on our Series B Preferred Stock, $21.0 million related to payments of acquisition-related contingent consideration obligations, $12.3 million related to a make-whole payment incurred in connection with the repurchase of our 7.875% senior notes, $7.0 million for payment of capital lease obligations and $6.2 million related to the repayment of short-term debt obligations. Fluctuations in foreign currencies negatively impacted our cash balance by $2.1 million during the year ended December 31, 2012.

Operating Cash Flows

Net cash provided by operating activities during 2012 was $319.7 million, which resulted from a net loss from continuing operations of $77.9 million and $37.7 million of cash used to meet net working capital requirements during the period, offset by $435.3 million of non-cash items. The $435.3 million of non-cash items included, among other items, $456.8 million related to depreciation and amortization, a $30.6 million increase related to other non-cash items, $21.5 million of interest expense related to the amortization of deferred financing costs and original issue discounts, $15.7 million related to non-cash stock-based compensation and a $4.7 million non-cash charge related to the write-up of inventory to fair value in connection with the acquisition of Axis-Shield, partially offset by a $84.6 million decrease related to changes in our deferred tax assets and liabilities, which resulted in part from amortization of intangible assets, and $13.2 million in equity earnings in unconsolidated entities.

Investing Cash Flows

Our investing activities during 2012 utilized $574.2 million of cash, including $424.6 million net cash paid for acquisitions, $137.4 million of capital expenditures and $56.3 million related to an increase in other assets, which includes a $46.0 million note receivable and purchases of various licensing agreements totaling approximately $4.3 million, partially offset by $22.4 million of proceeds received from the sale of property, plant and equipment, a $12.7 million return on investment from equity method investments, which included $11.2 million return of capital from SPD, a $5.9 million decrease in our restricted cash balance and $3.1 million received from the sales of marketable securities.

Financing Cash Flows

Net cash provided by financing activities during 2012 was $285.7 million. Financing activities during 2012 primarily included approximately $648.5 million of net proceeds received in connection with long-term debt issuances, which included $443.2 million of net proceeds received in connection with the issuance of our 7.25% senior notes and $198.0 million of net proceeds received in connection with the Incremental B-2 term loans entered under our secured credit facility, $14.3 million of net proceeds under various revolving credit facilities, which included $22.5 million borrowed against our secured credit facility revolving line-of-credit, and $14.9 million of cash received from common stock issuances under employee stock option and stock purchase plans. The $443.2 million received in connection with the issuance of the 7.25% senior notes was offset by $267.4 million of cash payments related to repurchases of our 7.875% senior notes and $170.0 million used to pay down a portion of the outstanding balance under our revolving line-of-credit. In addition, we utilized approximately $21.3 million for dividend payments related to our Series B preferred stock, $21.0 million for payments of

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acquisition-related contingent consideration obligations, $12.3 million related to a make-whole payment incurred in connection with the repurchase of our 7.875% senior notes, $7.0 million for payment of capital lease obligations and $6.2 million related to the repayment of short-term debt obligations.

As of December 31, 2012, we had an aggregate of $19.6 million in outstanding capital lease obligations which are payable through 2019.

Income Taxes

As of December 31, 2012, we had approximately $60.6 million of domestic NOL and domestic capital loss carryforwards, approximately $981.1 million of state NOL carryforwards and $211.6 million of foreign NOL and foreign capital loss carryforwards, which either expire on various dates through 2032 or can be carried forward indefinitely. As of December 31, 2012, we had approximately $57.7 million of domestic research and development, foreign tax and alternative minimum tax credits which either expire on various dates through 2031 or can be carried forward indefinitely. These loss carryforwards and tax credits may be available to reduce future federal, state and foreign taxable income, if any, and are subject to review and possible adjustment by the appropriate tax authorities. Effective January 1, 2009, we adopted a new accounting standard for business combinations. Prior to adoption of this standard, the pre-acquisition losses were applied first to reduce to zero any goodwill and other non-current intangible assets related to the acquisitions, prior to reducing our income tax expense. Upon adoption of the new accounting standard, the reduction of a valuation allowance is generally recorded to reduce our income tax expense.

Furthermore, all domestic losses and credits are subject to the Internal Revenue Service Code Section 382, and 383 limitation, respectively, and may be limited in the event of certain cumulative changes in ownership interests of significant shareholders over a three-year period in excess of 50%. Section 382 and 383 imposes an annual limitation on the use of these losses or credits to an amount equal to the value of the company at the time of the ownership change multiplied by the long-term tax exempt rate. We have recorded a valuation allowance against a portion of the deferred tax assets related to our NOLs and credits and certain of our other deferred tax assets to reflect uncertainties that might affect the realization of such deferred tax assets, as these assets can only be realized via profitable operations.

Off-Balance Sheet Arrangements

We had no material off-balance sheet arrangements as of December 31, 2012.

Contractual Obligations

The following table summarizes our principal contractual obligations as of December 31, 2012 (in thousands):

		Payments Due by Period			
Contractual Obligations	**Total**	**2013**	**2014-2015**	**2016-2017**	**Thereafter**
Long-term debt obligations(1)	$ 3,697,771	$ 60,232	$ 98,049	$ 2,685,239	$ 854,251
Capital lease obligations(2)	19,601	6,683	9,428	2,782	708
Operating lease obligations(3)	234,321	43,148	70,293	58,384	62,496
Pension obligations	5,805	893	1,786	1,786	1,340
Acquisition-related obligations(4)	28,714	24,160	2,790	1,764	
Purchase obligations capital expenditure	30,254	29,424	830		
Purchase obligations other(5)	60,475	58,535	1,940		
Interest on debt(6)	530,374	109,918	215,972	153,894	50,590
Total	$ 4,607,315	$ 332,993	$ 401,088	$ 2,903,849	$ 969,385

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(1) See the description of various financing arrangements in Note 6 of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

(2) See Note 8 of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

(3) See Note 11(a) of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

(4) Includes $4.7 million and $1.8 million in deferred payments associated with the acquisitions of Standard Diagnostics and Bioeasy Diagnostica Ltda., or Bioeasy, respectively. In addition, this balance includes approximately $22.3 million of contingent consideration obligations that have been accrued as of December 31, 2012.

(5) Other purchase obligations relate to inventory purchases and other operating expense commitments.

(6) Includes our non-variable interest-bearing debt. See the description of various financing arrangements in Note 6 of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

In addition to the contractual obligations detailed above, we have contractual contingent consideration arrangements related to the following acquisitions:

Ionian Technologies, Inc. has a maximum earn-out of $57.5 million that, if earned, is expected to be paid during 2013.

TwistDx, Inc. has a maximum earn-out of up to $125.0 million that, if earned, is expected to be paid during an eight-year period ending on the eighth anniversary of the acquisition, but could extend thereafter.

AdnaGen has a maximum earn-out of $42.0 million that, if earned, is expected to be paid during 2013 through 2016.

Medlab Produtos Medicos Hospitalares Ltda, now known as Alere S.A., has a maximum remaining earn-out potential of $6.0 million that, if earned, is expected to be paid in annual amounts during 2014 through 2017.

Bioeasy has a maximum remaining earn-out potential of approximately $2.5 million that, if earned, is expected to be paid during 2014.

Laboratory Data Systems, Inc., has a maximum remaining earn-out of approximately $7.5 million that, if earned, is expected to be paid during 2013 and 2014.

Mologic Limited has a maximum remaining earn-out potential of $14.8 million that, if earned, is expected to be paid in cash or shares of our common stock during 2014.

Forensics Limited, or ROAR, has a maximum remaining earn-out of approximately £9.3 million (approximately $15.2 million at December 31, 2012) that, if earned, is expected to be paid during 2013 and 2014.

Standing Stone, Inc., has a maximum remaining earn-out of $2.8 million that, if earned, is expected to be paid during 2014. The maximum amount of employee bonuses that we are required to make pursuant to the Standing Stone acquisition agreement is $0.1 million, which, if earned, is also expected to be paid during 2014.

Method Factory, Inc. (d/b/a Wellogic) has a maximum remaining earn-out potential of $49.8 million based on operational targets and an earn-out with no maximum based on profit targets that, if earned, is expected to be paid during 2014 through 2020.

eScreen has a maximum earn-out potential of $70.0 million that, if earned, is expected to be paid during 2014 and 2015.

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MedApps has a maximum earn-out potential of $21.2 million that, if earned, is expected to be paid during 2013 through 2015.

Amedica has a maximum remaining amount potential of $8.1 million that, if earned, is expected to be paid in 2014.

DiagnosisOne has a maximum earn-out potential of $33.0 million that, if earned, is expected to be paid during 2013 through 2015.

Diagnostik Nord has a maximum earn-out potential of 1.4 million (approximately $1.9 million at December 31, 2012) that, if earned, is expected to be paid during 2013 and 2014.

Healthcare Connections Limited has a maximum earn-out potential of £3.5 million (approximately $5.7 million at December 31, 2012) that, if earned, is expected to be paid in 2014.

NationsHealth, Inc., has a maximum earn-out potential of $8.0 million that, if earned, is expected to be paid in 2013 and 2014.

Branan has a maximum remaining amount potential of $3.0 million that, if earned, is expected to be paid during 2013 through 2015.

For further information pertaining to our contractual contingent arrangements see Note 11 of our accompanying Consolidated Financial Statements.

Further, as of December 31, 2012, we had additional contractual obligations as follows:

Agreements with Epocal

In November 2009, we entered into a definitive agreement to acquire all of the issued and outstanding equity securities of Epocal, Inc. As amended as of December 31, 2012, that agreement provided for a total potential purchase price of up to $263.0 million, including milestone payments of up to $90.5 million if Epocal achieves certain other milestones relating to its gross margin and product development efforts on or prior to October 31, 2014. The agreement contains a working capital adjustment whereby the purchase price is increased or decreased to the extent that Epocal s working capital at closing is more or less than a specified amount. We also agreed that, if the acquisition is consummated, we will provide $12.5 million in management incentive arrangements, 25% of which will vest over three years and 75% of which will be payable only upon the achievement of certain milestones.

In February 2013, we completed the acquisition of Epocal. After working capital and other adjustments made at closing, we paid approximately $166.0 million in cash to acquire Epocal, which included a $15.0 million payment for the achievement of the first two financial milestones specified in the agreement. Additional earn-out payments of up to $75.5 million could be triggered if milestones linked to the delivery of additional product offerings on the Epocal platform are achieved.

Critical Accounting Policies

The Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K are prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The accounting policies discussed below are considered by our management and our audit committee to be critical to an understanding of our financial statements because their application depends on management s judgment, with financial reporting results relying on estimates and assumptions about the effect of matters that are inherently uncertain. Specific risks for these critical accounting policies are described in the following paragraphs. For all of these policies, management cautions that future events rarely develop exactly as forecast and the best estimates routinely require adjustment. In addition, the notes to our audited Consolidated Financial Statements for the year ended December 31, 2012, included elsewhere in this Annual Report on Form 10-K, include a comprehensive summary of the significant accounting policies and methods used in the preparation of our consolidated financial statements.

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Revenue Recognition

We primarily recognize revenue when the following four basic criteria have been met: (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services rendered, (3) the fee is fixed or determinable and (4) collection is reasonably assured.

The majority of our revenue is derived from product sales. We recognize revenue upon title transfer of the products to third-party customers, less a reserve for estimated product returns and allowances. Determination of the reserve for estimated product returns and allowances is based on our management s analyses and judgments regarding certain conditions. Should future changes in conditions prove management s conclusions and judgments on previous analyses to be incorrect, revenue recognized for any reporting period could be adversely affected.

For products that include installation, if the installation meets the criteria to be considered a separate element, product revenue is recognized upon delivery, and installation revenue is recognized when the installation is complete. For sales that include customer-specified acceptance criteria, revenue is recognized after the acceptance criteria have been met. Certain of our products require specialized installation. Revenue for these products is deferred until installation is completed. Revenue from services is deferred and recognized over the contractual period, or as services are rendered and accepted by the customer. When arrangements include multiple elements, we use objective evidence of fair value to allocate revenue to the elements, and recognize revenue when the criteria for revenue recognition have been met for each element, in accordance with authoritative guidance on multiple-element arrangements.

Additionally, we generate services revenue in connection with contracts with health plans (both commercial and governmental) and self-insured employers, whereby we provide clinical expertise through fee-based arrangements. Revenue for fee-based arrangements is recognized over the period in which the services are provided. Some contracts provide that a portion of our fees are at risk if our customers do not achieve certain financial cost savings or we do not achieve certain other clinical and operational metrics, over a period of time, typically one year. Revenue subject to refund is not recognized if (i) sufficient information is not available to calculate performance measurements or (ii) interim performance measurements indicate that we are not meeting performance targets. If either of these two conditions exists, we record the amounts as other current liabilities in the consolidated balance sheet, deferring recognition of the revenue until we establish that we are meeting the performance criteria. If we do not meet the performance targets at the end of the contractual period we are obligated under the contract to refund some or all of the at-risk fees.

We also receive license and royalty revenue from agreements with third-party licensees. Revenue from fixed-fee license and royalty agreements is recognized on a straight-line basis over the obligation period of the related license agreements. License and royalty fees that the licensees calculate based on their sales, which we have the right to audit under most of our agreements, are generally recognized upon receipt of the license or royalty payments, unless we are able to reasonably estimate the fees as they are earned. License and royalty fees that are determinable prior to the receipt thereof are recognized in the period they are earned.

Use of Estimates for Sales Returns and Other Allowances and Allowance for Doubtful Accounts

Certain sales arrangements require us to accept product returns. From time to time, we also enter into sales incentive arrangements with our retail customers, which generally reduce the sale prices of our products. As a result, we must establish allowances for potential future product returns and claims resulting from our sales incentive arrangements against product revenue recognized in any reporting period. Calculation of these allowances requires significant judgments and estimates. When evaluating the adequacy of the sales returns and other allowances, our management analyzes historical returns, current economic trends and changes in customer and consumer demand and acceptance of our

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products. When such analysis is not available and a right of return exists, we record revenue when the right of return is no longer applicable. Material differences in the amount and timing of our product revenue for any reporting period may result if changes in conditions arise that would require management to make different judgments or utilize different estimates.

Our total provision for sales returns and other allowances related to sales incentive arrangements amounted to $67.8 million, $47.5 million and $37.3 million, or 4%, 3% and 3%, respectively, of net product sales in 2012, 2011 and 2010, respectively, which have been recorded against product sales to derive our net product sales. Of these amounts, approximately $43.7 million, $23.6 million and $14.0 million for 2012, 2011 and 2010, respectively, represent allowances for future deductions which have been provided against our related accruals for such charges with the balance charged directly against net sales.

Similarly, our management must make estimates regarding uncollectible accounts receivable balances. When evaluating the adequacy of the allowance for doubtful accounts, management analyzes specific accounts receivable balances, historical bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in our customer payment terms and patterns. Our accounts receivable balance was $524.3 million and $475.8 million, net of allowances for doubtful accounts of $36.4 million and $24.6 million, as of December 31, 2012 and 2011, respectively.

Inventory

We state our inventories at the lower of the actual cost to purchase or manufacture the inventory or the estimated current market value of the inventory, less cost to sell. In addition, we periodically review the inventory quantities on hand and record a provision for excess and obsolete inventory. This provision reduces the carrying value of our inventory and is calculated based primarily upon factors such as forecasts of our customers demands, shelf lives of our products in inventory, loss of customers and manufacturing lead times. Evaluating these factors, particularly forecasting our customers demands, requires management to make assumptions and estimates. Actual product and services revenue may prove our forecasts to be inaccurate, in which case we may have underestimated or overestimated the provision required for excess and obsolete inventory. If, in future periods, our inventory is determined to be overvalued, we would be required to recognize the excess value as a charge to our cost of sales at the time of such determination. Likewise, if, in future periods, our inventory is determined to be undervalued, we would have over-reported our cost of sales, or understated our earnings, at the time we recorded the excess and obsolete provision. Our inventory balance was $337.1 million and $320.3 million, net of a reserve for excess and obsolete inventory of $21.8 million and $13.6 million, as of December 31, 2012 and 2011, respectively.

Goodwill and Other Long-Lived and Intangible Assets

Our long-lived assets include property, plant and equipment, goodwill and other intangible assets. As of December 31, 2012, the balances of property, plant and equipment, goodwill and other intangible assets, net of accumulated depreciation and amortization, were $534.5 million, $3.0 billion and $1.9 billion, respectively.

Goodwill relates to amounts that arose in connection with our various business combinations and represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets when accounted for using the acquisition method of accounting. Goodwill is not amortized, but is subject to periodic review for impairment.

We test goodwill and other intangible assets with indefinite lives at the reporting unit level for impairment on an annual basis and between annual tests, if events and circumstances indicate it is more likely than not that the fair value of a reporting unit is less than its carrying value. Events that would indicate impairment and trigger an interim impairment assessment include, but are not limited to,

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current economic and market conditions, including a decline in market capitalization, a significant adverse change in legal factors, business climate or operational performance of the business and an adverse action or assessment by a regulator.

In performing the impairment test, we utilize the two-step approach. The first step, or Step 1, requires a comparison of the carrying value of each reporting unit to its estimated fair value. To estimate the fair value of our reporting units for Step 1, we use a combination of the income approach and the market approach. The income approach is based on a discounted cash flow analysis, or DCF, and calculates the fair value by estimating the after-tax cash flows attributable to a reporting unit and then discounting the after-tax cash flows to a present value, using a risk-adjusted discount rate. Assumptions used in the DCF require the exercise of significant judgment, including judgment about appropriate discount rates and terminal values, growth rates and the amount and timing of expected future cash flows. The forecasted cash flows are based on our most recent budget and for years beyond the budget, our estimates are based on assumed growth rates. We believe our assumptions are consistent with the plans and estimates used to manage the underlying businesses. The discount rates, which are intended to reflect the risks inherent in future cash flow projections, used in the DCF are based on estimates of the weighted-average cost of capital, or WACC, of market participants relative to each respective reporting unit. The market approach considers comparable market data based on multiples of revenue or earnings before interest, taxes, depreciation and amortization, or EBITDA.

If the carrying value of a reporting unit exceeds its estimated fair value, we are required to perform the second step, or Step 2, of the goodwill impairment test to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compares the implied fair value of a reporting unit s goodwill to its carrying value. The implied fair value of goodwill is calculated as the difference between the fair value of the reporting unit and the estimated fair value of its assets and liabilities. To the extent this amount is below the carrying value of goodwill, an impairment charge is recorded.

The estimate of fair value requires significant judgment. We based our fair value estimates on assumptions that we believe to be reasonable but that are unpredictable and inherently uncertain, including estimates of future growth rates and operating margins and assumptions about the overall economic climate and the competitive environment for our business units. There can be no assurance that our estimates and assumptions made for purposes of our goodwill and identifiable intangible asset testing as of the time of testing will prove to be accurate predictions of the future. If our assumptions regarding business plans, competitive environments or anticipated growth rates are not correct, we may be required to record goodwill and/or intangible asset impairment charges in future periods, whether in connection with our next annual impairment testing or earlier, if an indicator of an impairment is present before our next annual evaluation.

Impairment charges related to goodwill have no impact on our cash balances or compliance with financial covenants under our Amended and Restated Credit Agreement.

2012 Annual Goodwill Impairment Test

We conducted our 2012 annual impairment test for our reporting units during the fourth quarter of 2012. Key assumptions (which vary by reporting unit) used in determining fair value under the discounted cash flow approach included discount rates ranging from 11.0% to 15.0%, projected compound average revenue growth rates of 3.0% to 8.1% and terminal value growth rates of 3.0% to 4.0%. In determining the appropriate discount rate, we considered the WACC for each reporting unit, which among other factors considers the cost of common equity capital and the marginal cost of debt of market participants. Key assumptions (which again vary by reporting unit) used in determining fair value under the market approach were based on observed market multiples of enterprise value to revenue and EBITDA for both comparable publicly-traded companies and recent merger and acquisition transactions involving similar companies to estimate appropriate controlling basis multiples

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to apply to each of the reporting units. Based on the multiples implied by this market data, we selected multiples of revenue of 0.9 to 2.4 times and multiples of EBITDA of 6.1 to 8.9 times. In assessing the reasonableness of our estimated fair values of the reporting units, management compared the results of the valuation analyses against our then-current market capitalization to imply a control premium. Based on this analysis, the implied control premium was within the range of comparable industry transactions.

The Step 1 impairment analysis indicated the estimated fair value of the professional diagnostics, health information solutions and consumer diagnostics reporting units exceeded the carrying value of their reporting unit s net assets by 7.9%, 9.4% and 27.2%, respectively.

2011 Annual Goodwill Impairment Test

We conducted our 2011 annual impairment test for our reporting units during the fourth quarter of 2011. Key assumptions (which vary by reporting unit) used in determining fair value under the discounted cash flow approach included discount rates ranging from 11.0% to 14.5%, projected compound average revenue growth rates of 4.9% to 10.0% and terminal value growth rates of 4.0%. In determining the appropriate discount rate, we considered the WACC for each reporting unit, which among other factors considers the cost of common equity capital and the marginal cost of debt of market participants. Key assumptions (which again vary by reporting unit) used in determining fair value under the market approach were based on observed market multiples of enterprise value to revenue and EBITDA for both comparable publicly-traded companies and recent merger and acquisition transactions involving similar companies to estimate appropriate controlling basis multiples to apply to each of the reporting units. Based on the multiples implied by this market data, we selected multiples of revenue of 0.8 to 2.6 times and multiples of EBITDA of 5.6 to 9.3 times. In assessing the reasonableness of our estimated fair values of the reporting units, management compared the results of the valuation analyses against our then-current market capitalization to imply a control premium. Based on this analysis, the implied control premium was within the range of comparable industry transactions.

The Step 1 impairment analysis indicated that the carrying value of the net assets of our health information solutions reporting unit exceeded the estimated fair value of the reporting unit. As a result, we were required to perform Step 2 of the goodwill impairment test to determine the amount, if any, of goodwill impairment charges for the health information solutions reporting unit. We completed Step 2, consistent with the procedures described above, and determined that a goodwill impairment charge in the amount of approximately $383.6 million was required. The resulting goodwill impairment charge is reflected in operating income (loss) in our accompanying Consolidated Statements of Operations.

This impairment was primarily driven by reduced future cash flow expectations from the reporting unit principally as a result of an increasingly competitive business environment for services provided by the reporting unit, including the insourcing of certain services by key customers and a reduction in spending by other customers as a result in part of the continuing difficult economic climate. Also contributing to the impairment charge was the lower valuations ascribed to similar comparable businesses in the public markets.

2010 Annual Goodwill Impairment Test

We conducted our 2010 annual impairment test for our reporting units during the fourth quarter of 2010. Key assumptions (which vary by reporting unit) used in determining fair value under the discounted cash flow approach included discount rates ranging from 12.5% to 13.0%, projected compound average revenue growth rates of 6.0% to 10.0% and terminal value growth rates of 4.0%. In determining the appropriate discount rate, we considered the WACC for each reporting unit, which among other factors considers the cost of common equity capital and the marginal cost of debt of market participants. Key assumptions (which again vary by reporting unit) used in determining fair

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value under the market approach were based on observed market multiples of enterprise value to revenue and EBITDA for both comparable publicly-traded companies and recent merger and acquisition transactions involving similar companies to estimate appropriate controlling basis multiples to apply to each of the reporting units. Based on the multiples implied by this market data, we selected multiples of revenue of 1.0 to 2.8 times and multiples of EBITDA of 7.5 to 10.0 times. In assessing the reasonableness of our estimated fair values of the reporting units, management compared the results of the valuation analyses against our then-current market capitalization to imply a control premium. Based on this analysis, the implied control premium was within the range of comparable industry transactions.

The Step 1 impairment analysis indicated that the carrying value of the net assets of our health information solutions reporting unit exceeded the estimated fair value of the reporting unit. As a result, we were required to perform Step 2 of the goodwill impairment test to determine the amount, if any, of goodwill impairment charges for the health information solutions reporting unit. We completed Step 2, consistent with the procedures described above, and determined that a goodwill impairment charge in the amount of approximately $1.0 billion was required. The resulting goodwill impairment charge is reflected in operating income (loss) in our accompanying Consolidated Statements of Operations.

This impairment was primarily driven by reduced future cash flow expectations from the reporting unit principally as a result of an increasingly competitive business environment for services provided by the reporting unit, including the insourcing of certain services by key customers and a reduction in spending by other customers as a result in part of the continuing difficult economic climate. Also contributing to the impairment charge was the lower valuations ascribed to similar comparable businesses in the public markets.

Valuation of Other Long-Lived Tangible and Intangible Assets

Factors we generally consider important which could trigger an impairment review on the carrying value of other long-lived tangible and intangible assets include the following: (1) significant underperformance relative to expected historical or projected future operating results, (2) significant changes in the manner of our use of acquired assets or the strategy for our overall business, (3) underutilization of our tangible assets, (4) discontinuance of product lines by ourselves or our customers, (5) significant negative industry or economic trends, (6) significant decline in our stock price for a sustained period, (7) significant decline in our market capitalization relative to net book value and (8) goodwill impairment identified during an impairment review.

We conduct our annual goodwill impairment test for our reporting units during the fourth quarter. The impairment tests conducted during 2011 and 2010 indicated there was an impairment of goodwill associated with our health information solutions reporting unit, and thus, a potential impairment of our long-lived tangible and intangible assets associated with the same reporting unit. We conducted an analysis as prescribed under ASC 360 *Property, Plant and Equipment,* utilizing an undiscounted cash flow model. The analysis conducted during 2011 and 2010 indicated there was no impairment of the long-lived tangible or intangible assets associated with our health information solutions reporting unit.

Stock-Based Compensation

Stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the vesting period. Determining the fair value of stock-based awards at the grant date requires judgment, including estimating our stock price volatility and employee stock option exercise behaviors. If actual results differ significantly from these estimates, stock-based compensation expense and our results of operations could be materially impacted.

Our expected volatility is based upon the historical volatility of our stock. The expected term is based on the assumption that all outstanding options will be exercised at the midpoint of the vesting

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date and the full contractual term, including data on experience to date. As stock-based compensation expense is recognized in our consolidated statements of operations based on awards ultimately expected to vest, the amount of expense has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. If factors change and we employ different assumptions, the compensation expense that we record in future periods may differ significantly from what we have recorded in the current period.

Accounting for Income Taxes

As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves estimating our actual current tax exposure and assessing temporary differences resulting from differing treatment of items, such as reserves and accruals and lives assigned to long-lived and intangible assets, for tax and accounting purposes. These differences result in deferred tax assets and liabilities. We must then assess the likelihood that our deferred tax assets will be recovered through future taxable income and, to the extent we believe that recovery is not more likely than not, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within our tax provision.

Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have recorded a valuation allowance of $68.6 million as of December 31, 2012, due to uncertainties related to the future benefits, if any, from our deferred tax assets related primarily to our foreign businesses and certain U.S. net operating losses, or NOLs, and tax credits. This is an increase of $17.0 million from the valuation allowance of $51.6 million as of December 31, 2011. The increase is primarily related to domestic state NOLs and certain foreign NOLs. The valuation allowance is based on our estimates of taxable income by jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods, we may need to establish an additional valuation allowance or reduce our current valuation allowance which could materially impact our tax provision.

We established reserves for tax uncertainties that reflect the use of the comprehensive model for the recognition and measurement of uncertain tax positions. We are currently undergoing routine tax examinations by U.S. federal, various state and foreign jurisdictions. Tax authorities periodically challenge certain transactions and deductions we reported on our income tax returns. We do not expect the outcome of these examinations, either individually or in the aggregate, to have a material adverse effect on our financial position, results of operations or cash flows.

Loss Contingencies

In the section of this Annual Report on Form 10-K entitled Part I, Item 3, Legal Proceedings, we have reported on material legal proceedings, if any. 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.

We do not accrue for potential losses on legal proceedings where our company is the defendant when we are not able to reasonably estimate our potential liability, if any, due to uncertainty as to the nature, extent and validity of the claims against us, uncertainty as to the nature and extent of the damages or other relief sought by the plaintiff and the complexity of the issues involved. Our potential liability, if any, in a particular case may become reasonably estimable and probable as the case progresses, in which case we will begin accruing for the expected loss.

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Recent Accounting Pronouncements

See Note 2(v) of the Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K, regarding the impact of certain recent accounting pronouncements on our Consolidated Financial Statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The following discussion about our market risk disclosures involves forward-looking statements. Actual results could differ materially from those discussed in the forward-looking statements. We are exposed to market risk related to changes in interest rates and foreign currency exchange rates. We do not use derivative financial instruments for speculative or trading purposes.

Interest Rate Risk

We are exposed to market risk from changes in interest rates primarily through our investing and financing activities. In addition, our ability to finance future acquisition transactions or fund working capital requirements may be impacted if we are not able to obtain appropriate financing at acceptable rates.

To manage our interest rate exposure, our strategy is to invest in short-term, highly-liquid investments. Our investment policy also requires investment in approved instruments with an initial maximum allowable maturity of eighteen months and an average maturity of our portfolio that should not exceed six months, with at least $500,000 cash available at all times. At December 31, 2012, our short-term investments consisted of money market funds with original maturities of 90 days or less. At December 31, 2012, our short-term investments approximated market value.

At December 31, 2012, under the credit agreement for our secured credit facility we had (i) term loans in an aggregate outstanding principal amount of $2.3 billion (consisting of A term loans (including the Delayed-Draw term loans) in the aggregate principal amount of $878.4 million, B term loans in the aggregate principal amount of $913.4 million, Incremental B-1 term loans in the aggregate principal amount of $247.5 million and Incremental B-2 term loans in the aggregate principal amount of $196.7 million), (ii) $22.5 million of outstanding borrowings under our revolving line of credit and (iii) subject to our continued compliance with the credit agreement, the ability to borrow a maximum of up to an additional $227.5 million under our revolving line of credit, which includes a $50.0 million sublimit for the issuance of letters of credit. Loans can be either Base Rate Loans or Eurodollar Rate Loans at our election, and interest accrues on loans and our other Obligations under the terms of the credit agreement as follows (with the terms referenced above and below in this paragraph having the meanings given to them in the credit agreement): (i) in the case of loans that are Base Rate Loans, at a rate per annum equal to the sum of the Base Rate and the Applicable Margin, each as in effect from time to time, (ii) in the case of loans that are Eurodollar Rate Loans, at a rate per annum equal to the sum of the Eurodollar Rate and the Applicable Margin, each as in effect for the applicable Interest Period, and (iii) in the case of other Obligations, at a rate per annum equal to the sum of the Base Rate and the Applicable Margin for Revolving Loans that are Base Rate Loans, each as in effect from time to time. The Base Rate is a floating rate which approximates the U.S. prime rate as in effect from time to time. The Eurodollar Rate is equal to the LIBOR rate and is set for a period of one, two, three or six months at our election. Applicable Margins for our A term loans (including the Delayed-Draw term loans) and revolving line of credit loans range from (i) with respect to such loans that are Base Rate Loans, 1.75% to 2.50% and (ii) with respect to such loans that are Eurodollar Rate Loans, 2.75% to 3.50%, in each case, depending upon our consolidated secured leverage ratio (as determined under the credit agreement). Applicable Margins for our B term loans, Incremental B-1 term loans and Incremental B-2 term loans range from (i) with respect to such loans that are Base Rate Loans, 2.50% to 3.25% and (ii) with respect to such loans that are Eurodollar Rate Loans, 3.50% to 4.25%, in each case, depending upon our consolidated secured leverage ratio. Interest on B term

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loans, Incremental B-1 term loans and Incremental B-2 term loans based on the Eurodollar Rate is subject to a 1.00% floor with respect to the base Eurodollar Rate.

Assuming no changes in our consolidated secured leverage ratio, the effect of interest rate fluctuations on outstanding borrowings as of December 31, 2012 over the next twelve months is quantified and summarized as follows (in thousands):

	Interest Expense Increase
Interest rates payable by us increase by 100 basis points	$ 22,586
Interest rates payable by us increase by 200 basis points	$ 45,172

Foreign Currency Risk

We face exposure to movements in foreign currency exchange rates whenever we, or any of our subsidiaries, enter into transactions with third parties that are denominated in currencies other than our, or its, functional currency. Intercompany transactions between entities that use different functional currencies also expose us to foreign currency risk. During 2012, the net impact of foreign currency changes on transactions was a loss of $7.9 million.

Gross margins of products we manufacture at our foreign plants and sell in U.S. dollars or manufacture in our U.S. plants and sell in currencies other than the U.S. dollar are also affected by foreign currency exchange rate movements. Our gross margin on total net product sales was 51.3% in 2012. If the U.S. dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during 2012, our gross margin on total net product sales would have been 51.4%, 51.7% and 52.1%, respectively.

In addition, because a substantial portion of our earnings is generated by our foreign subsidiaries, whose functional currencies are other than the U.S. dollar (in which we report our consolidated financial results), our earnings could be materially impacted by movements in foreign currency exchange rates upon the translation of the earnings of such subsidiaries into the U.S. dollar.

If the U.S. dollar had been uniformly stronger by 1%, 5% or 10%, compared to the actual average exchange rates used to translate the financial results of our foreign subsidiaries, our net product sales and net income would have been impacted by approximately the following amounts (in thousands):

	Approximate Decrease in Net Revenue	Approximate Decrease in Net Income
If, during 2012, the U.S. dollar was stronger by:		
1%	$ (8,810)	$ (257)
5%	$ (45,670)	$ (1,285)
10%	$ (91,746)	$ (2,570)

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and supplementary data, except for selected quarterly financial data which are summarized below, are listed under Item 15(a) and have been filed as part of this Annual Report on Form 10-K on the pages indicated.

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The following table presents selected quarterly financial data for each of the quarters in the years ended December 31, 2012 and 2011 (in thousands, except per share data):

	2012			
	First Quarter(2)	Second Quarter(3)	Third Quarter(4)	Fourth Quarter(5)
Net revenue	$ 671,129	$ 700,517	$ 691,416	$ 755,763
Gross profit	$ 353,071	$ 355,608	$ 345,775	$ 373,868
Income (loss) from continuing operations	$ 1,029	$ (12,879)	$ (3,517)	$ (62,540)
Net loss available to common stockholders(1)	$ (4,095)	$ (18,194)	$ (9,155)	$ (68,031)
Basic Loss per common share attributable to Alere Inc. and Subsidiaries:				
Loss per common share from continuing operations	$ (0.05)	$ (0.23)	$ (0.11)	$ (0.84)
Net loss per common share(1)	$ (0.05)	$ (0.23)	$ (0.11)	$ (0.84)
Diluted Loss per common share attributable to Alere Inc. and Subsidiaries:				
Loss per common share from continuing operations	$ (0.05)	$ (0.23)	$ (0.11)	$ (0.84)
Net loss per common share(1)	$ (0.05)	$ (0.23)	$ (0.11)	$ (0.84)

	2011			
	First Quarter(6)(7)	Second Quarter(8)	Third Quarter(9)	Fourth Quarter(7)(10)
Net revenue	$ 582,464	$ 567,185	$ 585,769	$ 651,109
Gross profit	$ 306,207	$ 292,728	$ 305,962	$ 340,938
Income (loss) from continuing operations	$ 277	$ (9,442)	$ 239,704	$ (363,848)
Net income (loss) available to common stockholders(1)	$ 8,094	$ (4,669)	$ 234,208	$ (369,288)
Basic Income (loss) per common share attributable to Alere Inc. and Subsidiaries:				
Income (loss) per common share from continuing operations	$ 0.09	$ (0.05)	$ 2.84	$ (4.67)
Net income (loss) per common share(1)	$ 0.09	$ (0.05)	$ 2.84	$ (4.67)
Diluted Income (loss) per common share attributable to Alere Inc. and Subsidiaries:				
Income (loss) per common share from continuing operations	$ 0.09	$ (0.05)	$ 2.48	$ (4.67)
Net income (loss) per common share(1)	$ 0.09	$ (0.05)	$ 2.48	$ (4.67)

(1) Net income (loss) available to common stockholders and basic and diluted net income (loss) per common share are computed consistent with the annual per share calculations described in Notes 2(o) and 12 of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

(2) Included in net loss for the first quarter of 2012 is $5.6 million related to restructuring charges associated with the decision to close various facilities, a write-off in the amount of $4.7 million relating to an inventory write-up recorded in connection with an acquisition, acquisition-related costs in the amount of $1.5 million recorded in accordance with ASC 805, *Business Combinations*, $5.0 million of expense recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations in accordance with ASC 805, *Business Combinations*, $1.3 million of interest expense recorded in connection with fees paid for certain debt modifications and the termination of our senior secured credit facility and $3.9 million of non-cash stock-based compensation expense.

(3) Included in net loss for the second quarter of 2012 is $1.4 million related to restructuring charges associated with the decision to close various facilities, acquisition-related costs in the amount of

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$3.8 million recorded in accordance with ASC 805, *Business Combinations*, $6.7 million of income recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations in accordance with ASC 805, *Business Combinations*, $1.3 million of interest expense recorded in connection with fees paid for certain debt modifications and the termination of our senior secured credit facility and $4.4 million of non-cash stock-based compensation expense.

(4) Included in net loss for the third quarter of 2012 is $3.3 million related to restructuring charges associated with the decision to close various facilities, acquisition-related costs in the amount of $0.8 million recorded in accordance with ASC 805, *Business Combinations*, $15.1 million of income recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations in accordance with ASC 805, *Business Combinations*, $1.3 million of interest expense recorded in connection with fees paid for certain debt modifications and the termination of our senior secured credit facility and $3.6 million of non-cash stock-based compensation expense.

(5) Included in net loss for the fourth quarter of 2012 is $10.3 million related to restructuring charges associated with the decision to close various facilities, acquisition-related costs in the amount of $3.6 million recorded in accordance with ASC 805, *Business Combinations*, $10.2 million of expense recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations in accordance with ASC 805, *Business Combinations*, $23.2 million of expense associated with the repurchase of substantially all of our 7.875% senior notes, $1.0 million of interest expense recorded in connection with fees paid for certain debt modifications and the termination of our senior secured credit facility and $3.8 million of non-cash stock-based compensation expense.

(6) Included in net income for the first quarter of 2011 is $6.4 million related to restructuring charges associated with the decision to close various facilities, acquisition-related costs in the amount of $1.9 million recorded in accordance with ASC 805, *Business Combinations*, $1.4 million of expense recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations in accordance with ASC 805, *Business Combinations*, a $1.9 million realized foreign currency loss associated with the settlement of an acquisition-related contingent consideration obligation and $5.8 million of non-cash stock-based compensation expense.

(7) The first and fourth quarters of 2011 include income tax benefits of $1.4 million and $5.6 million, respectively, to correct items related to periods between 2007 and 2010. We do not believe that the corrected items are material to the 2011 annual financial statements or any previously reported quarterly or annual financial statements.

(8) Included in net loss for the second quarter of 2011 is $10.5 million related to restructuring charges associated with the decision to close various facilities, acquisition-related costs in the amount of $1.4 million recorded in accordance with ASC 805, *Business Combinations*, $7.2 million of income recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations in accordance with ASC 805, *Business Combinations*, $29.9 million of interest expense recorded in connection with fees paid for certain debt modifications and the termination of our senior secured credit facility and related interest rate swap agreement and $6.2 million of non-cash stock-based compensation expense.

(9) Included in net income for the third quarter of 2011 is $3.4 million related to restructuring charges associated with the decision to close various facilities, acquisition-related costs in the amount of $2.9 million recorded in accordance with ASC 805, *Business Combinations*, $3.8 million of income recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations in accordance with ASC 805, *Business Combinations*, $1.3 million of interest expense recorded in connection with fees paid for certain debt modifications and the termination of our senior secured credit facility, an $18.1 million unrealized foreign currency loss associated with a bank account funded for the acquisition of Axis-Shield plc, recognition of a $288.9 million gain originally recorded in connection with the formation of SPD, our 50/50 joint venture with P&G, a $0.6 million fair value write-down recorded in connection with an idle facility and $4.3 million of non-cash stock-based compensation expense.

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(10) Included in net loss for the fourth quarter of 2011 is a goodwill impairment charge in the amount of approximately $383.6 million related to our health information solutions reporting unit and business segment, $8.8 million related to restructuring charges associated with the decision to close various facilities, a write-off in the amount of $6.0 million relating to an inventory write-up recorded in connection with acquisitions, acquisition-related costs in the amount of $5.3 million recorded in accordance with ASC 805, *Business Combinations*, $4.4 million of income recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations in accordance with ASC 805, *Business Combinations*, $1.3 million of interest expense recorded in connection with fees paid for certain debt modifications and the termination of our senior secured credit facility, a $5.4 million realized foreign currency gain associated with a bank account funded for the acquisition of Axis-Shield plc, a $0.5 million gain related to previously-owned shares of Axis-Shield plc recorded in connection with the completion of the acquisition and $4.9 million of non-cash stock-based compensation expense.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Management s Conclusions Regarding the Effectiveness of Our Disclosure Controls and Procedures

Our management evaluated, with the participation of our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the required time periods and that such information is accumulated and communicated to our management, including the CEO and CFO, as appropriate to allow timely decisions regarding required disclosure.

Our management understands, nonetheless, that controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management, necessarily, was required to apply its judgment in evaluating and implementing controls and procedures.

Management s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is a process designed under the supervision of our CEO and CFO to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

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(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2012. In making this assessment, management used the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management determined that the Company maintained effective internal control over financial reporting as of December 31, 2012.

In conducting management s evaluation of the effectiveness of our internal control over financial reporting, management excluded 14 entities acquired in purchase business combinations during 2012 from its assessment. The acquisitions represented approximately 1% and 5% of total assets and net revenue, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2012. Refer to Note 4 of the accompanying consolidated financial statements for a list of the 2012 acquisitions.

The effectiveness of our internal control over financial reporting as of December 31, 2012 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Changes in internal control over financial reporting

There was no change in our internal control over financial reporting that occurred during our fourth fiscal quarter of 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information regarding directors, executive officers and corporate governance included in our definitive Proxy Statement to be filed pursuant to Regulation 14A in connection with our 2013 Annual Meeting of Shareholders, or the Proxy Statement, is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information regarding executive compensation included in the Proxy Statement is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information regarding security ownership of certain beneficial owners and management and related stockholder matters included in the Proxy Statement is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information regarding certain relationships and related transactions, and director independence included in the Proxy Statement is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information regarding principal accounting fees and services included in the Proxy Statement is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

1. Financial Statements.

The financial statements listed below have been filed as part of this report on the pages indicated:

2. Financial Statement Schedules.

All schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission have been omitted because they are inapplicable or the required information is shown in the Consolidated Financial Statements or the notes thereto included herein.

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3. Exhibits.

Some of the agreements filed as exhibits to this Annual Report on Form 10-K contain representations and warranties that were made solely for the benefit of the parties to the agreement. These representations and warranties:

- may have been qualified by disclosures that were made to the other party or parties in connection with the negotiation of the agreements, which disclosures are not necessarily reflected in the agreements;
- may apply standards of materiality that differ from those of investors;
- may have constituted an allocation of risk and responsibility among the parties rather than statements of fact; and
- were made only as of specified dates contained in the agreements and are subject to subsequent developments and changed circumstances.

Accordingly, these representations and warranties may not describe the actual state of affairs as of the date that these representations and warranties were made or at any other time. Investors should not rely on them as statements of fact.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2012)
3.2	Amended and Restated By-laws of the Company (incorporated by reference to Exhibit 3.3 to the Company s Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
4.1	Indenture, dated May 14, 2007, between the Company and U.S. Bank Trust National Association (incorporated by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K, event date May 9, 2007, filed on May 15, 2007)
4.2	Indenture dated as of May 12, 2009 between Inverness Medical Innovations, Inc., as issuer, and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K, event date May 12, 2009, filed on May 12, 2009)
4.3	First Supplemental Indenture dated as of May 12, 2009 to Indenture dated as of May 12, 2009 among Inverness Medical Innovations, Inc., as issuer, the guarantor subsidiaries named therein, as guarantors, and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.2 to the Company s Current Report on Form 8-K, event date May 12, 2009, filed on May 12, 2009)
4.4	Second Supplemental Indenture to Indenture dated as of May 12, 2009 (to add the guarantee of Matria of New York Inc.) dated as of June 9, 2009 among Matria of New York Inc., as guarantor, the Company, as issuer, the other guarantor subsidiaries named therein, as guarantors, and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.4 to Matria of New York Inc. s Registration Statement on Form 8-A filed on June 9, 2009)
4.5	Third Supplemental Indenture to Indenture dated as of May 12, 2009 (to add the guarantees of GeneCare Medical Genetics Center, Inc. and Alere CDM LLC) dated as of August 4, 2009 among GeneCare Medical Genetics Center, Inc., as guarantor, Alere CDM LLC, as guarantor, the Company, as issuer, the other guarantor subsidiaries named therein, as guarantors and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.5 to GeneCare Medical Genetics Center, Inc. and Alere CDM LLC s Registration Statement on Form 8-A filed on August 4, 2009)

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Exhibit No.	Description
4.6	Fourth Supplemental Indenture to Indenture dated as of May 12, 2009 (to add the guarantee of ZyCare, Inc.) dated as of September 22, 2009 among ZyCare, Inc., as guarantor, the Company, as issuer, the other guarantor subsidiaries named therein, as guarantors and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.6 to ZyCare, Inc. s Registration Statement on Form 8-A filed on September 24, 2009)
4.7	Fifth Supplemental Indenture to Indenture dated as of May 12, 2009 (to add the guarantees of Free & Clear, Inc. and Tapestry Medical, Inc.) dated as of November 25, 2009 among Free & Clear, Inc., as guarantor, Tapestry Medical, Inc., as guarantor, the Company, as issuer, the other guarantor subsidiaries named therein, as guarantors, and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.7 to Free & Clear, Inc. and Tapestry Medical, Inc. s Registration Statement on Form 8-A, filed on November 25, 2009)
4.8	Sixth Supplemental Indenture to Indenture dated as of May 12, 2009 (to add the guarantee of RMD Networks, Inc.) dated as of February 1, 2010 among RMD Networks, Inc., as guarantor, the Company, as issuer, the other guarantor subsidiaries named therein, as guarantors, and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.8 to RMD Networks, Inc. s Registration Statement on Form 8-A, filed on February 1, 2010)
4.9	Seventh Supplemental Indenture to Indenture dated as of May 12, 2009 (to add the guarantees of Laboratory Specialists of America, Inc., Kroll Laboratory Specialists, Inc. and Scientific Testing Laboratories, Inc.) dated as of March 1, 2010 among Laboratory Specialists of America, Inc., Kroll Laboratory Specialists, Inc. and Scientific Testing Laboratories, Inc., as guarantors, the Company, as issuer, the other guarantor subsidiaries named therein, as guarantors, and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.9 to Laboratory Specialists of America, Inc., Kroll Laboratory Specialists, Inc. and Scientific Testing Laboratories, Inc. s, Registration Statement on Form 8-A, filed on March 2, 2010)
4.10	Eighth Supplemental Indenture to Indenture dated as of May 12, 2009 (to add the guarantees of Alere NewCo, Inc., Alere NewCo II, Inc., New Binax, Inc. and New Biosite, Inc.) dated as of March 19, 2010 among Alere NewCo, Inc., Alere NewCo II, Inc., New Binax, Inc. and New Biosite, Inc., as guarantors, the Company, as issuer, the other guarantor subsidiaries named therein, as guarantors, and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.10 to Alere NewCo, Inc., Alere NewCo II, Inc., New Binax, Inc. and New Biosite, Inc. s Registration Statement on Form 8-A, filed on March 19, 2010)
4.11	Ninth Supplemental Indenture dated September 21, 2010 to Indenture date as of May 12, 2009 among Alere Inc., as issuer, the subsidiary guarantors named therein, as guarantors, and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K, event date September 15, 2010, filed with the SEC on September 21, 2010)
4.12	Tenth Supplemental Indenture to Indenture dated as of May 19, 2009 (relating to the Record Date Amendments and Waivers) dated as of June 16, 2011, among the Company, the subsidiary guarantors party thereto and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K, event date June 16, 2011, filed on June 22, 2011)
4.13	Eleventh Supplemental Indenture to Indenture dated as of May 19, 2009 (relating to the Record Date Amendments and Waivers) dated as of June 16, 2011, among the Company, the subsidiary guarantors party thereto and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.3 to the Company s Current Report on Form 8-K, event date June 16, 2011, filed on June 22, 2011)

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Exhibit No.	Description
4.14	Twelfth Supplemental Indenture to Indenture dated as of May 19, 2009 (relating to the Restricted Payments Amendments and Waivers) dated as of June 16, 2011, among the Company, the subsidiary guarantors party thereto and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.2 to the Company s Current Report on Form 8-K, event date June 16, 2011, filed on June 22, 2011)
4.15	Thirteenth Supplemental Indenture to Indenture dated as of May 19, 2009 (relating to the Restricted Payments Amendments and Waivers) dated as of June 16, 2011, among the Company, the subsidiary guarantors party thereto and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.4 to the Company s Current Report on Form 8-K, event date June 16, 2011, filed on June 22, 2011)
4.16	Indenture dated as of August 11, 2009 between Inverness Medical Innovations, Inc., as issuer, and The Bank of New York Mellon Trust Company, N.A., as trustee (incorporated by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K, event date August 11, 2009, filed on August 11, 2009)
4.17	Fifteenth Supplemental Indenture, dated as of December 11, 2012, by and among the Company, the subsidiary guarantors named therein and Bank of New York Mellon Trust Company, N.A., as trustee (incorporated by reference to Exhibit 4.2 to the Company s Current Report on Form 8-K, event date December 11, 2012, filed on December 14, 2012)
4.18	Registration Rights Agreement, dated as of December 11, 2012, by and among the Company, the guarantors named therein, and Jefferies & Company, Inc., Goldman, Sachs & Co., and Credit Suisse Securities (USA) LLC, as representatives of the Initial Purchasers (incorporated by reference to Exhibit 4.4 to the Company s Current Report on Form 8-K, event date December 11, 2012, filed on December 14, 2012)
+10.1	BNP Assay Development, Manufacture and Supply Agreement between Biosite Incorporated and Beckman Coulter, Inc. effective June 24, 2003 (incorporated by reference to Exhibit 10.22 to Annual Report of Biosite Incorporated on Form 10-K, filed on March 12, 2007)
+10.2	Shareholder Agreement dated as of May 17, 2007 among Inverness Medical Switzerland GmbH, Procter & Gamble International Operations, SA and SPD Swiss Precision Diagnostics GmbH (incorporated by reference to Exhibit 10.12 to Company s Quarterly Report on Form 10-Q for the period ended June 30, 2007)
10.3	Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan, as amended (incorporated by reference to Appendix A to the Company s Proxy Statement filed on Schedule 14A as filed with the SEC on April 30, 2009)
10.4	Alere Inc. 2010 Stock Option and Incentive Plan, as amended (incorporated by reference to Appendix B to the Company s Proxy Statement filed on Schedule 14A as filed with the SEC on June 1, 2012)
10.5	Rules of Alere Inc. HM Revenue and Customs Approved Share Option Plan (2007), as amended (authorized for use under the Alere Inc. 2001 Stock Option and Incentive Plan and the Alere Inc. 2010 Stock Option and Incentive Plan) (incorporated by reference to Exhibit 10.5 to the Company s Quarterly Report on Form 10-Q for the period ended June 30, 2010)
* 10.6	Summary of Terms of Stock Option Agreements under Alere Inc. Stock Option and Incentive Plans

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Exhibit No.	Description
10.7	Summary of Non-Employee Director Compensation (incorporated by reference to Exhibit 10.8 to the Company s Quarterly Report on Form 10-Q for the period ended September 30, 2010)
10.8	Alere Inc. 2001 Employee Stock Purchase Plan, as amended (incorporated by reference to Appendix B to the Company s Proxy Statement filed on Schedule 14A as filed with the SEC on June 17, 2011)
* 10.9	Restricted Stock Unit Agreement, dated December 30, 2012, between Alere Inc. and Namal Nawana
** 10.10	Consulting Agreement, dated August 30, 2009, between Inverness Medical Switzerland GmbH and Citros V.O.F. (incorporated by reference to Exhibit 10.15 to the Company s Annual Report on Form 10-K/A, for the year ended December 31, 2011)
** 10.11	Management Consultancy Agreement, dated June 26, 2008, between Gesellschaft für Patientenhilfe DGP mbH and Leiter & Partner Unternehmensberater Partnerschaftsgesellschaft (incorporated by reference to Exhibit 10.16 to the Company s Annual Report on Form 10-K/A, for the year ended December 31, 2011)
** 10.12	Amendment of the Contract on the Provision of Consulting, Lease and Other Services, dated April 21, 2011, between Gesellschaft für Patientenhilfe DGP mbH and Leiter & Cie. GmbH (incorporated by reference to Exhibit 10.17 to the Company s Annual Report on Form 10-K/A, for the year ended December 31, 2011)
10.13	Purchase Agreement dated November 28, 2012 among Alere Inc., the subsidiary guarantors named therein and Jefferies & Company, Inc., Goldman, Sachs & Co. and Credit Suisse Securities (USA) LLC, as Representatives of the Initial Purchasers (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K, event date November 28, 2012, filed with the SEC on November 30, 2012)
10.14	Credit Agreement dated as of June 30, 2011 among Alere Inc., as Borrower, the Lenders and L/C Issuers party thereto, General Electric Capital Corporation, as Administrative Agent, Jefferies Finance LLC, as Syndication Agent, and Credit Suisse Securities (USA) LLC, Goldman Sachs Bank USA, DnB Nor Bank ASA and SunTrust Bank, as Co-Documentation Agents (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K, event date June 30, 2011, filed on July 7, 2011)
10.15	Guaranty and Security Agreement dated as of June 30, 2011 among Alere Inc., as Borrower, and each Grantor party thereto and General Electric Capital Corporation, as Administrative Agent (incorporated by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K, event date June 30, 2011, filed on July 7, 2011)
10.16	First Amendment to Credit Agreement dated as of July 27, 2011 among Alere Inc., as Borrower, the Lenders and L/C Issuers party thereto, General Electric Capital Corporation, as Administrative Agent, Jefferies Finance LLC, as Syndication Agent, and Credit Suisse Securities (USA) LLC, Goldman Sachs Bank USA, DnB Nor Bank ASA and SunTrust Bank, as Co-Documentation Agents (incorporated by reference to Exhibit 10.3 to the Company s Quarterly Report on Form 10-Q for the period ended June 30, 2011)
10.17	Second Amendment to Credit Agreement dated as of December 7, 2011 among Alere Inc., as Borrower, the Lenders party thereto, and General Electric Capital Corporation, as Administrative Agent (incorporated by reference to Exhibit 10.3 to the Company s Current Report on Form 8-K, event date December 7, 2011, filed on December 9, 2011)

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Exhibit No.	Description
10.18	Third Amendment to Credit Agreement dated as of March 28, 2012 among Alere Inc., as Borrower, the Lenders party thereto, and General Electric Capital Corporation, as Administrative Agent (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K, event date March 28, 2012, filed on April 2, 2012)
*21.1	List of Subsidiaries of the Company as of February 25, 2013
*23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
*31.1	Certification by Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act
*31.2	Certification by Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act
*32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act
*101	Interactive Data Files regarding (a) our Consolidated Statements of Operations for the Years Ended December 31, 2012, 2011 and 2010, (b) our Consolidated Statements of Comprehensive Income (Loss) for the Years Ended December 31, 2012, 2011 and 2010 (c) our Consolidated Balance Sheets as of December 31, 2012 and 2011, (d) our Consolidated Statements of Equity for the Years Ended December 31, 2012, 2011 and 2010, (e) our Consolidated Statements of Cash Flows for the Years Ended December 31, 2012, 2011 and 2010 and (f) the Notes to such Consolidated Financial Statements.

* Filed herewith.

** The Company agrees to furnish supplementally to the Securities and Exchange Commission (the Commission) a copy of any omitted schedule or exhibit to this agreement upon request by the Commission.

+ We have omitted portions of this exhibit which have been granted confidential treatment.

Management contract or compensatory plan or arrangement, or amendment thereto.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ALERE INC.

Date: March 1, 2013

By: /s/ Ron Zwanziger
Ron Zwanziger
Chairman, Chief Executive Officer and President

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Ron Zwanziger Ron Zwanziger	Chief Executive Officer, President and Director (Principal Executive Officer)	March 1, 2013
/s/ David Teitel David Teitel	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 1, 2013
/s/ Eli Y. Adashi Eli Y. Adashi, MD	Director	March 1, 2013