ALERE INC.
Form 10-K
March 05, 2015
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTIONS 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 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. þ

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

Large accelerated filer þ Accelerated filer ¨ Non-accelerated filer ¨ 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.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive proxy statement to be filed in connection with the registrant s 2015 annual meeting of shareholders are incorporated by reference into Part III of this Form 10-K.

Table of Contents

ALERE INC.

FORM 10-K

For The Fiscal Year Ended December 31, 2014

Table of Contents

PART I

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

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

ITEM 1. BUSINESS

General

Alere 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 17 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

Table of Contents

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 24 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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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

Table of Contents

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;

Table of Contents

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-3 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 19% from Europe and approximately 27% and 26% from other locations.

For further financial information about geographic areas, see Note 16 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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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

Table of Contents

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;

Table of Contents

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.

Table of Contents

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;

Table of Contents

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.

16

Table of Contents

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

Table of Contents

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.

Table of Contents

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

Table of Contents

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

Table of Contents

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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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;

25

Table of Contents

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

26

Table of Contents

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.

Table of Contents

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

Table of Contents

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

Table of Contents

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

Table of Contents

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 identified a material weakness in our internal control over financial reporting as of December 31, 2014 and the occurrence of this, or any other material weakness, could have a material adverse effect on our ability to report accurate financial information in a timely manner.

Our management recently concluded that, as described under the heading Item 9A. Controls and Procedures, 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 a timely basis. The material weakness related to the failure to design controls to assess the accounting for deferred tax assets which became recognizable as a result of the disposition. We are taking steps to remediate the material weakness. However, the remedial measures we are taking may not be adequate to prevent future 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, assumptions about the likelihood of future events, the soundness of our systems, 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 or 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, it is possible that our financial statements will not comply with generally accepted accounting principles, will contain a material misstatement or will 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 and liabilities arising from stockholder litigation.

Table of Contents

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 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

Table of Contents

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, 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.

I TEM 4. MINE SAFETY DISCLOSURES

Not applicable.

Table of Contents

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.

Table of Contents

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 in