ALERE INC.
Form 10-K/A
May 28, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K/A

(Amendment No. 2)

ANNUAL REPORT PURSUANT TO SECTIONS 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2014

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

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. ¨

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 ¨ Smaller reporting company ¨
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No 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 30, 2014 (the last business day of the registrant s most recently completed second fiscal quarter) was $2,918,891,906.

As of March 2, 2015, the registrant had 84,486,762 shares of common stock, par value $0.001 per share, outstanding.

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Explanatory Note

This Amendment No. 2 on Form 10-K/A to the Annual Report on Form 10-K of Alere Inc. (the Company) for the year ended December 31, 2014 (the Annual Period), as originally filed with the Securities and Exchange Commission (the SEC) on March 5, 2015 (the Original Report), is being filed to restate the Company s previously issued consolidated financial statements for the Annual Period and to revise related disclosures, including Management s Discussion and Analysis of Financial Condition and Results of Operations for the Annual Period. Concurrently with the filing of this Form 10-K/A, the Company is also filing Amendment No. 1 on Form 10-Q/A to the Company s Quarterly Report on Form 10-Q for the three months ended September 30, 2014 (the Quarterly Period), as originally filed with the SEC on November 7, 2014, to provide similar updates.

This Form 10-K/A includes restated financial information for (i) the year ended December 31, 2014 and (ii) each of the three months ended September 30, 2014 and December 31, 2014. In addition, this Form 10-K/A includes revised, but not restated, financial information for (i) the years ended December 31, 2012 and 2013 and (ii) each of the three months ended March 31, 2013, June 30, 2013, September 30, 2013, December 31, 2013, March 31, 2014 and June 30, 2014 to reflect certain uncorrected errors previously deemed immaterial. Further, we assessed the materiality of the errors in accordance with Securities and Exchange Commission (SEC) Staff Accounting Bulletin No. 99, Materiality, and concluded that these errors were not material to the consolidated financial statements as of and for the years then ended December 31, 2012 and 2013, and each of the three months ended March 31, 2013, June 30, 2013, September 30, 2013, December 31, 2013, March 31, 2014 and June 30, 2014. In accordance with SEC Staff Accounting Bulletin No. 108, Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements, the consolidated financial statements as have been revised as of and for the years then ended December 31, 2012 and 2013, and each of the three months ended March 31, 2013, June 30, 2013, September 30, 2013, December 31, 2013, March 31, 2014 and June 30, 2014 in this filing. Refer to Note 2, Revision of Previously Reported Amounts, in the notes to the accompanying consolidated financial statements for additional information about this revision.

As previously reported in the Company s Current Report on Form 8-K filed with the SEC on May 5, 2015, on May 1, 2015, the Audit Committee of the Board of Directors of the Company, after considering the recommendations of management, concluded that the Company s consolidated financial statements and other financial data for the Annual Period and all interim periods therein (the Non-Reliance Periods), as reported in the Original Report and the Company s Quarterly Reports on Form 10-Q filed on May 6, 2014, August 6, 2014 and November 7, 2014, should not be relied upon because of errors identified therein. Following the completion of the Company s review of those errors and related matters, the Audit Committee of the Board of Directors determined that the consolidated financial statements and other financial information in the Company s Quarterly Reports on Form 10-Q filed on May 6, 2014 and August 6, 2014 did not require any restatement and could therefore be relied upon as originally filed, in all material respects. The Company s consolidated financial statements (including audit reports), other financial information and related disclosures included in the Original Report and the Company s Quarterly Report on Form 10-Q for the three months ended September 30, 2014 as originally filed with the SEC on November 7, 2014, as well as press releases, investor presentations or other communications issued prior to the date hereof that relate to the Non-Reliance Periods should not be relied upon and are superseded in their entirety by this Form 10-K/A and the Form 10-Q/A being filed concurrently herewith.

As more fully described in Note 2 to the accompanying consolidated financial statements, the errors that caused the Audit Committee to conclude that the Company s consolidated financial statements and other financial information for the Non-Reliance Periods should not be relied upon were identified during the course of preparing the Company s consolidated financial statements and other financial data for the quarter ended March 31, 2015. The errors corrected by the restatements relate primarily to the accounting for deferred taxes for the Company s discontinued operations, including in connection with the divestiture of the health management business which was completed in January 2015 and the ACS Companies divestiture which was completed in October 2014. The error

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in the accounting for income taxes associated with the divestiture of the health management business was primarily due to the incorrect determination of the book and tax basis of the businesses sold and other tax attributes of the transaction that resulted in an incorrect determination of realizable deferred tax assets and the resulting tax benefit that was recorded in discontinued operations in the three months ended December 31, 2014. The error in accounting for the ACS Companies divestiture was primarily due to the failure to record deferred taxes associated with the reversal, in the three months ended September 30, 2014, of contingent consideration that originated from a taxable business combination.

For the convenience of the reader, this Form 10-K/A sets forth the Original Report in its entirety (other than Part III, which is not being amended hereby); however, this Form 10-K/A amends and restates only the following items of the Original Report (other than internal cross-references and the like, which are updated throughout the document):

Part I

Item 1A Risk Factors

Part II

Item 6. Selected Consolidated Financial Data
Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations
Item 8. Financial Statements and Supplementary Data
Item 9A. Controls and Procedures

Part IV

Item 15. Exhibits and Financial Statement Schedules

In order to preserve the nature and character of the disclosures set forth in the Original Report, this Form 10-K/A speaks as of the date of the filing of the Original Report, March 5, 2015, and the disclosures contained in this Form 10-K/A have not been updated to reflect events occurring subsequent to that date, other than those associated with the restatement.

In Item 9A of the Original Report, the Company disclosed that its internal control over financial reporting and its disclosure controls and procedures were not effective as of December 31, 2014 because of a material weakness in the Company s controls to assess the accounting for deferred taxes related to dispositions. The Company noted in the Original Report that this control deficiency could result in the failure to prevent or detect misstatements of its deferred tax assets and its income from discontinued operations that could result in a material misstatement of its consolidated financial statements. The Company believes that this material weakness resulted in the material adjustments to our deferred taxes and income from discontinued operations that led to the restatement of the Company s financial statements for the year ended December 31, 2014 and the three and nine-months ended September 30, 2014. The effects of the material weakness, as well as the Company s plan to remediate the material weakness, are discussed in more detail in Item 9A.

Currently dated certifications from the Company s Chief Executive Officer and Chief Financial Officer are attached to this Form 10-K/A as Exhibits 31.1, 31.2 and 32.1. This Form 10-K/A should be read in conjunction with Amendment No. 1 to the Original Report and the Company s other filings with the SEC.

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ALERE INC.

FORM 10-K/A

For The Fiscal Year Ended December 31, 2014

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PART I

This Amendment No. 2 on Form 10-K/A to our Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Readers can identify these statements by forward-looking words such as may, could, should, would, intend, will, expect, anticipate, believe, estimate, continue or similar words. Readers should carefully review statements that contain these words because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other forward-looking information. We caution investors that all such forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from any projected results or expectations that we discuss in this report. You should therefore carefully review the risk factors and uncertainties discussed in Item 1A entitled Risk Factors, which begins on page 13 of this report, as well as those factors identified from time to time in our periodic filings with the Securities and Exchange Commission. We undertake no obligation to update any forward-looking statements.

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

ITEM 1. BUSINESS

General

Alere delivers reliable and actionable health information through rapid diagnostic tests, resulting in better clinical and economic healthcare outcomes globally. Our high-performance diagnostics for infectious disease, cardiometabolic disease and toxicology are designed to meet the growing global demand for accurate, easy-to-use and cost-effective near-patient tests. Our goal is to make Alere products accessible to more people around the world, even those located in remote and resource-limited areas, by making them affordable and usable in any setting. By making critical clinical diagnostic information available to doctors and patients in an actionable timeframe, Alere products help streamline healthcare delivery and improve patient outcomes.

Our company, formerly known as Inverness Medical Innovations, Inc., was formed in 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.

Our reportable operating segments are professional diagnostics, patient self-testing and consumer diagnostics. Financial information about our reportable segments is provided in Note 18 of the notes to consolidated financial statements which are included elsewhere in this report.

Recent Divestitures

On January 9, 2015, we completed the sale of our condition management, case management, wellbeing, wellness, and women s and children s health businesses, which we refer to collectively as

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our health management business, to OptumHealth Care Solutions for a purchase price of $600.1 million, subject to a customary post-closing working capital and net cash adjustment. We used the net cash proceeds of the sale to repay $575.0 million in aggregate principal amount of outstanding indebtedness under our secured credit facility. On October 10, 2014, we completed the sale of our subsidiary, Alere Accountable Care Solutions, LLC, or ACS.

Except for our patient self-testing products and services, the health management business and ACS together represented substantially all of the assets and activities comprising our former health information solutions segment, which we now refer to as our patient self-testing segment. We reclassified the assets and liabilities of the health management business as held for sale within the accompanying consolidated balance sheet as of December 31, 2014, and the results of the operations of the health management business and ACS are reported as income (loss) from discontinued operations, net of tax, for all periods presented in our accompanying consolidated statements of operations. See Note 3 to our accompanying consolidated financial statements for more information about these divestitures and discontinued operations.

Products & Services

Professional Diagnostics

Our professional diagnostic solutions allow patients and their healthcare providers to work together to better manage patients conditions over the continuum of care, from the hospital to home. 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 the developing patient self-testing and patient self-management markets where we believe that we can directly and immediately improve patient health outcomes. 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. Our current professional diagnostic products include point-of-care and laboratory tests within the following areas:

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), gastrointestinal disease, vector-borne diseases such as malaria and dengue, herpes and other sexually-transmitted diseases. In addition, antimicrobial resistance continues to be a major global health issue requiring healthcare professionals to urgently and accurately identify the nature of a pathogen in order to define the appropriate treatment strategy with the optimal clinical results. Healthcare institutions around the world are actively seeking antimicrobial

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stewardship programs and solutions in order to improve their use of antibiotics. Our Test Target Treat initiative is designed to drive education and awareness among healthcare professionals as to how they can utilize rapid diagnostics to make more targeted treatment decisions sooner than would otherwise be possible with conventional diagnostics, thereby reducing inappropriate antimicrobial use and the spread of resistance.

We have continued to expand our product offerings to meet the growing demand for infectious disease diagnostics and we now offer one of the world s largest infectious disease test menus, including tests based on leading-edge technologies that enable rapid and accurate diagnosis and monitoring of the most prevalent infectious diseases. We develop and market a wide variety of point-of-care tests for influenza A & B, RSV, strep A, pneumococcal 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 i, Alere Determine, Acceava, BinaxNOW, Clearview, DoubleCheckGold, Panbio, Pima, SD, TECHLAB and Alere TestPack.

In January 2014, we announced the commercial availability of the Alere i Influenza A & B test in Austria, France, Spain, Switzerland, Germany, Italy and the U.K., and in June 2014, this test received clearance from the U.S. Food and Drug Administration, or FDA, and is currently available for sale in the United States. Alere i is a rapid point-of-care molecular, instrument-based, isothermal platform for the qualitative detection of infectious diseases. Our unique Alere i isothermal nucleic acid amplification technology provides molecular results in just minutes, allowing healthcare providers to make quick and effective clinical decisions. In January 2015, the Alere i Influenza A & B test was granted the first CLIA waiver for a nucleic acid-based flu diagnostic test by the FDA and, as a result, may be used in physician offices, clinics and other public health settings, where influenza patients are frequently examined and treated. Alere i tests for strep A, *C. difficile*, RSV, chlamydia and gonorrhea are currently in development.

Our offerings for the diagnosis and management of HIV infection includes the Alere Determine HIV-1/2 Ag/Ab Combo, the first FDA-approved and CLIA-waived rapid, point-of-care test that detects both HIV-1/2 antibodies and free HIV-1 p24 antigen. Due to its capability to detect p24 antigen, which can appear only days after infection and before the HIV antibody is detectable, this fourth generation test may detect HIV infection earlier in the course of the disease. By enabling healthcare providers to diagnose HIV infection earlier, individuals can receive medical care sooner. The Alere Determine HIV-1/2 Ag/Ab Combo received CLIA-waived status in December 2014, allowing healthcare providers in settings such as physician s offices, clinics and other public health settings to improve clinical outcomes through earlier diagnosis and treatment of patients who test positive for HIV.

The installed base of our Alere Pima Analyzer, previously known as the Alere CD4 Analyzer, continues to expand across Africa and Asia. An absolute CD4 count can help HIV-infected patients to monitor their drug therapy and seek medical intervention if problems arise. The Alere Pima Analyzer provides CD4 results in 20 minutes or less, using disposable, single-use fingerstick cartridges. CD4 results delivered quickly and accurately at the point of care can improve both patient retention and access to treatment. Program data from the Alere Pima Analyzer can be transmitted and managed using our Alere Data Point connectivity solution, which is designed to enable data transmission from analyzers in the field to a web portal in order to assist in the management of local HIV treatment programs.

During 2014, we began a field evaluation of our new Alere q Analyzer technology. The Alere q Analyzer utilizes a versatile, single-use test cartridge to automatically extract, amplify and detect multiple molecular targets from a single patient sample. In February 2015, our first assay for this platform, Alere q HIV-1/2 Detect, received CE IVD accreditation in Europe. The Alere q HIV-1/2 Detect assay can detect HIV 1 and HIV 2 from fingerstick or heelstick samples in under 60 minutes, with current field evaluations of the assay in Africa showing high utility in the early diagnosis of infants born to HIV-positive mothers. Anticipated expansions for Alere q include cartridges for the quantification of HIV viral load and the diagnosis of tuberculosis.

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These products are examples of our deployment of leading-edge technologies to enable rapid and accurate diagnosis and monitoring of the most prevalent infectious diseases around the world.

In addition to point-of-care products, we also offer a line of indirect fluorescent antibody, or IFA, assays for 17 viral, bacterial and autoimmune diseases, a full line of serology diagnostic products covering a broad range of disease categories and 40 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.

Cardiometabolic Disease. Cardiometabolic disease encompasses a spectrum of conditions and illnesses, including both cardiovascular conditions and diabetes. Cardiovascular diseases, which include high blood pressure, high cholesterol, metabolic syndrome, coronary artery disease, heart attack, heart failure and stroke, impact an estimated 86 million American adults, while diabetes impacts approximately 387 million patients worldwide. We estimate that the worldwide market for point-of-care, cardiovascular diagnostic tests, including the markets for heart failure diagnostics, coronary artery disease risk assessment, coagulation testing and acute coronary syndrome, exceeds $2.0 billion per year. Our Alere Triage, Alere Cholestech LDX and Alere INRatio products have established us as a leader in this market.

The Alere Triage System is a leading rapid diagnostic test system comprised of the Alere Triage MeterPro, a high-performance, comprehensive portable testing platform, and a comprehensive menu of test devices that enable physicians to promote improved health outcomes through the rapid diagnosis of critical diseases and health conditions, as well as the detection of certain drugs of abuse. This system aids in the diagnosis, assessment and risk stratification of patients having critical care issues, including congestive heart failure, acute coronary syndromes, acute myocardial infarction, or AMI, and acute kidney injury, and can reduce hospital admissions and improve clinical and economic outcomes. Alere Triage cardiovascular rapid tests include immunoassays for B-type Natriuretic Peptide (BNP), creatine kinase-MB (CK-MB), d-dimer, myoglobin, neutrophil gelantinase-associated lipocalin (NGAL), troponin I and N-terminal pro-Brain Natriuretic Peptide (NT-proBNP). Alere Triage tests for NGAL, troponin I and NT-proBNP, as well as certain test panels which include a combination of immunoassays, are not available for sale in the United States. We also offer a version of the Alere Triage BNP Test for use on Beckman Coulter lab analyzers.

Our Alere Cholestech LDX System is a small, portable point-of-care analyzer and test cassette system for testing blood glucose, cholesterol and related lipids. 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 Alere Cholestech LDX System provides results in five minutes per test cassette and is CLIA-waived, meaning the 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.

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Our Alere INRatio2 System is an easy-to-use, hand-held blood coagulation monitoring system for use by appropriate patients and healthcare professionals in the management of warfarin, a commonly prescribed medication used to prevent blood clots. The Alere INRatio2 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 self-testing by appropriate patients, 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 and utilizes small patient sample sizes.

We also offer the epoc Blood Analysis System for blood gas, electrolyte and metabolite testing. 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 Blood Analysis System produces laboratory-quality results in critical and acute care settings in about 30 seconds.

We 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.

We also offer point-of-care diabetes products, including our Afinion Test System and our NycoCard Test System. The Afinion and NycoCard Test Systems make 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. HbA1c results provide information regarding the patient s average blood sugar levels over a period of time. These systems 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 a patient s motivation to comply with treatment and lifestyle changes and thereby optimize their prognosis. In June 2012, we added our CE-marked Lipid Panel, an important tool for cardiovascular disease risk assessment, to the Afinion Test System. The Afinion Test System can also measure a patient s Albumin Creatinine Ratio, which aids in the early detection of kidney disease often present in diabetic patients. The NycoCard Test System, which is a widely distributed, low-cost product suited to countries with developing healthcare systems, includes tests for C-reactive protein, or CRP, D-Dimer and HbA1c. Physicians test for elevated levels of CRP in connection with the diagnosis, therapy and monitoring of inflammatory diseases. Information regarding the level of CRP in a patient s bloodstream can help physicians discriminate between a serious inflammatory illness, such as pneumonia, and less severe conditions, such as acute bronchitis and other respiratory tract infections. Through our subsidiary Arriva Medical, we are a major, national mail order supplier of diabetic testing supplies, including blood glucose monitors, test strips, lancets, lancing devices, and control solutions, as well as other related medical supplies in the U.S. These products are usually covered by Medicare, Medicaid and other third-party payers.

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 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

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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 saliva-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 and solutions test using urine or, for certain applications, saliva, hair or other body fluids. We believe that early detection can lead to improved health outcomes through early intervention, treatment and recovery, and can also help employers to reduce unnecessary employee injuries and related medical expenses.

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 used in hospital and clinical testing as a laboratory instrument to aid in the detection of drug abuse. Our Drug Detection System is an enhanced, on-site, saliva-based 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 currently sell this product only in markets outside of the United States, but we have begun multiple trials for roadside use by law enforcement agencies in the United States. We believe that a significant market for this product will develop in the United States as the trend towards the decriminalization of marijuana accelerates, and if federal and state regulators develop impairment policies, as there will be an increased need for multiple forms of roadside and evidentiary tests for impaired driving.

We also offer comprehensive laboratory-based testing services throughout Europe by Alere Toxicology, and in the United States by 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 provide laboratory-based testing services for pain management and rehabilitation providers that monitor and document adherence to prescription drug treatment or drug abstinence plans. 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.

We also provide automated and efficient workplace drug testing services through our eScreen business, which we acquired in 2012. These services have become part of our core set of Toxicology products and solutions. The addition of the eScreen business to our portfolio of toxicology offerings helps to position us as a full-service solution provider to a broad range of domestic and foreign employers in the transport, oil and gas, mining, retail 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.

Patient Self-testing

As a result of the sale of our health management business in January 2015 and ACS in October 2014, as discussed under heading Recent Divestitures beginning on page 2 of this report, our former health information solutions segment, now referred to as our patient self-testing segment, consists

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primarily of our Alere Home Monitoring patient self-testing services. These services support anticoagulation management through frequent self-testing by patients who take warfarin to control their risk for stroke and clotting disorders. These services are designed to provide physicians with actionable data that allow them to make more effective decisions in real time, deliver quality care, and put the individuals they treat on a pathway to better health. Alere Home Monitoring 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. 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 diabetes testing supplies business provides its products via mail-order to patients in the United States. 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.

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; Ottawa, Canada; Hangzhou and Shanghai, China; Jena, Germany; Matsudo, Japan; Oslo, Norway;

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Dundee, Scotland; and Yongin, South Korea. We also manufacture products at a number of other facilities in the United States, India, Israel 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, and the digital tests and 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 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 cardiometabolic disease, infectious disease, toxicology and metabolic syndrome products and services. 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, Canada, China, Germany, 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 32 countries.

Our professional diagnostic products are sold throughout the world. Our patient self-testing services are provided almost exclusively in the United States. During 2014 and 2013, respectively, we generated approximately 53% and 55% of our net revenue from continuing operations from the United States, approximately 20% and 20% from Europe and approximately 27% and 25% from other locations.

For further financial information about geographic areas, see Note 18 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 infectious disease, cardiometabolic disease and toxicology. Competition for rapid diagnostic products is intense and is primarily based on price, quality, technology, speed of results, breadth of product line and distribution capabilities. Some competitors in the market for professional rapid diagnostic products, such as Becton Dickinson, are large companies with substantial resources, while numerous smaller, yet aggressive companies also compete with us, particularly where barriers to entry are low. 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, Danaher, Ortho-Clinical Diagnostics, Roche and other large diagnostic companies.

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Our rapid diagnostic tests targeted at infectious disease compete primarily with products offered by BD, Quidel and Meridian Bioscience. Our products, particularly our HIV products, also compete with tests offered by OraSure Technologies. Our Alere i, Alere q and Alere Pima point of care analyzers compete indirectly with larger, laboratory-based analyzers from companies including Abbott, Becton Dickinson, Roche, Cepheid and Hologic which also offer molecular technologies for amplifying DNA and RNA.

We also sell ELISA and multiplex immunoassay diagnostic testing products, as well as serology, IFA and microbiology tests, primarily targeted at infectious and autoimmune diseases. Our ELISA tests compete against large diagnostics companies similar to those named above, which manufacture automated immunoassay systems and a wide array of diagnostic products designed for processing on those systems. Other competitors, including INOVA Diagnostics, DiaSorin and Diamedix, 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 and Immuno Concepts. 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.

In cardiometabolic disease, 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 cardiovascular testing market. Although we offer our Alere Triage BNP test for use on Beckman Coulter Immunoassay Systems, our other primary cardiovascular 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 competitor for our Alere INRatio PT/INR monitoring system is Roche, which currently accounts for a majority of the domestic sales of PT/INR point-of-care and patient self-testing devices.

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, 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.

In the field of diabetes, the competitors for the Afinion Test System and NycoCard Test System include Siemens Healthcare, Bio-Rad Laboratories, Roche Diagnostics, EKF and Samsung. Arriva Medical, 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 small number of mail order suppliers. Competition for reimbursed diabetes testing supplies, which represent the majority of our business, changed significantly in 2013 as a result of CMS decision, based on a competitive bidding process, to reimburse only 18 selected suppliers willing to accept a fixed lowered reimbursement rate. As a result of the competitive bidding process, Arriva Medical was awarded a national mail-order contract.

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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.

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

Patient Self-testing. The primary competitors for our PT/INR patient self-testing business are mdIRN and Roche Diagnostics. This monitoring service is primarily marketed through a direct, dedicated sales force to clinicians who prescribe warfarin. Customer service levels are an important differentiator for Alere.

Patents and Proprietary Technology; Trademarks

We have built a strong intellectual property portfolio including patents, patent applications, copyrights, trade secrets and other 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. We own or license patents related to certain of our U.S. lateral flow professional and consumer diagnostics products that expired in 2015. Our access to these patents was not exclusive, as they were widely licensed in various fields. We do not currently anticipate that the expiration of these patents will materially impact our business although we do expect that our royalty revenue will decline in 2015 as a result of these patent expirations.

The medical device industry, including the diagnostic testing industry, historically has been characterized by extensive litigation regarding patents, licenses and other intellectual property rights.

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 patient self-testing services place considerable importance on obtaining and enforcing patent, trade secret, and trademark protection for new technologies, products, services and processes. Our success therefore depends, in part, on our ability

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to obtain and enforce the patents and trademark registrations necessary to protect our products, to obtain and preserve our trade secrets and other confidential intellectual property and to avoid or neutralize intellectual property threats from third parties. We cannot, however, guarantee our success in enforcing or maintaining our patent, trademark, trade secret and other intellectual property rights; in obtaining (including by license) future patents, trademarks, trade secrets or other intellectual property rights in a timely manner or at all; or as to the breadth or degree of protection that our patents, trade secrets, trademark registrations or other intellectual property rights might afford us. For more information regarding the risks associated with our reliance on intellectual property rights, see the discussion in Item 1A entitled Risk Factors on pages 13 through 31 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. From time to time, we have been subject to inquiries and enforcement actions by governmental authorities alleging that we have not fully complied with our legal and regulatory obligations, some of which have not yet been resolved. While we take significant steps designed to ensure that 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 sold in the United States are subject to the Federal Food, Drug and Cosmetic Act, or the FDCA, as implemented and enforced by the FDA. 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. 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 the clinicians who provide services in our patient self-testing business, 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 jurisdiction in which they are physically present and, if applicable, states in which they visit or interact with patients, to the extent such licensure is required.

Under Section 6002 of the 2010 Affordable Care Act, which is commonly referred to as the Physician Payment Sunshine Act, or the Sunshine Act, and analogous state laws, we are required to

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collect data on and annually report to CMS and state regulatory agencies 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 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. We are also subject to laws regulating fraud and abuse in the healthcare industry, including anti-kickback and false claim laws. We are also subject to a number of legal requirements relating to our international operations, including the U.S. Foreign Corrupt Practices Act and the U.K. Bribery Act, which generally prohibit engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. We are also subject to the customs, export, trade sanctions and anti-boycott laws of the U.S., including those administered by the U.S. Customs and Border Protection, the Bureau of Industry and Security, the Department of Commerce and the Office of Foreign Assets Control of the Treasury Department, as well as those of other nations in which we do business. These laws may prohibit us from doing business with nationals of designated countries, including Iran, Syria and Cuba, or importing or exporting certain of our products and technologies without first obtaining a license or confirming a general license.

For more information about the governmental regulations to which our business is subject and the risk associated with non-compliance with those regulations, see the risk factors discussed in Item 1A entitled Risk Factors on pages 13 through 31 of this report.

Employees

As of January 31, 2015, we had approximately 9,800 employees, of which approximately 4,000 are located in the United States.

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.

Competition in the medical diagnostic product and other markets in which we operate 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. 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;

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- 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 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. We have submitted evidence of our completion of most of the actions we committed to in response to the FDA Form 483 and warning letter. In September 2014, as follow up to a further inspection of our San Diego facility, the FDA notified us that this most recent inspection was classified voluntary action indicated, meaning that the objectionable conditions or practices found in the inspection do not meet the threshold of significance requiring regulatory action, but that the formal close-out of the October 2012 warning letter could not occur until after a future inspection.

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 have provided documents in response to the OIG subpoena, and the investigation is ongoing.

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.

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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;
- 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 outside the United States, including in Africa, Australia, Brazil, China, Germany, India, Ireland, Israel, Japan, Norway, the Philippines, 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 further deteriorate, thus reducing the purchasing power of European customers and the dollar value of European sales;
- 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;

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

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

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

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

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

increased financial accounting and reporting burdens and complexities;

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

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

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

Our international operations subject us to varied and complex domestic, foreign and international laws and regulations, as further discussed below. 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.

As a result of our international operations, we are subject to a number of legal requirements, including the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act and the customs, export, trade sanctions and anti-boycott laws of the U.S., including those administered by the U.S. Customs and Border Protection, the Bureau of Industry and Security, the Department of Commerce and the Office of Foreign Assets Control of the Treasury Department, as well as those of other nations in which we do business. Compliance with these laws and regulations is complex and involves significant costs. In addition, our training and compliance programs and our other internal control policies may not always protect us from acts committed by our employees or agents. Any violation of these requirements by us, our employees or our agents may subject us to significant criminal and civil liability.

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. Eight of our ten largest manufacturing operations are located in Canada, China, Germany, Japan, Norway, South Korea and the United Kingdom, and we also have manufacturing operations in India and Israel. 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 2014, approximately 47% 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. 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.

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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. The ACA contains many provisions designed to generate the revenues necessary to fund the coverage expansions and reduce the costs of Medicare and Medicaid. While certain provisions of the ACA took effect immediately, others have delayed effective dates. Given the scope of the changes made by the ACA and the ongoing implementation efforts, we cannot predict the impact of every aspect of the new law on our operations.

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 sold outside of the retail setting. For 2014, we incurred $9.8 million in excise tax expense related to the domestic sale of our medical device products as a result of the implementation of this tax. 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.

Additionally, revenues associated with our diabetes business have been impacted by the Durable Medical Equipment, Prosthetics, Orthotics and Supplies, or the DMEPOS, Competitive Bidding Program operated by the Centers for Medicare & Medicaid Services, or CMS. Under this program, Medicare no longer reimburses suppliers for certain products and services, including mail-order diabetes testing supplies, based on the Medicare fee schedule amount. Instead CMS now provides reimbursement for those products and services based on a competitive bidding process. While the DMEPOS Competitive Bidding Program limits the number of potential participants in the mail-order diabetes testing supplies market, it also requires us to sell diabetes supplies subject to Medicare reimbursement at significantly lower prices, which has had a material adverse effect on the profitability of these products.

Legislative and regulatory bodies, including Congress, 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

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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 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 may 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 2015, 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. Some foreign governments require export certificates from the FDA in order for us to market our products in their countries. If we are unable to obtain these certificates from the FDA, we may be unable to market our products in certain foreign countries.

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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 notices of correction or product recalls, such as our December 2014 voluntary urgent medical device correction initiated with respect to our Alere INRatio and Alere INRatio2 systems and our April 2014 recall of our Alere INRatio2 PT/INR Professional Test Strips, or even withdrawal of the product from the market. In addition, in some cases we may sell products or provide services which are reliant on the use or commercial availability of products of third parties, including medical devices, equipment or pharmaceuticals, and regulatory restrictions placed upon any such third-party products could have a material adverse impact on the sales or commercial viability of our related products or services. We are subject to routine inspection by the FDA and other agencies for compliance with the Quality System Regulation and Medical Device Reporting requirements in the United States and other applicable regulations worldwide. Our manufacturing facilities and those of our suppliers and distributors also are, or can be, subject to periodic regulatory inspections.

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 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.

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

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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 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.

On December 5, 2014, CMS issued a final rule titled *Requirements for Medicare Incentive Reward Program and Provider Enrollment*. This rule implemented several provider enrollment requirements, including a significant, new regulatory provision that will permit CMS to revoke Medicare billing privileges for a provider or supplier that has a pattern or practice of submitting claims that fail to meet Medicare requirements. The provisions of the new rule became effective on February 3, 2015. In determining whether a provider or suppler is subject to revocation of its billing privileges pursuant to this rule, CMS will consider the following criteria:

- the percentage of submitted claims that were denied;
- the reason(s) for the claim denials;
- whether the provider or supplier has any history of final adverse actions and the nature of any such actions;
- the length of time over which the pattern continued;
- how long the provider or supplier has been enrolled in Medicare; and
- any other information regarding the provider or supplier s specific circumstances that CMS deems relevant.

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 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. Governmental payers and their agents, including Medicare Administrative Contractors, Zone Program Integrity Contractors, and

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others, as well as the Department of Health and Human Services, the OIG, CMS and state Medicaid programs, conduct audits in the ordinary course of our operations. These audits focus on compliance with coverage and reimbursement rules and guidelines under Medicare and Medicaid. These types of audits often lead to determinations that certain claims should not have been paid by Medicare and/or Medicaid, and the programs seek to recoup or offset amounts they assert have been paid in error. We regularly receive notices of such determinations of overpayment, which vary widely in amount. These determinations are subject to administrative appeal rights, which we routinely pursue. The timeframe for these appeals can be long and the results are often unpredictable. Depending on the nature of the audit, overpayment determinations can be substantial.

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.

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.

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, malware attacks by hackers and similar breaches, can cause all or portions of our websites to be unavailable, create system disruptions, shutdowns, erasure of critical data and software or unauthorized disclosure of confidential information. We invest in security technology to protect our data against risks of data security breaches and cyber-attacks and we have implemented solutions, processes, and procedures to help mitigate these risks, such as encryption, virus protection, security firewalls and comprehensive information security and privacy policies. However, despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. The age of our information technology systems, as well as the level of our protection and business continuity or disaster recovery capability, varies from site to site, and there can be no guarantee that any such plans, to the extent they are in place, will be effective. 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 further security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, we may be subject to legal claims or proceedings, or we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data, which could have a material adverse impact on our business, financial condition and results of operations. See Item 3 Legal Proceedings. While we currently expend resources to protect against cyber-attacks and security breaches, hackers and other cyber criminals are using increasingly sophisticated and constantly evolving techniques, and we may need to expend additional resources to continue to protect

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against potential security breaches or to address problems caused by such attacks or any breach of our safeguards. In addition, a data security breach could distract management or other key personnel from performing their primary operational duties.

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.

Our growth is subject to global economic and political conditions, and operational disruptions at our facilities.

Our business is affected by global economic conditions and the state of the financial markets. There can be no assurance that global economic conditions and financial markets will not worsen and that we will not experience any adverse effects that may be material to our consolidated cash flows, results of operations, financial positions or our ability to access capital, such as the adverse effects resulting from a prolonged shutdown in government operations in both the United States and internationally. Our business is also affected by local economic conditions, including inflation, recession, financial liquidity and currency volatility or devaluation. Political changes, some of which may be disruptive, could interfere with our supply chain, our customers and all of our activities in a particular location.

Poor economic conditions may negatively impact our toxicology business.

The high rates of unemployment that have recently affected 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 conflict minerals rules will continue to increase our costs and adversely affect our results of operations.

We are subject to the SEC s 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 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 have incurred and expect to incur further 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. Because our supply chain is complex, the country of origin inquiry and due diligence procedures that we have implemented 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, privacy claims, 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, results of operations and 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 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. 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

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and different industries and markets. Third parties may have or obtain patents which our products and services or technology may actually or allegedly infringe. Any of these third parties might assert infringement claims against us. Any litigation could result in the expenditure of significant financial resources and the diversion of management s time and resources. In addition, litigation in which we are accused of infringement may result in negative publicity, have an impact on prospective customers, cause product delays, or require us to develop alternative 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 business could be materially and adversely affected as a result of the risks associated with acquisitions.

Since our inception, we acquired numerous businesses, including Axis-Shield in 2011, eScreen in 2012 and Epocal in 2013. While our business strategy no longer focuses on acquisitions, we may acquire other businesses in the future. The ultimate success of our acquisitions depends, in part, on our ability to realize the anticipated synergies, cost savings and growth opportunities from integrating 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 quality systems, where appropriate;

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integrating newly-acquired businesses or product lines into a uniform financial reporting system;

coordinating sales, distribution and marketing functions and strategies;

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. Our acquisitions have often provided for future contingent payments, or earn-outs, based on the achievement of performance targets or milestones. These arrangements can impact or restrict integration of acquired businesses and can result in disputes, including litigation. 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. In 2010 and 2011, we recorded significant goodwill impairment charges. 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.

Our business could be materially and adversely affected as a result of the risks associated with divestitures.

Since our inception, we have, from time to time, disposed of various assets or business units, including ACS in October 2014 and our health management business in January 2015, and we are continuing to pursue potential dispositions of other non-core assets. We may encounter difficulty in finding buyers or exit opportunities on advantageous terms and in a timely manner. If we are unable to dispose of any such assets, we may shut down the related operations, which could lead to additional expenses, accounting charges, write-offs and payments to resolve outstanding contractual obligations and other claims, any of which could be material. Further, any disposition we do undertake may be subject to pre-closing conditions and approvals, which, if not satisfied or obtained, may prevent us from completing the transaction. Any consummated disposition may also have an adverse effect on our operations or financial results that is more significant that we expect.

Divestitures may also involve continued financial obligations with respect to the divested assets or business, including through continuing equity ownership, guarantees, indemnities or other financial

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obligations, any of which may be material. In some circumstances, some of our indemnification obligations in connection with divestitures may be unlimited in duration or amount. In addition, dispositions that provide for future contingent payments, or earn-outs, based on the achievement of performance targets or milestones can result in disputes, including litigation, and may not generate proceeds we expect to receive.

We may be required under the agreements governing our indebtedness to obtain the consent of our lenders to certain dispositions or to apply all or a portion of the proceeds from a disposition to the repayment of our outstanding indebtedness. If we make any future dispositions or enter into any alternative transactions, such as strategic alliances, joint ventures or other business combinations, we may be unable to structure them in a way that will enhance our creditworthiness, meet our strategic alternatives or otherwise be successful.

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

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

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

Our business has substantial indebtedness.

We currently have, and will likely continue to have, a substantial amount of indebtedness. Our indebtedness could, among other things, make it more difficult for us to satisfy our debt obligations, require us to use a large portion of our cash flow from operations to repay and service our debt or otherwise create liquidity problems, limit our flexibility to adjust to market conditions, place us at a competitive disadvantage and expose us to interest rate fluctuations. As of December 31, 2014, we had total debt outstanding of $3.7 billion, which included $2.2 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 $785.9 million, B term loans (including the term loans previously referred to as Incremental B-1 term loans and Incremental B-2 term loans, which term loans have been converted into and consolidated with the B term loans) in the aggregate principal amount of $1,330.8 million and revolving credit loans in the aggregate principal amount of $127.0 million. Our secured credit facility has various final maturity dates occurring in 2016 and 2017, subject to the possible acceleration of such maturity dates to November 15, 2015 if any of our 3% convertible senior subordinated notes remain outstanding on that date, as discussed below. At December 31, 2014, we also had $1.3 billion in aggregate principal amount of indebtedness outstanding under our 7.25% senior notes, our 8.625% senior subordinated notes and our 6.5% senior subordinated notes, all of which mature in 2018 or 2020, as well as $150.0 million in aggregate principal amount of indebtedness outstanding under our 3% convertible senior subordinated notes, which mature 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, dispositions of non-core assets, and potentially from 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.

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The maturity dates of our secured credit facility could be accelerated if we are unable to refinance our 3% convertible senior subordinated notes before November 15, 2015.

Our secured credit facility has various final maturity dates occurring in 2016 and 2017, but if any of our 3% convertible senior subordinated notes remain outstanding on November 15, 2015 (subject to certain exceptions provided in the credit agreement governing our secured credit facility), our secured credit facility will instead mature on such date. We may not forcibly redeem the 3% convertible senior subordinated notes prior to their stated maturity on May 15, 2016. Accordingly, unless we are able to secure the participation of the holders of all of the 3% convertible senior subordinated notes in a tender offer for the repurchase, refinancing or other similar transaction relating to all of those notes prior to November 15, 2015 or are able to secure adequate waivers of the maturity acceleration requirement from the lenders under our secured credit facility, we may be required to repay or make arrangements to restructure or refinance the indebtedness outstanding under our secured credit facility earlier than we had expected, which we may be unable to do on acceptable terms.

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 on our stock;

repurchase or redeem our stock or senior or subordinated debt;

prepay indebtedness;

dispose of assets; and

consolidate, merge or sell all or substantially all of our assets.

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

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

The agreements governing our secured credit facility subject us to various financial and other restrictive covenants with which we must comply on an ongoing or periodic basis. These include covenants pertaining to maximum consolidated secured leverage ratios, minimum consolidated interest coverage ratios and limits on capital expenditures. If we violate any of these covenants, we may suffer a material adverse effect. Most notably, our outstanding debt under our secured credit facility could become immediately due and payable, our lenders thereunder 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

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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, our 7.25% senior notes, our 8.625% senior subordinated notes or our 6.5% 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 satisfy our repayment and repurchase obligations would constitute a default under the relevant indentures and under our secured credit facility and could have material adverse consequences for us and our stakeholders.

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

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

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

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

Changes in tax laws or tax rulings could materially impact our effective tax rate. There are several proposals to reform U.S. tax rules being considered by U.S. law makers, including proposals that may reduce or eliminate the deferral of U.S. income tax on our unrepatriated earnings, potentially requiring those earnings to be taxed at the U.S. federal income tax rate, reduce or eliminate our ability to claim foreign tax credits, and eliminate various tax deductions until foreign earnings are repatriated to the U.S. In addition, as part of its base erosion and profit shifting initiative, the Organization for Economic Co-operation and Development, or OECD, has proposed a number of changes to the tax codes of its member states that are designed to address perceived tax avoidance by multinational organizations. 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

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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.

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 issuances of substantial numbers of shares of our common stock potentially issuable upon conversion of our Series B Preferred Stock or our 3% convertible senior subordinated notes or by 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 1.8 million shares of Series B Preferred Stock outstanding as of December 31, 2014 could convert into 5.7703 shares of our common stock, or a total of 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. The $150.0 million in aggregate outstanding principal amount of our 3% convertible senior subordinated notes is convertible into shares of our common stock at a conversion price of approximately $43.98 per share, or a total of 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, 2014, the outstanding shares of our Series B Preferred Stock had an aggregate stated liquidation preference of $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

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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 best interests, and may prevent attempts by our stockholders to replace or remove our current management. For example, 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.

We are restating some of our previously issued consolidated financial statements, which may lead to additional risks and uncertainties, including shareholder litigation, loss of investor confidence, and negative impacts on our stock price.

As discussed in the Explanatory Note to this Form 10-K/A and Note 2 to our accompanying consolidated financial statements, we are restating our audited consolidated financial statements for the year ended December 31, 2014 and our unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2014. The determination to restate these financial statements was made by our audit committee, after discussions with management, following the identification of errors relating primarily to the accounting for income taxes for our discontinued operations, including in connection with the divestiture of our health management business which was completed in January 2015 and another divestiture completed in October 2014. As a result of these events, we have become subject to a number of additional risks and uncertainties, including unanticipated costs for accounting and legal fees in connection with or related to the restatement, potential shareholder litigation and government investigations. If any litigation or investigation were to occur, we could incur substantial defense costs regardless of the outcome of the litigation or investigation. These events could also divert our management s time and attention. If we do not prevail in any such litigation, we could be required to pay substantial damages or settlement costs. In addition, the fact that we have completed a restatement may lead to a loss of investor confidence and have negative impacts on the trading prices of our securities.

We identified a material weakness in our internal control over financial reporting as of December 31, 2014, and this or other material weaknesses could continue to materially impair our ability to report accurate financial information in a timely manner.

As described in Item 9A, Controls and Procedures, our management concluded in connection with the filing of the Original Report that we had a material weakness as of December 31, 2014 and therefore did not maintain effective internal control over financial reporting or effective disclosure controls and procedures as of that date. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on

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a timely basis. The material weakness related to the failure to design controls to assess the accounting for deferred taxes related to dispositions. During the course of preparing our consolidated financial statements and other financial data for the three months ended March 31, 2015, we identified errors in our consolidated financial statements for 2014 and all interim periods therein relating primarily to the accounting for income taxes for our discontinued operations, including in connection with the divestiture of our health management business which was completed in January 2015 and another divestiture completed in October 2014. As a result, on May 1, 2015, the audit committee of our board of directors concluded that the previously filed consolidated financial statements and other financial data for those periods should not be relied upon. We believe that the material weakness described above resulted in the failure to prevent or detect these errors. Following the completion of our review of those errors and related matters, our audit committee determined that we should restate our consolidated financial statements for the year ended December 31, 2014 and the three and nine months ended September 30, 2014. As a result of the restatement, we were unable to timely file our quarterly report on Form 10-Q for the three months ended March 31, 2015.

We are taking steps to remediate the material weakness. However, the remedial measures we are taking may not be adequate to prevent additional misstatements or avoid other control deficiencies or material weaknesses. The effectiveness of our internal control over financial reporting is subject to various inherent limitations, including cost limitations, judgments used in decision making, the nature and complexity of the transactions we undertake, assumptions about the likelihood of future events, the soundness of our systems, the adequacy of training and experience, the possibility of human error and the risk of fraud. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions and the risk that the degree of compliance with policies or procedures may deteriorate over time. Because of these limitations, there can be no assurance that any system of internal control over financial reporting will be successful in preventing all errors or fraud or in making all material information known in a timely manner to the appropriate levels of management. As a result, our financial statements may contain one or more material misstatements and may not be available on a timely basis, any of which could cause investors to lose confidence in us and lead to, among other things, unanticipated legal, accounting and other expenses, delays in filing required financial disclosures, enforcement actions by government authorities, fines, penalties, the delisting of our securities, a decline in the prices of our securities, liabilities arising from stockholder litigation and defaults under our secured credit facility and notes indentures.

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, and a call center in Taguig City, Philippines. 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 ten primary manufacturing operations, as well as significant administrative and research and development operations for our professional diagnostics business. Our buildings on this property total approximately 330,000 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; Jena, Germany; Matsudo, Japan; Oslo, Norway; Dundee, Scotland; Ottawa, Canada and Yongin, South Korea. We manufacture some of our consumer and professional diagnostic products in

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a manufacturing facility of approximately 498,000 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 Alere Pima Analyzer in a facility of approximately 159,000 square feet in Jena, Germany, which we own. We manufacture our Determine products in a leased space of approximately 34,700 square feet in Matsudo, Japan. Standard Diagnostics manufactures most of its professional diagnostic products in three facilities in Yongin, South Korea; a 64,390 square foot facility and a 112,547 square foot facility which we own, and a 84,766 square foot facility which we lease. 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 135,000 square feet in Oslo, Norway and a leased space of approximately 54,000 square feet in Dundee, Scotland. We also manufacture point-of-care products in a leased space of approximately 30,000 square feet in Ottawa, Canada. We manufacture certain professional diagnostic products in a 118,176 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 two SAMHSA certified laboratories in the United States, located in Gretna, Louisiana and Richmond, Virginia. We also operate toxicology laboratories in Austin, Texas; Clearwater, Florida; Santa Rosa, California; London and Abingdon, England, and we operate an accredited forensic laboratory in Malvern, England.

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. We have submitted evidence of our completion of most of the actions committed to in response to the FDA Form 483 and warning letter. In September 2014, as follow up to a further inspection of our San Diego facility, the FDA notified us that this most recent inspection was classified voluntary action indicated, meaning that the objectionable conditions or practices found in the inspection do not meet the threshold of significance requiring regulatory action, but that formal close-out of the October 12 Warning Letter could not occur until after a future inspection.

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 have provided documents in response 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.

Matters Related to Theft of Laptop

In September 2012, a password-protected laptop containing personally identifiable information of approximately 116,000 patients was stolen from an employee of Alere Home Monitoring, or AHM. On January 24, 2013, a class action complaint was filed in the U.S. District Court for the Northern District of California against AHM, asserting claims for damages and other relief under California state law,

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including under California s Confidentiality of Medical Information Act, or CMIA, arising out of this theft. On October 7, 2014, the class action was dismissed with leave to amend the complaint. On October 28, 2014, an amended complaint was filed, and on November 17, 2014 AHM responded by filing another motion to dismiss. On February 23, 2015, AHM s motion to dismiss was granted in part, but denied as to the plaintiffs amended CMIA claims.

Claims in the Ordinary Course and Other Matters

We are not a party to any other pending legal proceedings that we currently believe could have a material adverse impact on our business. However, on December 10, 2014, we and our subsidiary, Avee Laboratories Inc., or Avee, received subpoenas from the United States Attorney for the District of New Jersey seeking marketing materials and other documents relating primarily to billing and marketing practices related to toxicology testing. We are cooperating with the investigation and have begun to provide documents responsive to the subpoenas. Our subsidiary, Arriva Medical, LLC, or Arriva, is also in the process of responding to a Civil Investigative Demand, or CID, from the United States Attorney for the Middle District of Tennessee in connection with an investigation of possible improper claims submitted to Medicare and Medicaid. The CID requests patient and billing records. Both investigations are in preliminary stages, and we cannot predict what effect, if any, the investigations, or any resulting claims, could have on Alere or its subsidiaries.

Our diabetes, toxicology and patient self-testing businesses are subject to audit and claims for reimbursement brought by Zone Program Integrity Contractors, or ZPICs, and Medicare Administrative Contractors, or MACs, to monitor compliance with coverage and reimbursement rules and guidelines under Medicare and Medicaid. These types of audits occur frequently in the ordinary course of seeking reimbursement under Medicare and Medicaid and often lead to determinations that certain claims should not have been paid by Medicare or Medicaid. The programs will seek to recoup or offset amounts they assert have been paid in error.

Our businesses may also be subject at any time to other commercial disputes, consumer product claims, negligence claims or various other lawsuits arising in the ordinary course of business, including infringement, employment or investor matters, and we expect that this will continue to be the case in the future. Such lawsuits or claims generally seek damages or reimbursement, sometimes in substantial amounts.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

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

Unregistered Sales of Equity Securities and Use of Proceeds

On December 30, 2012, our Chief Executive Officer, Namal Nawana, was granted 110,000 Restricted Stock Units, or RSUs, that vest as follows: 5,000 RSUs vest one year after the grant date, 5,000 RSUs vest two years after the grant date, and 100,000 RSUs vest three years after the grant date. As part of this arrangement, Mr. Nawana was issued 5,000 shares of common stock on December 30, 2013 and 5,000 shares of common stock on December 30, 2014. We issued these shares pursuant to the exemption from registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended.

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 2014 and 2013:

	High	Low
Fiscal 2014		
Fourth Quarter	$ 40.50	$ 35.62
Third Quarter	$ 43.00	$ 33.76
Second Quarter	$ 37.88	$ 31.94
First Quarter	$ 39.90	$ 32.98
Fiscal 2013		
Fourth Quarter	$ 36.78	$ 30.16
Third Quarter	$ 35.38	$ 24.00
Second Quarter	$ 29.57	$ 24.33
First Quarter	$ 25.55	$ 18.64

On March 2, 2015, there were 1,197 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, 2009 through December 31, 2014 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, 2009 in our common stock, and compares its performance with the NYSE Composite Index and the Dow Jones U.S. Health Care 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, 2009 and the last trading day of each subsequent year end through December 31, 2014.

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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
12/31/09	$ 100.00	$ 100.00	$ 100.00
12/31/10	$ 88.17	$ 110.84	$ 104.12
12/30/11	$ 55.63	$ 104.07	$ 115.84
12/31/12	$ 44.57	$ 117.52	$ 137.52
12/31/13	$ 87.21	$ 144.75	$ 194.25
12/31/14	$ 91.54	$ 150.86	$ 240.34

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, 2014 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/A.

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.

On October 10, 2014, we completed the sale of our ACS subsidiary, our health information exchange business, to ACS Acquisition, LLC for a purchase price consisting primarily of contingent consideration.

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On January 9, 2015, we completed the sale of our health management business to OptumHealth Care Solutions for a purchase price of $600.1 million, subject to a customary post-closing working capital and net cash adjustment. We used the net cash proceeds of the sale to repay $575.0 million in aggregate principal amount of outstanding indebtedness under our senior secured credit facility.

The results of the vitamins and nutritional supplements business, ACS and the health management 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 health management 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.

We have restated our consolidated financial statements for the year ended December 31, 2014 and have revised our consolidated financial statements for the years ended December 31, 2010, 2011, 2012 and 2013. See Note 2 of our accompanying consolidated financial statements for additional information.

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For a discussion of certain factors, such as acquisitions and dispositions, 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 3, 4(v) and 6 of our consolidated financial statements included elsewhere in this report.

	Year Ended December 31,				
	2014 (Restated)	2013	2012	2011	2010
	(in thousands, except per share data)				
Statement of Operations Data:					
Net product sales	$ 2,035,666	$ 2,056,519	$ 1,899,913	$ 1,667,408	$ 1,454,995
Services revenue	531,988	532,616	465,882	254,971	181,729
Net product sales and services revenue	2,567,654	2,589,135	2,365,795	1,922,379	1,636,724
License and royalty revenue	21,050	27,229	28,576	23,473	20,759
Net revenue	2,588,704	2,616,364	2,394,371	1,945,852	1,657,483
Cost of net product sales	1,069,422	1,017,501	920,617	782,186	673,053
Cost of services revenue	294,753	274,045	220,510	106,068	84,125
Cost of net product sales and services revenue	1,364,175	1,291,546	1,141,127	888,254	757,178
Cost of license and royalty revenue	5,592	7,763	7,354	7,036	7,149
Cost of net revenue	1,369,767	1,299,309	1,148,481	895,290	764,327
Gross profit	1,218,937	1,317,055	1,245,890	1,050,562	893,156
Operating expenses:					
Research and development	144,828	159,053	181,735	150,165	133,218
Sales and marketing	513,801	566,137	556,594	470,572	391,552
General and administrative	453,988	435,199	347,379	252,617	285,536
Goodwill impairment charge				8,027	
Impairment and gain (loss) on dispositions, net	7,742	5,124			
Operating income	98,578	151,542	160,182	169,181	82,850
Interest expense, including amortization of original issue discounts and write-off of deferred financing costs and other income (expense), net	(209,922)	(266,606)	(229,260)	86,352	(124,256)
Income (loss) from continuing operations before provision (benefit) for income taxes	(111,344)	(115,064)	(69,078)	255,533	(41,406)
Provision (benefit) for income taxes	82,193	(42,014)	(10,742)	(4,160)	10,240
Income (loss) from continuing operations before equity earnings of unconsolidated entities, net of tax	(193,537)	(73,050)	(58,336)	259,693	(51,646)
Equity earnings of unconsolidated entities, net of tax	17,509	17,443	13,245	8,524	10,566
Income (loss) from continuing operations	(176,028)	(55,607)	(45,091)	268,217	(41,080)
Income (loss) from discontinued operations, net of tax	138,318	(16,126)	(33,126)	(402,806)	(977,352)
Net income (loss)	(37,710)	(71,733)	(78,217)	(134,589)	(1,018,432)
Less: Net income attributable to non-controlling interests	30	976	275	233	1,418

Net income (loss) attributable to Alere Inc. and Subsidiaries	(37,740)	(72,709)	(78,492)	(134,822)	(1,019,850)
Preferred stock dividends	(21,293)	(21,293)	(21,293)	(22,049)	(24,235)
Preferred stock repurchase				23,936	
Net loss available to common stockholders(1)	$ (59,033)	$ (94,002)	$ (99,785)	$ (132,935)	$ (1,044,085)

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	Year Ended December 31,				
	2014 (Restated)	2013	2012	2011	2010
	(in thousands, except per share data)				
Basic net loss per common share attributable to Alere Inc. and Subsidiaries:					
Income (loss) per common share from continuing operations	$ (2.38)	$ (0.95)	$ (0.83)	$ 3.25	$ (0.79)
Income (loss) per common share from discontinued operations	1.67	(0.20)	(0.41)	(4.85)	(11.57)
Net loss per common share(1)(2)	$ (0.71)	$ (1.15)	$ (1.24)	$ (1.60)	$ (12.36)

	December 31,				
	2014 (Restated)	2013	2012	2011	2010
	(In thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$ 378,461	$ 355,431	$ 316,479	$ 287,541	$ 381,530
Working capital	$ 1,047,018	$ 1,000,525	$ 1,034,126	$ 958,828	$ 1,003,293
Total assets	$ 6,678,956	$ 7,062,085	$ 7,064,715	$ 6,665,962	$ 6,325,796
Total debt	$ 3,725,061	$ 3,841,104	$ 3,708,011	$ 3,353,335	$ 2,397,214
Other long-term obligations	$ 376,221	$ 446,065	$ 543,445	$ 458,727	$ 512,068
Total stockholders equity	$ 1,905,599	$ 2,073,256	$ 2,177,167	$ 2,226,289	$ 2,573,373

(1) Net loss available to common stockholders and basic and diluted net loss per common share are computed consistent with annual per share calculations described in Notes 4(o) and 13 of our consolidated financial statements included elsewhere in this report.

(2) Dilutive net loss per common share of $(1.10) includes income from continuing operations of $3.01 and loss from discontinued operations of $(4.11) for the year ended December 31, 2011. Basic and dilutive net loss per common share is consistent for all other years presented.

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

Forward-Looking Statements

This Annual Report on Form 10-K/A, 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 divestitures of non-core assets, our ability to improve our working capital and operating margins, our ability to improve our organic revenue growth rates, the effectiveness of steps we may take to improve our operational efficiency, 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 13 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 deliver reliable and actionable health information through rapid diagnostic tests, resulting in better clinical and economic healthcare outcomes globally. Our high-performance diagnostics for infectious disease, cardiometabolic disease and toxicology are designed to meet the growing global demand for accurate, easy-to-use and cost-effective near-patient tests. Our goal is to make Alere products accessible to more people around the world, even those located in remote and resource-limited areas, by making them affordable and usable in any setting. By making critical clinical diagnostic information available to doctors and patients in an actionable timeframe, Alere products help streamline healthcare delivery and improve patient outcomes.

On June 30, 2014, our Board of Directors refocused our strategy to concentrate on our core strength as a leader in rapid diagnostics, appointing Namal Nawana as our new Interim Chief Executive Officer, and announced initiatives to rationalize our investment in connected health concepts and technologies and reduce overall operating expenses by winding down certain non-core operations. Since that time, under Mr. Nawana s leadership, we have made substantial progress against those initiatives, and we expect that the insights garnered during the strategic review process initiated in 2013 will continue to enable our transformation into an organization with a more focused business portfolio.

On October 28, 2014, the same day that our Board of Directors removed the interim status from the title of Mr. Nawana, we announced that we had reached a definitive agreement to sell our condition management, case management, wellbeing, wellness, and women s and children s health businesses, which we refer to collectively as our health management business, to Optum for $600.1 million. We completed this sale on January 9, 2015 and used the net cash proceeds to repay $575.0 million in aggregate principal amount of outstanding indebtedness under our secured credit facility. With this divestiture, we effectively exited the traditional health management business, meaning the business of providing condition and case management services to employers, health plans and other health care providers. We remain committed to divesting non-core assets and intend to follow a disciplined approach to managing our business portfolio in the future.

During the second half of 2014, we also undertook cost-cutting measures based primarily on insights gained through our management consultant-led strategic review. During this period, we reduced headcount to eliminate redundancies arising from our historic pattern of acquisitions. We also restructured our research and development organization by closing or beginning the process of closing several facilities in the United Kingdom and concentrating our research and development activities on core projects which resulted in additional savings.

During 2014, we continued to emphasize quality, and we have made substantial progress in this area by achieving the status of Voluntary Action Indicated in connection with the FDA inspection and warning letter relating to our San Diego facility. This status allows us to continue with our voluntary improvement programs and also allows the release of export certificates required by certain foreign governments in order for us to market our products in their countries. However, our progress has not come without challenges. We have encountered product issues related to our Alere INRatio systems resulting in a May 2014 recall of our Alere INRatio2 PT/INR Professional Test Strips in the United States and a December 2014 voluntary urgent medical device correction initiated with respect to our Alere INRatio and Alere INRatio2 systems to inform users not to use these systems to test patients with certain medical conditions. We have transitioned customers from the recalled Alere INRatio2 PT/INR Professional Test Strip to the Alere INRatio PT/INR Test Strip, which was not included in the recall. While it is too early to understand the full impact of the voluntary urgent medical device correction, we believe that our emphasis on quality during 2014 has enabled us to respond to these developments more effectively than in the past and will help to mitigate any negative impact. We plan to continue our improvements to quality and regulatory compliance during 2015 and beyond.

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During 2014, we built substantial momentum behind the new products and technologies which we expect to propel growth in future years and establish Alere as a leading innovator of point-of-care diagnostics. In January 2014, we announced the initial launch of the Alere i Influenza A & B test, which received FDA clearance in June 2014 and is currently available for sale in the United States. Alere i is a rapid point-of-care molecular, instrument-based, isothermal platform for the qualitative detection of infectious diseases which provides results in just minutes, allowing healthcare providers to make quick and effective clinical decisions. In January 2015, the FDA granted a CLIA waiver for the Alere i Influenza A & B test, a nucleic acid-based flu diagnostic test and, as a result, it may be used in physician offices, clinics and other public health settings where influenza patients are frequently examined and treated. Alere i tests for strep A, *C. difficile*, RSV, chlamydia and gonorrhea are currently in development.

In July 2014, we submitted our first assay for our new Alere q Analyzer, Alere q HIV-1/2 Detect, for CE IVD accreditation in Europe and this accreditation was received in February 2015. The Alere q Analyzer technology utilizes a versatile, single-use test cartridge to automatically extract, amplify and detect multiple molecular targets from a single patient sample. The Alere q HIV-1/2 Detect assay can detect HIV 1 and HIV 2 from fingerstick or heelstick samples in under 60 minutes, with current field evaluations of the assay in Africa showing high utility in the early diagnosis of infants born to HIV-positive mothers. Anticipated expansions for Alere q include cartridges for the quantification of HIV viral load and the diagnosis of tuberculosis.

In December 2014, the Alere Determine HIV-1/2 Ag/Ab Combo, launched during 2013, received CLIA-waived status, allowing healthcare providers in physician s offices, clinics and other public health services to improve clinical outcomes through earlier diagnosis and treatment of patients who test positive for HIV. The Alere Determine HIV-1/2 Ag/Ab Combo is the first FDA-approved and CLIA-waived rapid, point-of-care test that detects both HIV-1/2 antibodies and free HIV-1 p24 antigen and may identify HIV earlier in the course of the disease.

Our efforts during 2014, as well as 2015, have sharpened our focus on our mission of enabling healthcare providers to improve clinical outcomes and lower costs with rapid diagnostic tests, and have enabled us to reduce indebtedness and enhance shareholder value. We remain engaged in active and ongoing discussions with multiple parties concerning divestitures of our remaining non-core businesses which, if consummated, will continue this momentum, leaving us and our shareholders positioned to take better advantage of our global-leading portfolio of accurate, easy-to-use and cost-effective near-patient tests.

We have restated our consolidated financial statements for the year ended December 31, 2014 and have revised our consolidated financial statements for the years ended December 31, 2010, 2011, 2012 and 2013. See Note 2 of our accompanying consolidated financial statements for additional information.

Recent Divestitures

As discussed above, on January 9, 2015, we completed the sale of our health management business. On October 10, 2014, we completed the sale of our subsidiary, Alere Accountable Care Solutions, LLC, or ACS.

Except for our patient self-testing products and services, our health management business and ACS together represented substantially all of the assets and activities comprising our former health information solutions segment, which we now refer to as our patient-self testing segment. We reclassified the assets and liabilities of the health management business as held for sale within the accompanying consolidated balance sheet as of December 31, 2014, and the results of the operations of the health management business and ACS are reported as loss from discontinued operations, net of tax, for all periods presented in our accompanying consolidated statements of operations. See Note 3 to our accompanying consolidated financial statements for more information about these divestitures and discontinued operations.

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2014 Financial Highlights

Net revenue decreased by $27.7 million, or 1%, to $2,588.7 million in 2014, from $2,616.4 million in 2013.

Gross profit decreased by $98.1 million, or 7%, to $1.2 billion in 2014, from $1.3 billion in 2013.

In 2014, we generated a net loss available to common stockholders of $59.0 million, or $0.71 per basic and diluted common share. In 2013, we generated a net loss available to common stockholders of $94.0 million, or $1.15 per basic and diluted common share.

Results of Operations

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.

Year Ended December 31, 2014 Compared to Year Ended December 31, 2013

Net Product Sales and Services Revenue. Net product sales and services revenue decreased by $21.5 million, or 1%, to $2,567.7 million in 2014, from $2,589.1 million in 2013. Excluding the impact of foreign currency translation, net product sales and services revenue in 2014 decreased by $12.0 million, or 1%, over 2013.

Net Product Sales and Services Revenue by Business Segment. Net product sales and services revenue by business segment for 2014 and 2013 is as follows (in thousands):

	2014 (Restated)	2013	% Increase (Decrease) (Restated)
Professional diagnostics	$ 2,321,916	$ 2,362,706	(2)%
Patient self-testing	137,096	123,647	11%
Consumer diagnostics	108,642	102,782	6%
Net product sales and services revenue	$ 2,567,654	$ 2,589,135	(1)%

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 2014 and 2013 (in thousands):

	2014 (Restated)	2013	% Increase (Decrease) (Restated)
Infectious disease	$ 711,369	$ 721,754	(1)%
Toxicology	627,755	631,244	(1)%
Cardiometabolic	442,742	462,725	(4)%
Diabetes	197,476	225,488	(12)%
Other	342,574	321,495	7%

Professional diagnostics net product sales and services revenue	$ 2,321,916	$ 2,362,706	(2)%

Net product sales and services revenue from our professional diagnostics business segment decreased by $40.8 million, or 2%, to $2.3 billion in 2014, from $2.4 billion in 2013. Excluding the

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impact of foreign currency translation, net product sales and services revenue from our professional diagnostics business segment decreased by $31.2 million, or 1%, comparing 2014 to 2013. We experienced revenue declines principally in the U.S., where revenue decreased by $91.9 million, or 8%, to $1.0 billion from $1.1 billion. Revenue decreased primarily as a result of a $22.6 million decrease in our U.S. flu-related net product sales, which decreased from $75.5 million during 2013 to $52.9 million during 2014, a $16.5 million decrease in U.S. revenues from our mail order diabetes sales, and $1.1 million and $15.9 million decreases in revenue as a result of our 2014 and 2013 dispositions of our Bionote business and our Spinreact operations, respectively, partially offset by $34.5 million in non-currency-adjusted incremental revenues attributable to acquisitions. Revenue from mail order diabetes sales decreased by 11% to $137.0 million for 2014 from $153.6 million for 2013, primarily as a result of a reduction in the Center for Medicare & Medicaid Services, or CMS , reimbursement rates for those products, which became effective on July 1, 2013. Revenues in the U.S. were further reduced by lower revenues from INRatio sales and lower toxicology pain management sales during 2014 compared to 2013. Net product sales of Alere Triage® meter-based products in the U.S. decreased by $3.6 million to $72.6 million during 2014 from $76.2 million during 2013. Revenues from international sales increased by $62.4 million to $1.2 billion during 2014 from $1.1 billion in 2013 due to continued strong performance in India, China and Africa, which together grew by $50.3 million, or 17%, which was partially offset by a $7.9 million decrease in revenues from markets in Latin America as a result of a reduction in diabetes revenue in Brazil and a weak dengue season in the region. Excluding the impact of acquisitions, the decrease in net product sales from meter-based Triage products in the U.S., the impact of the decrease in flu-related sales, the decrease in organic revenues from our U.S. mail order diabetes sales, and the dispositions of our BioNote business and Spinreact operations, the currency-adjusted organic growth for our professional diagnostics net product sales and services revenue was $26.4 million, or 1%, from 2013 to 2014. New products contributed favorably to our overall adjusted growth rate, with sales of our CD4 products increasing from $21.5 million in 2013 to $29.3 million in 2014 and Epoc sales increasing from $22.7 million to $26.8 million for the same periods.

Within our professional diagnostics business segment, our infectious disease net product sales and services revenue decreased by $10.4 million, or 1%, to $711.4 million for 2014, from $721.8 million for 2013. The decrease was primarily due to a $22.6 million decrease in our U.S. flu-related net product sales from $75.5 million during 2013 to $52.9 million during 2014, as discussed above, partially offset by an overall increase in our international sales, as discussed above. Toxicology net product sales and services revenue decreased by $3.5 million, or 1%, to $627.8 million for 2014, from $631.2 million for 2013, primarily as a result of lower pain management revenues. Cardiometabolic net product sales and services revenue decreased by $20.0 million, or 4%, to $442.7 million for 2014, from $462.7 million for 2013, primarily as a result of a decline in sales of our Alere INRatio2 PT/INR professional test strip in the U.S. due to a voluntary recall. Our diabetes net product sales and services revenue decreased by $28.0 million, or 12%, to $197.5 million for 2014, from $225.5 million for 2013. This decrease was primarily the result of the decline in revenue attributable to the reduction in CMS reimbursement rates described above, which was partially offset by our recent acquisitions of the Liberty business and Simplex, which contributed a combined net $34.5 million of the non-currency adjusted incremental diabetes-related revenue. Included in the $197.5 million of diabetes-related revenue for 2014 was $137.0 million of mail order diabetes sales, compared to $153.6 million for 2013.

Patient Self-testing

As a result of the sales of our health management business in January 2015 and ACS in October 2014, our former health information solutions segment, now referred to as our patient self-testing segment, consists primarily of our Alere Home Monitoring patient self-testing services.

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The following table summarizes our net product sales and services revenue from our patient self-testing business segment by groups of similar products and services for 2014 and 2013 (in thousands):

	2014	2013	% Increase (Decrease)
Patient self-testing services	$ 116,779	$ 102,919	13%
Other	20,317	20,728	(2)%
Patient self-testing net product sales and services revenue	$ 137,096	$ 123,647	11%

Our patient self-testing net product sales and services revenue increased by $13.4 million, or 11%, to $137.1 million for 2014, from $123.6 million for 2013, reflecting growth in our Alere Home Monitoring patient self-testing services from $102.9 million in 2013 to $116.8 million in 2014. The increase in our Alere Home monitoring patient self-testing services net product sales and services revenue was 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.

Consumer Diagnostics

Net product sales and services revenue from our consumer diagnostics business segment revenue increased by $5.9 million, or 6%, to $108.6 million for 2014, from $102.8 million for 2013. The increase in revenue primarily resulted from an increase in our manufacturing revenue associated with SPD, as SPD successfully launched the Clearblue Advanced Pregnancy Test with Weeks Estimator product in the U.S. during the third quarter of 2013. SPD sales were $185.7 million and $178.4 million during 2014 and 2013.

Net Product Sales and Services Revenue by Geographic Location. Net product sales and services revenue by geographic location for 2014 and 2013 is as follows (in thousands):

	2014 (Restated)	2013	% Increase (Decrease) (Restated)
United States	$ 1,350,134	$ 1,424,235	(5)%
Europe	528,030	505,725	4%
Elsewhere(1)	689,490	659,175	5%
Net product sales and services revenue	$ 2,567,654	$ 2,589,135	(1)%

(1) Includes, among many others, the following countries: China, India, Japan, South Korea, Brazil, Canada, and Australia.

Net product sales and services revenue of $1.35 billion and $1.42 billion generated in the United States was 53% and 55% of total net product sales and services revenue for 2014 and 2013, respectively. The decrease in net product sales and services revenue in the United States principally related to lower revenues from flu-related, mail-order diabetes and INRatio sales, lost revenues from dispositions and lower toxicology pain management revenues, as discussed above. The increase in net product sales and services revenue outside the United States resulted primarily from an increase in toxicology-related sales in Europe and a growing demand for our HIV and malaria products in Asia, Africa and Latin America.

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 decreased by $6.2 million, or 23%, to $21.1 million for 2014, from $27.2 million for 2013. The decrease in royalty revenue for 2014, compared to 2013, is primarily a result of lower royalties earned under

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existing licensing agreements. Included in royalty revenue in 2013 was an $8.5 million one-time, upfront issuance fee associated with the license of certain of our molecular intellectual property. We expect our future royalty revenue to decline as certain patents related to our lateral flow technology expired in 2015.

Gross Profit and Margin Percentage. Gross profit decreased by $98.1 million, or 7%, to $1.2 billion for 2014, from $1.3 billion for 2013. The decrease in gross profit during 2014, compared to 2013, was largely attributed to the decrease in net product sales and services revenue principally resulting from lower revenues from INRatio sales and lower pain management and rehabilitation toxicology revenues, as discussed above, weak U.S. flu-related sales, a larger-than-expected reduction in U.S. healthcare utilization which primarily impacted our U.S. infectious disease revenue, decline in diabetes revenue attributable to the reduction in CMS reimbursement rates described above, coupled with the impacts of a recall of INRatio2 test strips and a recall of certain Triage BNP Calibrators during 2014, which included revenue and cost of sales charges totaling $7.5 million during 2014.

Cost of net revenue included amortization expense of $64.5 million and $68.1 million for 2014 and 2013, respectively, and $2.5 million of non-cash charges relating to the write-up of inventory to fair value in connection with certain acquisitions during 2013. Reducing gross profit for 2014 and 2013 was $11.8 million and $6.1 million, respectively, in restructuring charges, which included $7.0 million in fixed asset and inventory impairments, $3.3 million of severance-related costs and $1.5 million in facility and transition costs for 2014, and $2.5 million of severance-related costs, $2.3 million in facility and transition costs and $1.3 million in fixed asset, intangible asset and inventory impairments for 2013.

Overall gross margin for 2014 was 47%, as compared to 50% for 2013. The lower gross margin in 2014 principally reflects lower revenues from INRatio sales and lower pain management and rehabilitation toxicology revenues, the impact of the reduced mail order diabetes reimbursement rates noted above, as well as revenue and cost of sales charges of $7.5 million incurred in the second quarter of 2014 in connection with our recall of INRatio2 test strips and our recall of certain Triage BNP Calibrators.

Gross Profit from Net Product Sales and Services Revenue, Total and by Business Segment. Gross profit from net product sales and services revenue decreased by $94.1 million, or 7%, to $1.2 billion in 2014, from $1.3 billion in 2013. Gross profit from net product sales and services revenue by business segment for 2014 and 2013 is as follows (in thousands):

	2014 (Restated)	2013	% Increase (Restated)
Professional diagnostics	$ 1,115,637	$ 1,218,900	(8)%
Patient self-testing	64,333	58,369	10%
Consumer diagnostics	23,509	20,320	16%
Gross profit from net product sales and services revenue	$ 1,203,479	$ 1,297,589	(7)%

Professional Diagnostics

Gross profit from our professional diagnostics net product sales and services revenue decreased by $103.3 million, or 8%, to $1.1 billion for 2014, compared to $1.2 billion for 2013. The lower gross profit for 2014 principally reflects lower revenues from INRatio sales during 2014 compared to 2013, lower pain management and rehabilitation toxicology revenues, lower U.S. flu-related sales and reduced mail order diabetes reimbursement rates. Cost of professional diagnostics net product sales and services revenue during 2013 included a non-cash charge of $2.5 million relating to the write-up of inventory to fair value in connection with certain acquisitions. Reducing gross profit during 2014 and 2013 was $11.8 million and $6.1 million, respectively, in restructuring charges.

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Cost of professional diagnostics net product sales and services revenue included amortization expense of $62.0 million and $64.3 million for 2014 and 2013, respectively.

As a percentage of our professional diagnostics net product sales and services revenue, gross profit for 2014 was 48%, as compared to 52% for 2013. The lower gross margin in 2014 principally reflects lower revenues from INRatio sales, a continued weakness in U.S. healthcare utilization and lower pain management and rehabilitation toxicology revenues, coupled with the impacts of a recall of INRatio2 test strips and our recall of certain Beckman Coulter Triage BNP Tests, lower U.S. flu-related sales and reduced mail order diabetes reimbursement rates, as compared to 2013.

Patient Self-testing

Gross profit from our patient self-testing net product sales and services revenue increased by $6.0 million, or 10%, to $64.3 million for 2014, compared to $58.4 million for 2013.

Cost of patient self-testing net product sales and services revenue included amortization expense of $2.3 million and $2.9 million for 2014 and 2013, respectively.

As a percentage of our patient self-testing net product sales and services revenue, gross profit for each of 2014 and 2013 was 47%.

Consumer Diagnostics

Gross profit from our consumer diagnostics net product sales and services revenue increased $3.2 million, or 16%, to $23.5 million during 2014, from $20.3 million in 2013. The increase in gross profit was primarily the result of an increase in manufacturing revenue, as discussed above.

Cost of consumer diagnostics net product sales and services revenue included amortization expense of $0.2 million and $0.9 million for 2014 and 2013, respectively.

As a percentage of our consumer diagnostics net product sales and services revenue, gross profit from our consumer diagnostics business was 22% for 2014, as compared to 20% in 2013.

Research and Development Expense. Research and development expense decreased by $14.2 million, or 9%, to $144.8 million in 2014, from $159.1 million in 2013. Research and development expense during 2014 is reported net of grant funding of $9.5 million arising from the research and development funding relationship with the Bill and Melinda Gates Foundation that we entered into in February 2013 and $0.4 million of funding related to our contract with the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority, or BARDA, that we entered into in September 2014. Restructuring charges associated with our various restructuring plans to integrate our newly-acquired businesses totaling $9.8 million and $1.8 million were included in research and development expense during 2014 and 2013, respectively. Amortization expense of $6.5 million and $4.9 million was included in research and development expense for 2014 and 2013, respectively.

Research and development expense as a percentage of net revenue was 6% for each of 2014 and 2013.

Sales and Marketing Expense. Sales and marketing expense decreased by $52.3 million, or 9%, to $513.8 million for 2014, from $566.1 million for 2013. The decrease in sales and marketing expense was primarily driven by lower amortization expense related to customer relationship intangibles during 2014, compared to 2013, as the underlying economic benefit of the intangibles is declining. Amortization expense of $154.4 million and $197.1 million was included in sales and marketing expense for 2014 and 2013, respectively. Restructuring charges associated with our various restructuring plans to reduce expenses and further integrate our businesses totaling $11.4 million and $1.6 million were included in sales and marketing expense for 2014 and 2013, respectively.

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Sales and marketing expense as a percentage of net revenue was 20% and 22% for 2014 and 2013, respectively.

General and Administrative Expense. General and administrative expense increased by $18.8 million, or 4%, to $454.0 million for 2014, from $435.2 million for 2013. The increase was primarily attributable to the inclusion in general and administrative expense for 2014 of $26.6 million of costs associated with potential business dispositions, which primarily related to an initial public offering in the United Kingdom proposed in early 2014 and subsequently abandoned and the divestiture of our health management business, as compared to $6.1 million during 2013, a $23.9 million increase in charges associated with our restructuring plans to further integrate our businesses, offset by a $1.8 million decrease in expense recorded for fair value adjustments to acquisition-related contingent consideration, the $5.6 million of costs associated with our 2013 proxy contest, as discussed above, a $8.8 million decrease in stock-based compensation expense, and a $2.2 million decrease in acquisition-related costs.

General and administrative expense as a percentage of net revenue was 18% and 17% for 2014 and 2013, respectively.

Impairment and Gain (Loss) on Dispositions, Net. In December 2014, our management decided to close our Alere Connect, LLC subsidiary located in Scottsdale, Arizona. In connection with this decision, we recorded an impairment charge of $10.8 million, which was offset by a net gain of approximately $3.1 million related to various immaterial business dispositions, resulting in a net $7.7 million impairment loss in 2014. See Note 24.

In July 2013, we sold our Spinreact operations located in Spain for $33.4 million in proceeds and, as a result of this transaction, we recorded a loss on disposition of $5.1 million during 2013. The financial results for our Spinreact operations are immaterial to our consolidated financial results. See Note 24.

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 decreased by $46.2 million, or 18%, to $209.2 million for 2014, from $255.3 million for 2013. The decrease is principally due to a $35.6 million loss recorded in connection with the repurchase of our 9% senior subordinated notes during 2013. Also contributing to the decrease was the lower interest rate associated with our 6.5% senior subordinated notes issued in May 2013, compared to the interest rate associated with our 9% senior subordinated notes which we redeemed in the second quarter of 2013.

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):

	2014 (Restated)	2013	Increase/ (Decrease) (Restated)
Interest income (expense), net	$ 2,391	$ 3,168	$ (777)
Foreign exchange gains (losses), net	(2,193)	(4,010)	1,817
Other	(929)	(10,418)	9,489
Total other income (expense), net	$ (731)	$ (11,260)	$ 10,529

Other expense of $0.9 million for 2014 primarily reflected $2.4 million write-off of an investment as a result of the dissolution of the investee, offset by a $1.5 million reversal of a legal settlement accrual.

Other expense of $10.4 million for 2013 is primarily comprised of $11.8 million of expense associated with various legal settlements, which includes a provision of $9.5 million to reflect our estimate of the settlement and litigation costs we expected to incur in connection with a dispute with a

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customer in our U.S. toxicology business, a $5.1 million write-off of an investment and $3.3 million in losses on disposals of fixed assets, with an offsetting $8.0 million bargain purchase gain relating to our acquisition of the Liberty business. The legal settlement associated with the $9.5 million provision was settled in 2014 for $8.0 million.

Provision (Benefit) for Income Taxes. The provision for income taxes increased by $124.2 million to an $82.2 million provision in 2014, from a $42.0 million benefit in 2013. The effective tax rate in 2014 was (74)%, compared to 37% in 2013. The increase in the provision for income taxes, and the corresponding effective tax rate, from 2013 to 2014 is primarily related to our jurisdictional mix of income (loss) and an increase in valuation allowance against U.S. foreign tax credit carryforwards.

The primary components of the 2014 provision for income taxes relate to U.S. federal and foreign income taxes, including a $79.4 million increase in valuation allowance against U.S. foreign tax credit carryforwards. The primary components of the 2013 benefit for income taxes relate to U.S. federal and state income tax benefits, including tax rate changes in foreign jurisdictions, U.S. research credits for 2012 and 2013, the U.S. manufacturing deduction, and the impact of the bargain purchase gain. These benefits are largely offset by increased provisions for changes in valuation allowances, contingent consideration losses not deductible for tax purposes, U.S. tax on foreign income from distributions during 2013 and increases in reserves for uncertain tax positions.

In December 2014, Congress signed into law the Tax Increase Prevention Act of 2014 which retroactively extended the U.S. Federal Research and Development Credit from January 1, 2014 through December 31, 2014. As a result, we recognized the retroactive benefit of the 2014 U.S. Federal Research and Development Credit of approximately $1.4 million as a discrete item in the fourth quarter of 2014, the period in which the legislation was enacted.

Equity Earnings of Unconsolidated Entities, Net of Tax. Equity earnings of unconsolidated entities are reported net of tax and includes our share of earnings in entities that we account for under the equity method of accounting. Equity earnings of unconsolidated entities, net of tax, for 2014 reflect the following: (i) our 50% interest in SPD in the amount of $16.2 million, and (ii) our 49% interest in TechLab, Inc., or TechLab, in the amount of $1.6 million. Loss on sale of our 40% interest in Vedalab S.A., or Vedalab, was in the amount of $0.4 million. Equity earnings of unconsolidated entities, net of tax, for 2013 reflect the following: (i) our 50% interest in SPD in the amount of $15.0 million, (ii) our 49% interest in TechLab in the amount of $2.0 million and (iii) our 40% interest in Vedalab in the amount of $0.6 million.

Income (Loss) from Discontinued Operations, Net of Tax. The results of the health management business and ACS are included in income (loss) from discontinued operations, net of tax, for all periods presented. For 2014, the discontinued operations generated income, net of tax, of $138.3 million, as compared to a loss, net of tax, of $16.1 million for 2013. The $138.3 million of income, net of tax, for 2014 reflects a $144.8 million tax benefit to record a deferred tax asset relating to the outside basis difference of our health management business, offset by the write down of $18.0 million ($11.2 million, net of tax) of finite-lived intangible assets and $1.1 million ($0.7 million, net of tax) of fixed assets to fair value. Also included in the $138.3 million of income from discontinued operations, net of tax, is a gain resulting from the elimination of a $26.3 million ($16.3 million, net of tax) contingent consideration obligation associated with our original purchase of ACS. See Note 3 of our consolidated financial statements included elsewhere in this report.

Year Ended December 31, 2013 Compared to Year Ended December 31, 2012

Net Product Sales and Services Revenue. Net product sales and services revenue increased by $223.3 million, or 9%, to $2.6 billion in 2013, from $2.4 billion in 2012. Net product sales and services revenue increased primarily as a result of our acquisitions which contributed an aggregate of $169.4 million of the increase. Excluding the impact of foreign currency translation, net product sales and services revenue in 2013 grew by $240.5 million, or 10%, over 2012.

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Net Product Sales and Services Revenue by Business Segment. Net product sales and services revenue by business segment for 2013 and 2012 is as follows (in thousands):

	2013	2012	% Increase
Professional diagnostics	$ 2,362,706	$ 2,166,699	9%
Patient self-testing	123,647	109,485	13%
Consumer diagnostics	102,782	89,611	15%
Net product sales and services revenue	$ 2,589,135	$ 2,365,795	9%

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 2013 and 2012 (in thousands):

	2013	2012	% Increase (Decrease)
Infectious disease	$ 721,754	$ 615,950	17%
Toxicology	631,244	588,744	7%
Cardiometabolic	462,725	503,534	(8)%
Diabetes	225,488	144,441	56%
Other	321,495	314,030	2%
Professional diagnostics net product sales and services revenue	$ 2,362,706	$ 2,166,699	9%

Net product sales and services revenue from our professional diagnostics business segment increased by $196.0 million, or 9%, to $2.4 billion in 2013, from $2.2 billion in 2012. Excluding the impact of foreign currency translation, net product sales and services revenue from our professional diagnostics business segment increased by $215.2 million, or 10%, comparing 2013 to 2012. Net product sales and services revenue increased primarily as a result of acquisitions, which contributed an aggregate of $167.2 million of the non-currency-adjusted increase. Also, contributing to the increase in revenue were North American flu-related sales, which increased $31.9 million, from $43.6 million in 2012 to $75.5 million 2013. 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 $76.2 million in 2013, as compared to $150.3 million in 2012. Furthermore, net product sales and services revenue from our professional diagnostics business segment was negatively impacted by the disposition of our Spinreact operations in Spain in July 2013, for which sales totaled $15.9 million in 2013 through the date of disposition, as compared to $22.2 million in 2012, a decrease of $6.3 million. Excluding the impact of acquisitions, the increase in flu-related sales during the comparable periods, the impact of the reduction in net product sales from meter-based Triage products in the U.S. and the disposition of our Spinreact operations in Spain, the currency-adjusted organic growth for our professional diagnostics net product sales and services revenue was $101.4 million, or 5%, from 2012 to 2013. This growth rate was additionally impacted by the reduction in CMS reimbursement rates which became effective on July 1, 2013 for our U.S. mail order diabetes business. Excluding organic revenues from our mail order diabetes business, along with all of the other impacts previously mentioned, our currency-adjusted organic growth was $132.1 million, or 7%, from 2012 to 2013.

Within our professional diagnostics business segment, net product sales and services revenue for our cardiometabolic business decreased by $40.8 million, or 8%, to $462.7 million in 2013, from $503.5 million in 2012, primarily as a result of the impact of the FDA review of certain of our meter-based Triage products in the U.S. Net product sales and services revenue for our infectious disease business increased by $105.8 million, or 17%, to $721.8 million in 2013, from $616.0 million in 2012. This change

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was driven principally by a growth in HIV, flu and malaria revenues during the comparable periods. Net product sales and services revenue for our toxicology business increased by $42.5 million, or 7%, to $631.2 million in 2013, from $588.7 million in 2012, with our recent toxicology-related acquisitions contributing a combined net of $54.1 million of the non-currency adjusted increase. Offsetting the increase in our toxicology net product sales and services revenue contributed by acquisitions was a $23.6 million decrease in net product sales related to our Triage toxicology products and reductions in commercial pricing for our pain management and rehabilitation services implemented in the second quarter of 2012 and fourth quarter of 2013. Our diabetes net product sales and services revenue increased by $81.0 million, or 56%, to $225.5 million in 2013, from $144.4 million in 2012. The increase was primarily the result of our recent acquisitions of AmMed Direct LLC, or AmMed, NationsHealth, Discount Diabetic, LLC, or Discount Diabetic, the Medicare fee-for-service assets of Liberty Medical, or the Liberty business, and Simplex Healthcare, Inc., or Simplex, which contributed a combined net $100.8 million of the non-currency adjusted increase. Included in the $225.5 million of revenue from our diabetes business for 2013 were $153.6 million of mail order diabetes sales, compared to $85.7 million for 2012.

Patient Self-testing

The following table summarizes our net product sales and services revenue from our patient self-testing business segment by groups of similar products and services for 2013 and 2012 (in thousands):

	2013	2012	% Increase (Decrease)
Patient self-testing services	$ 102,919	$ 90,088	14%
Other	20,728	19,397	7%
Patient self-testing net product sales and services revenue	$ 123,647	$ 109,485	13%

Net product sales and services revenue from our patient self-testing business segment increased by $14.2 million to $123.6 million in 2013, from $109.5 million in 2012. Our Alere Home Monitoring patient self-testing services net product sales and services revenue increased $12.8 million, or 14%, to $102.9 million in 2013, compared to $90.1 million in 2012, 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.

Consumer Diagnostics

Net product sales and services revenue from our consumer diagnostics business segment increased by $13.2 million, or 15%, to $102.8 million in 2013, from $89.6 million in 2012. The increase in revenue primarily resulted from an increase in our manufacturing revenue associated with SPD, as SPD successfully launched the Clearblue Advanced Pregnancy Test with Weeks Estimator product in the U.S. during 2013. SPD sales were $178.4 million and $187.8 million during 2013 and 2012, respectively.

Net Product Sales and Services Revenue by Geographic Location. Net product sales and services revenue by geographic location for 2013 and 2012 is as follows (in thousands):

	2013	2012	% Increase
United States	$ 1,424,235	$ 1,276,612	12%
Europe	505,725	481,074	5%
Elsewhere(1)	659,175	608,109	8%
Net product sales and services revenue	$ 2,589,135	$ 2,365,795	9%

(1) Includes, among many others, the following countries: China, Japan, Brazil, India, South Korea, Canada, and Australia.

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Net product sales and services revenue of $1.4 billion and $1.3 billion generated in the United States was approximately 55% and 54% of total net product sales and services revenue for 2013 and 2012, respectively. The growth in net product sales and services revenue in the United States was primarily due to an increase of $71.1 million in our domestic diabetes net product sales and services revenue, resulting primarily from our recent diabetes-related acquisitions discussed above. 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.

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 decreased by $1.3 million, or 5%, to $27.2 million in 2013, from $28.6 million in 2012. Included in royalty revenues in 2013 was an $8.5 million one-time, up-front issuance fee associated with the license of certain of our molecular intellectual property, compared with an $11.0 million one-time, up-front issuance fee during 2012.

Gross Profit and Margin Percentage. Gross profit increased by $71.2 million, or 6%, to $1.3 billion in 2013, from $1.2 billion in 2012. The increase in gross profit during 2013 was largely attributed to the increase in net product sales and services revenue resulting from acquisitions. Cost of net revenue during 2013 and 2012 included amortization of $2.5 million and $4.7 million, respectively, relating to the write up of inventory to fair value in connection with certain acquisitions. Reducing gross profit for 2013 and 2012 was $6.1 million and $2.3 million, respectively, in restructuring charges, which included $2.5 million of severance-related costs, $2.3 million in facility and transition costs and $1.3 million in fixed asset, intangible asset and inventory impairments for 2013, and $1.3 million of severance-related costs, $0.7 million in facility and transition costs and $0.3 million in inventory impairments for 2012.

Cost of net revenue included amortization expense of $68.1 million and $69.3 million for 2013 and 2012, respectively.

Overall gross margin percentage was 50% in 2013, compared to 52% in 2012. The decrease in gross margin principally reflects the impact of the reduction in diabetes reimbursement rates that took effect in July 2013, as well as the increased costs of manufacturing certain of our meter-based Triage products.

Gross Profit from Net Product Sales and Services Revenue, Total and by Business Segment. Gross profit from net product sales and services revenue increased by $72.9 million, or 6%, to $1.3 billion in 2013, from $1.2 billion in 2012. Gross profit from net product sales and services revenue by business segment for 2013 and 2012 is as follows (in thousands):

	2013	2012	% Increase
Professional diagnostics	$ 1,218,900	$ 1,152,808	6%
Patient self-testing	58,369	52,555	11%
Consumer diagnostics	20,320	19,305	5%
Gross profit from net product sales and services revenue	$ 1,297,589	$ 1,224,668	6%

Professional Diagnostics

Gross profit from our professional diagnostics net product sales and services revenue increased by $66.1 million, or 6%, to $1.22 billion during 2013, from $1.15 billion in 2012, principally as a result of gross profit earned on revenue from acquired businesses, as discussed above. Comparing 2013 to 2012, gross profit was negatively impacted by the lower volume of our U.S. meter-based Triage product sales and a reduction in commercial pricing for our toxicology products in our pain management and addiction medicine lines of business, as discussed above. The continued impact of the FDA inspection of our San Diego facility and the related recall of certain of our meter-based Triage products also resulted in increased incremental

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costs during 2013, principally due to unfavorable manufacturing variances. Cost of professional diagnostics net product sales and services revenue during 2013 and 2012 included a non-cash charge of $2.5 million and $4.7 million, respectively, relating to the write-up of inventory to fair value in connection with our acquisition of Epocal, Inc., or Epocal. Reducing gross profit for 2013 and 2012 was $6.1 million and $2.3 million, respectively, in restructuring charges.

Cost of professional diagnostics net product sales and services revenue included amortization expense of $64.3 million and $64.4 million for 2013 and 2012, respectively.

As a percentage of our professional diagnostics net product sales and services revenue, gross profit from our professional diagnostics business was 52% in 2013, compared to 53% in 2012. The continued impact of the FDA inspection and the related product recall, discussed above, which resulted in increased incremental costs during 2013, contributed to the lower gross profit.

Patient Self-testing

Gross profit from our patient self-testing net product sales and services revenue increased by $5.8 million, or 11%, to $58.4 million during 2013, as compared to $52.6 million in 2012. Reducing gross profit for 2013 and 2012 was $0.1 million and $0.0 million, respectively, in restructuring charges.

Cost of patient self-testing net product sales and services revenue included amortization expense of $2.9 million and $3.7 million for 2013 and 2012, respectively.

As a percentage of our patient self-testing net product sales and services revenue, gross profit from our patient self-testing business was 47% and 48% for 2013 and 2012, respectively.

Consumer Diagnostics

Gross profit from our consumer diagnostics net product sales and services revenue increased $1.0 million, or 5%, to $20.3 million during 2013, from $19.3 million in 2012. The increase in gross profit was primarily the result of an increase in manufacturing revenue, as discussed above, and a $0.7 million charge related to our manufacturing agreement with SPD recorded during 2012.

Cost of consumer diagnostics net product sales and services revenue included amortization expense of $0.9 million and $1.2 million for 2013 and 2012, respectively.

As a percentage of our consumer diagnostics net product sales and services revenue, gross profit from our consumer diagnostics business was 20% for 2013, compared to 22% in 2012.

Research and Development Expense. Research and development expense decreased by $22.7 million, or 12%, to $159.1 million in 2013, from $181.7 million in 2012. Research and development expense during 2013 is reported net of grant funding of $6.6 million arising from the research and development funding relationship with the Bill and Melinda Gates Foundation that we entered into in February 2013. Restructuring charges associated with our various restructuring plans to integrate our newly-acquired businesses totaling $1.8 million and $1.3 million were included in research and development expense during 2013 and 2012, respectively. Amortization expense of $4.9 million and $26.9 million was included in research and development expense for 2013 and 2012, 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 which were discontinued in 2012.

Research and development expense as a percentage of net revenue was 6% and 8% for 2013 and 2012, respectively.

Sales and Marketing Expense. Sales and marketing expense increased by $9.5 million, or 2%, to $566.1 million in 2013, from $556.6 million in 2012. Amortization expense of $197.1 million and

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$197.9 million was included in sales and marketing expense for 2013 and 2012, respectively. Restructuring charges associated with our various restructuring plans to integrate our newly-acquired businesses totaling $1.5 million and $2.1 million were included in sales and marketing expense during 2013 and 2012, respectively.

Sales and marketing expense as a percentage of net revenue was 22% and 23% for 2013 and 2012, respectively.

General and Administrative Expense. General and administrative expense increased by $87.8 million, or 25%, to $435.2 million in 2013, from $347.4 million in 2012. The increase in general and administrative expense from 2012 to 2013 was primarily attributable to a $25.8 million increase in expense related to fair value adjustments to acquisition-related contingent consideration obligations, a $4.6 million increase in amortization expense, and a $3.5 million increase in restructuring plans to further integrate our businesses, as well as the inclusion in general and administrative expense for 2013 of $7.5 million in excise tax expense related to the domestic sale of our medical device products as a result of the 2.3% excise tax that went into effect January 1, 2013, $5.6 million of costs associated with the conduct of a contested proxy solicitation in 2013 and $6.1 million of costs associated with potential business dispositions, which were partially offset in 2013 by a $6.6 million decrease in acquisition-related costs in 2013.

General and administrative expense as a percentage of net revenue was 17% and 15% for 2013 and 2012, respectively.

Impairment and Gain (Loss) on Dispositions, Net. In July 2013, we sold our Spinreact operations located in Spain, which was part of our professional diagnostics reporting unit and business segment, for approximately $33.4 million in proceeds and, as a result of this transaction, we recorded a loss on disposition of $5.1 million during 2013. The financial results for our Spinreact operations are immaterial to our consolidated financial results.

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 $14.9 million, or 6%, to $255.3 million in 2013, from $240.4 million in 2012. The increase is principally due to a $35.6 million loss recorded in connection with the repurchase of our 9% senior subordinated notes during 2013, which was partially offset by the effect of lower interest rates associated with our 6.5% senior subordinated notes and our 7.25% senior notes, issued in May 2013 and December 2012, respectively, compared to the higher interest rates associated with our 7.875% senior notes, which we redeemed in December 2012 and February 2013, and our 9% senior subordinated notes, which we redeemed in May and June 2013.

Interest expense in 2012 includes $23.2 million of expense associated with the repurchase of substantially all of our 7.875% senior notes.

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):

	2013	2012	Increase/ (Decrease)
Interest income (expense), net	$ 3,168	$ 1,922	$ 1,246
Foreign exchange gains (losses), net	(4,010)	(7,887)	3,877
Other	(10,418)	17,102	(27,520)
Total other income (expense), net	$ (11,260)	$ 11,137	$ (22,397)

Other expense of $10.4 million for 2013 is primarily comprised of $11.8 million of expense associated with various legal settlements, which includes a provision of $9.5 million to reflect our

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estimate of the settlement and litigation costs we expected to incur in connection with a dispute with a customer in our U.S. toxicology business, a $5.1 million write-off of an investment and $3.3 million in losses on disposals of fixed assets, with an offsetting $8.0 million bargain purchase gain relating to our acquisition of the Liberty business.

Other income of $17.1 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 $3.9 million.

Provision (Benefit) for Income Taxes. The benefit for income taxes increased by $31.3 million to a $42.0 million benefit in 2013, from a $10.7 million benefit in 2012. The effective tax rate in 2013 was 37%, compared to 16% in 2012. The increase in the benefit for income taxes, and the corresponding effective tax rate, from 2012 to 2013 is primarily related to tax rate changes in foreign jurisdictions, U.S. research credits for 2012 and 2013, the U.S. manufacturing deduction, and the impact of the bargain purchase gain. The effective tax rate was also impacted by contingent consideration losses not deductible for tax purposes and U.S. tax on foreign income from distributions during 2013.

The primary components of the 2013 benefit for income taxes relate to U.S. federal and state income tax benefits, U.S. research credits for 2012 and 2013, the U.S. manufacturing deduction and the impact of the bargain purchase gain. These benefits are largely offset by foreign tax provision, U.S. tax on foreign income from distributions during 2013, and increases in reserves for uncertain tax positions. The primary components of the 2012 benefit for income taxes relate to U.S. federal and state income tax benefits, offset by tax provisions on foreign income, increases in certain valuation allowances, an increase in the reserve for uncertain tax positions, and increases for other permanent adjustments.

Equity Earnings of Unconsolidated Entities, Net of Tax. Equity earnings of 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 of unconsolidated entities, net of tax, for 2013 primarily reflect the following: (i) earnings from our 50% interest in SPD in the amount of $15.0 million, (ii) earnings from our 40% interest in Vedalab in the amount of $0.6 million and (iii) earnings from our 49% interest in TechLab in the amount of $2.0 million. Equity earnings of unconsolidated entities, net of tax, for 2012 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 in the amount of $0.4 million and (iii) earnings from our 49% interest in TechLab in the amount of $2.3 million.

Loss from Discontinued Operations, Net of Tax. The results of the health management business and ACS are included in loss from discontinued operations, net of tax, for all periods presented. For 2013, the discontinued operations generated a loss, net of tax, of $16.1 million, as compared to a loss, net of tax, of $33.1 million for 2012.

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. Additionally, we remain engaged in discussions concerning potential divestitures, and we expect that if and when we complete divestitures we will use the net proceeds primarily to reduce our

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outstanding debt. Upon the completion of our divestiture of our health management business on January 9, 2015, we used $575.0 million of the $600.1 million in cash proceeds from the sale to repay outstanding indebtedness under our secured credit facility. See Note 27 of our consolidated financial statements included elsewhere in this report for more information about our use of proceeds from the sale of our health management business. As of December 31, 2014, we had $378.5 million of cash and cash equivalents, of which $103.9 million was held by domestic subsidiaries and $274.6 million was held by foreign entities. We do not currently 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, other commitments including our contractual contingent consideration obligations, and future acquisitions. As of December 31, 2014, we had outstanding borrowings totaling $127.0 million under the $250.0 million revolving line of credit under our secured credit facility, leaving $123.0 million available to us for additional borrowings. The terms and conditions of our outstanding debt instruments contain covenants that expressly restrict our ability to incur additional indebtedness and conduct other financings. As of December 31, 2014, we had $3.7 billion in aggregate principal amount of outstanding indebtedness, comprised of $2.2 billion in aggregate principal amount outstanding under our secured credit facility, including borrowings under our revolving line of credit, $450.0 million in aggregate outstanding principal amount of our 7.25% senior notes due 2018, $400.0 million in aggregate outstanding principal amount of our 8.625% senior subordinated notes due 2018, $425.0 million in aggregate outstanding principal amount of our 6.5% senior subordinated notes due 2020, and $150.0 million in aggregate outstanding principal amount of our 3% convertible senior subordinated notes due 2016.

Our secured credit facility has various final maturity dates occurring in 2016 and 2017, but if any of our 3% convertible senior subordinated notes remain outstanding on November 15, 2015 (subject to certain exceptions provided in the credit agreement governing our secured credit facility), our secured credit facility will instead mature on such date. Unless we are able to secure the participation of the holders of all of the 3% convertible senior subordinated notes in a tender offer for the repurchase of, refinancing of or other similar transaction relating to all of those notes prior to November 15, 2015 or are able to secure adequate waivers of the maturity acceleration requirement from the lenders under our secured credit facility, we may be required to repay or make arrangements to restructure or refinance the indebtedness outstanding under our secured credit facility earlier than we had expected.

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 if our underlying assumed revenues and expenses are not realized. In particular, we could experience unexpected costs associated with our potential divestitures, operational integration efforts, core research and development projects, cost-saving initiatives and existing or unforeseen lawsuits against us. 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.

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Cash Flow Summary (in thousands)

	Year Ended December 31,		
	2014 (Restated)	2013	2012
Net cash from operating activities:			
Continuing operations	$ 188,055	$ 174,668	$ 279,477
Discontinued operations	43,468	69,232	40,204
Net cash provided by operating activities	231,523	243,900	319,681
Net cash from investing activities:			
Continuing operations	(48,231)	(230,483)	(542,119)
Discontinued operations	(8,972)	(26,963)	(32,070)
Net cash used in investing activities	(57,203)	(257,446)	(574,189)
Net cash from financing activities:			
Continuing operations	(116,684)	51,824	287,149
Discontinued operations	(1,471)	(2,833)	(1,406)
Net cash provided by (used in) financing activities	(118,155)	48,991	285,743
Foreign exchange effect on cash and cash equivalents	(16,312)	(1,871)	(2,064)
Net increase (decrease) in cash and cash equivalents	39,853	33,574	29,171
Cash and cash equivalents, beginning of period continuing operations	355,431	316,479	287,541
Cash and cash equivalents, beginning of period discontinued operations	6,477	11,855	11,622
Cash and cash equivalents, end of period	401,761	361,908	328,334
Less: Cash and cash equivalents of discontinued operations, end of period	23,300	6,477	11,855
Cash and cash equivalents of continuing operations, end of period	$ 378,461	$ 355,431	$ 316,479

Summary of Changes in Cash Position

As of December 31, 2014, we had cash and cash equivalents of continuing operations of $378.5 million, a $23.0 million increase from December 31, 2013. Our primary sources of cash for continuing operations during 2014 included $188.1 million generated by our continuing operating activities, $51.6 million of cash received from common stock issuances under employee stock option and stock purchase plans, $45.1 million received from dispositions, net of cash divested, $9.5 million received from the sale of our 40% equity investment in Vedalab, $1.5 million in proceeds from the sale of property and equipment and $1.0 million from a decrease in other assets. Our primary uses of cash for our continuing operations during 2014 were $100.6 million of capital expenditures, $65.1 million related to the repayment of long-term debt obligations, $42.5 million related to net payments under revolving credit facilities, $32.9 million related to payments of acquisition-related contingent consideration obligations, $21.3 million for cash dividends paid on our Series B Preferred Stock, a $5.4 million increase in our restricted cash balance, $6.1 million for principal payments on our capital lease obligations and $1.5 million paid for financing costs. Fluctuations in foreign currencies unfavorably impacted our cash balance by $16.3 million during 2014. Our discontinued operations contributed $33.0 million of cash during 2014.

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As of December 31, 2013, we had cash and cash equivalents of continuing operations of $355.4 million, an increase of $38.9 million from December 31, 2012. Our primary sources of cash for our continuing operations during 2013 included $174.7 million generated by our continuing operating activities, $459.0 million of net proceeds received in connection with long-term debt issuances, which included $425.0 million of gross proceeds received in connection with the issuance of our 6.5% senior subordinated notes, $139.0 million of net proceeds under various revolving credit facilities, which included $190.0 million borrowed against our secured credit facility revolving line-of-credit, $29.0 million received from the disposition of our Spinreact operations, $14.7 million related to a decrease in other assets, $20.9 million of cash received from common stock issuances under employee stock option and stock purchase plans, $29.3 million return of capital related to an equity investment and $3.6 million in proceeds from the sale of property and equipment. Our primary uses of cash for our continuing operations during 2013 were $470.6 million of cash payments on long-term debt, which included $400.0 million of cash payments related to the repurchase of our 9% senior subordinated notes, $176.1 million net cash paid for acquisitions, $99.9 million of capital expenditures, $31.2 million related to an increase in restricted cash, $40.1 million related to payments of acquisition-related contingent consideration obligations, $19.0 million related to tender offer consideration and call premium incurred in connection with the repurchase of our 9% senior subordinated notes, $21.3 million for cash dividends paid on our Series B preferred stock, $9.8 million related to the payment of debt-related financing costs and $6.5 million for payment of capital lease obligations. Fluctuations in foreign currencies unfavorably impacted our cash balance by $1.9 million during 2013. Our discontinued operations contributed $39.4 million of cash during 2013.

As of December 31, 2012, we had cash and cash equivalents of continuing operations of $316.5 million, an increase of $28.9 million from December 31, 2011. Our primary sources of cash from our continuing operations during 2012 included $279.5 million generated by our continuing 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, $21.6 million in proceeds 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 of capital related to equity investments, a $5.9 million decrease in restricted cash and $3.1 million from sales of marketable securities. Our primary uses of cash for our continuing operations during 2012 included $420.0 million net cash paid for acquisitions, $311.3 million related to cash payments on long-term debt, $109.1 million of capital expenditures, $56.4 million related to an increase in other assets, $21.3 million for cash dividends paid on our Series B preferred stock, $20.1 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, $10.1 million related to financing costs, $6.7 million for payment of capital lease obligations and $6.2 million related to the repayment of short-term debt. Fluctuations in foreign currencies negatively impacted our cash balance by $2.1 million during 2012. Our discontinued operations contributed $6.7 million of cash during 2012.

Cash Flows from Operating Activities

Net cash provided by continuing operating activities during 2014 was $188.1 million, which resulted from a loss from continuing operations of $176.0 million, and $15.2 million of cash used to meet working capital needs during the period, offset by $379.3 million of non-cash items. The $379.3 million of non-cash items included $335.8 million related to depreciation and amortization, $16.2 million of interest expense related to the amortization of deferred financing costs and original issue discounts, $12.5 million related to non-cash stock-based compensation, $9.8 million of tax benefit related to discontinued operations retained by Alere Inc., $7.0 million of impairment of long-lived assets, and a $7.7 million loss related to impairment and net gain on dispositions, which reflects both a $10.7 million impairment charge associated with a closed business and a $3.0 million net gain from business dispositions, a $6.5 million loss on the disposition of fixed assets, a $3.1 million loss on inventory

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disposal and $5.0 million related to other non-cash items, partially offset by $17.5 million in equity earnings of unconsolidated entities, net of tax, and a $7.0 million increase related to changes in our deferred tax assets and liabilities, which resulted in part from amortization of intangible assets. In addition, $43.5 million of net cash was provided by discontinued operations for operating activities.

Net cash provided by continuing operating activities during 2013 was $174.7 million, which resulted from a loss from continuing operations of $55.6 million and $98.0 million of cash used to meet net working capital requirements during the year, offset by $328.2 million of non-cash items. The $328.2 million of non-cash items included, among other items, $374.5 million related to depreciation and amortization, $35.6 million related to a loss on extinguishment of debt, $21.2 million related to non-cash stock-based compensation, $17.8 million of interest expense related to the amortization of deferred financing costs and original issue discounts, $10.5 million related to other non-cash items, $7.9 million of tax benefit related to discontinued operations retained by us, $5.8 million related to the impairment of long-lived assets, $5.1 million loss from the disposition of our Spinreact operations, $0.7 million related to the impairment of intangible assets, a $1.5 million loss on the sale of fixed assets and a $2.5 million non-cash charge related to the write up of inventory to fair value in connection with the acquisition of Epocal, partially offset by a $129.7 million decrease related to changes in our deferred tax assets and liabilities, which resulted in part from amortization of intangible assets, $17.4 million in equity earnings of unconsolidated entities, net of tax, and $8.0 million relating to a bargain purchase gain in connection with our acquisition of the Liberty business. In addition, $69.2 million of net cash was provided by discontinued operations for operating activities.

Net cash provided by continuing operating activities during 2012 was $279.5 million, which resulted from a loss from continuing operations of $45.1 million and $62.8 million of cash used to meet net working capital requirements during the period, offset by $387.4 million of non-cash items. The $387.4 million of non-cash items included, among other items, $383.9 million related to depreciation and amortization, $23.2 million related to a loss on extinguishment of debt, a $7.4 million increase related to other non-cash items, $21.3 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, $4.9 million of tax benefit related to discontinued operations retained by us 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 $57.9 million decrease related to changes in our deferred tax assets and liabilities, which resulted in part from amortization of intangible assets, $13.2 million in equity earnings in unconsolidated entities and $3.1 million gain on the sale of fixed assets. In addition, $40.2 million of net cash was provided by discontinued operations for operating activities.

Cash Flows from Investing Activities

Our investing activities for continuing operations during 2014 utilized $48.2 million of cash, including, among other items, $100.6 million of capital expenditures and a $5.4 million increase in our restricted cash balance, partially offset by $45.1 million of cash received from dispositions, $9.5 million of cash proceeds from the sale of our 40% equity investment in Vedalab, $1.5 million of proceeds from the sale of property, plant and equipment and a $1.0 million decrease in other assets. In addition, discontinued operations used $9.0 million of net cash for investing activities.

Our investing activities for continuing operations during 2013 utilized $230.5 million of cash, including $176.1 million net cash paid for acquisitions, $99.9 million of capital expenditures and an increase in our restricted cash balance of $31.2 million, which was principally driven by a $29.4 million deposit in connection with a foreign bank loan arrangement and $7.9 million of cash received from the Bill and Melinda Gates Foundation, of which $5.7 million was used to fund qualified expenditures, partially offset by a $29.3 million return of capital related to equity investments, $29.0 million in proceeds relating to the disposition of our Spinreact operations, a $14.7 million decrease in other assets and $3.6 million of proceeds from the sale of property and equipment. In addition, discontinued operations used $27.0 million of net cash for investing activities.

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Our investing activities for continuing operations during 2012 utilized $542.1 million of cash, including $420.0 million net cash paid for acquisitions, $109.1 million of capital expenditures and $56.4 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 $21.6 million of proceeds from the sale of property, plant and equipment, a $12.7 million return of capital from equity investments, which included an $11.2 million return of capital from SPD, a $5.9 million decrease in our restricted cash balance and $3.1 million from sales of marketable securities. In addition, discontinued operations used $32.1 million of net cash for investing activities.

Cash Flows from Financing Activities

Net cash used in financing activities for continuing operations during 2014 was $116.7 million. Financing activities during 2014 included, among other items, $65.1 million for the payment of long-term debt obligations, $42.5 million for net payments for revolving credit facilities, $32.9 million for payments of acquisition-related contingent consideration obligations, $21.3 million for dividend payments related to our Series B preferred stock, $6.1 million for payment of capital lease obligations and $1.5 million related to financing costs. We received $51.6 million of cash from common stock issuances under employee stock option and stock purchase plans and had a $1.0 million excess tax benefit associated with exercised stock options. In addition, discontinued operations used $1.5 million of net cash for financing activities.

Net cash provided by financing activities for continuing operations during 2013 was $51.8 million. Financing activities during 2013 primarily included $459.0 million of net proceeds received in connection with long-term debt issuances, which included $425.0 million of gross proceeds received in connection with the issuance of our 6.5% senior subordinated notes, $139.0 million of net proceeds under various revolving credit facilities, which included $190.0 million borrowed, net of $42.5 million paid, against our secured credit facility revolving line-of-credit, and $20.9 million of cash received from common stock issuances under employee stock option and stock purchase plans. In addition, we utilized $470.6 million of cash payments on long-term debt, which included $400.0 million of cash payments related to the repurchase of our 9% senior subordinated notes, $40.1 million for payments of acquisition-related contingent consideration obligations, $21.3 million for dividend payments related to our Series B preferred stock, $19.0 million related to tender offer consideration and call premium incurred in connection with the repurchase of our 9% senior subordinated notes, $9.8 million related to the payment of debt-related financing costs and $6.6 million for payment of capital lease obligations. In addition, discontinued operations used $2.8 million of net cash for financing activities.

Net cash provided by financing activities for continuing operations during 2012 was $287.1 million. Financing activities during 2012 primarily included $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, $14.9 million of cash received from common stock issuances under employee stock option and stock purchase plans and $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. 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 $21.3 million for dividend payments related to our Series B preferred stock, $20.1 million for 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, $10.1 million related to the payment of debt-related financing costs, $6.7 million for payment of capital lease obligations and $6.2 million related to the repayment of short-term debt obligations. In addition, discontinued operations used $1.4 million of net cash for financing activities.

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As of December 31, 2014, we had an aggregate of $14.8 million in outstanding capital lease obligations which are payable through 2019.

Income Taxes

As of December 31, 2014, we had $46.9 million of U.S. federal net operating loss, or NOL, carryforwards, $740.2 million of state NOL carryforwards and $244.8 million of foreign NOL and capital loss carryforwards, which either expire on various dates through 2034 or can be carried forward indefinitely. As of December 31, 2014, we had $14.6 million of U.S. federal and state research and development credit, $108.0 million of U.S. foreign tax credit and $1.3 million of other foreign tax credit carryforwards which either expire on various dates through 2034 or can be carried forward indefinitely. These loss and tax credit carryforwards may be available to reduce future U.S. federal, state and foreign taxable income and taxes, if any, and are subject to review and possible adjustment by the appropriate tax authorities when utilized.

Furthermore, all U.S. federal loss carryforwards and credits are subject to the limitations imposed by Sections 382 and 383 of the Internal Revenue Code, 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%. Sections 382 and 383 impose an annual limitation on the use of these loss carryforwards 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. Additionally, certain U.S. state and foreign losses and credits may be subject to similar and/or other limitations based on local provisions.

We have recorded a valuation allowance against a portion of the deferred tax assets related to our U.S. foreign tax credits and certain other NOL, capital loss and credit carryforwards, as well as certain of our other deferred tax assets to reflect uncertainties that might affect the realization of such deferred tax assets.

Off-Balance Sheet Arrangements

We had no material off-balance sheet arrangements as of December 31, 2014.

Contractual Obligations

The following table summarizes our principal contractual obligations as of December 31, 2014 (in thousands):

		Payments Due by Period			
Contractual Obligations	**Total**	**2015**	**2016-2017**	**2018-2019**	**Thereafter**
Long-term debt obligations(1)	$ 3,685,715	$ 63,203	$ 2,343,529	$ 851,612	$ 427,371
Short-term debt obligations	25,672	25,672			
Capital lease obligations(2)	14,801	4,241	7,041	2,468	1,051
Operating lease obligations(3)	155,998	37,565	56,786	34,512	27,135
Pension obligations	7,588	1,787	3,574	2,227	
Minimum royalty obligations	9,695	1,848	3,431	3,031	1,385
Acquisition-related obligations(4)	13,877	9,692	4,185		
Purchase obligations capital expenditure	11,620	11,620			
Purchase obligations other(5)	53,438	48,972	4,466		
Interest on debt(6)	414,645	100,728	192,330	107,657	13,930
Contingent consideration obligations(7)	139,671	61,314	34,486	33,481	10,390
Total	$ 4,532,720	$ 366,642	$ 2,649,828	$ 1,034,988	$ 481,262

(1) See the description of various financing arrangements in Note 8 of our consolidated financial statements included elsewhere in this report. See Note 27 of our consolidated financial statements included elsewhere in this report.

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(2) See Note 10 of our consolidated financial statements included elsewhere in this report.

(3) See Note 12(a) of our consolidated financial statements included elsewhere in this report.

(4) Includes $3.5 million of deferred purchase price payments, $1.0 million of non-compete payments and $9.4 million of management incentive payments related to our acquisition of Epocal.

(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 8 of our consolidated financial statements included elsewhere in this report.

(7) In connection with certain of our acquisitions, additional contingent consideration may become payable to the sellers upon the satisfaction of certain performance milestones. Amounts represent the estimated fair value of these obligations. For further information pertaining to our contingent consideration arrangements see Note 12(b) of our consolidated financial statements included elsewhere in this report.

In addition to the contractual obligations included in the table above, we recorded reserves for uncertain tax positions, including interest and penalties in the amount of $47.9 million as non-current liabilities. It is uncertain if, or when, such amounts may be settled. See disclosure regarding uncertain tax positions in Note 17 of our consolidated financial statements included elsewhere in this report.

Critical Accounting Policies

The consolidated financial statements included elsewhere in this report 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, 2014, included elsewhere in this report, include a comprehensive summary of the significant accounting policies and methods used in the preparation of our consolidated financial statements.

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

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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, with respect to our health management business which is included in discontinued operations, 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. However, revenue recognized for fees subject to refund before the end of the contract period is realizable under the termination provisions or other provisions of the contract. 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 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 $91.3 million, $98.6 million and $67.8 million, or 4%, 5% and 4%, respectively, of net product sales in 2014, 2013 and 2012, respectively, which have been recorded against product sales to derive our net product sales. Of these amounts, $42.4 million, $65.6 million and $39.2 million for 2014, 2013 and 2012, 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 $466.1 million and $487.4 million, net of allowances for doubtful accounts of $76.2 million and $69.1 million, as of December 31, 2014 and 2013, respectively.

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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 $365.2 million and $365.3 million, net of a reserve for excess and obsolete inventory of $27.3 million and $21.4 million, as of December 31, 2014 and 2013, respectively.

Goodwill and Other Long-Lived and Intangible Assets

Our long-lived assets include property, plant and equipment, net; goodwill; other intangible assets with indefinite lives; and finite-lived intangible assets, net. As of December 31, 2014 and 2013, respectively, we had property, plant and equipment, net of $453.6 million and $466.5 million; goodwill of $2.9 billion and $3.0 billion; other intangible assets with indefinite lives of $43.7 million and $56.7 million; and finite-lived intangible assets, net of $1.3 billion and $1.6 billion.

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, 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, the market comparable approach and the market transaction approach. The income approach is based on a discounted cash flow analysis, or DCF approach, 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 approach 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 approach are based on estimates of the weighted-average cost of capital, or WACC, of market participants relative to each respective reporting unit. The market approaches consider comparable and transactional market data based on multiples of revenue or earnings before interest, taxes, depreciation and amortization, or EBITDA, based on trading multiples of selected guideline companies and deal multiples of selected target companies.

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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. Step 2 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 to write down the carrying value to its implied value.

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

2014 Annual Goodwill Impairment Test

We conducted our 2014 annual impairment test for our reporting units during the fourth quarter of 2014. For our patient self-testing reporting unit, we utilized the purchase price for the sale of our health management business as the estimated fair value of the health management business and combined that with the estimated fair value of the remaining patient self-testing reporting unit which was determined using a combination of the income approach, the market comparable approach and the market transaction approach to arrive at the total estimated fair value of the patient self-testing business. Key assumptions (which vary by reporting unit) used in determining fair value under the DCF approach included discount rates ranging from 10.5% to 15.5%, projected compound average revenue growth rates of 3.0% to 11.0%, 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 approaches 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 1.2 to 2.9 times and multiples of EBITDA of 7.1 to 11.8 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 test indicated the estimated fair value of the professional diagnostics, patient self-testing and consumer diagnostics reporting units exceeded the carrying value of their reporting unit s net assets as follows: by $2.2 billion, $515.6 million and $86.8 million, respectively, or 42.4%, 162.1% and 38.0%, respectively.

As discussed in Note 3 of the notes to our consolidated financial statements included elsewhere in this report, our health management business met the criteria for assets held for sale as of December 31, 2014 and the sale was subsequently completed on January 9, 2015. Accordingly, we performed a Step 1 impairment test on the goodwill remaining in the patient self-testing reporting unit at December 31, 2014. The Step 1 impairment test indicated that the estimated fair value of the remaining patient self-testing reporting unit exceeded the carrying value of the reporting unit s net assets by 67.0%.

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.

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2013 Annual Goodwill Impairment Test

We conducted our 2013 annual impairment test for our reporting units during the fourth quarter of 2013. Key assumptions (which vary by reporting unit) used in determining fair value under the DCF approach included discount rates ranging from 11.0% to 14.0%, projected compound average revenue growth rates of 4.0% to 11.4%, and terminal value growth rates of 3.0% to 4.0%. The factors considered in determining the appropriate discount rate and the key assumptions were the same as those in the 2014 annual goodwill impairment test described above. Based on the multiples implied by this market data, we selected multiples of revenue of 0.8 to 2.9 times and multiples of EBITDA of 6.4 to 10.6 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 test indicated the estimated fair value of the professional diagnostics, patient self-testing and consumer diagnostics reporting units exceeded the carrying value of their reporting unit s net assets as follows: by $1.6 billion, $34.7 million and $92.7 million, respectively, or 30.3%, 8.5% and 45.5%, respectively.

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 DCF 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%. The factors considered in determining the appropriate discount rate and the key assumptions were the same as those in the 2014 annual goodwill impairment test described above. 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 5.4 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 test indicated the estimated fair value of the professional diagnostics, patient self-testing and consumer diagnostics reporting units exceeded the carrying value of their reporting unit s net assets as follows: by $399.2 million, $45.2 million and $53.9 million, or 7.9%, 10.2% and 27.2%, respectively.

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.

Stock-Based Compensation

Stock-based compensation expense 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.

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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 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 $269.2 million as of December 31, 2014, 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. NOLs, capital losses, and tax credits. This is an increase of $184.9 million from the valuation allowance of $84.3 million as of December 31, 2013. The increase is primarily related to domestic state NOLs, certain foreign NOLs, capital losses and foreign tax credits. 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 establish 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 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 report 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 we are 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 4(v) of the consolidated financial statements included elsewhere in this report, 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, 2014, our short-term investments consisted of money market funds with original maturities of 90 days or less. At December 31, 2014, our short-term investments approximated market value.

At December 31, 2014, under the credit agreement for our secured credit facility we had (i) term loans in an aggregate outstanding principal amount of $2.2 billion (consisting of A term loans (including the Delayed-Draw term loans) in the aggregate principal amount of $785.9 million and B term loans (including the term loans previously referred to as Incremental B-1 term loans and Incremental B-2 term loans, which term loans have been converted into and consolidated with the B term loans) in the aggregate principal amount of $1,330.8 million), (ii) $127.0 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 $123.0 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, as of December 31, 2014, 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 range from (i) with respect to such loans that are Base Rate Loans, 2.00% to 2.75% and (ii) with respect to such loans that are Eurodollar Rate Loans, 3.00% to 3.75%, in each case, depending upon our consolidated secured leverage ratio. Interest on B term loans that is based on the Eurodollar Rate is subject to a 1.00% floor with respect to the base Eurodollar Rate.

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Assuming no changes in our consolidated secured leverage ratio, the effect of interest rate fluctuations on outstanding borrowings as of December 31, 2014 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	$ 22,437
Interest rates payable by us increase by 200 basis points	$ 44,875

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 2014, the net impact of foreign currency changes on transactions was a loss of $12.8 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 47.4% in 2014. If the U.S. dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during 2014, our gross margin on total net product sales would have been 47.4%, 47.6% and 47.8%, 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 the following amounts (in thousands):

	Approximate Decrease in Net Revenue	Approximate Decrease in Net Income
If, during 2014, the U.S. dollar was stronger by:		
1%	$ (10,079)	$ (446)
5%	$ (50,395)	$ (2,232)
10%	$ (100,789)	$ (4,464)

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(1) and have been filed as part of this report on the pages indicated.

As described in Note 2 of our accompanying consolidated financial statements, we have restated our financial statements for each of the three months ended September 30 and December 31, 2014 and have revised our financial statements for each of the three-month periods ended in 2013 and each of the three months ended March 31 and June 30, 2014. We have also revised the selected quarterly financial data for the quarters presented below to correct the intra-period tax allocations between continuing operations and discontinued operations.

On October 10, 2014, we completed the sale of ACS, and on January 9, 2015, we completed the sale of our health management business. The results of ACS and the health management business are included in income (loss) from discontinued operations, net of tax, for all periods presented in the selected quarterly financial data below. See Note 3 to our accompanying consolidated financial statements for more information about these divestitures and discontinued operations.

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The following table presents selected quarterly financial data for each of the quarters in the years ended December 31, 2014 and 2013 (in thousands, except per share data):

	2014			
	First Quarter(2)	Second Quarter(3)	Third Quarter(4) (Restated)	Fourth Quarter(5) (Restated)
Net revenue	$ 625,239	$ 647,398	$ 649,210	$ 666,857
Gross profit	$ 310,358	$ 298,693	$ 301,622	$ 308,264
Loss from continuing operations	$ (2,850)	$ (57,941)	$ (84,289)	$ (30,948)
Income (loss) from discontinued operations, net of tax	$ (2,596)	$ 12,915	$ (14,401)	$ 142,400
Net income (loss) available to common stockholders(1)	$ (10,804)	$ (50,397)	$ (103,751)	$ 105,919
Basic and diluted net income (loss) per common share attributable to Alere Inc. and Subsidiaries:				
Loss per common share from continuing operations	$ (0.10)	$ (0.77)	$ (1.08)	$ (0.44)
Income (loss) per common share from discontinued operations	$ (0.03)	$ 0.16	$ (0.17)	$ 1.71
Net income (loss) per common share(1)	$ (0.13)	$ (0.61)	$ (1.25)	$ 1.27

	2013			
	First Quarter(6)	Second Quarter(7)	Third Quarter(8)	Fourth Quarter(9)
Net revenue	$ 633,989	$ 659,839	$ 650,648	$ 671,888
Gross profit	$ 318,938	$ 337,132	$ 320,495	$ 340,490
Income (loss) from continuing operations	$ (803)	$ (42,126)	$ (17,156)	$ 4,478
Income (loss) from discontinued operations, net of tax	$ 14,333	$ (24,746)	$ (1,916)	$ (3,797)
Net income (loss) available to common stockholders(1)	$ 8,305	$ (72,448)	$ (24,798)	$ (5,061)
Basic and diluted net income (loss) per common share attributable to Alere Inc. and Subsidiaries:				
Net income (loss) per common share from continuing operations	$ (0.08)	$ (0.59)	$ (0.28)	$ (0.01)
Net income (loss) per common share from discontinued operations	$ 0.18	$ (0.30)	$ (0.02)	$ (0.05)
Net income (loss) per common share(1)	$ 0.10	$ (0.89)	$ (0.30)	$ (0.06)

(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 4(o) and 13 of our consolidated financial statements included elsewhere in this report.

(2) Included in net loss from continuing operations for the first quarter of 2014 is $4.4 million of restructuring charges, $5.7 million of stock-based compensation expense, $0.3 million of acquisition-related costs, $1.4 million of expense recorded for fair value adjustments to acquisition-related contingent consideration, $3.0 million of costs associated with potential business dispositions, $0.4 million of interest expense recorded in connection with fees paid for certain debt modifications, $0.4 million in compensation charges and $0.1 million of related interest accretion associated with acquisition-related contingent consideration obligations.

(3) Included in net loss from continuing operations for the second quarter of 2014 is $15.4 million of restructuring charges, $0.1 million of acquisition-related costs, $16.7 million of expense recorded for fair value adjustments to acquisition-related contingent consideration, $11.6 million of costs associated with potential business dispositions, $0.4 million of interest expense recorded in connection with fees paid for certain debt modifications, a $0.6 million loss associated with the

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disposition of a component of our Alere Informatics business, $0.6 million in compensation charges and $0.1 million of related interest accretion associated with acquisition-related contingent consideration obligations, offset by the reversal of $1.1 million of stock-based compensation expense.

(4) Included in net loss from continuing operations for the third quarter of 2014 is $79.4 million of valuation allowance establishment against deferred tax assets associated with our U.S. foreign tax credit carryforwards, $17.3 million of restructuring charges, $3.2 million of stock-based compensation expense, $0.3 million of acquisition-related costs, $6.2 million of costs associated with potential business dispositions, $0.4 million of interest expense recorded in connection with fees paid for certain debt modifications, $0.7 million in compensation charges and $0.1 million of related interest accretion associated with acquisition-related contingent consideration obligations, $0.4 million loss on the sale of our equity investment in Vedalab S.A., offset by the reversal of $5.5 million of expense recorded for fair value adjustments to acquisition-related contingent consideration.

(5) Included in net loss from continuing operations for the fourth quarter of 2014 is $60.8 million of amortization, $21.6 million of restructuring charges, $4.7 million of stock-based compensation expense, $0.2 million of acquisition-related costs, $5.8 million of costs associated with potential business dispositions, $0.4 million of interest expense recorded in connection with fees paid for certain debt modifications, $0.2 million in compensation charges and $0.1 million of related interest accretion associated with acquisition-related contingent consideration obligations and $7.1 million in impairment and gain (loss) on dispositions, net, offset by the reversal of $4.8 million of expense recorded for fair value adjustments to acquisition-related contingent consideration.

(6) Included in net income from continuing operations for the first quarter of 2013 is $2.0 million related to restructuring charges associated with the decision to close various facilities, acquisition-related costs in the amount of $0.9 million, $9.3 million of expense recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations in accordance with ASC 805, *Business Combinations*, $1.0 million of interest expense recorded in connection with fees paid for certain debt modifications and the termination of our former senior secured credit facility, $4.1 million of non-cash stock-based compensation expense, $0.7 million in compensation charges associated with acquisition-related contingent consideration obligations, a $0.5 million charge associated with the write-up to fair market value of inventory acquired in connection with the acquisition of Epocal Inc. and $0.2 million of expense associated with the extinguishment of debt.

(7) Included in net loss from continuing operations for the second quarter of 2013 is $2.1 million related to restructuring charges associated with the decision to close various facilities, acquisition-related costs in the amount of $0.4 million, $5.2 million of expense recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations in accordance with ASC 805, *Business Combinations*, $35.6 million of loss in connection with the repurchase of our 9% senior subordinated notes, $8.1 million of bargain purchase gain associated with our acquisition of the Liberty business, $5.1 million of non-cash write-off of an investment, $0.8 million of interest expense recorded in connection with fees paid for certain debt modifications and the termination of our former senior secured credit facility, $4.7 million of non-cash stock-based compensation expense, $0.5 million in compensation charges and $0.2 million of related interest accretion associated with acquisition-related contingent consideration obligations, and a $0.7 million charge associated with the write-up to fair market value of inventory acquired in connection with the acquisition of Epocal Inc.

(8) Included in net loss from continuing operations for the third quarter of 2013 is $6.1 million related to restructuring charges associated with the decision to close various facilities, acquisition-related costs in the amount of $0.5 million, $1.8 million of expense recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations in accordance with ASC 805, *Business Combinations*, $5.5 million of costs associated with the conduct of a contested

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proxy solicitation, $5.9 million of loss on disposition of our Spinreact operations, $0.4 million of interest expense recorded in connection with fees paid for certain debt modifications, $5.7 million of non-cash stock-based compensation expense, $0.8 million in compensation charges and $0.1 million of related interest accretion associated with acquisition-related contingent consideration obligations, and a $0.7 million charge associated with the write-up to fair market value of inventory acquired in connection with the acquisition of Epocal Inc.

(9) Included in net loss from continuing operations for the fourth quarter of 2013 is amortization of $70.5 million, $4.2 million of restructuring charges, $6.7 million of stock-based compensation expense, $1.3 million of acquisition-related costs, $6.1 million of costs associated with potential business dispositions, $0.4 million of interest expense recorded in connection with fees paid for certain debt modifications, $0.8 million in compensation charges and $0.1 million of related interest accretion associated with acquisition-related contingent consideration obligations, a $0.6 million charge associated with the write-up to fair market value of inventory acquired in connection with the acquisition of Epocal Inc., $0.1 million of costs associated with the proxy contest, offset by an $0.8 million reduction in the loss on disposition of our Spinreact, S.A. subsidiary located in Spain and $1.6 million of income recorded for fair value adjustments to acquisition-related contingent consideration.

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

In connection with the filing of the Original Report on March 5, 2015, our management evaluated, with the participation of our Chief Executive Officer (CEO) and our then-serving 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 the Original Report. Based on that evaluation, our CEO and then-serving CFO concluded in the Original Report that, because of the material weakness described below, our disclosure controls and procedures were not effective to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, 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. The conclusion reached in the Original Report has not changed as of the filing of this report.

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, 2014. In making this assessment, management used the criteria established in *Internal Control Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. We did not design effective controls to assess the accounting for deferred taxes related to dispositions. This control deficiency resulted in an adjustment to our deferred tax assets and income from discontinued operations which was reflected in our consolidated financial statements for the year ended December 31, 2014 included in the Original Report.

Subsequent to the filing of the Original Report, the material weakness also resulted in the restatement of the consolidated financial statements for the interim period ended September 30, 2014 and the year ended December 31, 2014. Management has determined that the restatements are additional effects of the material weakness described above. Additionally, management concluded that the material weakness could result in misstatements of the aforementioned accounts and disclosures that could result in a material misstatement of the consolidated financial statements that would not be prevented or detected.

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The effectiveness of our internal control over financial reporting as of December 31, 2014 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 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Plan for Remediation of Material Weakness in Internal Control Over Financial Reporting

With the oversight of senior management and the audit committee, we have begun taking steps to remediate the material weakness described above and plan to take additional actions to remediate the underlying cause of this material weakness, primarily through:

(1) enhancing the income tax controls to include specific activities to assess the accounting for deductible outside basis differences that could reverse as a result of transactions to dispose of components of the company,

(2) holding training for our accounting and tax professionals specifically related to accounting for income taxes relating to transactions to dispose of components of the company, and

(3) supplementing our accounting and tax professionals with additional resources that have expertise in accounting for the income tax effects of dispositions and other complex transactions.

These actions are subject to ongoing review by our senior management, as well as oversight by the audit committee of our board of directors. Although we plan to complete this remediation process as quickly as possible, we cannot, at this time, estimate when such remediation may occur, and our initiatives may not prove successful in remediating this material weakness. Management may determine to enhance other existing controls and/or implement additional controls as the implementation progresses. It will take time to determine whether the additional controls we are implementing will be sufficient to accomplish their intended purpose; accordingly, the material weakness may continue for a period of time.

ITEM 9B. OTHER INFORMATION

None.

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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 report 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
***2.1	Membership Interest Purchase Agreement dated October 27, 2014, by and among Alere Inc., Alere Health, LLC and OptumHealth Care Solutions, Inc. (incorporated by reference to Exhibit 2.1 to the Company s Current Report on Form 8-K, event date October 27, 2014, filed October 28, 2014)
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 September 30, 2014)
3.2	Amended and Restated By-laws of the Company (incorporated by reference to Exhibit 3.2 to the Company s Current Report on Form 8-K, event date August 21, 2014, filed with the SEC on August 26, 2014)
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	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)
4.4	Eleventh Supplemental Indenture to Indenture dated as of May 12, 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
4.5	Thirteenth Supplemental Indenture to Indenture dated as of May 12, 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)
4.6	Fifteenth Supplemental Indenture to Indenture dated as of May 12, 2009 (to add the guarantees of Alere Informatics, Inc., Alere Wellogic, LLC, ATS Laboratories, Inc., Avee Laboratories Inc., eScreen, Inc., Global Analytical Development LLC, Ionian Technologies Inc., Pembrooke Occupational Health, Inc., Screen Tox, Inc., and Standing Stone, Inc.) dated as of April 3, 2013 among Alere Informatics, Inc., Alere Wellogic, LLC, ATS Laboratories, Inc., Avee Laboratories Inc., eScreen, Inc., Global Analytical Development LLC, Ionian Technologies Inc., Pembrooke Occupational Health, Inc., Screen Tox, Inc., and Standing Stone, 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 4.2 to the Company s Quarterly Report on Form 10-Q for the period ended March 31, 2013)
4.7	Seventeenth Supplemental Indenture to Indenture dated as of May 12, 2009 (relating to the BBI Transaction) dated as of June 5, 2014, 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 May 30, 2014, filed on June 5, 2014)
*4.8	Nineteenth Supplemental Indenture to Indenture dated as of May 12, 2009 (to add the guarantees of NewCo SS, LLC, Newco AA, Inc., Newco RD, LLC, Newco RD2, LLC, and Alere Holdco, Inc.) dated October 30, 2014 among NewCo SS, LLC, Newco AA, Inc., Newco RD, LLC, Newco RD2, LLC, and Alere Holdco, Inc., as guarantors, the Company as issuer, the other guarantor subsidiaries named therein, as guarantors, and U.S. Bank National Association, as trustee
4.9	Sixteenth Supplemental Indenture dated as of May 24, 2013 to Indenture dated as of May 12, 2009, by and among the Company, the subsidiary guarantors named therein 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 23, 2013, filed May 30, 2013)
4.10	Eighteenth Supplemental Indenture to Indenture dated as of May 12, 2009 (relating to the BBI Transaction) dated as of June 5, 2014, 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 May 30, 2014, filed on June 5, 2014)
*4.11	Twentieth Supplemental Indenture to Indenture dated as of May 12, 2009 (to add the guarantees of NewCo SS, LLC, Newco AA, Inc., Newco RD, LLC, Newco RD2, LLC, and Alere Holdco, Inc.) dated October 30, 2014 among NewCo SS, LLC, Newco AA, Inc., Newco RD, LLC, Newco RD2, LLC, and Alere Holdco, Inc., as guarantors, the Company as issuer, the other guarantor subsidiaries named therein, as guarantors, and U.S. Bank National Association, as trustee
4.12	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)

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Exhibit No.	Description
4.13	Fifteenth Supplemental Indenture dated as of December 11, 2012 to Indenture dates as of August 11, 2009, 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)
4.14	Sixteenth Supplemental Indenture, dated April 3, 2013 (to add the guarantees of Alere Informatics, Inc., Alere Wellogic, LLC, ATS Laboratories, Inc., Avee Laboratories Inc., eScreen, Inc., Global Analytical Development LLC, Ionian Technologies Inc., Pembrooke Occupational Health, Inc., Screen Tox, Inc., and Standing Stone, Inc.) to Indenture dated as of August 11, 2009 among Alere Informatics, Inc., Alere Wellogic, LLC, ATS Laboratories, Inc., Avee Laboratories Inc., eScreen, Inc., Global Analytical Development LLC, Ionian Technologies Inc., Pembrooke Occupational Health, Inc., Screen Tox, Inc., and Standing Stone, Inc., as guarantors, the Company as issuer, the other guarantor subsidiaries named therein, as guarantors, and Bank of New York Mellon Trust Company, N.A., as trustee (incorporated by reference to Exhibit 4.6 of the Company s Registration Statement on Form S-4 (File No. 333-187776))
4.15	Seventeenth Supplemental Indenture to Indenture dated as of August 11, 2009 (relating to the BBI Transaction) dated as of June 5, 2014, among the Company, the subsidiary guarantors party thereto and 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 May 30, 2014, filed on June 5, 2014)
*4.16	Eighteenth Supplemental Indenture to Indenture dated as of August 11, 2009 (to add the guarantees of NewCo SS, LLC, Newco AA, Inc., Newco RD, LLC, Newco RD2, LLC, and Alere Holdco, Inc.) dated October 30, 2014 among NewCo SS, LLC, Newco AA, Inc., Newco RD, LLC, Newco RD2, LLC, and Alere Holdco, Inc., as guarantors, the Company as issuer, the other guarantor subsidiaries named therein, as guarantors, and Bank of New York Mellon Trust Company, N.A., as trustee
4.17	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)
4.18	Registration Rights Agreement, dated as of May 24, 2013, by and among the Company, the guarantors named therein, and Goldman, Sachs & Co., Jefferies LLC and Credit Suisse Securities (USA) LLC, as representatives of the Initial Purchasers (incorporated by reference to Exhibit 4.3 to the Company s Current Report on Form 8-K, event date May 23, 2013, filed May 30, 2013)
+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)

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Exhibit No.	Description
10.4	Alere Inc. 2010 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 July 17, 2014)
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 Award Agreements under Alere Inc. Stock Option Plans (incorporated by reference to Exhibit 10.4 to the Company s Quarterly Report on Form 10-Q, for the period ended September 30, 2014)
10.7	Form of Change of Control Agreement between the Company and each of its executive officers (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K, event date October 25, 2014, filed on October 28, 2014)
10.8	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)
10.9	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 July 17, 2014)
10.10	Restricted Stock Unit Agreement, dated December 30, 2012, between Alere Inc. and Namal Nawana (incorporated by reference to Exhibit 10.9 to the Company s Annual Report on Form 10-K, for the year ended December 31, 2012)
10.11	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)
10.12	Summary of Arrangement with Chairman of the Board Regarding Expense Reimbursement (incorporated by reference to Exhibit 10.2 to the Company s Quarterly Report on Form 10-Q ,for the quarter ended June 30, 2014)
10.13	Purchase Agreement dated May 13, 2013 among Alere Inc., the subsidiary guarantors named therein and Goldman, Sachs & Co., Jefferies LLC 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 May 10, 2013, filed May 16, 2013)
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)

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Exhibit No.	Description
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)
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)
10.19	Fourth Amendment to Credit Agreement, dated as of March 22, 2013, among Alere Inc., as Borrower, each of the Guarantors (as defined therein), the Lenders party thereto, and General Electric Capital Corporation, as Administrative Agent (incorporated by reference to Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q for the period ended March 31, 2013)
10.20	Fifth Amendment to Credit Agreement, dated as of May 30, 2014, among Alere Inc., as Borrower, each of the Guarantors (as defined therein), 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 dated May 30, 2014, filed June 5, 2014)
*10.21	Sixth Amendment to Credit Agreement, dated as of December 1, 2014, among Alere Inc., as Borrower, each of the Guarantors (as defined therein), the Lenders party thereto, and General Electric Capital Corporation, as Administrative Agent
*21.1	List of Subsidiaries of the Company as of March 5, 2015
**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, 2014, 2013 and 2012, (b) our Consolidated Statements of Comprehensive Income (Loss) for the Years Ended December 31, 2014, 2013 and 2012 (c) our Consolidated Balance Sheets as of December 31, 2014 and 2013, (d) our Consolidated Statements of Equity for the Years Ended December 31, 2014, 2013 and 2012, (e) our Consolidated Statements of Cash Flows for the Years Ended December 31, 2014, 2013 and 2012 and (f) the Notes to such consolidated financial statements.

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* Previously filed.
** 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.