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# CONNECT



**2012** ANNUAL REPORT



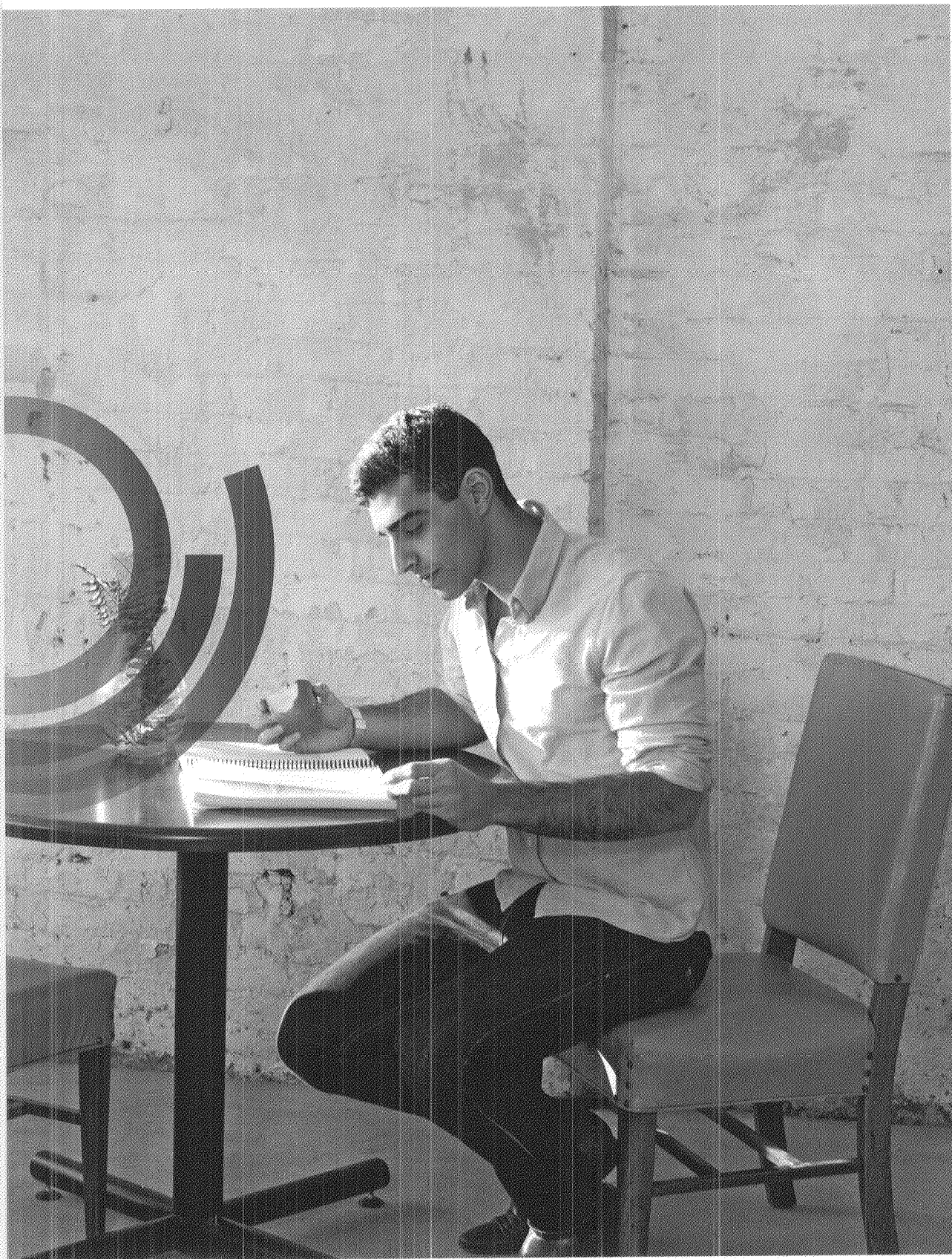
The traditional approach to healthcare creates fragmentation. Errors, unnecessary tests, and lack of coordination result in costly emergency room visits, extended hospital stays, and preventable surgeries.

Our solutions close the gaps in today's fragmented healthcare landscape, allowing for earlier interventions, personalized treatment, fewer hospitalizations, better coordination, and robust decision making, analysis, and reporting. We help healthcare providers working across the continuum of care deliver better outcomes at both an individual and population level.









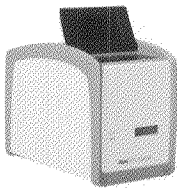


## CHAIRMAN'S LETTER

■ In 2012, Alere strengthened its position as the world's leading provider of near-patient diagnostics, overcoming many of the regulatory challenges that often face large, global enterprises. We also broadened our footprint in the health information technology arena, adding a new set of tools to our portfolio that enable clinicians to make more effective health decisions in real time and better manage patients across the care continuum. Our commitment to empowering individuals to take greater control of their health under medical supervision remains strong, and we are rapidly progressing towards the achievement of this mission by continuing to move our diagnostic platforms closer to the patient. We are achieving this by integrating actionable data from these devices and other sources into longitudinal health records that all care providers can access, and supporting this engine with care management and monitoring programs that allow for earlier clinical interventions and facilitate true behavior change at the patient level.

As I visit our many offices around the world, I am reminded of how much our reach has grown, not just geographically, but also in terms of our ability to address the healthcare challenges facing individuals today. I am especially proud of the extent to which we have improved interaction among patients, care providers, and payers, activating information from diagnostic technologies in so many different areas of healthcare and in so many different venues.

For example, while a woman living in the remote corners of Africa with HIV is tested with our Alere™ CD4 Analyzer to monitor the effectiveness of her antiretroviral treatment, another woman in the United States uses the Alere INRatio® System to monitor her anticoagulation therapy from home. Concurrently, a physician in India depends on our test for Dengue Fever to diagnose a critically ill patient, while doctors in an emergency room in Germany rely on the Alere Triage® tests to diagnose and manage patients who present with symptoms of chest pain and shortness of breath. Alere tests are being administered in virtually every country in the world, and we are the market's leading diagnostic provider for several cardiovascular conditions, infectious and tropical diseases, and abused substances. These facts are a testament to both the quality and effectiveness of our products, as well as the commitment and innovation of our employees.

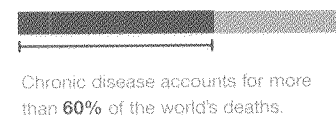
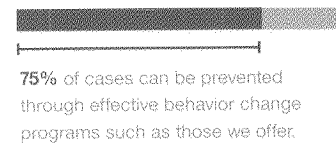


Alere™ CD4 Analyzer monitors the effectiveness of antiretroviral therapy.

We also believe that fundamental changes to the way healthcare is practiced are inevitable, and we are in a position to successfully drive those changes well into the future. Providers will now be held more accountable for the efficacy of their diagnoses and treatments, as well as their ability to control costs and improve outcomes at a population level. Our products, programs, and information solutions are designed to help them achieve these goals.



Today, for instance, chronic disease accounts for more than 60% of the world's deaths, represents an enormous economic burden, and in 75% of cases can be prevented through effective behavior change programs such as those we offer. Chronically ill patients are also more likely to be hospitalized for critical events and treated by a variety of physicians beyond their general practitioners, most of whom work in separate record-keeping systems and consequently lack a holistic view into their patients' health.



By feeding output from our near-patient monitoring platforms into a health information exchange, which also extracts data from disparate medical record systems and integrates it within a single electronic health record that all care providers can access, Alere is able to address the challenges encountered in treating people with chronic diseases. Our model not only improves the physician's visibility into what is happening with the patient, but also deploys world-class analytics and decision support tools that enable healthcare providers to risk stratify patients more effectively, intervene earlier, personalize treatment plans, reduce costs by preventing hospital readmissions, and measure outcomes improvements at both a patient and population level.

Our acquisition pace slowed considerably in 2012, as we believe that the company is essentially built to the degree that we had envisioned, but we did make a few small acquisitions this year to expand our diabetes supply business and strengthen our foothold in the health information arena. Going forward, we ascribe to the same approach towards acquisitions that we took in 2012, which consisted of some small, niche acquisitions to support our growth in health-care information technology and diabetes.

With regard to our R&D programs, 2012 provided FDA clearances for two new tests performed on our wireless point-of-care epoc<sup>®</sup> platform, creatinine and chloride. These tests, which have been added to the epoc<sup>®</sup> test card measuring blood gases, electrolytes and metabolites, will create new market opportunities for Alere in hospital emergency room and radiology departments.

Two molecular programs stand out for 2013. We look forward to the launch of our rapid molecular HIV viral load device, the Alere<sup>™</sup> Q, later this year. While initially developed to facilitate better monitoring and management of antiretroviral therapy, we anticipate the expansion of the platform in the years ahead to support molecular testing for the Hepatitis C Virus and tuberculosis. In fact, we recently announced that we received a grant from the Bill & Melinda Gates Foundation that will help us expedite the development and commercialization of a tuberculosis test for this platform. We are also eagerly awaiting the launch of our second point-of-care molecular platform, the Alere<sup>™</sup> I, which will initially feature a rapid flu test, followed by applications for Strep A and other infectious diseases.



In the area of Toxicology, we are very excited about the potential for our hand-held drug testing meter and expect to file for 510(k) clearance with the FDA in 2014. With the relaxation of laws related to marijuana possession in some states, and its legalization in others, state legislatures recognize the importance of defining drug-impairment levels and their associated criminality. Our roadside testing device, a saliva-based system, will detect several different drugs, including marijuana. It is currently being evaluated by the NHTSA and some law enforcement agencies within the US and Canada. This device would also be effective for employers at the workplace.

Overall, 2012 was a year in which our vision of contributing to a connected healthcare system that incorporates patients, providers, and payers in a unified model became more of a reality. With our near-patient diagnostic platforms connected to our proprietary health information exchange systems, we find ourselves well positioned to deliver a better model of healthcare, providing better outcomes for patients, better real-time data for healthcare practitioners, and more efficient cost structures for payers. When it comes to addressing and delivering these benefits, moreover, we feel we are at the forefront of the national dialogue.

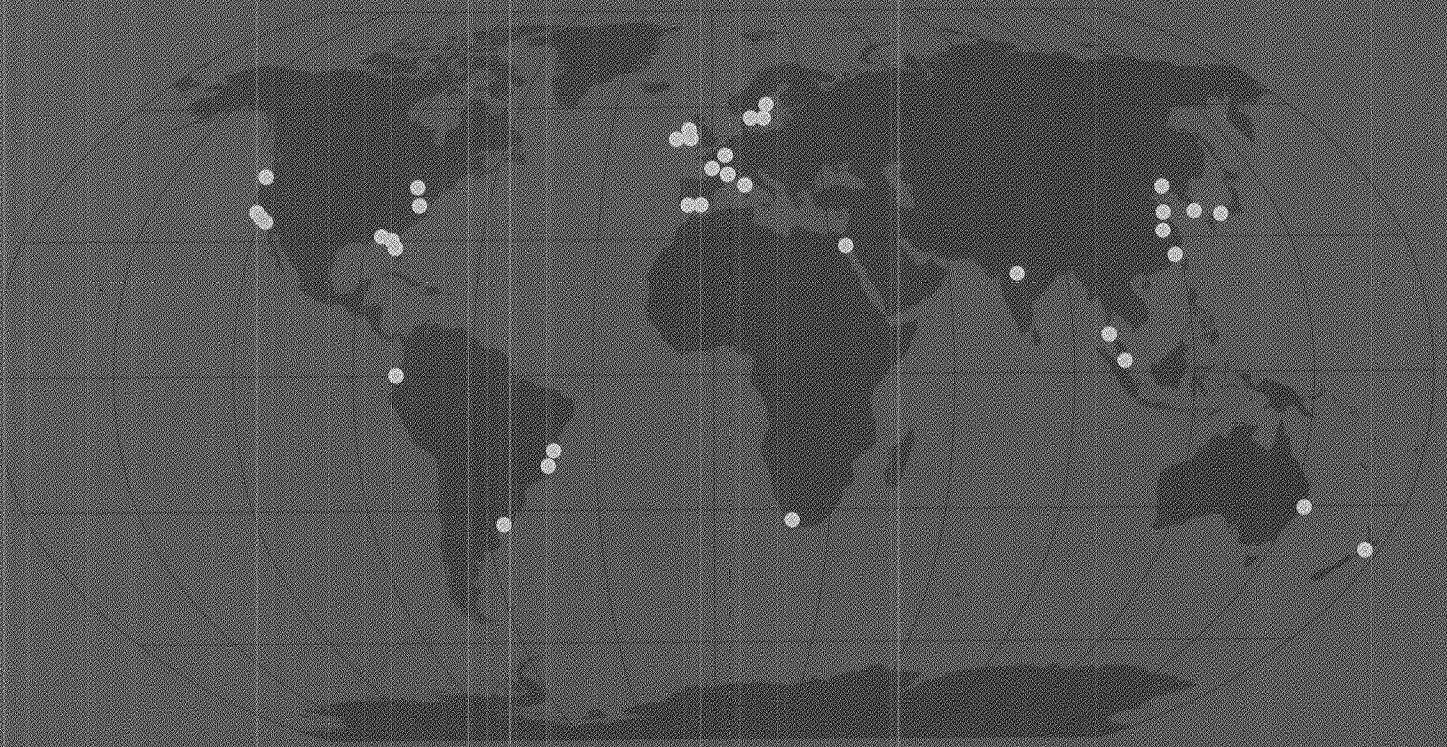
Additionally, we are pleased to welcome Namal Nawana as our Chief Operating Officer. Namal joined us in December, from Johnson & Johnson, where he most recently served as the Worldwide President of DePuy Synthes Spine and managed the company's global operations. He was also responsible for the integration of several acquired businesses, including the multi-billion-dollar Synthes acquisition. We believe that Namal will be a perfect fit to address the operational demands of our expanded global footprint, which necessitate the integration of the companies we have acquired to ensure consistent performance and accelerated growth, while reducing the cost to service our customers.

I believe that this is a most exciting time for Alere, as years of hard work and innovation are coalescing in the launch of several connected, proprietary near-patient diagnostic platforms, the company's expansion into new geographies where the introduction of these and existing platforms will drive rapid growth, and the widespread adoption of an internal philosophy that modifying behavior is key to improving health outcomes. None of this would be possible without the insight of our worldwide workforce and our employees' commitment to put Alere at the forefront of innovation for connected healthcare, for which I sincerely thank them. I would also like to thank our long-term stakeholders for their continued faith in our vision, staying on board through some of the company's more challenging periods, as well as our new stakeholders, for recognizing the importance of what we are trying to accomplish.



Ron Zwanziger  
Chairman, President, and CEO

## The World's Leading Provider of Rapid Diagnostics





**Improving Outcomes in Acute Care Settings //**  
Our novel diagnostic tools enable medical professionals to evaluate risk, diagnose, and assess disease severity in acute care settings, helping to ensure that critically-ill patients receive the right course of treatment sooner.

## Featured Products

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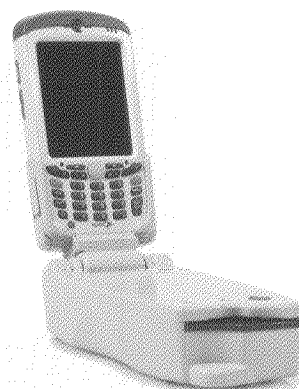


### The Alere Triage® System

Leading diagnostic platform that helps physicians identify several critical health conditions, including heart failure and myocardial infarction, and reduce the time to diagnosis by hours.

### The epoc® Blood Analysis System

Diagnostic platform that offers the broadest blood analysis menu on a single test card. With epoc®, critical care providers are not only able to detect several electrolyte and metabolic disorders in a matter of minutes, but they can also identify renal injury—which helps to expedite treatment, prevent more serious injury, and enable quicker recovery.



## Bringing Diagnosis Closer to the Patient //

Our products and services enable the effective management of patients living with chronic conditions that include heart failure, diabetes, and dyslipidemia, as well as those taking oral anticoagulants.

### Featured Products

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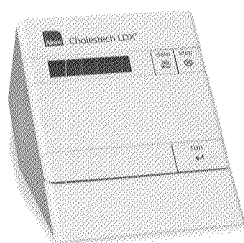
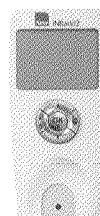


#### The Alere™ Heart Check

FACT: 50% of hospitalizations for heart failure decompensation are preventable. Data from the recently published HABIT trial has shown that frequent BNP testing can identify risk for these events, which may trigger earlier interventions that reduce hospitalizations and readmissions.

#### Alere™ Home Monitoring

FACT: Alere™ Home Monitoring weekly patient self-testers spend 74% of the time in therapeutic range—which is significantly better than the time individuals testing in leading anticoagulation clinics spend in therapeutic range.



#### Alere Cholestech LDX® System

FACT: Reductions in serum cholesterol can reduce heart disease risk by 50%, but as much as 1/3 of the population who may be at risk for developing heart disease is not screened. The Alere Cholestech LDX® System makes screening quick and easy at the point of care, allowing for responsive treatment that may help to reduce risk.

#### Alere Afinion™ Analyzer

FACT: 20% of hospitalizations are diabetes-related. The Alere Afinion™ Analyzer is one of the only systems in use today that provides a lab-quality reading of HbA1c, a measure of blood glucose control, at the point of care.





**Revolutionizing the Diagnosis and Management of Infectious Disease** // Alere is the world's leading provider of near-patient diagnostics for the most prevalent infectious and tropical diseases.

**Market-Leading Provider**

HIV Screening

Influenza

Malaria

*C.Difficile*

*Strep pneumo*

*Legionella*

Strep A

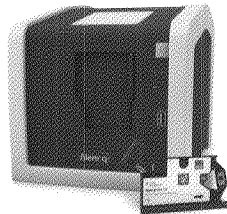
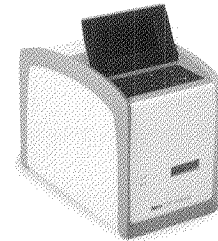
Dengue Fever

RSV

**Novel Platforms That Will Transform Diagnosis & Patient Management**

**Alere™ CD4 Analyzer**

The Alere™ CD4 Analyzer is the world's first device to provide absolute CD4 results at the point of care and has been shown to help initiate and improve the management of antiretroviral therapy.

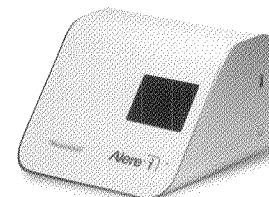


**The Alere™ Q**

Also the first of its kind, the Alere™ Q enables molecular viral load testing for HIV at the point of care. Applications for HCV and tuberculosis are currently in development, and development for our TB application has been supported by a recent grant from the Gates Foundation.

**The Alere™ I**

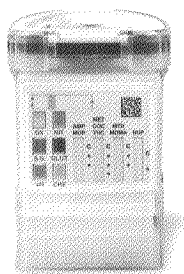
A molecular platform for acute, near-patient testing, the Alere™ I will offer significant improvements over today's lateral-flow technology, enabling healthcare providers working in lower-tech settings to diagnose with lab-quality accuracy. Launch of the platform's first application for influenza is expected in 2014.



**Full-Service Toxicology Provider** // We are the world's leading provider of toxicology diagnostics and specialty drug-testing services, with a portfolio that encompasses reagents, point-of-care analyzers, lab services, and program solutions.

## Featured Solutions

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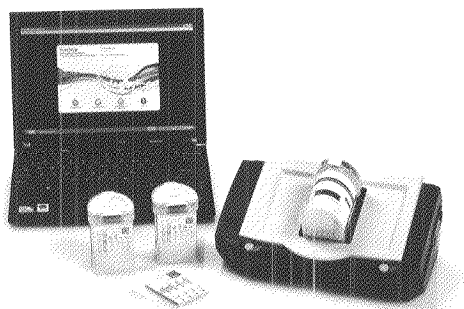


### Lab & Third-Party Administrative Services

We have built a strong franchise of lab and third-party solutions over the past several years, helping employers maintain drug-free workforces with our best-in-class technology and screening services. Additionally, we enable employers to move to a paperless screening process, reduce overall program costs, and improve compliance management.

### Roadside & Point-of-Care Testing

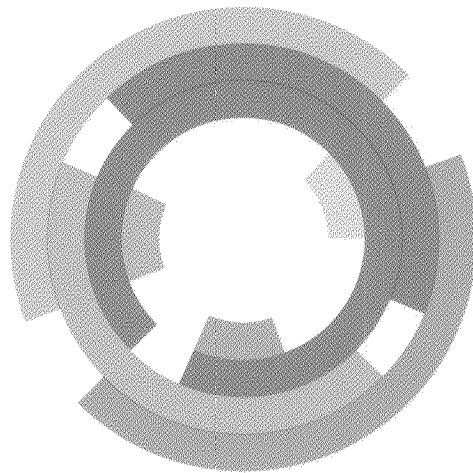
The use of illegal substances continues to grow worldwide, and statistics indicate that the number of drivers under the influence of these substances is increasing rapidly. We offer several diagnostic tools, including the Alere DDS<sup>®</sup>2 Mobile Test System, which enable individuals working in law enforcement or drug treatment facilities to accurately detect abused substances at roadside or the point of care within a matter of minutes.



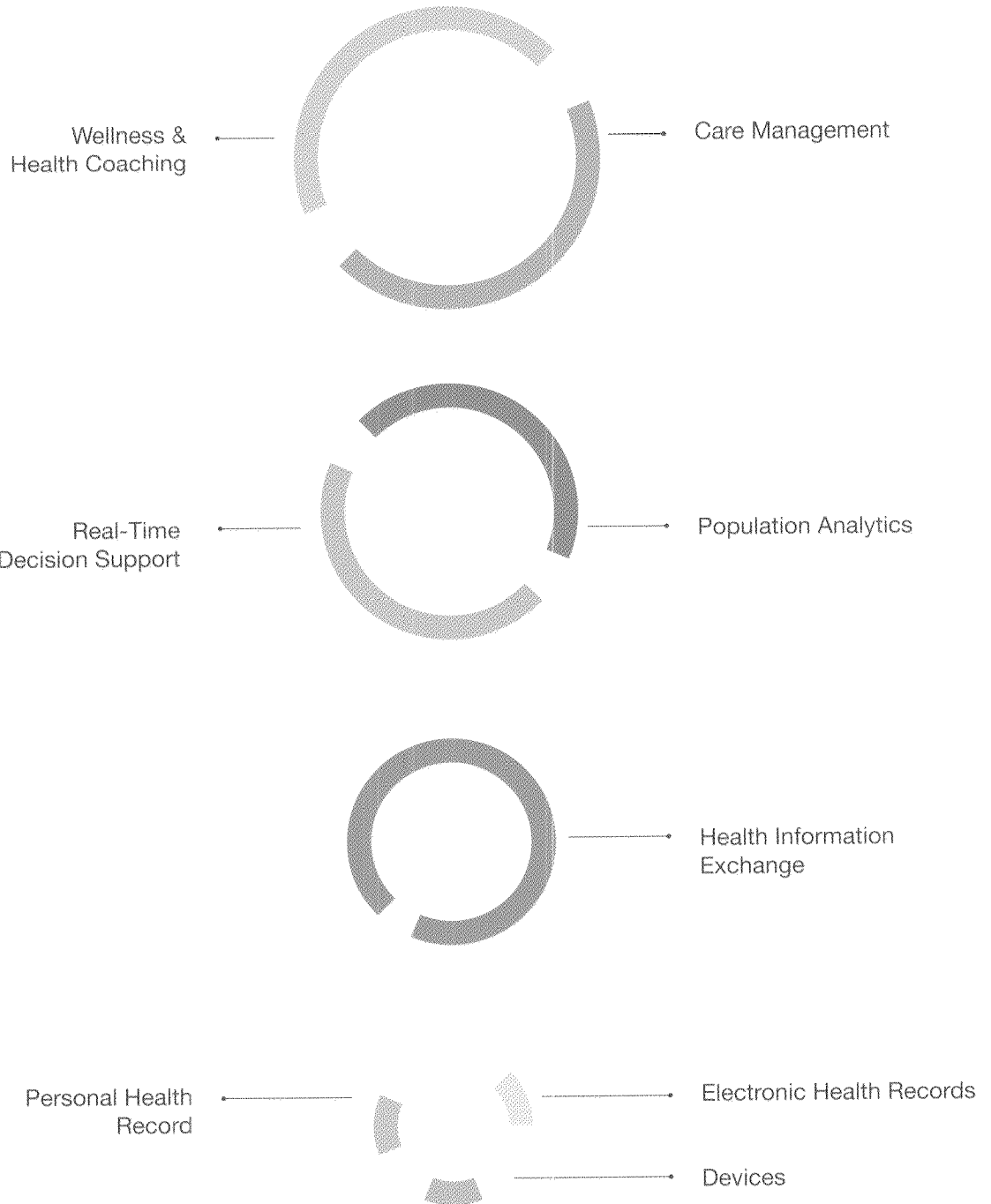
### Drug Monitoring & Addiction Treatment

We understand that substance abuse is much like any other chronic disease, requiring active monitoring and patient management to facilitate true behavior change. Solutions like the Alere<sup>™</sup> DataLink *Dx* enable clinicians to track the health and progress of their patients' recoveries by providing them with instant, secure access to test results online.

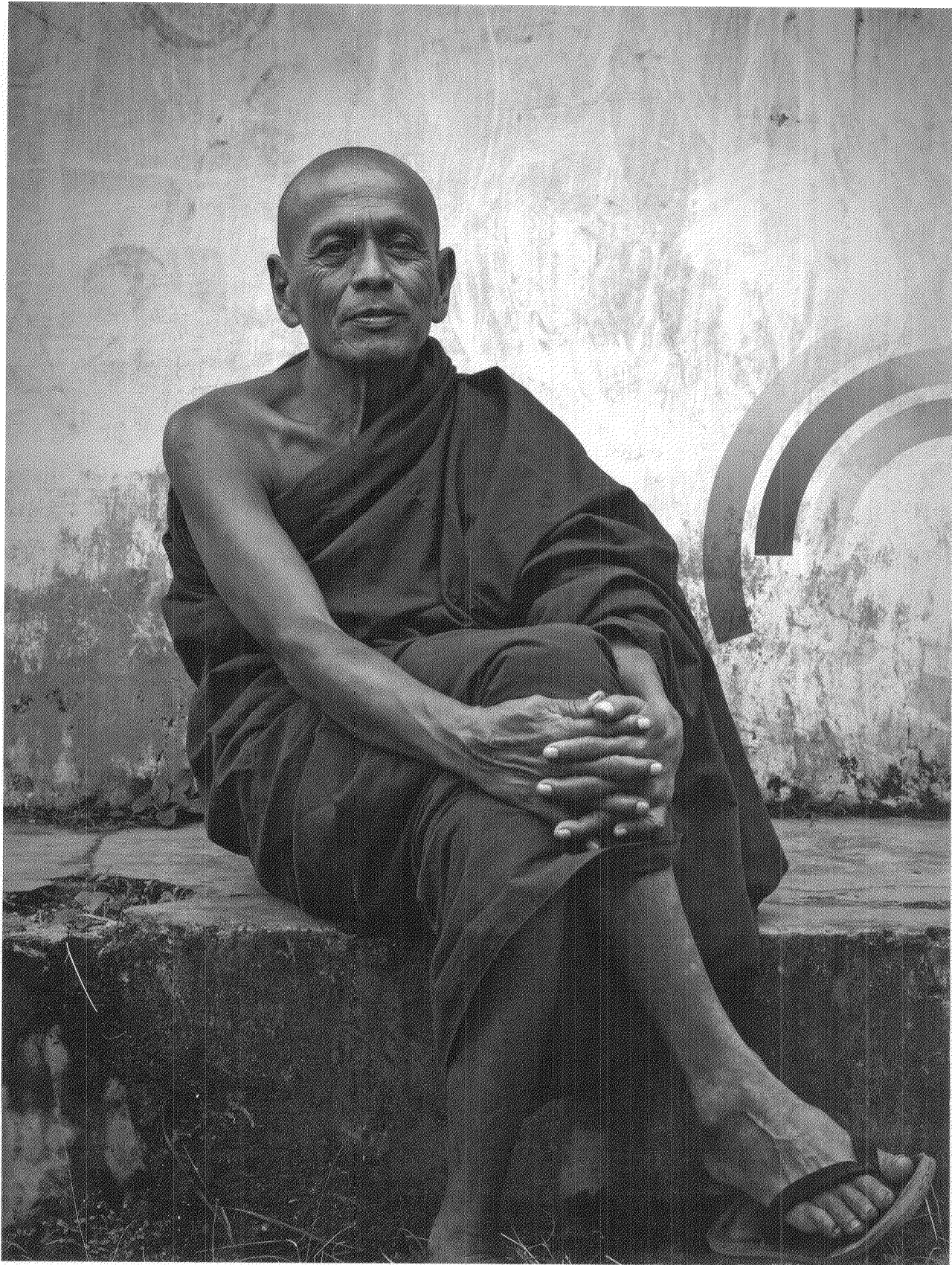




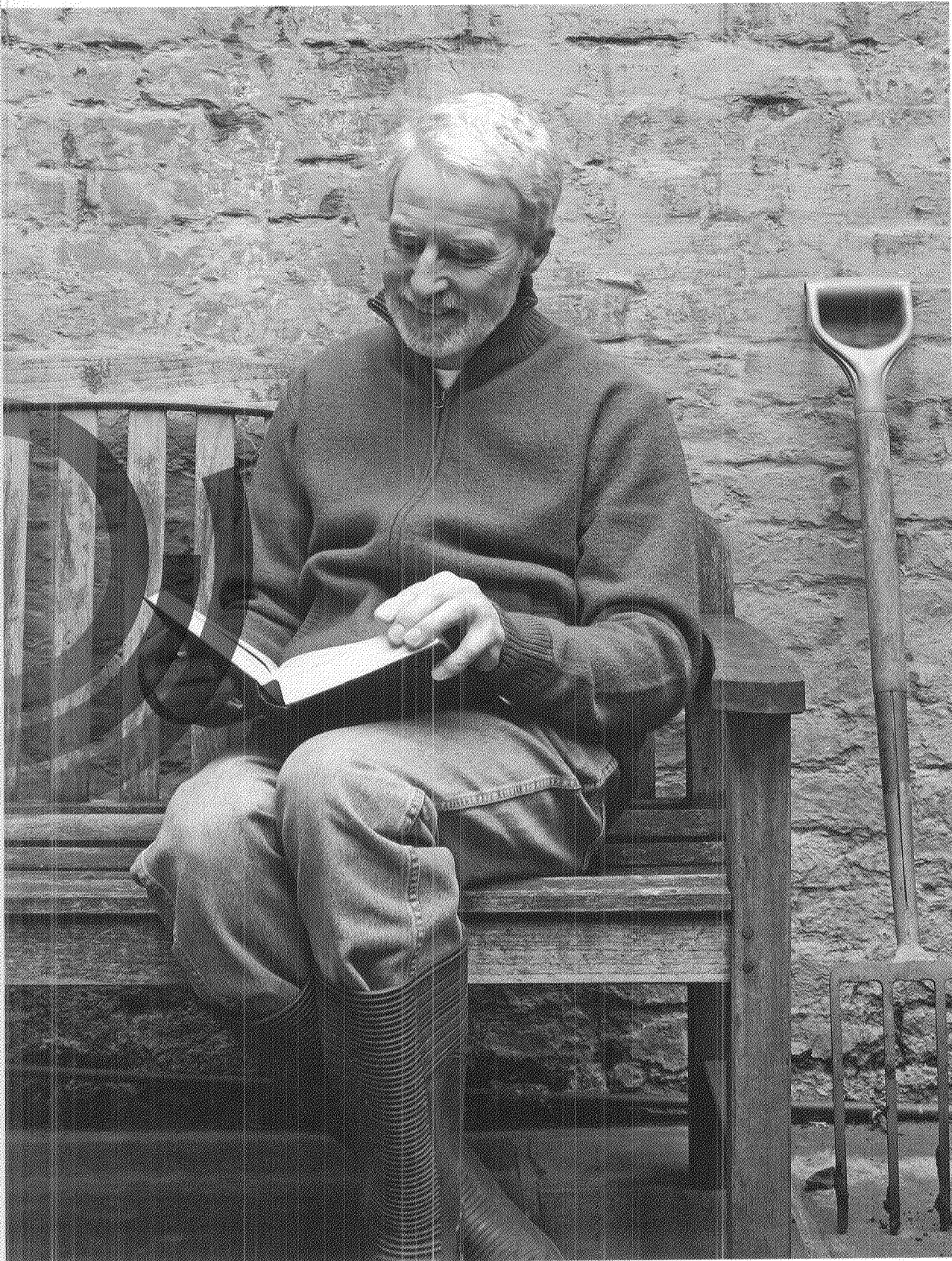
**Our Patient-Centric Integrated Platform enables healthcare providers to take the next step in achieving value-driven care. Our offering is comprised of diagnostic devices, technology solutions, and care management programs that drive real-time, actionable physician interventions and patient behavior change.**





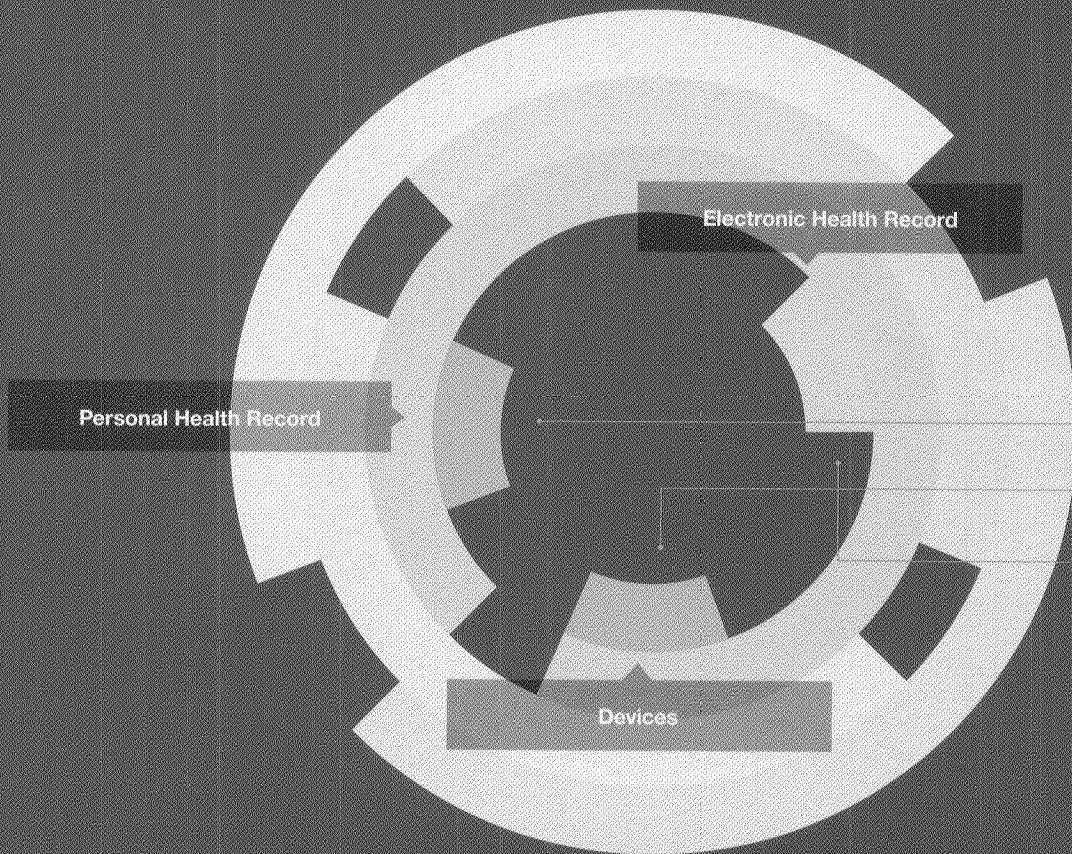






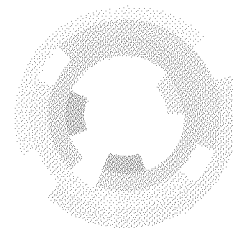


**Actionable data from connected devices along with information from personal and electronic health records give healthcare providers the ability to speed up and customize treatment for each patient.**



**Devices** Diagnostic platforms developed around proprietary biomarkers, designed for easy use in all settings, and propelled by best-in-class technology that ensures the secure transmission of all data represent the foundation of our health information solutions.

- » We are the world's leading provider of rapid point-of-care diagnostics and home monitoring services in several disease categories.
- » Our devices transmit critical, real-time information to connected data portals, making it accessible across the care continuum.
- » This approach improves visibility, providing early warnings to healthcare practitioners, and accelerates decision making, which in turn helps to produce better outcomes.



**Personal Health Record (PHR)** provides a complete summary of an individual's medical history that can be accessed online and securely maintained by that individual.

- » Patients can access data from biometric devices and any reported wellness activities, see their entire medical history, input additional information, manage referrals and prescriptions, and view educational materials.
- » Active engagement and collaboration between patients and physicians through our PHR can lead to better outcomes, increase satisfaction, and reduce costs.

**Electronic Health Record (EHR)** gives care practitioners working in a variety of settings the ability to access complete and up-to-the-minute information for entire patient populations.

- » Designed with extensive clinician input, our web-based EHR offers a best-in-class interface that meets the needs and evolving expectations of real-world users.
- » A single screen provides a comprehensive patient history as well as real-time notifications that guide care when it is most critical.
- » Connects directly and securely to our health information exchange (HIE), PHR, devices, and other medical record systems; offers flexible access via browser, mobile devices, tablets, or APIs.



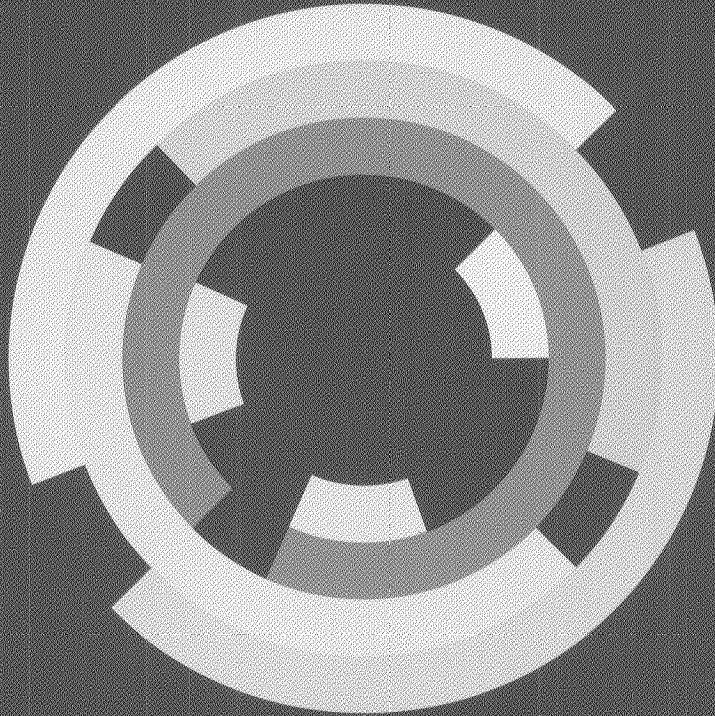








**Health Information Exchange (HIE) creates a virtual community where clinicians can access the most up-to-date patient information and better coordinate care and treatment.**



**Health Information Exchange**

(HIE) extracts clinical information from several different repositories and integrates that data within a single longitudinal health record that all care providers can securely access.

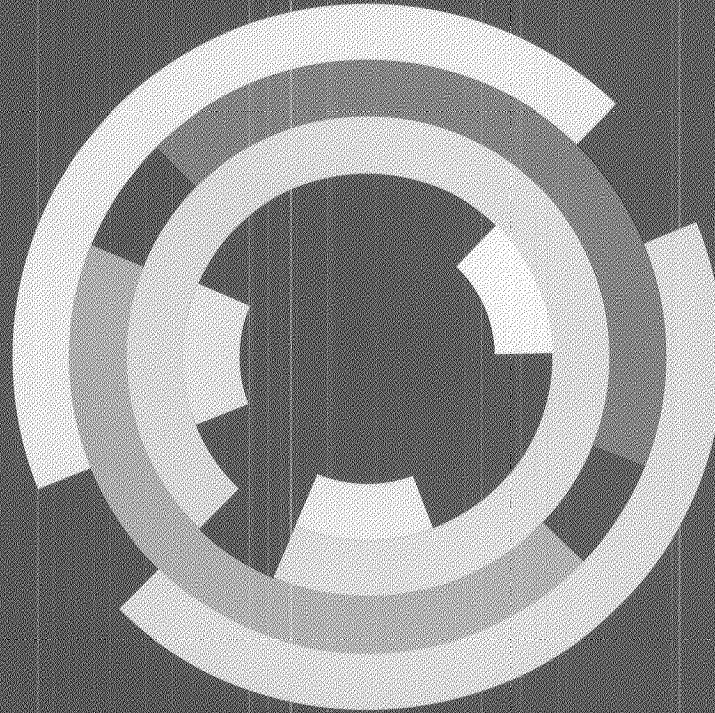


payers devices patients doctors

- » Our HIE captures data from patients, doctors, payers, and devices, integrating it in one patient-centered health record.
- » Award-winning usability, standards-based architecture, and the ability to incorporate data from other medical record systems make our HIE the only one capable of connecting entire health networks.

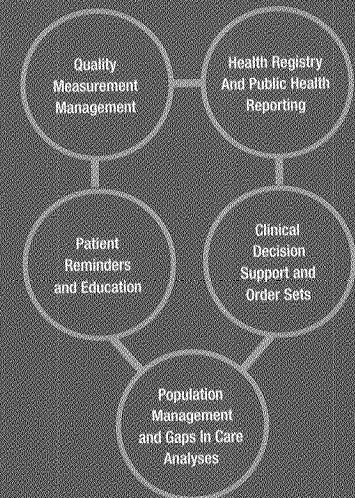


**Decision support and analytic tools provide meaningful data-driven interventions that reduce gaps in care, avoidable errors, and costly complications.**

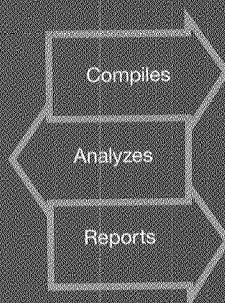


### Solution Elements

*The breadth of our decision support capabilities enables care organizations to meet performance and incentive requirements easily, preventing investment in multiple systems.*



### Decision Support And Analytic Tools



We are the only company to offer a single platform that integrates decision support tools with robust analytics. As a result, we are able to provide healthcare practitioners with a complete view of all patient data, eliminating the discrepancies encountered with multiple vendors and enabling the use of real-time analytics to drive immediate behavior change.

- » Our platform compiles, analyzes, and reports on disparate clinical data sets for hospital systems, multi-million-member insurers, government bodies, and healthcare IT vendors.
- » The world's largest library of more than 30,000 evidence-based medical best practices that, when combined with actual patient data, enables real-time patient and population assessment, predictive modeling, and risk stratification.



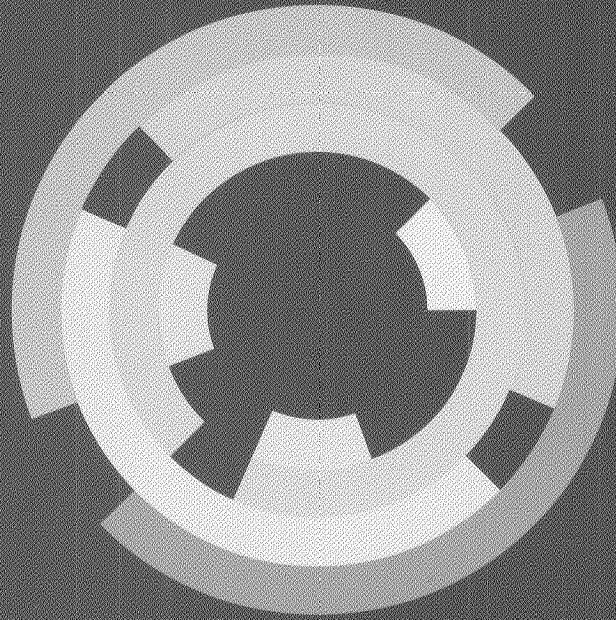








**Driven by actionable data and decision support tools, our care management programs reduce hospital readmissions, streamline office protocols, and improve patient quality of life.**



**Care Management and Wellness**

Our care management and wellness programs address the most prevalent, costly chronic conditions, deploying real-time diagnostics data, robust analytics, and advanced decision support capabilities to identify high-risk individuals and set personalized care plans.

- » Our care management programs enable individuals with chronic conditions to better manage their health through education about their illnesses, potential complications, and the importance of therapy compliance.
- » Highly-trained nurses proactively contact participants to monitor their progress and ensure compliance with the care plans set by their physicians.
- » We offer a suite of integrated wellness programs and resources that are designed to reduce participant health risks and healthcare-related costs.
- » Our wellness programs include screening for risk factors associated with chronic disease, particularly tobacco use, poor nutrition, physical inactivity, and chronic stress.
- » We identify individual barriers to change and overcome these barriers through a variety of personalized interactions that include health assessments, mobile and online education, personal coaching, activity monitoring, and medication support.

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

**FORM 10-K  
ANNUAL REPORT PURSUANT TO SECTIONS 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2012.  
Commission file number 000-16789



**ALERE INC.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**04-3565120**

(I.R.S. Employer Identification No.)

**51 Sawyer Road, Suite 200, Waltham, Massachusetts**

(Address of principal executive offices)

**02453**

(Zip Code)

**(781) 647-3900**

(Registrant's telephone number, including area code)

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

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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

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

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

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

**DOCUMENTS INCORPORATED BY REFERENCE**

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

**ALERE INC.**  
**FORM 10-K**  
**For The Fiscal Year Ended December 31, 2012**

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## PART I

*This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Readers can identify these statements by forward-looking words such as “may,” “could,” “should,” “would,” “intend,” “will,” “expect,” “anticipate,” “believe,” “estimate,” “continue” or similar words. Readers should carefully review statements that contain these words because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other “forward-looking” information. We caution investors that all such forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from any projected results or expectations that we discuss in this report. You should therefore carefully review the risk factors and uncertainties discussed in Item 1A entitled “Risk Factors,” which begins on page 17 of this report, as well as those factors identified from time to time in our periodic filings with the Securities and Exchange Commission. We undertake no obligation to update any forward-looking statements.*

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

### ITEM 1. BUSINESS

#### GENERAL

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

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

Our principal executive offices are located at 51 Sawyer Road, Suite 200, Waltham, Massachusetts 02453 and our telephone number is (781) 647-3900. Our website is [www.alere.com](http://www.alere.com), and we make available through the investor center of this site, free of charge, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the Securities and Exchange Commission, or the SEC. We also make our code of ethics and certain other governance documents and policies available through our website. We intend to make required disclosures of amendments to our code of ethics, or waivers of a provision of our code of ethics, on the “Corporate Governance” page of our website’s investor center.

## Segments

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

## Products and Services

### *Professional Diagnostics*

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

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

*Cardiology.* Cardiovascular disease encompasses a spectrum of conditions and illnesses, including high blood pressure, high cholesterol, metabolic syndrome, coronary artery disease, heart attack, heart failure and stroke. It is estimated that 82 million American adults alone have one or more types of cardiovascular disease. The worldwide cardiology point-of-care diagnostics market, including the markets for heart failure diagnostics, coronary artery disease risk assessment, coagulation testing and acute coronary syndrome, exceeds \$2.0 billion. Our Alere Triage, Alere Cholestech LDX and Alere INRatio products, have established us as a leader in this market. The Alere Triage system consists of a portable fluorometer that interprets consumable test devices for cardiovascular conditions, as well as the detection of certain drugs of abuse. Alere Triage cardiovascular tests include the following:

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

increased risk of cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease. Alere Triage NT-proBNP is CE marked, but not available for sale in the United States.

- *Alere Triage Cardiac Panel.* An immunoassay for the quantitative determination of creatine kinase-MB (CK-MB), myoglobin and troponin I in whole blood or plasma, used as an aid in the diagnosis of acute myocardial infarction.
- *Alere Triage CardioProfilER Panel.* An immunoassay for use as an aid in the diagnosis of acute myocardial infarction, the diagnosis and assessment of severity of congestive heart failure and the risk stratification of patients with acute coronary syndromes and heart failure. This panel combines troponin I, CK-MB, myoglobin and BNP to provide rapid, accurate results in whole blood and plasma.
- *Alere Triage ProfilER Shortness of Breath (S.O.B.) Panel.* An immunoassay for use as an aid in the diagnosis of myocardial infarction, the diagnosis and assessment of severity of congestive heart failure, the assessment and evaluation of patients suspected of having disseminated intravascular coagulation and thromboembolic events, including pulmonary embolism and deep vein thrombosis, and the risk stratification of patients with acute coronary syndromes. This panel combines troponin I, CK-MB, myoglobin, BNP and D-dimer to provide rapid, accurate results in whole blood and plasma.
- *Alere Triage Cardio3 Panel.* An immunoassay for the rapid quantitative determination of CK-MB, troponin I and BNP in whole blood and plasma specimens. This panel is used as an aid in the diagnosis of myocardial infarction, the diagnosis and assessment of severity of congestive heart failure and the risk stratification of patients with acute coronary syndromes and heart failure. Alere Triage Cardio3 is CE marked, but not available for sale in the United States.
- *Alere Triage Cardio2 Panel.* An immunoassay for the rapid quantitative determination of troponin I and BNP in whole blood and plasma specimens. This panel is used as an aid in the diagnosis of myocardial infarction, the diagnosis and assessment of severity of congestive heart failure and the risk stratification of patients with acute coronary syndromes and heart failure. Alere Triage Cardio2 is CE marked, but not available for sale in the United States.
- *Alere Triage Troponin I.* An immunoassay for the quantitative determination of troponin I in whole blood and plasma specimens. The test is used as an aid in the diagnosis of myocardial infarction.
- *Alere Triage D-Dimer Test.* An immunoassay for use as an aid in the assessment and evaluation of patients suspected of having disseminated intravascular coagulation or thromboembolic events, including pulmonary embolism and deep vein thrombosis.
- *Alere Triage NGAL.* An immunoassay for use in the rapid, quantitative determination of neutrophil gelatinase-associated lipocalin (NGAL) in anticoagulated whole blood or plasma specimens. Studies have shown a link between elevated NGAL levels and the later occurrence of elevated creatinine indicative of prior acute kidney injury. Alere Triage NGAL is CE marked, but not available for sale in the United States.
- *Alere Triage CardioRenal Panel.* An immunoassay for use as an aid in the diagnosis of acute kidney injury and congestive heart failure, and the risk stratification of patients with heart failure and acute coronary syndromes. This panel combines two biomarkers, BNP and NGAL, to provide rapid, accurate quantitative results in whole blood or plasma. Alere Triage CardioRenal Panel is CE marked, but is not available for sale in the United States.

Our Alere Cholestech LDX System is a point-of-care monitor of blood cholesterol and related lipids which is used to test patients at risk of, or suffering from, heart disease and related conditions. The Alere Cholestech LDX System makes it possible to provide a complete lipid profile with tests for total cholesterol, high-density lipoprotein cholesterol (HDL) and low-density lipoprotein cholesterol (LDL), triglycerides, and glucose. The system can also provide coronary heart disease risk assessment from



the patient's results as measured on the lipid profile cassette. The Alere Cholestech LDX System provides results in five minutes per test cassette and is CLIA-waived, meaning the United States Food and Drug Administration, or FDA, has waived the more stringent requirements for laboratory testing applicable to moderate or high complexity laboratories based on the Alere Cholestech LDX System's ease of use and accuracy. This waiver allows the Alere Cholestech LDX System to be marketed to physician offices and clinics, rather than hospitals or larger laboratories, and to be used in health screening by medical professionals.

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

We also offer the epoc Blood Analysis System for blood gas, electrolyte and metabolite testing, which is manufactured by our recently acquired Epocal division. The epoc (enterprise point-of-care) platform is a point-of-care analysis system which provides wireless bedside blood gas, electrolyte and metabolite measurement testing solutions and complements our Alere Triage products in cardiology and emergency room settings. Utilizing easy to use, low-cost disposable Smart-Cards™, the epoc System produces laboratory-quality results in critical and acute care settings in about 30 seconds.

During 2010, we launched the Alere Heart Check System in Europe. The Alere Heart Check System provides a quantitative reading of BNP in less than 15 minutes using a fingerstick sample (12 microliters) with substantially equivalent performance to lab instruments. Initially being marketed as a point-of-care device, the Alere Heart Check System is ultimately designed for home use and is intended to enable doctors to remotely monitor BNP levels of congestive heart failure patients and adjust their therapy accordingly.

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

*Infectious Disease.* We believe that the demand for infectious disease diagnostic products is growing faster than many other segments of the immunoassay market due to the increasing incidence and awareness of certain diseases or groups of diseases, including viral hepatitis, respiratory syncytial virus (RSV), influenza, pneumonia, tuberculosis, human immunodeficiency virus (HIV) / acquired immunodeficiency syndrome (AIDS), enteric disease, vector-borne diseases such as malaria and dengue, herpes and other sexually-transmitted diseases. To meet this demand, we have continued to expand our product offerings and now offer one of the world's largest infectious disease test menus. We develop and market a wide variety of point-of-care tests for influenza A/B, RSV, strep throat, pneumonia, *C. difficile*, infectious mononucleosis, HIV, herpes simplex virus (HSV-2), hepatitis C (HCV), hepatitis B (HBV), malaria, lyme disease, Chlamydia, *H. pylori*, rubella and other infectious diseases. Our tests for infectious disease are currently sold under brand names that include Alere, Alere Determine, Acceava, BinaxNOW, Clearview, DoubleCheckGold, Panbio, SD, TECHLAB and Alere TestPack. We are also expanding commercialization of the Alere CD4 Analyzer in several countries in Africa, Asia and Europe, as well as in South America and the Caribbean. The Alere CD4 Analyzer is one of the first point-of-care CD4 platforms which measures absolute CD4 counts. A CD4 count is a measure of the number of T-helper lymphocytes per cubic millimeter of blood, which is used to stage a patient's HIV disease as well as monitor HIV disease progression. The Alere CD4 Analyzer

provides results in 20 minutes or less, using single-use, disposable fingerstick cartridges. CD4 results delivered quickly and accurately at the point of care can improve patient retention and access to treatment.

In addition to point-of-care products, we also offer a line of indirect fluorescent antibody, or IFA, assays for over 20 viral, bacterial and autoimmune diseases, a full line of serology diagnostic products covering a broad range of disease categories and over 50 enzyme-linked immunosorbent assay, or ELISA, tests for a wide variety of infectious and autoimmune diseases, as well as a full line of automated instrumentation for processing ELISA tests. We are the exclusive U.S. distributor of the AtheNA Multi-Lyte® Test System, a multiplexed, fluorescent bead-based system designed to simultaneously perform multiple assays from a single sample using just one well. It offers a simple and streamlined alternative to IFA and ELISA testing, providing improved clinical sensitivity and comparable clinical specificity in a labor-saving, automation-friendly format. Our IFA, serology and ELISA products, which generally serve the clinical diagnostics laboratory markets, are generally marketed under our Wampole brand.

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

*Toxicology.* Drug abuse is a major global health problem, as well as a social and economic burden. In addition to being a primary cause of lost workforce productivity, family conflict and drug-related crime, abuse of illicit and prescription drugs is linked globally to the spread of HIV/AIDS, hepatitis and other blood-borne pathogens through the use of contaminated needles. This misuse of drugs and drug addiction are among the costliest health problems in the United States, and increasingly abroad. As a result, employers, law enforcement officials, healthcare professionals and others expend considerable effort to ensure that their employees, patients and other constituents are free of substance abuse and misuse. This critical need creates a significant market for simple and reliable laboratory-based, point-of-care and rapid toxicology tests to detect the most commonly abused substances and an ever-evolving set of newly-formulated, synthetic and regional toxins. Additionally, physicians and treatment centers are increasingly utilizing drug testing to identify and address signs of prescription drug misuse, whether illicit or by prescription, and more broadly, to improve outcomes in addiction medicine. Finally, both domestically and abroad, a substantial market exists for services to help employers and governments manage their workforces' compliance with drug, alcohol and/or related fitness-for-duty health policies.

Urine and oral-based screening and confirmation tests for drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method for toxicology screening at the point of care.

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

Our rapid toxicology tests are sold primarily under the brands Alere Toxicology, Alere Triage, Alere iScreen and SureStep. The Alere Triage TOX Drug Screen panel sold for use with our Alere Triage MeterPro system detects the presence of many of the illicit and prescription drugs listed above at the point of care in approximately 15 minutes. It is widely used in hospital and clinical testing as a laboratory instrument to aid in the detection of drug abuse. Our Drug Detection System, or DDS, is an

enhanced, on-site saliva drug detection system utilized in roadside testing which displays results for the presence of two drugs in less than 90 seconds and six different drugs in less than five minutes.

We also offer comprehensive laboratory-based testing services throughout Europe under the name Alere Toxicology, formerly Concateno, and in the United States under the names Alere Toxicology Services, or Alere Toxicology, and Redwood Toxicology Laboratory, or Redwood. Three of Alere Toxicology's laboratories are certified to the highest standard by the U.S. Substance Abuse and Mental Health Services Administration, or SAMHSA. In addition, we are expanding our offerings in the growing market for pain management and addiction medicine services, or the monitoring and documentation of adherence to prescription drug treatment or drug abstinence plans through complex laboratory testing. Through Redwood, we offer comprehensive, low-cost laboratory testing services to multiple domestic clients, including law enforcement agencies, penal systems, insurers and employers in the United States.

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

Diabetes. We offer point-of-care diabetes products, including our Afinion Analyzer System and our NycoCard System. The Afinion Analyzer System makes it possible to easily and rapidly determine the level of glycated hemoglobin, or HbA1c, in a patient's blood at the physician's office during the visit, which can provide information regarding the patient's average blood sugar levels over a period of time. This system will simplify monitoring of any type of diabetes, facilitating treatment management and prevention of complications. By providing timely information regarding a patient's blood sugar levels over time, it may also increase the patient's motivation to comply with treatment and lifestyle changes to optimize prognosis. In June 2012, we added our CE-marked Lipid Panel, an important tool for cardiovascular disease risk assessment, to the Afinion Analyzer System. The NycoCard System, which is a widely distributed, low-cost product suited to countries with developing healthcare systems, includes tests for CRP and HbA1c. Physicians test for elevated levels of CRP in a patient's bloodstream to detect signs of inflammation or tissue damage, which can be associated with a wide variety of chronic and acute conditions. Through our subsidiary Arriva, we are a major, national mail order supplier of diabetic testing supplies, including blood glucose monitors, test strips, lancets, lancing devices, and control solution, as well as other related medical supplies in the U.S. These products are usually covered by Medicare, Medicaid and other third-party payers.

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

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

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



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

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

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

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

Our Alere Connect products include:

- HealthPAL: A small, portable hub device for collecting health readings from compatible medical monitors and transmitting them to a user's EHR. HealthPAL provides the proactive benefits of remote health monitoring and is designed to be a cost-effective telehealth solution.
- HealthCOM: A web-based application for healthcare professionals to remotely monitor and manage the data collected with HealthPAL. HealthCOM also provides professional administration features to assist healthcare practitioners in managing their patient populations and associated equipment inventory.

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

#### *Health Information Solutions (formerly Health Management)*

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

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

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

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

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

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

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

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

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

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

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

Our personalized health support model differs from more traditional models in that it applies a more disciplined approach to defining which patients could benefit from particular interactions and the best means of initiating these interactions. A second key differentiator is the use of biometric devices for participants in programs focused on higher-risk conditions. The Alere Disease Management Program currently assists individuals with the following chronic diseases or conditions: asthma, coronary artery disease, chronic obstructive pulmonary disease, diabetes, heart failure, pain, weight management and depression.

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

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



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

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

#### *Consumer Diagnostics*

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

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

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

#### **Methods of Distribution and Customers**

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

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

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

## **Manufacturing**

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

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

## **Research and Development**

Our primary research and development centers are in San Diego, California; Scarborough, Maine; Jena, Germany and Cambridge and Dundee, United Kingdom. We also conduct research and development at some of our other facilities, including facilities in the United States, the United Kingdom, China, Israel, Japan and South Korea. Our research and development programs focus on the development of cardiology, infectious disease, toxicology, diabetes, oncology and women's health products together with health information technologies that will facilitate connectivity and information and data management solutions. Information about research and development expenses for the last three fiscal years is provided on page F-4 of the Consolidated Financial Statements.

## **Global Operations**

We are a global company with major manufacturing facilities in the United States, China, Japan, Norway, South Korea and the United Kingdom and significant research and development operations in the United States, Germany and the United Kingdom. Our distribution network supporting our professional diagnostics business includes offices in over 30 countries.

Our professional diagnostic products are sold throughout the world. Our health information solutions are sold almost exclusively in the United States but we now offer our health information solutions in Australia, Germany and the United Kingdom. During both 2012 and 2011, we generated approximately 61% of our net revenue from the United States, approximately 17% from Europe and approximately 22% from other locations.

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

## **Competition**

*Professional Diagnostics.* Our professional diagnostics products are primarily point-of-care rapid diagnostic testing products sold within the areas of cardiology, infectious disease, toxicology, diabetes, oncology and women's health. Competition for rapid diagnostic products is intense and is primarily

based on price, quality, breadth of product line, technology and distribution capabilities. Some competitors in the market for professional rapid diagnostic products, such as BD, are large companies with substantial resources, while numerous smaller, yet aggressive companies also compete with us. We believe that no competitor, small or large, offers a portfolio of professional rapid diagnostic products as broad as ours and, as a result, our competitors differ significantly within each of our areas of focus. Automated immunoassay systems also compete with our products, depending on government regulations or when labor shortages force laboratories to automate or when the unit costs of such systems are lower and other indirect costs are not taken into account. Such systems are provided by Abbott, Siemens, Beckman Coulter, Johnson & Johnson, Roche and other large diagnostic companies.

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

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

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

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



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

Our Alere NMP22 diagnostic products aid in diagnosing and monitoring bladder cancer patients, in conjunction with standard diagnostic procedures, and are based on our proprietary nuclear matrix protein technology. The Alere NMP22 BladderChek Test is currently the only in-office test approved by the FDA as an aid in the diagnosis of bladder cancer. However, competition in the development and marketing of cancer diagnostics and therapeutics, using a variety of other technologies, is intense. Competing diagnostic products based on other technologies may be introduced by other companies and could adversely affect our competitive position. In a larger sense, our tests also compete with more invasive or expensive procedures, such as surgery, bone scans, magnetic resonance imaging and other *in vivo* imaging techniques. In the market for urine-based diagnostic tests, our Alere NMP22 tests also compete with existing cellular-based tests, such as the microscopic examination of suspicious cells, and UroVysion, which is a fluorescent in-situ hybridization test.

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

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

*Health Information Solutions.* Competition in the health information space is intense due to low barriers to entry. Athenahealth, Cerner Corporation, Allscripts Healthcare Solutions, Greenway Medical Technologies, and McKesson provide health information exchange, data management, and clinical support solutions that compete directly with our health information solutions. Additionally, Health Dialog, Healthways, Optum Health, Active Health and a number of smaller service providers offer products that compete with our integrated care management solutions. Our competitors and potential competitors also include health plans, self-insured employers, healthcare providers, pharmaceutical companies, pharmacy benefit management companies, case management companies and other organizations that provide services to health plans, governments, governmental programs and self-insured employers. Some of these entities, particularly health plans and self-insured employers, may be customers or potential customers and may own, acquire or establish health information service providers or capabilities for the purpose of providing health information solutions in-house. Many of these competitors are considerably larger than we are and have access to greater resources. We believe that our ability to improve clinical and financial outcomes and our technology platforms, including our Apollo system, provide us with certain competitive advantages.

*Consumer Diagnostics.* Our First Check tests compete against over-the-counter diagnostic tests sold primarily by Phamatech, but also by other smaller competitors. Essentially, all of our remaining consumer diagnostic product sales are to SPD, our joint venture. These products are sold by SPD in

retail markets where competition is intense and based primarily on brand recognition and price. Our revenues, as well as our share of the profits from the sale of these products by SPD, are dependent upon SPD's ability to effectively compete in these markets.

### **Patents and Proprietary Technology; Trademarks**

We have built a strong intellectual property portfolio including an increasing number of patents, patent applications, copyrights, trade secrets and licensed intellectual property, which are intended to protect our vision of the technologies, products and services of the future. Our intellectual property portfolio includes patents and other intellectual property that we own and, in some cases, patents or other intellectual property that we license from third parties, which may be limited with respect to term and in terms of field of use or transferability and may require royalty payments.

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

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

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

The medical device industry and the market for health information solutions, place considerable importance on obtaining and enforcing patent and trade secret protection for new technologies, products, services and processes. Trademark protection is an important factor in the success of certain of our product lines and health information solutions. Our success therefore depends, in part, on our ability to obtain and enforce the patents and trademark registrations necessary to protect our products, to preserve our trade secrets and to avoid or neutralize threats to our proprietary rights from third parties. We cannot, however, guarantee our success in enforcing or maintaining our patent rights; in obtaining future patents or licensed patents in a timely manner or at all; or as to the breadth or degree of protection that our patents or trademark registrations or other intellectual property rights might afford us. For more information regarding the risks associated with our reliance on intellectual property rights, see the discussion in Item 1A entitled "Risk Factors" on pages 17 through 36 of this report.

### **Government Regulation**

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

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably, all of our diagnostic products, and certain of our health information technologies and solutions, sold in

the United States are subject to the Federal Food, Drug and Cosmetic Act, or the FDCA, as implemented and enforced by the FDA. Our diagnostic products sold in the United States, including any imbedded or stand-alone software which has been classified by the FDA as a Class II medical device, generally require either FDA clearance to market under Section 510(k) of the FDCA, or Premarket Approval, or PMA, which may require pre-clinical and clinical trials. Certain of our health information solutions are classified by the FDA as Medical Device Data Systems, or MDDS, which are software systems distinct from Class II medical device software, that transfer, store, convert and display medical device data. MDDS do not require FDA clearance or approval to be marketed and sold, but are subject to the FDA-mandated quality standards. Foreign countries may require similar or more onerous approvals to manufacture or market these products. The marketing of our consumer diagnostic products is also subject to regulation by the U.S. Federal Trade Commission, or the FTC. In addition, we are required to meet regulatory requirements in countries outside the United States, which can change rapidly with relatively short notice. We must also demonstrate to the FDA that our diagnostic tests intended for home use or for use by laboratories holding a Certificate of Waiver under the Clinical Laboratory Improvement Act of 1967 and the Clinical Laboratory Amendments of 1988, or CLIA, including most physician office laboratories, are simple with a low risk of error. Foreign countries may require similar or more onerous approvals to manufacture or market our products.

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

Certain of our clinicians, such as nurses, must comply with individual licensing requirements. We believe that all of our clinicians who are subject to licensing requirements are licensed in the state in which they are physically present, such as the location of the call center from which they operate and, if applicable, states in which they visit or interact with patients, to the extent such licensure is required.

In 2013, we will assume reporting responsibilities under Section 6002 of the 2010 Affordable Care Act, which is commonly referred to as the Physician Payment Sunshine Act, or the Sunshine Act. We will be required to collect data on and annually report to CMS certain payments or other transfers of value to physicians and teaching hospitals and annually report certain ownership and investment interests held by physicians or their immediate family members.

Many areas of our business, including but not limited to our health improvement, diabetes supply and patient self-testing services are subject to unique licensing or permit requirements by state and local health agencies. In addition, these and other areas of our business are subject to HIPAA and the HITECH Act. We are also required to obtain certification to participate in certain governmental payment programs, such as various state or federal Medicare/Medicaid programs. Some states have established Certificate of Need/Determination of Need, or CON/DON, programs regulating the expansion of healthcare operations. The failure to obtain, renew or maintain any of the required licenses, certifications or CON/DONs could adversely affect our business.

For more information about the governmental regulations to which our business is subject and the risk associated with non-compliance with those regulations, see the risk factors discussed in Item 1A entitled "Risk Factors" on pages 17 through 36 of this report.

## **Employees**

As of January 31, 2013, we had approximately 17,400 employees, including temporary and contract employees, of which approximately 9,200 employees are located in the United States. In addition, we utilize consultants specializing in areas such as research and development, risk management, regulatory compliance and marketing.



## ITEM 1A. RISK FACTORS

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

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

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

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

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

### **We face risks and uncertainties relating to the FDA warning letter and OIG subpoena.**

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

In May 2012, Alere San Diego, Inc. received a subpoena from the Office of Inspector General of the Department of Health and Human Services, or the OIG, seeking documents relating primarily to the quality control testing and performance characteristics of our Alere Triage cardiac marker devices and

the Triage TOX Drug Screen manufactured at Alere San Diego. We are in the process of responding to the OIG subpoena and the investigation is ongoing.

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

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

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

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

- any of our products or services under development will prove to be safe and effective in clinical trials;
- we will be able to obtain, in a timely manner or at all, necessary regulatory approvals;
- the products and services we develop can be manufactured or provided at acceptable cost and with appropriate quality; or
- these products and services, if and when approved, can be successfully marketed.

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

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

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

- lost revenues as a result of macroeconomic developments, such as the current European budgetary issues, debt crisis and related European financial restructuring efforts, which may cause European governments to reduce spending and cause the value of the Euro to deteriorate, thus reducing the purchasing power of European customers;
- decreased liquidity resulting from longer accounts receivable collection cycles typical of foreign countries;
- lower productivity resulting from difficulties we encounter in staffing and managing sales, support, and research and development operations across many countries;
- lost revenues or unexpected expenses resulting from difficulties associated with enforcing agreements and collecting receivables through foreign legal systems;
- lost revenues or unexpected expenses resulting from disputes with third-party distributors of our products or from third parties claiming distribution rights to our products under foreign laws or legal systems;
- lost revenues or unexpected expenses resulting from the imposition by foreign governments of trade barriers such as tariffs, quotas, preferential bidding, and import restrictions;
- higher cost of sales resulting from import or export licensing requirements;
- lost revenues or other adverse effects resulting from acts of war, terrorism, theft or other lawless conduct or otherwise resulting from economic, social or political instability in or affecting foreign countries in which we sell our products or operate;
- lost revenues or other adverse effects resulting from international sanctions regimes;
- adverse effects resulting from changes in foreign regulatory or other laws affecting sales of our products or our foreign operations;
- greater tax liability resulting from international tax laws, including U.S. taxes on foreign subsidiaries;
- increased financial accounting and reporting burdens and complexities;
- increased costs to comply with changes in legislative or regulatory requirements;



- lost revenues or increased expenses resulting from the failure of laws to protect our intellectual property rights; and
- lost revenues resulting from delays in obtaining import or export licenses, transportation difficulties and delays resulting from inadequate local infrastructure.

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

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

Our business relies heavily on our foreign operations. Six of our eight largest manufacturing operations are located in China, Japan, Norway, South Korea and the United Kingdom, and we also have manufacturing operations in Australia, Germany, India, Israel, South Africa and Spain. We have significant research and development operations in Germany and the United Kingdom, and we conduct additional research and development activities in China, Israel, Japan and South Korea. In addition, for the year ended December 31, 2012, approximately 39% of our net revenue was derived from sales outside the United States. Because of the scope of our foreign operations and foreign sales, we face significant exposure to movements in foreign currency exchange rates. Our primary exposures are related to the operations of our European and Asia Pacific subsidiaries and our manufacturing facilities in China, Japan and South Korea. These exposures may change over time as our business practices evolve and could result in increased costs or reduced revenue and could affect our actual cash flow. Changes in the relative values of currencies occur regularly and, in some instances, may have a significant impact on our operating results. We cannot predict with any certainty changes in foreign currency exchange rates or the degree to which we can cost-effectively mitigate these risks.

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

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

The ACA requires that providers of health insurance plans maintain specified minimum medical loss ratios. We believe that the majority of our health information solutions would qualify as “quality improving

activities”, but there have been no regulations specifically classifying our services in such a manner. If our health information solutions are not classified as “quality improving activities” under the ACA, health insurance providers will not be permitted to count expenditures on those services toward the calculation of their medical loss ratios, which may have a material adverse effect on demand for our health information solutions and the results of operations of our health information solutions business.

Additionally, revenues associated with our recently-acquired diabetes business will be impacted by the Durable Medical Equipment, Prosthetics, Orthotics and Supplies, or the DMEPOS, Competitive Bidding Program. Under this program, Medicare will no longer reimburse suppliers for certain products and services, including mail-order diabetes testing supplies, based on the Medicare fee schedule amount. Instead the Centers for Medicare and Medicaid Services, or CMS, will provide reimbursement for those products and services based on a competitive bidding process. Our Arriva business has been selected through the bidding process and offered a contract to have its products reimbursed by Medicare. However, the DMEPOS Competitive Bidding Program will require us to sell diabetes supplies subject to Medicare reimbursement at significantly lower prices, which will have a material adverse effect on the profitability of these products.

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

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

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

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

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

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

In the United States, clearance or approval to commercially distribute new medical devices is received from the FDA through clearance of a Premarket Notification 510(k), or 510(k), or through a Premarket Approval, or PMA. The FDA may deny 510(k) clearance because, among other reasons, it

determines that our product is not substantially equivalent to another U.S. legally marketed device. The FDA may deny a PMA because, among other reasons, it determines that our product is not sufficiently safe or effective. As part of the clearance or approval process, if we intend to sell certain diagnostic tests for home use or for use by laboratories holding a CLIA Certificate of Waiver, including most physician office laboratories, we must generally provide data, demonstrating to the FDA's satisfaction, that the criteria for our tests are simple with a low risk of error. Failure to obtain FDA clearance or approval would preclude commercialization in the U.S. and failure to obtain or maintain CLIA-waived status for any product would preclude us from selling that product for home use or to CLIA-waived laboratories, which could materially and adversely affect our future results of operations.

Modifications or enhancements that could significantly affect safety or effectiveness, or that constitute a major change in the intended use of the device, require new 510(k) or PMA submissions. We have made modifications to some of our products since receipt of initial 510(k) clearance or PMA. With respect to several of these modifications, we filed new 510(k)s describing the modifications and received FDA 510(k) clearance. We have made other modifications to some of our products that we believe do not require the submission of new 510(k)s or PMAs. The FDA may not agree with any of our determinations not to submit a new 510(k) or PMA for any of these modifications made to our products. If the FDA requires us to submit a new 510(k) or PMA for any device modification, we may be prohibited from marketing the modified products until the new submission is cleared or approved by the FDA. As long as our San Diego facility remains subject to the FDA Warning Letter that we received in October 2012, that facility will be ineligible to receive PMA approvals. While no PMA submissions are currently pending for that facility and we do not plan any new submissions for that facility in 2013, if we are unable to resolve the Warning Letter in a timely manner, our ability to gain approval for new or enhanced products could be adversely impacted.

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

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

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

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

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



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

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

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

We are also subject to laws relating to matters such as privacy, safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances.

We may incur significant costs to comply with these laws and regulations. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products or injunctions against our distribution of products, termination of our service agreements by our customers, disgorgement of money, operating restrictions and criminal prosecution. Changes in applicable laws, changes in the interpretation or application of such laws, or any failure to comply with existing or future laws, regulations or standards which could have a material adverse effect on our results of operations, financial condition, business and prospects. Moreover, new laws may be enacted, or regulatory agencies may impose new or enhanced standards, that would increase our costs, as well as expose us to risks associated with non-compliance.

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

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

Other laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, or are for items or services that were not provided as claimed. These laws may also be triggered by failure to return identified overpayments to a payer. Anti-kickback and false claims laws prescribe civil and/or criminal penalties for noncompliance that can be substantial including, in some instances, fines, imprisonment and, within the United States, exclusion from participation in government healthcare programs. Furthermore, since we are reimbursed directly by federal healthcare programs for certain goods and services and, given that many of our customers rely on reimbursement from Medicare, Medicaid and other governmental programs to cover a substantial portion of their expenditures, our exclusion from such programs as a result of a violation of these laws could have a material adverse effect on our business, results of operations, financial condition and cash flows. The interpretation and enforcement of these laws and regulations are uncertain and subject to rapid change.

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

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

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

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

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

- our ability to obtain, retain and renew contracts with customers and potential customers with favorable pricing as competition increases and to the extent that customers attempt to provide health information solutions themselves.

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

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

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

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

**A portion of our health information solutions fees are contingent upon performance.**

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

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

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

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

Our ability to negotiate favorable contracts with non-governmental payers, including managed-care plans, significantly affects the revenues and operating results of our health information solutions business. Our customers continue to face cost reduction pressures that may cause them to curtail their use of, or reimbursement for, health information solutions, to negotiate reduced fees or other



concessions or to delay payment. Furthermore, the increasing leverage of organized buying groups among non-governmental payers may reduce market prices for our products and services, thereby reducing our profitability. Reductions in price increases or the amounts received from current customers or lower pricing for our services to new customers could have a material adverse effect on the financial position, cash flows and results of operations of our health information solutions business.

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

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

Due to budgetary shortfalls, many states are considering, or have enacted, cuts to existing preventative care programs. These cuts have included, or may include, elimination or reduction of coverage for some or all of our preventative care programs. For example, in 2012, nearly half of Alere Wellbeing's state clients partially, or substantially, reduced their funding of smoking cessation programs we provided. During 2012, approximately 62% of the net revenue of our Alere Wellbeing business was derived from sales to state governments. Continued state budgetary pressures could lead to further reductions in funding for our services which, in turn, could have a material adverse effect on our financial position and operating results.

In addition, some states may reduce current spending on preventative care programs in order to conserve funds for use in anticipated future programs, which may or may not occur. For example, the Centers for Disease Control and Prevention, or CDC, conducted a successful anti-smoking campaign in 2012. The CDC has announced that it is planning to implement another such campaign in 2013. We believe that, in anticipation of that campaign, many states are reducing spending on tobacco cessation programs so that they will have funds available to spend in conjunction with the CDC's expected campaign. If the CDC cancels, delays or substantially modifies its 2013 campaign, if states do not spend the expected funds in conjunction with that campaign, or if tobacco users are reluctant to respond to the campaign, funding for our services could be negatively impacted, which could have a material adverse effect on our financial position and operating results.

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

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

We expect that we will need to continue to improve and further integrate our information technology systems on an ongoing basis in order to effectively run our business. If we fail to successfully manage our information technology systems, our business and operating results could be adversely affected.

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

We are highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store electronic information, including personal information of our customers. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches, can create system disruptions, shutdowns or unauthorized disclosure of confidential information. In addition, a security breach or privacy violation that leads to disclosure of consumer information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state breach notification laws and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, or we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data.

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

**Poor economic conditions may negatively impact our toxicology business.**

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

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

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

In addition, our marketing of monitoring services may cause us to be subjected to various product liability or other claims, including, among others, claims that inaccurate monitoring results lead to injury or death, or, in the case of our toxicology monitoring services, the imposition of criminal sanctions. Any

product liability or other claim brought against us, regardless of merit, could be costly to defend and could result in an increase to our insurance premiums. If we are held liable for a claim, that claim could materially damage our business and financial condition.

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

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

The manufacturing of certain of our products is concentrated in one or more of our plants, with limited alternate facilities. Any event that negatively impacts our manufacturing facilities, our manufacturing systems or equipment, or our contract manufacturers or suppliers could delay or suspend shipments of products or the release of new products or could result in the delivery of inferior products. Our revenues from the affected products would decline and we could incur losses until such time as we or our contract manufacturers are able to restore our or their production processes or we are able to put in place alternative contract manufacturers or suppliers.

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

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

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

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



These new requirements could also have the effect of limiting the pool of suppliers from which we source these minerals, and we may be unable to obtain conflict-free minerals at competitive prices, which could increase our costs and adversely affect our manufacturing operations and our profitability.

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

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

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

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

- pending patent applications we have filed, or to which we have exclusive rights, may not result in issued patents or may take longer than we expect to result in issued patents;
- patents licensed or issued to us or our customers may not provide a competitive advantage;
- other parties may challenge patents or patent applications licensed or issued to us or our customers;
- other companies may design around technologies we have patented, licensed or developed; and
- all patents have a limited life, meaning at some point valuable patents will expire and we will lose the competitive advantage they provide. For example, certain patents related to our lateral flow technology expire in 2014 and 2015.

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

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

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

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

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

- assert claims of infringement;
- enforce licensing terms and conditions;
- protect our trade secrets or know-how; or
- determine the enforceability, scope and validity of the proprietary rights of ourselves or others.

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

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

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

As part of our business strategy, we seek to acquire or invest in businesses that offer products, services or technologies complementary to ours. If we are unable to identify and consummate acquisition opportunities, we may not achieve our growth targets. We may lose acquisition opportunities to competitors who offer a higher purchase price or who reach agreement with the target company earlier

than we do. We may fail to complete acquisitions for many reasons, including failure to obtain antitrust or other regulatory clearances, failure to obtain requisite shareholder approval and failure to obtain necessary financing, and we may incur significant expenses, including potentially the expense of litigation, pursuing acquisitions, whether or not consummated.

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

Since our inception, we have acquired numerous businesses, including Axis-Shield in 2011 and eScreen in 2012. The ultimate success of our acquisitions depends, in part, on our ability to realize the anticipated synergies, cost savings and growth opportunities from integrating newly-acquired businesses or assets into our existing businesses. However, the acquisition and successful integration of independent businesses or assets is a complex, costly and time-consuming process, and the benefits we realize may not exceed the costs of the acquisition. The risk and difficulties associated with acquiring and integrating companies and other assets include, among others:

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

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

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

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

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

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

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

**Our business has substantial indebtedness.**

We currently have, and will likely continue to have, a substantial amount of indebtedness. Our indebtedness could, among other things, make it more difficult for us to satisfy our debt obligations, require us to use a large portion of our cash flow from operations to repay and service our debt or otherwise create liquidity problems, limit our flexibility to adjust to market conditions, place us at a competitive disadvantage and expose us to interest rate fluctuations. As of December 31, 2012, we had total debt outstanding of approximately \$3.7 billion, which included approximately \$2.3 billion in aggregate principal amount of indebtedness outstanding under our secured credit facility, consisting of "A" term loans (including "Delayed Draw" term loans) in the aggregate principal amount of \$878.4 million, "B" term loans in the aggregate principal amount of \$913.4 million, "Incremental B-1" term loans in the aggregate principal amount of \$247.5 million, "Incremental B-2" term loans in the aggregate principal amount of \$196.7 million and revolving credit loans in the aggregate principal amount of \$22.5 million. Our secured credit facility has various final maturity dates occurring in 2016 and 2017, but if certain of our notes remain outstanding as of defined measurement dates in 2015, our secured credit facility will mature on those dates. At December 31, 2012, we also had an aggregate of approximately \$1.2 billion in aggregate principal amount of indebtedness outstanding under our senior and senior subordinated notes, all of which mature in 2016 or 2018, as well as \$150.0 million in aggregate principal amount of indebtedness outstanding under our 3% convertible senior subordinated notes, which matures in 2016.

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

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

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

- acquire other businesses or make investments;
- raise additional capital;
- incur additional debt or create liens on our assets;
- pay dividends or make distributions or repurchase or redeem our stock or senior or subordinated debt;



- prepay indebtedness; and
- consolidate, merge or sell all or substantially all of our assets.

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

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

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

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

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

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

If we undergo a change of control, as provided in our secured credit facility, the senior notes or the senior subordinated notes, or a fundamental change or termination of trading, as provided in the 3% convertible senior subordinated notes, we may be required to repay or repurchase some or all of such indebtedness. We may not have sufficient financial resources to satisfy all of our repayment and repurchase obligations. Our failure to purchase notes as required under the senior or senior subordinated notes or the 3% convertible senior subordinated notes would constitute a default under the relevant indentures and under our secured credit facility and could have material adverse consequences for us and our stakeholders.

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

In December 2012, we made a \$40.0 million secured loan to a third party in connection with a potential acquisition. In February 2013, the issuer of the note filed for protection under Chapter 11 of the U.S. Bankruptcy Code. The Bankruptcy Court subsequently granted us “continuing, valid, binding, enforceable and perfected first priority liens and security interests” in all of the post-petition collateral of the debtor to the “same extent, priority and enforceability” held on pre-petition collateral, in order to

secure any and all obligations of the debtor to us under the note, and other related agreements. We have assessed the note for impairment and determined that the note remains fully realizable and, accordingly, we have not recorded a reserve against the amount receivable as of December 31, 2012. The bankruptcy process is inherently complicated and subject to uncertainties and future changes in circumstances and there can be no certainty as to the outcome of these proceedings and that the note will remain realizable.

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

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

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

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

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

**We may incur losses in excess of our insurance coverage.**

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

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

Our future success depends on our continued ability to attract, hire and retain highly qualified personnel, including our executive officers and scientific, technical, sales and marketing employees, and their ability to manage growth successfully. Experienced personnel in our industry are in high

demand and competition for their talents is intense. If we are unable to attract and retain key personnel, our business may be harmed. In addition, the loss of any of our key personnel, particularly key research and development personnel, could harm our business and prospects and could impede the achievement of our research and development, operation or strategic objectives.

**Future sales of our common stock, including shares issuable upon conversion of our Series B Convertible Perpetual Preferred Stock, or Series B Preferred Stock, or our 3% convertible senior subordinated notes, may adversely affect the market price of our common stock.**

Sales of a substantial number of shares of our common stock or other equity securities in the public market could depress the price of our common stock and impair our ability to raise capital through the sale of additional equity securities. The price of our common stock could be affected by possible sales of the substantial number of shares of our common stock potentially issuable upon conversion of our Series B Preferred Stock or our 3% convertible senior subordinated notes and by other hedging or arbitrage trading activity that may develop involving our common stock. If the conditions applicable to the conversion of our Series B Preferred Stock were satisfied, then subject to adjustment, each of the approximately 1.8 million shares of Series B Preferred Stock outstanding as of December 31, 2012 could convert into 5.7703 shares of our common stock, or approximately 10.2 million shares of our common stock. Upon certain extraordinary transactions, depending on the market price of our common stock at that time, the conversion rate could increase such that significantly more shares of common stock could be issued. Our \$150.0 million in aggregate principal amount of 3% convertible senior subordinated notes is convertible into shares of our common stock at a conversion price of approximately \$43.98 per share, or approximately 3.4 million shares.

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

As of December 31, 2012, the outstanding shares of our Series B Preferred Stock had an aggregate stated liquidation preference of approximately \$709.8 million. Dividends accrue on the shares of Series B Preferred Stock at a rate of 3% per annum, and we have the option to pay these dividends in cash or in shares of common stock or additional shares of Series B Preferred Stock. If we pay these dividends in shares of common stock or additional shares of Series B Preferred Stock, the number of shares of common stock or Series B Preferred Stock issued will be based upon market prices at the time of such payment. Upon a liquidation of our company, the holders of shares of Series B Preferred Stock will be entitled to receive a liquidation payment prior to the payment of any amount with respect to the shares of our common stock. The amount of this preferential liquidation payment is the aggregate stated liquidation preference, plus any accrued and unpaid dividends. Because of the substantial liquidation preference to which the holders of the Series B Preferred Stock are entitled, the amount available to be distributed to the holders of our common stock upon a liquidation of our company could be substantially limited or reduced to zero.

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

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

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

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

- although we have amended our certificate of incorporation to declassify our board of directors , under Delaware law certain continuing directors have terms ending in 2014 and 2015. By preventing stockholders from voting on the election of all of our directors at our annual meetings of stockholders in 2013 and 2014, the longer terms of these continuing directors may have the effect of keeping the current members of our board of directors in control for a longer period of time than stockholders may desire; and
- subject to the rights of the holders of our Series B Preferred Stock, our certificate of incorporation authorizes our board of directors to issue shares of preferred stock without stockholder approval and to establish the preferences and rights of any preferred stock issued, which would allow the board to issue one or more classes or series of preferred stock that could discourage or delay a tender offer or change in control.

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

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

Our corporate headquarters, together with the administrative office for our United States consumer operations, is located at 51 Sawyer Road, Suite 200, Waltham, Massachusetts. From our office in Galway, Ireland, we oversee and conduct much of our professional diagnostic products business in Europe. We also operate a shared service center in Orlando, Florida, which houses certain critical back-office and sales operations supporting our U.S. professional diagnostics operations. Our health information solutions business is headquartered in Atlanta, Georgia. These key administrative facilities are leased from third parties.

We own approximately 18.8 acres of land in San Diego, California which houses one of our eight primary manufacturing operations, as well as significant administrative and research and development operations for our professional diagnostics business. Our buildings on this property total 336,000 square feet and include 167,000 square feet of manufacturing space for professional diagnostic products.

Our other primary manufacturing operations are in Scarborough, Maine; Hangzhou and Shanghai, China; Matsudo, Japan; Oslo, Norway; Dundee, Scotland and Yongin, South Korea. We manufacture some of our consumer and professional diagnostic products in a manufacturing facility of approximately 448,000 square feet in Hangzhou, China, which we own. The majority of our consumer diagnostic products are manufactured in a facility of approximately 133,000 square feet in Shanghai, China, which we lease. We manufacture our Determine products in a leased space of approximately 35,000 square feet in Matsudo, Japan. Standard Diagnostics manufactures most of its professional diagnostic products in a 63,000 square foot facility in Yongin, South Korea, which we own. Axis-Shield, which we acquired in late 2011, manufactures the majority of our point-of-care products for patients with diabetes in a leased space of approximately 47,500 square feet in Oslo, Norway and a leased space of approximately 51,000 square feet in Dundee, Scotland. We manufacture certain professional diagnostic products in a 64,000 square foot facility that we lease in Scarborough, Maine.



We increasingly rely on our network of toxicology laboratories to provide reliable drugs-of-abuse test results to customers. We own three SAMHSA certified laboratories in the United States, located in Gretna, Louisiana; Santa Rosa, California and Richmond, Virginia. We also operate toxicology laboratories in Austin, Texas; Clearwater, Florida; London, England and Abingdon, England, and we operate an accredited forensic laboratory in Malvern, England.

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

### **ITEM 3. LEGAL PROCEEDINGS**

#### *Matters Relating to our San Diego Facility*

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

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

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

#### *Class Action Litigation against Alere Home Monitoring*

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

#### *Claims in the Ordinary Course and Other Matters*

Because of the nature of our business, we may be subject at any particular time to lawsuits or other claims arising in the ordinary course of our business, and we expect that this will continue to be the case in the future. Such lawsuits often seek damages, sometimes in substantial amounts. An adverse ruling in such a lawsuit could have a material adverse impact on our sales, operations or financial performance.

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

## PART II

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

#### Unregistered Sales of Equity Securities and Use of Proceeds

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

#### Market Information

Our common stock trades on the New York Stock Exchange (NYSE) under the symbol "ALR." The following table sets forth the high and low sales prices of our common stock for each quarter during fiscal 2012 and 2011:

	<u>High</u>	<u>Low</u>
<b>Fiscal 2012</b>		
Fourth Quarter .....	\$22.10	\$17.20
Third Quarter .....	\$20.54	\$17.13
Second Quarter .....	\$26.50	\$17.62
First Quarter .....	\$27.22	\$21.51
<b>Fiscal 2011</b>		
Fourth Quarter .....	\$26.62	\$17.82
Third Quarter .....	\$38.53	\$19.62
Second Quarter .....	\$41.18	\$33.83
First Quarter .....	\$40.55	\$34.75

On February 25, 2013, there were 1,598 holders of record of our common stock.

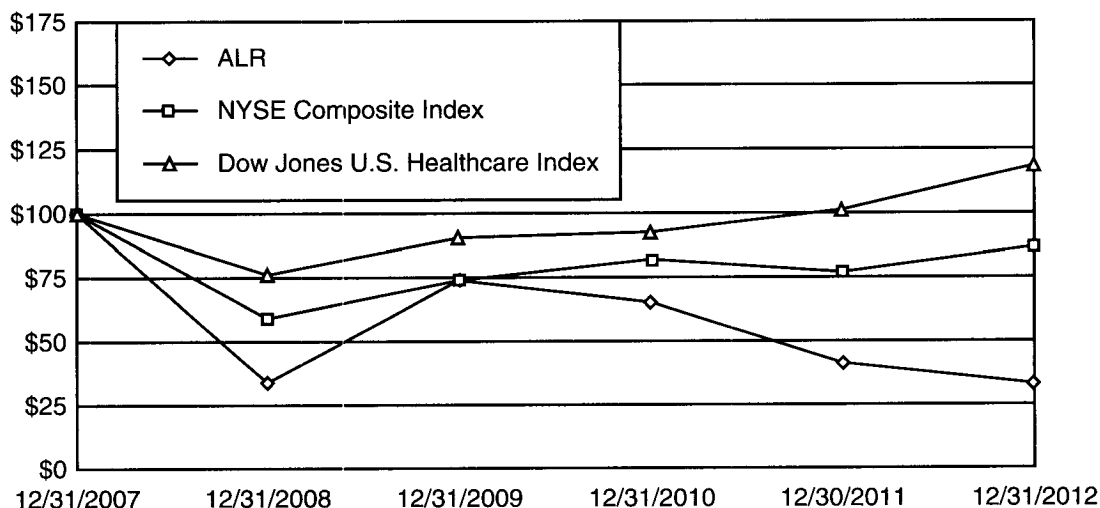
#### Dividend Policy

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

#### Stock Performance Graph

The following line graph compares the cumulative total stockholder return on our common stock from December 31, 2007 through December 31, 2012 with the cumulative total return of a broad equity market index and a published industry index. This graph assumes an investment of \$100.00 on December 31, 2007 in our common stock, and compares its performance with the NYSE Composite Index and the Dow Jones U.S. Healthcare Index (the "Current Indices"). We paid no dividends on our common stock during the period covered by the graph. The Current Indices reflect a cumulative total return based upon the reinvestment of dividends of the stocks included in those indices. Measurement points are December 31, 2007 and the last trading day of each subsequent year end through December 31, 2012.

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



#### Current Indices

Date	ALR	NYSE Composite Index	Dow Jones U.S. Healthcare Index
12/31/07	\$100.00	\$100.00	\$100.00
12/31/08	\$ 33.66	\$ 59.11	\$ 75.97
12/31/09	\$ 73.89	\$ 73.77	\$ 90.31
12/31/10	\$ 65.15	\$ 81.76	\$ 92.50
12/30/11	\$ 41.10	\$ 76.76	\$101.27
12/31/12	\$ 32.93	\$ 86.69	\$118.17

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

#### ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

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

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

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

	For the Year Ended December 31,				
	2012	2011	2010	2009	2008
	(in thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Net product sales	\$1,913,731	\$1,683,132	\$ 1,472,403	\$1,365,079	\$1,151,265
Services revenue	876,518	679,922	662,185	528,487	405,462
Net product sales and services revenue	2,790,249	2,363,054	2,134,588	1,893,566	1,556,727
License and royalty revenue	28,576	23,473	20,759	29,075	25,826
Net revenue	2,818,825	2,386,527	2,155,347	1,922,641	1,582,553
Cost of net product sales	932,150	795,424	688,325	619,503	543,317
Cost of services revenue	450,999	338,232	325,286	240,026	177,098
Cost of net product sales and services revenue	1,383,149	1,133,656	1,013,611	859,529	720,415
Cost of license and royalty revenue	7,354	7,036	7,149	8,890	8,620
Cost of net revenue	1,390,503	1,140,692	1,020,760	868,419	729,035
Gross profit	1,428,322	1,245,835	1,134,587	1,054,222	853,518
Operating expenses:					
Research and development	183,001	150,165	133,278	112,848	111,828
Sales and marketing	643,423	565,583	499,124	441,646	381,939
General and administrative	492,766	399,330	446,917	357,033	295,059
Goodwill impairment charge	—	383,612	1,006,357	—	—
Gain on dispositions, net	—	—	—	(3,355)	—
Operating income (loss)	109,132	(252,855)	(951,089)	146,050	64,692
Interest expense, including amortization of original issue discounts and write-off of deferred financing costs and other income (expense), net	(230,603)	86,808	(116,697)	(105,802)	(102,939)
Income (loss) from continuing operations before provision (benefit) for income taxes	(121,471)	(166,047)	(1,067,786)	40,248	(38,247)
Provision (benefit) for income taxes	(30,319)	(24,214)	(29,931)	15,627	(16,644)
Income (loss) from continuing operations before equity earnings of unconsolidated entities, net of tax	(91,152)	(141,833)	(1,037,855)	24,621	(21,603)
Equity earnings of unconsolidated entities, net of tax	13,245	8,524	10,566	7,626	1,050
Income (loss) from continuing operations	(77,907)	(133,309)	(1,027,289)	32,247	(20,553)
Income (loss) from discontinued operations, net of tax	—	—	11,397	1,934	(1,048)
Net income (loss)	(77,907)	(133,309)	(1,015,892)	34,181	(21,601)
Less: Net income attributable to non-controlling interests	275	233	1,418	465	167
Net income (loss) attributable to Alere Inc. and Subsidiaries	(78,182)	(133,542)	(1,017,310)	33,716	(21,768)
Preferred stock dividends	(21,293)	(22,049)	(24,235)	(22,972)	(13,989)
Preferred stock repurchase	—	23,936	—	—	—
Net income (loss) available to common stockholders(1)	\$ (99,475)	\$ (131,655)	\$ (1,041,545)	\$ 10,744	\$ (35,757)



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

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

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

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

### Forward-Looking Statements

*This Annual Report on Form 10-K, including this Item 7, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. You can identify these statements by forward-looking words such as "may," "could," "should," "would," "intend," "will," "expect," "anticipate," "believe," "estimate," "continue" or similar words. You should read statements that contain these words carefully because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other "forward-looking" information. Forward-looking statements include, without limitation, statements regarding anticipated expansion and growth in certain of our product and service offerings, the impact of our research and development activities, potential new product and technology achievements, the potential for selective acquisitions, including acquisitions of health information solutions businesses outside the United States, our ability to improve our working capital and operating margins, our expectations with respect to Apollo, our integrated health information solutions technology platform, our ability to improve care and lower healthcare costs for both providers and patients, and our funding plans for our future working capital needs and commitments. Actual results or developments could differ materially from those projected in such statements as a result of numerous factors, including, without limitation, those risks and uncertainties set forth in Item 1A entitled "Risk Factors," which begins on page 17 of this report, as well as those factors identified from time to time in our filings with the Securities and Exchange Commission. We do not undertake any obligation to update any forward-looking statements. This report and, in particular, the following discussion and analysis of our financial condition and results of operations, should be read in light of those risks and uncertainties and in conjunction with our accompanying consolidated financial statements and notes thereto.*

## Overview

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

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

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

- During the second half of 2011, we acquired RALS, the point-of-care industry's leading data management solution, and AegisPOC, the first web-based data management solution designed for critical care settings, which we have since enhanced and renamed RALS Freedom. Our RALS systems provide bidirectional interfaces that connect a hospital's glucose meters and other point-of-care devices measuring blood gases, prothrombin time, and cardiac parameters to its laboratory and health information systems.
- In December 2011, we acquired Wellogic, now Alere Accountable Care Solutions, or Alere ACS. Through Alere ACS, we deliver health information solutions that help provider organizations meet CMS "Meaningful Use" requirements and improve coordination across multiple venues of care. These solutions include the Alere Health Information Exchange, which harmonizes multiple streams of data from disparate sources in a single patient-centered record, and Consult EHR, which gives healthcare practitioners greater visibility into a patient's health status.
- In July 2012, we acquired MedApps, now Alere Connect. Alere Connect develops and sells remote health monitoring solutions designed to collect health readings from compatible medical monitors and transmit them to a user's electronic health record, as well as web-based applications to help practitioners manage this data. Alere Connect's comprehensive health information platform and suite of cloud-based software tools enhance care for patients in both wellness and chronic disease management programs.
- In July 2012, we also acquired DiagnosisOne, now Alere Analytics. Through Alere Analytics, we offer a broad array of analytical and clinical decision support tools, which are delivered on our smartPath platform.

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

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

## 2012 Financial Highlights

- Net revenue increased by \$432.3 million, or 18%, to \$2.8 billion in 2012, from \$2.4 billion in 2011.
- Gross profit increased by \$182.5 million, or 15%, to \$1.4 billion in 2012, from \$1.2 billion in 2011.
- For the year ended December 31, 2012, we generated a net loss available to common stockholders of \$99.5 million, or \$1.23 per basic and diluted common share. For the year ended December 31, 2011, we generated a net loss available to common stockholders of \$131.7 million, or \$1.58 per basic and diluted common share. The 2011 net loss included a \$383.6 million non-cash charge associated with the impairment of goodwill in our health information solutions business segment and reporting unit.

## Results of Operations

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

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

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

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

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

### Professional Diagnostics

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

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

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

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



### Health Information Solutions

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

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

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

### Consumer Diagnostics

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

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

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

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

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

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

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

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

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

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

*Professional Diagnostics*

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

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

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

#### *Health Information Solutions*

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

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

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

#### *Consumer Diagnostics*

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

### Professional Diagnostics

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

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

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

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

### Health Information Solutions

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

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

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

#### *Consumer Diagnostics*

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

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

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

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

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

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



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

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

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

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

*Professional Diagnostics*

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

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

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

*Health Information Solutions*

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

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

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

*Consumer Diagnostics*

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

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

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

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

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

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

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

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

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

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

reduction or impairment of the value of goodwill or other intangible assets will result in additional charges against earnings, which could materially reduce our reported results of operations in future periods. Further details of the goodwill impairment analysis are disclosed in Note 2 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

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

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

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

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

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

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

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

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

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

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

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

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

## **Liquidity and Capital Resources**

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

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

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

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

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

#### *Cash Flow Summary*

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

#### *Summary of Changes in Cash Position*

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



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

### *Operating Cash Flows*

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

### *Investing Cash Flows*

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

### *Financing Cash Flows*

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

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

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

#### Income Taxes

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

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

#### Off-Balance Sheet Arrangements

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

#### Contractual Obligations

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

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

- (1) See the description of various financing arrangements in Note 6 of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.
- (2) See Note 8 of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.
- (3) See Note 11(a) of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.
- (4) Includes \$4.7 million and \$1.8 million in deferred payments associated with the acquisitions of Standard Diagnostics and Bioeasy Diagnostica Ltda., or Bioeasy, respectively. In addition, this balance includes approximately \$22.3 million of contingent consideration obligations that have been accrued as of December 31, 2012.
- (5) Other purchase obligations relate to inventory purchases and other operating expense commitments.
- (6) Includes our non-variable interest-bearing debt. See the description of various financing arrangements in Note 6 of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

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

- Ionian Technologies, Inc. has a maximum earn-out of \$57.5 million that, if earned, is expected to be paid during 2013.
- TwistDx, Inc. has a maximum earn-out of up to \$125.0 million that, if earned, is expected to be paid during an eight-year period ending on the eighth anniversary of the acquisition, but could extend thereafter.
- AdnaGen has a maximum earn-out of \$42.0 million that, if earned, is expected to be paid during 2013 through 2016.
- Medlab Produtos Medicos Hospitalares Ltda, now known as Alere S.A., has a maximum remaining earn-out potential of \$6.0 million that, if earned, is expected to be paid in annual amounts during 2014 through 2017.
- Bioeasy has a maximum remaining earn-out potential of approximately \$2.5 million that, if earned, is expected to be paid during 2014.
- Laboratory Data Systems, Inc., has a maximum remaining earn-out of approximately \$7.5 million that, if earned, is expected to be paid during 2013 and 2014.
- Mologic Limited has a maximum remaining earn-out potential of \$14.8 million that, if earned, is expected to be paid in cash or shares of our common stock during 2014.
- Forensics Limited, or ROAR, has a maximum remaining earn-out of approximately £9.3 million (approximately \$15.2 million at December 31, 2012) that, if earned, is expected to be paid during 2013 and 2014.
- Standing Stone, Inc., has a maximum remaining earn-out of \$2.8 million that, if earned, is expected to be paid during 2014. The maximum amount of employee bonuses that we are required to make pursuant to the Standing Stone acquisition agreement is \$0.1 million, which, if earned, is also expected to be paid during 2014.
- Method Factory, Inc. (d/b/a Wellogic) has a maximum remaining earn-out potential of \$49.8 million based on operational targets and an earn-out with no maximum based on profit targets that, if earned, is expected to be paid during 2014 through 2020.
- eScreen has a maximum earn-out potential of \$70.0 million that, if earned, is expected to be paid during 2014 and 2015.

- MedApps has a maximum earn-out potential of \$21.2 million that, if earned, is expected to be paid during 2013 through 2015.
- Amedica has a maximum remaining amount potential of \$8.1 million that, if earned, is expected to be paid in 2014.
- DiagnosisOne has a maximum earn-out potential of \$33.0 million that, if earned, is expected to be paid during 2013 through 2015.
- Diagnostik Nord has a maximum earn-out potential of €1.4 million (approximately \$1.9 million at December 31, 2012) that, if earned, is expected to be paid during 2013 and 2014.
- Healthcare Connections Limited has a maximum earn-out potential of £3.5 million (approximately \$5.7 million at December 31, 2012) that, if earned, is expected to be paid in 2014.
- NationsHealth, Inc., has a maximum earn-out potential of \$8.0 million that, if earned, is expected to be paid in 2013 and 2014.
- Branan has a maximum remaining amount potential of \$3.0 million that, if earned, is expected to be paid during 2013 through 2015.

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

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

- Agreements with Epocal

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

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

### **Critical Accounting Policies**

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

### *Revenue Recognition*

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

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

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

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

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

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

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



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

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

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

#### *Inventory*

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

#### *Goodwill and Other Long-Lived and Intangible Assets*

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

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

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

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

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

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

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

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

### ***2012 Annual Goodwill Impairment Test***

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

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

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

### ***2011 Annual Goodwill Impairment Test***

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

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

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

### ***2010 Annual Goodwill Impairment Test***

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

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

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

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

#### *Valuation of Other Long-Lived Tangible and Intangible Assets*

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

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

#### *Stock-Based Compensation*

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

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

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

### *Accounting for Income Taxes*

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

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

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

### *Loss Contingencies*

In the section of this Annual Report on Form 10-K entitled "Part I, Item 3, Legal Proceedings," we have reported on material legal proceedings, if any. Because of the nature of our business, we may be subject at any particular time to lawsuits or other claims arising in the ordinary course of our business, and we expect that this will continue to be the case in the future.

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



## Recent Accounting Pronouncements

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

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

### Interest Rate Risk

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

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

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

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

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

	<u>Interest Expense Increase</u>
Interest rates payable by us increase by 100 basis points .....	\$22,586
Interest rates payable by us increase by 200 basis points .....	\$45,172

### Foreign Currency Risk

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

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

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

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

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

### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

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

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

- (1) Net income (loss) available to common stockholders and basic and diluted net income (loss) per common share are computed consistent with the annual per share calculations described in Notes 2(o) and 12 of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.
- (2) Included in net loss for the first quarter of 2012 is \$5.6 million related to restructuring charges associated with the decision to close various facilities, a write-off in the amount of \$4.7 million relating to an inventory write-up recorded in connection with an acquisition, acquisition-related costs in the amount of \$1.5 million recorded in accordance with ASC 805, *Business Combinations*, \$5.0 million of expense recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations in accordance with ASC 805, *Business Combinations*, \$1.3 million of interest expense recorded in connection with fees paid for certain debt modifications and the termination of our senior secured credit facility and \$3.9 million of non-cash stock-based compensation expense.
- (3) Included in net loss for the second quarter of 2012 is \$1.4 million related to restructuring charges associated with the decision to close various facilities, acquisition-related costs in the amount of

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

- (4) Included in net loss for the third quarter of 2012 is \$3.3 million related to restructuring charges associated with the decision to close various facilities, acquisition-related costs in the amount of \$0.8 million recorded in accordance with ASC 805, *Business Combinations*, \$15.1 million of income recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations in accordance with ASC 805, *Business Combinations*, \$1.3 million of interest expense recorded in connection with fees paid for certain debt modifications and the termination of our senior secured credit facility and \$3.6 million of non-cash stock-based compensation expense.
- (5) Included in net loss for the fourth quarter of 2012 is \$10.3 million related to restructuring charges associated with the decision to close various facilities, acquisition-related costs in the amount of \$3.6 million recorded in accordance with ASC 805, *Business Combinations*, \$10.2 million of expense recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations in accordance with ASC 805, *Business Combinations*, \$23.2 million of expense associated with the repurchase of substantially all of our 7.875% senior notes, \$1.0 million of interest expense recorded in connection with fees paid for certain debt modifications and the termination of our senior secured credit facility and \$3.8 million of non-cash stock-based compensation expense.
- (6) Included in net income for the first quarter of 2011 is \$6.4 million related to restructuring charges associated with the decision to close various facilities, acquisition-related costs in the amount of \$1.9 million recorded in accordance with ASC 805, *Business Combinations*, \$1.4 million of expense recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations in accordance with ASC 805, *Business Combinations*, a \$1.9 million realized foreign currency loss associated with the settlement of an acquisition-related contingent consideration obligation and \$5.8 million of non-cash stock-based compensation expense.
- (7) The first and fourth quarters of 2011 include income tax benefits of \$1.4 million and \$5.6 million, respectively, to correct items related to periods between 2007 and 2010. We do not believe that the corrected items are material to the 2011 annual financial statements or any previously reported quarterly or annual financial statements.
- (8) Included in net loss for the second quarter of 2011 is \$10.5 million related to restructuring charges associated with the decision to close various facilities, acquisition-related costs in the amount of \$1.4 million recorded in accordance with ASC 805, *Business Combinations*, \$7.2 million of income recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations in accordance with ASC 805, *Business Combinations*, \$29.9 million of interest expense recorded in connection with fees paid for certain debt modifications and the termination of our senior secured credit facility and related interest rate swap agreement and \$6.2 million of non-cash stock-based compensation expense.
- (9) Included in net income for the third quarter of 2011 is \$3.4 million related to restructuring charges associated with the decision to close various facilities, acquisition-related costs in the amount of \$2.9 million recorded in accordance with ASC 805, *Business Combinations*, \$3.8 million of income recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations in accordance with ASC 805, *Business Combinations*, \$1.3 million of interest expense recorded in connection with fees paid for certain debt modifications and the termination of our senior secured credit facility, an \$18.1 million unrealized foreign currency loss associated with a bank account funded for the acquisition of Axis-Shield plc, recognition of a \$288.9 million gain originally recorded in connection with the formation of SPD, our 50/50 joint venture with P&G, a \$0.6 million fair value write-down recorded in connection with an idle facility and \$4.3 million of non-cash stock-based compensation expense.

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

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

Not applicable.

#### **ITEM 9A. CONTROLS AND PROCEDURES**

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

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

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

##### *Management's Annual Report on Internal Control over Financial Reporting*

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

- (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and



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

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

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

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

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

#### *Changes in internal control over financial reporting*

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

#### **ITEM 9B. OTHER INFORMATION**

None.

### PART III

#### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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

#### ITEM 11. EXECUTIVE COMPENSATION

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

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

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

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

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

#### ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

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

### PART IV

#### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

##### 1. Financial Statements.

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

Report of Independent Registered Public Accounting Firm .....	F-2
Consolidated Statements of Operations for the Years Ended December 31, 2012, 2011 and 2010 .....	F-3
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##### 2. Financial Statement Schedules.

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

### 3. Exhibits.

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

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

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

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

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

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



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

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

\* Filed herewith.

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

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

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



**ALERE INC. AND SUBSIDIARIES**  
**CONSOLIDATED FINANCIAL STATEMENTS**

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## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Alere Inc.,

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of equity, of comprehensive income (loss) and of cash flows present fairly, in all material respects, the financial position of Alere Inc. and its subsidiaries at December 31, 2012 and December 31, 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

As described in Management's Annual Report on Internal Control over Financial Reporting, management has excluded 14 entities from its assessment of internal control over financial reporting as of December 31, 2012 because they were acquired by the Company in purchase business combinations during 2012. We have also excluded these entities from our audit of internal control over financial reporting. The total assets and net revenue of these entities represented 1% and 5%, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2012.

**/s/ PricewaterhouseCoopers LLP**

Boston, Massachusetts  
March 1, 2013



**ALERE INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except per share amounts)

	Year Ended December 31,		
	2012	2011	2010
Net product sales	\$1,913,731	\$1,683,132	\$ 1,472,403
Services revenue	876,518	679,922	662,185
Net product sales and services revenue	2,790,249	2,363,054	2,134,588
License and royalty revenue	28,576	23,473	20,759
<b>Net revenue</b>	<b>2,818,825</b>	<b>2,386,527</b>	<b>2,155,347</b>
Cost of net product sales	932,150	795,424	688,325
Cost of services revenue	450,999	338,232	325,286
Cost of net product sales and services revenue	1,383,149	1,133,656	1,013,611
Cost of license and royalty revenue	7,354	7,036	7,149
<b>Cost of net revenue</b>	<b>1,390,503</b>	<b>1,140,692</b>	<b>1,020,760</b>
<b>Gross profit</b>	<b>1,428,322</b>	<b>1,245,835</b>	<b>1,134,587</b>
Operating expenses:			
Research and development	183,001	150,165	133,278
Sales and marketing	643,423	565,583	499,124
General and administrative	492,766	399,330	446,917
Goodwill impairment charge	—	383,612	1,006,357
<b>Operating income (loss)</b>	<b>109,132</b>	<b>(252,855)</b>	<b>(951,089)</b>
Interest expense, including amortization of original issue discounts and deferred financing costs	(240,560)	(203,971)	(139,435)
Other income (expense), net	9,957	1,883	22,738
Gain on sale of joint venture interest	—	288,896	—
<b>Loss from continuing operations before benefit for income taxes</b>	<b>(121,471)</b>	<b>(166,047)</b>	<b>(1,067,786)</b>
Benefit for income taxes	(30,319)	(24,214)	(29,931)
<b>Loss from continuing operations before equity earnings of unconsolidated entities, net of tax</b>	<b>(91,152)</b>	<b>(141,833)</b>	<b>(1,037,855)</b>
Equity earnings of unconsolidated entities, net of tax	13,245	8,524	10,566
Loss from continuing operations	(77,907)	(133,309)	(1,027,289)
Income from discontinued operations, net of tax	—	—	11,397
<b>Net loss</b>	<b>(77,907)</b>	<b>(133,309)</b>	<b>(1,015,892)</b>
Less: Net income attributable to non-controlling interests	275	233	1,418
<b>Net loss attributable to Alere Inc. and Subsidiaries</b>	<b>(78,182)</b>	<b>(133,542)</b>	<b>(1,017,310)</b>
Preferred stock dividends	(21,293)	(22,049)	(24,235)
Preferred stock repurchase	—	23,936	—
<b>Net loss available to common stockholders</b>	<b>\$ (99,475)</b>	<b>\$ (131,655)</b>	<b>\$(1,041,545)</b>
Basic and diluted net loss per common share attributable to Alere Inc. and Subsidiaries:			
Loss from continuing operations	\$ (1.23)	\$ (1.58)	\$ (12.47)
Income from discontinued operations	—	—	0.14
Net loss per common share	<b>\$ (1.23)</b>	<b>\$ (1.58)</b>	<b>\$ (12.33)</b>
<b>Weighted-average shares — basic and diluted</b>	<b>80,587</b>	<b>83,128</b>	<b>84,445</b>

The accompanying notes are an integral part of these consolidated financial statements.

**ALERE INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**  
(in thousands)

	Year Ended December 31,		
	2012	2011	2010
<b>Net loss</b> .....	\$(77,907)	\$(133,309)	\$(1,015,892)
Other comprehensive income (loss), before tax:			
Changes in cumulative translation adjustment .....	54,642	(35,830)	(210)
Unrealized gains (losses) on available for sale securities .....	(216)	(471)	1,151
Unrealized gains on hedging instruments .....	388	11,504	3,965
Minimum pension liability adjustment .....	(1,042)	(3,070)	(113)
Other comprehensive income (loss), before tax .....	53,772	(27,867)	4,793
Income tax provision (benefit) related to items of other comprehensive income (loss) .....	(372)	3,093	1,649
Other comprehensive income (loss), net of tax .....	54,144	(30,960)	3,144
<b>Comprehensive loss</b> .....	(23,763)	(164,269)	(1,012,748)
Less: Comprehensive income attributable to non-controlling interests .....	275	233	1,418
<b>Comprehensive loss attributable to Alere Inc. and Subsidiaries</b> .....	\$(24,038)	\$(164,502)	\$(1,014,166)

The accompanying notes are an integral part of these consolidated financial statements.

**ALERE INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
(in thousands, except par value amounts)

	<b>As of December 31,</b>	
	<b>2012</b>	<b>2011</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents .....	\$ 328,346	\$ 299,173
Restricted cash .....	3,076	8,987
Marketable securities .....	904	1,086
Accounts receivable, net of allowances of \$36,396 and \$24,577 at December 31, 2012 and December 31, 2011, respectively .....	524,332	475,824
Inventories, net .....	337,121	320,269
Deferred tax assets .....	67,722	42,975
Prepaid expenses and other current assets .....	145,236	145,413
<b>Total current assets</b> .....	<b>1,406,737</b>	<b>1,293,727</b>
Property, plant and equipment, net .....	534,469	491,205
Goodwill .....	3,048,405	2,821,271
Other intangible assets with indefinite lives .....	36,451	69,546
Finite-lived intangible assets, net .....	1,834,225	1,785,925
Deferred financing costs, net, and other non-current assets .....	108,857	113,241
Investments in unconsolidated entities .....	90,491	85,138
Marketable securities .....	—	2,254
Deferred tax assets .....	8,293	10,394
<b>Total assets</b> .....	<b>\$ 7,067,928</b>	<b>\$ 6,672,701</b>
<b>LIABILITIES AND EQUITY</b>		
<b>Current liabilities:</b>		
Current portion of long-term debt .....	\$ 60,232	\$ 61,092
Current portion of capital lease obligations .....	6,684	6,083
Short-term debt .....	—	6,240
Accounts payable .....	169,974	155,464
Accrued expenses and other current liabilities .....	411,919	395,573
<b>Total current liabilities</b> .....	<b>648,809</b>	<b>624,452</b>
<b>Long-term liabilities:</b>		
Long-term debt, net of current portion .....	3,628,675	3,267,451
Capital lease obligations, net of current portion .....	12,917	12,629
Deferred tax liabilities .....	428,188	380,700
Other long-term liabilities .....	166,635	153,398
<b>Total long-term liabilities</b> .....	<b>4,236,415</b>	<b>3,814,178</b>
<b>Commitments and contingencies</b> (Notes 8, 9 and 11)		
<b>Redeemable non-controlling interest</b> .....	—	2,497
<b>Stockholders' equity:</b>		
Series B preferred stock, \$0.001 par value (liquidation preference: \$709,763 at December 31, 2012 and 2011); Authorized: 2,300 shares; Issued: 2,065 shares at December 31, 2012 and 2011; Outstanding: 1,774 shares at December 31, 2012 and 2011 .....	606,468	606,468
Common stock, \$0.001 par value; Authorized: 200,000 shares; Issued: 88,576 shares at December 31, 2012 and 87,647 shares at December 31, 2011; Outstanding: 80,897 shares at December 31, 2011 and 79,968 shares at December 31, 2011 .....	89	88
Additional paid-in capital .....	3,299,935	3,324,710
Accumulated deficit .....	(1,564,973)	(1,486,791)
Treasury stock, at cost, 7,679 shares at December 31, 2012 and 2011 .....	(184,971)	(184,971)
Accumulated other comprehensive income (loss) .....	23,874	(30,270)
<b>Total stockholders' equity</b> .....	<b>2,180,422</b>	<b>2,229,234</b>
Non-controlling interests .....	2,282	2,340
<b>Total equity</b> .....	<b>2,182,704</b>	<b>2,231,574</b>
<b>Total liabilities and equity</b> .....	<b>\$ 7,067,928</b>	<b>\$ 6,672,701</b>

The accompanying notes are an integral part of these consolidated financial statements.

**ALERE INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF EQUITY**  
(in thousands)

	Preferred Stock		Common Stock			Accumulated Other Compre- hensive Income (Loss)	Treasury Stock, at cost		Total Stockholders' Equity	Non- controlling Interest	Total Equity	Redeemable Non- controlling Interest
	Number of Shares	Amount	Number of Shares	\$0.001 Par Value	Additional Paid-in Capital		Accumulated Deficit	Number of Shares				
BALANCE, DECEMBER 31, 2009	1,984	\$694,427	83,567	\$84	\$3,195,476	\$ (359,874)	21	\$(104)	\$ 3,527,555	\$ 1,334	\$ 3,528,889	\$ —
Issuance of common stock and warrants in connection with acquisitions	—	—	536	—	16,276	—	—	—	16,276	—	16,276	—
Exercise of common stock options, warrants and shares issued under employee stock purchase plan	—	—	825	1	19,024	—	—	—	19,025	—	19,025	—
Preferred stock dividends	107	24,127	—	—	(24,279)	—	—	—	(152)	—	(152)	—
Forfeiture of restricted stock awards	—	—	—	—	—	—	3	—	—	—	—	—
Stock-based compensation related to grants of common stock options	—	—	—	—	29,879	—	—	—	29,879	—	29,879	—
Excess tax benefits on exercised stock options	—	—	—	—	789	—	—	—	789	—	789	—
Minimum pension liability adjustment, net of tax	—	—	—	—	—	—	—	—	(113)	—	(113)	—
Changes in cumulative translation adjustment, net of tax	—	—	—	—	—	—	—	—	(210)	—	(210)	—
Unrealized gain on interest rate swap, net of tax	—	—	—	—	—	—	—	—	2,423	—	2,423	—
Unrealized gain on available-for-sale securities, net of tax	—	—	—	—	—	—	—	—	1,044	—	1,044	—
Acquisition of non-controlling interests	—	—	—	—	(4,168)	—	—	—	(4,168)	1,251	(2,917)	(1,315)
Redeemable non-controlling interest in subsidiaries' income	—	—	—	—	—	—	—	—	—	(1,315)	(1,315)	1,315
Net income (loss)	—	—	—	—	—	(1,017,310)	—	—	(1,017,310)	1,418	(1,015,892)	—
BALANCE, DECEMBER 31, 2010	<u>2,091</u>	<u>\$718,554</u>	<u>84,928</u>	<u>\$85</u>	<u>\$3,232,997</u>	<u>\$(1,377,184)</u>	<u>24</u>	<u>\$(104)</u>	<u>\$ 2,575,038</u>	<u>\$ 2,688</u>	<u>\$ 2,577,726</u>	<u>\$ —</u>

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**ALERE INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF EQUITY (Continued)**

(in thousands)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Compre- hensive Income (Loss)	Treasury Stock, at cost		Total Stockholders' Equity	Non- controlling Interest	Total Equity	Redeemable Non- controlling Interest
	Number of Shares	Amount	Number of Shares	\$0.001 Par Value				Number of Shares	Value				
BALANCE, DECEMBER 31, 2010 . . .	2,091	\$ 718,554	84,928	\$85	\$3,232,997	\$(1,377,184)	\$ 690	24	\$ (104)	\$2,575,038	\$ 2,688	\$2,577,726	\$ —
Issuance of common stock in connection with acquisitions . . . . .	—	—	832	1	16,183	—	—	—	—	16,184	—	16,184	—
Exercise of common stock options, warrants and shares issued under employee stock purchase plan . . . . .	—	—	1,887	2	37,885	—	—	—	—	37,887	—	37,887	—
Repurchase of common stock . . . . .	—	—	—	—	—	—	—	7,655	(184,867)	(184,867)	—	(184,867)	—
Repurchase of preferred stock . . . . .	(358)	(123,005)	—	—	—	23,935	—	—	—	(99,070)	—	(99,070)	—
Preferred stock dividends . . . . .	41	10,919	—	—	(21,632)	—	—	—	—	(10,713)	—	(10,713)	—
Stock-based compensation related to grants of common stock options . . .	—	—	—	—	21,215	—	—	—	—	21,215	—	21,215	—
Excess tax benefits on exercised stock options . . . . .	—	—	—	—	3,423	—	—	—	—	3,423	—	3,423	—
Minimum pension liability adjustment, net of tax . . . . .	—	—	—	—	—	—	(1,618)	—	—	(1,618)	—	(1,618)	—
Changes in cumulative translation adjustment, net of tax . . . . .	—	—	—	—	—	—	(35,830)	—	—	(35,830)	—	(35,830)	—
Unrealized gain on hedging instruments, net of tax . . . . .	—	—	—	—	(297)	—	6,855	—	—	6,558	—	6,558	—
Unrealized loss on available-for-sale securities, net of tax . . . . .	—	—	—	—	—	—	(367)	—	—	(367)	—	(367)	—
Acquisition of non-controlling interests . . . . .	—	—	—	—	—	—	—	—	—	—	34,936	34,936	—
Purchase of subsidiary shares from non-controlling interest . . . . .	—	—	—	—	34,936	—	—	—	—	34,936	(34,936)	—	2,500
Dividend relating to non-controlling interest . . . . .	—	—	—	—	—	—	—	—	—	—	(584)	(584)	—
Redeemable non-controlling interest in subsidiaries' income . . . . .	—	—	—	—	—	—	—	—	—	—	3	3	(3)
Net income (loss) . . . . .	—	—	—	—	—	(133,542)	—	—	—	(133,542)	233	(133,309)	—
<b>BALANCE, DECEMBER 31, 2011 . . .</b>	<b>1,774</b>	<b>\$ 606,468</b>	<b>87,647</b>	<b>\$88</b>	<b>\$3,324,710</b>	<b>\$(1,486,791)</b>	<b>\$(30,270)</b>	<b>7,679</b>	<b>\$(184,971)</b>	<b>\$2,229,234</b>	<b>\$ 2,340</b>	<b>\$2,231,574</b>	<b>\$2,497</b>

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**ALERE INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF EQUITY (Continued)**  
(in thousands)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Compre- hensive Income (Loss)	Treasury Stock, at cost		Total Stockholders' Equity	Non- controlling Interest	Total Equity	Redeemable Non- controlling Interest
	Number of Shares	Amount	Number of Shares	\$0.001 Par Value				Number of Shares	Value				
BALANCE, DECEMBER 31, 2011	1,774	\$606,468	87,647	\$88	\$3,324,710	\$(1,486,791)	\$(30,270)	7,679	\$(184,971)	\$2,229,234	\$2,340	\$2,231,574	\$ 2,497
Exercise of common stock options, warrants and shares issued under employee stock purchase plan	—	—	862	1	14,923	—	—	—	—	14,924	—	14,924	—
Issuance of common stock for settlement of an acquisition-related contingent consideration obligation	—	—	67	—	1,243	—	—	—	—	1,243	—	1,243	—
Preferred stock dividends	—	—	—	—	(21,293)	—	—	—	—	(21,293)	—	(21,293)	—
Stock-based compensation related to grants of common stock options	—	—	—	—	15,665	—	—	—	—	15,665	—	15,665	—
Excess tax benefits on exercised stock options	—	—	—	—	(234)	—	—	—	—	(234)	—	(234)	—
Minimum pension liability adjustment, net of tax	—	—	—	—	—	—	(756)	—	—	(756)	—	(756)	—
Changes in cumulative translation adjustment, net of tax	—	—	—	—	—	—	54,642	—	—	54,642	—	54,642	—
Unrealized gain on hedging instruments, net of tax	—	—	—	—	—	—	388	—	—	388	—	388	—
Unrealized loss on available-for-sale securities, net of tax	—	—	—	—	—	—	(130)	—	—	(130)	—	(130)	—
Purchase of subsidiary shares from non- controlling interest (Note 5)	—	—	—	—	(35,079)	—	—	—	—	(35,079)	—	(35,079)	(2,433)
Dividend relating to non-controlling interest	—	—	—	—	—	—	—	—	—	—	(396)	(396)	—
Net income (loss)	—	—	—	—	—	(78,182)	—	—	—	(78,182)	338	(77,844)	(64)
BALANCE, DECEMBER 31, 2012	<u>1,774</u>	<u>\$606,468</u>	<u>88,576</u>	<u>\$89</u>	<u>\$3,299,935</u>	<u>\$(1,564,973)</u>	<u>\$ 23,874</u>	<u>7,679</u>	<u>\$(184,971)</u>	<u>\$2,180,422</u>	<u>\$2,282</u>	<u>\$2,182,704</u>	<u>\$ —</u>

**ALERE INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	<b>For The Year Ended December 31,</b>		
	<b>2012</b>	<b>2011</b>	<b>2010</b>
<b>Cash Flows from Operating Activities:</b>			
Net loss	\$ (77,907)	\$ (133,309)	\$(1,015,892)
Income from discontinued operations, net of tax	—	—	11,397
Loss from continuing operations	(77,907)	(133,309)	(1,027,289)
Adjustments to reconcile loss from continuing operations to net cash provided by operating activities:			
Non-cash interest expense, including amortization of original issue discounts and deferred financing costs	21,490	37,590	13,758
Depreciation and amortization	456,847	391,576	366,188
Non-cash charges for sale of inventories revalued at the date of acquisition	4,681	6,010	6,602
Non-cash stock-based compensation expense	15,665	21,215	29,879
Impairment of inventory	295	445	848
Impairment of long-lived assets	3,489	1,549	1,411
Impairment of goodwill	—	383,612	1,006,357
Impairment of intangible assets	2,988	2,938	—
Gain on sale of joint venture interest	—	(288,896)	—
(Gain) loss on sale of fixed assets	(2,151)	1,577	998
Gain on sales of marketable securities	(751)	(840)	(4,504)
Equity earnings of unconsolidated entities, net of tax	(13,245)	(8,524)	(10,566)
Deferred income taxes	(84,568)	(56,761)	(74,418)
Other non-cash items	30,571	(12,247)	3,802
Changes in assets and liabilities, net of acquisitions:			
Accounts receivable, net	(22,165)	(39,408)	(9,360)
Inventories, net	(16,791)	(20,399)	(22,845)
Prepaid expenses and other current assets	(2,526)	(53,115)	8,310
Accounts payable	(10,127)	6,985	(9,088)
Accrued expenses and other current liabilities	49,431	14,282	22,202
Other non-current liabilities	(35,543)	16,973	(27,452)
Net cash provided by continuing operations	319,683	271,253	274,833
Net cash provided by discontinued operations	—	—	591
<b>Net cash provided by operating activities</b>	<b>319,683</b>	<b>271,253</b>	<b>275,424</b>
<b>Cash Flows from Investing Activities:</b>			
(Increase) decrease in restricted cash	5,911	(6,406)	(141)
Purchases of property, plant and equipment	(137,393)	(132,532)	(96,241)
Proceeds from sale of property, plant and equipment	22,390	947	795
Proceeds from disposition of business	—	11,491	—
Cash paid for acquisitions, net of cash acquired	(424,586)	(631,311)	(523,507)
Proceeds from sales of marketable securities	3,056	9,202	3,182
Net cash received from (paid for) equity method investments	12,707	(121,903)	12,354
Increase in other assets	(56,276)	(27,684)	(12,900)
Net cash used in continuing operations	(574,191)	(898,196)	(616,458)
Net cash provided by discontinued operations	—	—	62,596
<b>Net cash used in investing activities</b>	<b>(574,191)</b>	<b>(898,196)</b>	<b>(553,862)</b>
<b>Cash Flows from Financing Activities:</b>			
Cash paid for financing costs	(10,139)	(74,680)	(13,045)
Cash paid for contingent purchase price consideration	(20,964)	(28,305)	—
Cash paid for dividends	(21,293)	(5,425)	—
Proceeds from issuance of common stock, net of issuance costs	14,924	37,886	19,024
Repurchase of preferred stock	—	(99,070)	—
Proceeds from issuance of long-term debt	648,535	2,096,277	400,000
Payments on short-term debt	(6,240)	—	—
Payments on long-term debt	(311,612)	(1,207,454)	(9,750)
Net proceeds (payments) under revolving credit facilities	14,272	10,715	(146,781)
Repurchase of common stock	—	(184,867)	—
Excess tax benefits on exercised stock options	504	3,423	1,683
Principal payments on capital lease obligations	(7,003)	(4,163)	(1,867)
Purchase of non-controlling interest	(2,972)	—	(52,864)
Other	(12,267)	(4,257)	(141)
<b>Net cash provided by financing activities</b>	<b>285,745</b>	<b>540,080</b>	<b>196,259</b>
Foreign exchange effect on cash and cash equivalents	(2,064)	(15,270)	(9,288)
Net increase (decrease) in cash and cash equivalents	29,173	(102,133)	(91,467)
Cash and cash equivalents, beginning of period	299,173	401,306	492,773
<b>Cash and cash equivalents, end of period</b>	<b>\$ 328,346</b>	<b>\$ 299,173</b>	<b>\$ 401,306</b>

The accompanying notes are an integral part of these consolidated financial statements.

## ALERE INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### **(1) Description of Business and Basis of Presentation**

Alere Inc. enables individuals to take greater control of their health at home, under the supervision of their healthcare providers, by combining near-patient diagnostics, health monitoring capabilities, and information technology solutions. A leading global provider of point-of-care diagnostics and services, we have developed a strong commercial presence in cardiology, infectious disease, toxicology, and diabetes.

Our business is organized into three operating segments: (i) professional diagnostics, (ii) health information solutions (formerly health management) and (iii) consumer diagnostics. The professional diagnostics segment includes an array of innovative rapid diagnostic test products and other in vitro diagnostic tests marketed to medical professionals and laboratories for detection of diseases and conditions within our areas of focus identified above. The health information solutions segment provides comprehensive, integrated programs and services focused on wellness, disease and condition management, productivity enhancement and informatics, all designed to reduce health-related costs and enhance the health and quality of life of the individuals we serve. The consumer diagnostics segment consists primarily of manufacturing operations related to our role as the exclusive manufacturer of products for SPD Swiss Precision Diagnostics, or SPD, our 50/50 joint venture with The Procter & Gamble Company, or P&G. SPD has significant operations in the worldwide over-the-counter pregnancy and fertility/ovulation test market.

Acquisitions have been an important part of our growth strategy. When we acquire businesses, we seek to complement existing products and services, enhance or expand our product lines and/or expand our customer base. We determine what we are willing to pay for each acquisition partially based upon our expectation that we can cost effectively integrate the products and services of the acquired companies into our existing infrastructure. In addition, we utilize existing infrastructure of the acquired companies to cost effectively introduce our products to new geographic areas. All of these factors contributed to the acquisition prices of acquired businesses that were in excess of the fair value of net assets acquired, resulting in goodwill (Note 4).

The consolidated financial statements include the accounts of Alere Inc. and its subsidiaries. Intercompany transactions and balances are eliminated and net earnings are reduced by the portion of the net earnings of subsidiaries applicable to non-controlling interests. Equity investments in which we exercise significant influence but do not control and are not the primary beneficiary are accounted for using the equity method. Investments in which we are not able to exercise significant influence over the investee and which do not have readily determinable fair values are accounted for under the cost method.

Certain amounts for prior periods have been reclassified to conform to the current period classification.

#### **(2) Summary of Significant Accounting Policies**

##### *(a) Use of Estimates*

To prepare our financial statements in conformity with accounting principles generally accepted in the United States of America, our management must make estimates, judgments and assumptions that may affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ significantly from such estimates under different assumptions or conditions.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(2) Summary of Significant Accounting Policies (Continued)**

*(b) Foreign Currencies*

In general, the functional currencies of our foreign subsidiaries are the local currencies. For the purpose of consolidating the financial statements of our foreign subsidiaries, all assets and liabilities of the foreign subsidiaries are translated into U.S. dollars using the exchange rate at each balance sheet date, while the stockholders' equity accounts are translated at historical exchange rates. Translation gains and losses that result from the conversion of the balance sheets of the foreign subsidiaries into U.S. dollars are recorded to cumulative translation adjustment, which is a component of accumulated other comprehensive income (loss) (Note 15) within stockholders' equity. The revenue and expenses of our foreign subsidiaries are translated using the average of the rates of exchange in effect during each fiscal month.

Net realized and unrealized foreign currency exchange transaction losses of \$7.9 million and \$22.9 million during 2012 and 2011, respectively, and gains of \$9.8 million during 2010 are included as a component of other income (expense), net in the accompanying consolidated statements of operations.

*(c) Cash and Cash Equivalents*

We consider all highly-liquid investments purchased with original maturities of three months or less at the date of acquisition to be cash equivalents. Cash equivalents consisted of money market funds at December 31, 2012 and 2011.

*(d) Restricted Cash*

We had restricted cash of \$3.1 million and \$9.0 million as of December 31, 2012 and 2011, respectively. Of the \$9.0 million as of December 31, 2011, approximately \$5.3 million was for the purchase of the remaining outstanding shares of Axis-Shield plc, or Axis-Shield, which were acquired prior to December 31, 2011, but settled in the first quarter of 2012.

*(e) Marketable Securities*

Securities classified as available-for-sale or trading are carried at fair value, as determined by quoted market prices at the balance sheet date. Realized gains and losses on securities are included in other income (expense), net, on a specific identification basis. Unrealized holding gains and losses (except for other than temporary impairments) on securities classified as available-for-sale, are reported in accumulated other comprehensive income, net of related tax effects. Marketable securities that are held indefinitely are classified in our accompanying consolidated balance sheets as long-term marketable securities.

*(f) Inventories*

Inventories are stated at the lower of cost (first-in, first-out) or market and are made up of raw material, work-in-process and finished goods. The cost elements of work-in-process and finished goods inventory consist of raw material, direct labor and manufacturing overhead. Where finished goods inventory is purchased from third-party manufacturers, the costs of finished goods inventory recorded in the financial statements represent the costs to acquire such inventory.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(2) Summary of Significant Accounting Policies (Continued)**

*(g) Property, Plant and Equipment*

We record property, plant and equipment at historical cost or, in the case of a business combination, at fair value on the date of the business combination. Depreciation is computed using the straight-line method based on the following estimated useful lives of the related assets: machinery, laboratory equipment and tooling, 1-15 years; buildings, 7-61 years; leasehold improvements, lesser of the remaining term of the lease or estimated useful life of the asset; computer software and equipment, 1-7 years and furniture and fixtures, 2-16 years. Land is not depreciated. Depreciation expense related to property, plant and equipment amounted to \$109.7 million, \$83.7 million and \$67.7 million in 2012, 2011 and 2010, respectively. Fully-depreciated property, plant and equipment that are still in use remain on the books until disposal or retirement. When property, plant and equipment are retired or disposed of, the cost and respective accumulated depreciation are removed from the books. Any gain or loss on disposal is recorded in the income statement. Expenditures for repairs and maintenance are expensed as incurred.

*(h) Goodwill and Other Intangible Assets with Indefinite Lives*

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

We test goodwill and other intangible assets with indefinite lives at the reporting unit level for impairment on an annual basis, and between annual tests, if events and circumstances indicate it is more likely than not that the fair value of a reporting unit is less than its carrying value. Events that would indicate impairment and trigger an interim impairment assessment include, but are not limited to, current economic and market conditions, including a decline in market capitalization, a significant adverse change in legal factors, business climate or operational performance of the business and an adverse action or assessment by a regulator.

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

If the carrying value of a reporting unit exceeds its estimated fair value, we are required to perform the second step, or Step 2, of the goodwill impairment test to measure the amount of impairment loss,

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(2) Summary of Significant Accounting Policies (Continued)**

if any. The second step of the goodwill impairment test compares the implied fair value of a reporting unit's goodwill to its carrying value. The implied fair value of goodwill is calculated as the difference between the fair value of the reporting unit and the estimated fair value of its assets and liabilities. To the extent this amount is below the carrying value of goodwill, an impairment charge is recorded.

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

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

***2012 Annual Goodwill Impairment Test***

We conducted our 2012 annual impairment test for our reporting units during the fourth quarter of 2012. Key assumptions (which vary by reporting unit) used in determining fair value under the discounted cash flow approach included discount rates ranging from 11.0% to 15.0%, projected compound average revenue growth rates of 3.0% to 8.1% and terminal value growth rates of 3.0% to 4.0%. In determining the appropriate discount rate, we considered the WACC for each reporting unit, which among other factors considers the cost of common equity capital and the marginal cost of debt of market participants. Key assumptions (which again vary by reporting unit) used in determining fair value under the market approach were based on observed market multiples of enterprise value to revenue and EBITDA for both comparable publicly-traded companies and recent merger and acquisition transactions involving similar companies to estimate appropriate controlling basis multiples to apply to each of the reporting units. Based on the multiples implied by this market data, we selected multiples of revenue of 0.9 to 2.4 times and multiples of EBITDA of 6.1 to 8.9 times. In assessing the reasonableness of our estimated fair values of the reporting units, management compared the results of the valuation analyses against our then-current market capitalization to imply a control premium. Based on this analysis, the implied control premium was within the range of comparable industry transactions.

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

***2011 Annual Goodwill Impairment Test***

We conducted our 2011 annual impairment test for our reporting units during the fourth quarter of 2011. Key assumptions (which vary by reporting unit) used in determining fair value under the discounted cash flow approach included discount rates ranging from 11.0% to 14.5%, projected compound average revenue growth rates of 4.9% to 10.0% and terminal value growth rates of 4.0%. In determining the appropriate discount rate, we considered the WACC for each reporting unit, which, among other factors,



**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(2) Summary of Significant Accounting Policies (Continued)**

considers the cost of common equity capital and the marginal cost of debt of market participants. Key assumptions (which again vary by reporting unit) used in determining fair value under the market approach were based on observed market multiples of enterprise value to revenue and EBITDA for both comparable publicly-traded companies and recent merger and acquisition transactions involving similar companies to estimate appropriate controlling basis multiples to apply to each of the reporting units. Based on the multiples implied by this market data, we selected multiples of revenue of 0.8 to 2.6 times and multiples of EBITDA of 5.6 to 9.3 times. In assessing the reasonableness of our estimated fair values of the reporting units, management compared the results of the valuation analyses against our then-current market capitalization to imply a control premium. Based on this analysis, the implied control premium was within the range of comparable industry transactions.

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

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

***2010 Annual Goodwill Impairment Test***

We conducted our 2010 annual impairment test for our reporting units during the fourth quarter of 2010. Key assumptions (which vary by reporting unit) used in determining fair value under the discounted cash flow approach included discount rates ranging from 12.5% to 13.0%, projected compound average revenue growth rates of 6.0% to 10.0% and terminal value growth rates of 4.0%. In determining the appropriate discount rate, we considered the WACC for each reporting unit, which, among other factors, considers the cost of common equity capital and the marginal cost of debt of market participants. Key assumptions (which again vary by reporting unit) used in determining fair value under the market approach were based on observed market multiples of enterprise value to revenue and EBITDA for both comparable publicly-traded companies and recent merger and acquisition transactions involving similar companies to estimate appropriate controlling basis multiples to apply to each of the reporting units. Based on the multiples implied by this market data, we selected multiples of revenue of 1.0 to 2.8 times and multiples of EBITDA of 7.5 to 10.0 times. In assessing the reasonableness of our estimated fair values of the reporting units, management compared the results of the valuation analyses against our then-current market capitalization to imply a control premium. Based on this analysis, the implied control premium was within the range of comparable industry transactions.

The Step 1 impairment analysis indicated that the carrying value of the net assets of our health information solutions reporting unit exceeded the estimated fair value of the reporting unit. As a result, we were required to perform Step 2 of the goodwill impairment test to determine the amount, if any, of goodwill impairment charges for the health information solutions reporting unit. We completed Step 2, consistent with the procedures described above, and determined that a goodwill impairment charge in

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(2) Summary of Significant Accounting Policies (Continued)**

the amount of approximately \$1.0 billion was required. The resulting goodwill impairment charge is reflected in operating income (loss) in our accompanying consolidated statements of operations.

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

*(i) Impairment of Other Long-Lived Tangible and Intangible Assets*

Our intangible assets consist primarily of core technology, in-process research and development, patents, trademarks, trade names, customer relationships, distribution rights and non-competition agreements. The majority of our intangible assets were recorded in connection with our various business combinations. Our intangible assets are recorded at fair value at the time of their acquisition. We amortize intangible assets over their estimated useful lives.

The estimated useful lives of the individual categories of intangible assets were based on the nature of the applicable intangible asset and the expected future cash flows to be derived from the intangible asset. Amortization of intangible assets with finite lives is recognized over the shorter of the respective lives of the agreement or the period of time the intangible assets are expected to contribute to future cash flows. We amortize our finite-lived intangible assets based on patterns on which the respective economic benefits are expected to be realized.

We evaluate long-lived tangible and intangible assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indicators of impairment are present with respect to long-lived tangible and intangible assets used in operations and undiscounted future cash flows are not expected to be sufficient to recover the assets' carrying amount, additional analysis is performed as appropriate and the carrying value of the long-lived assets is reduced to the estimated fair value, if this is lower, and an impairment loss is charged to expense in the period the impairment is identified.

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

*(j) Acquired In-Process Research and Development (IPR&D)*

Acquired IPR&D represents the fair value assigned to research and development assets that we acquire as part of business combinations, and which have not been completed at the date of acquisition. The acquired IPR&D is capitalized as an intangible asset and tested for impairment at least annually until commercialization, after which time the IPR&D is amortized over its estimated useful life.

*(k) Business Acquisitions*

Our business acquisitions have historically been made at prices above the fair value of the assets acquired and liabilities assumed, resulting in goodwill, based on our expectations of synergies and

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(2) Summary of Significant Accounting Policies (Continued)**

other benefits of combining the businesses. These synergies and benefits include elimination of redundant facilities, functions and staffing; use of our existing commercial infrastructure to expand sales of the products of the acquired businesses; and use of the commercial infrastructure of the acquired businesses to expand product sales in a cost-efficient manner.

Significant judgment is required in estimating the fair value of intangible assets and in assigning their respective useful lives. The fair value estimates are based on available historical information and on future expectations and assumptions deemed reasonable by management, but are inherently uncertain.

We generally employ the income method to estimate the fair value of intangible assets, which is based on forecasts of the expected future cash flows attributable to the respective assets. Significant estimates and assumptions inherent in the valuations reflect a consideration of other marketplace participants, and include the amount and timing of future cash flows (including expected growth rates and profitability), the underlying product life cycles, economic barriers to entry, a brand's relative market position and the discount rate applied to the cash flows. Unanticipated market or macroeconomic events and circumstances may occur, which could affect the accuracy or validity of the estimates and assumptions.

Net assets acquired are recorded at their fair value and are subject to adjustment upon finalization of the fair value analysis. We are not aware of any information that indicates the final fair value analysis will differ materially from the preliminary estimates.

During 2012, 2011, and 2010, we expensed acquisition-related costs of \$9.7 million \$11.5 million and \$8.2 million, respectively, in general and administrative expense.

*(l) Income Taxes*

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts that are more likely than not to be realized in the future (Note 16).

We account for uncertain tax positions using a "more-likely-than-not" threshold for recognizing and resolving uncertain tax positions. We evaluate uncertain tax positions on a quarterly basis and consider various factors, including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position.

*(m) Revenue Recognition*

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

The majority of our revenue is derived from product sales. We recognize revenue upon transfer of the title of the products to third-party customers, less a reserve for estimated product returns and

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(2) Summary of Significant Accounting Policies (Continued)**

allowances. Determination of the reserve for estimated product returns and allowances is based on our management's analyses and judgments regarding certain conditions. Should future changes in conditions prove management's conclusions and judgments on previous analyses to be incorrect, revenue recognized for any reporting period could be adversely affected.

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

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

We also receive license and royalty revenue from agreements with third-party licensees. Revenue from license and royalty agreements is recognized on a straight-line basis over the obligation period of the related license agreements, or at the time when we have no further obligations. License and royalty fees that the licensees calculate based on their sales, which we have the right to audit under most of our agreements, are generally recognized upon receipt of the license or royalty payments unless we are able to reasonably estimate the fees as they are earned. License and royalty fees that are determinable prior to the receipt thereof are recognized in the period they are earned.

*(n) Employee Stock-Based Compensation Arrangements*

We account for share-based payments in accordance with Accounting Standards Codification, or ASC 718, *Compensation — Stock Compensation*. Compensation expense associated with stock options includes amortization based on the grant-date fair value estimated in accordance with the provisions of ASC 718. In addition, we record expense over the offering period in connection with shares issued under our employee stock purchase plan. Compensation expense for stock-based compensation awards includes an estimate for forfeitures and is recognized over the vesting period of the options using the straight-line method. It is our policy to recognize, through additional paid in capital, the excess or windfall tax benefits on stock option deductions, as those deductions are recognized on tax returns.

Our stock option plans provide for grants of options to employees to purchase common stock at or above the fair market value of such shares on the grant date of the award. The options generally vest

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(2) Summary of Significant Accounting Policies (Continued)**

over a four-year period, beginning on the date of grant, with a graded vesting schedule of 25% at the end of each of the four years. The fair value of each option grant is estimated on the date of grant primarily using a Black-Scholes option-pricing method. We use historical data to estimate the expected price volatility and the expected forfeiture rate. The contractual term of our stock option awards is ten years. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant with a remaining term equal to the expected term of the option. We have not made any dividend payments to common shareholders nor do we have plans to pay dividends in the foreseeable future.

*(o) Net Loss per Common Share*

Net loss per common share is based upon the weighted-average number of outstanding common shares and the dilutive effect of common share equivalents, such as options and warrants to purchase common stock, convertible preferred stock and convertible notes, if applicable, that are outstanding each year (Note 12).

*(p) Other Operating Expenses*

We expense advertising costs as incurred. In 2012, 2011 and 2010, advertising costs amounted to \$22.6 million, \$9.9 million and \$14.4 million, respectively, and are included in sales and marketing expenses in the accompanying consolidated statements of operations.

Shipping and handling costs are included in cost of net revenue in the accompanying consolidated statements of operations. When we charge our customers for shipping and handling costs, these costs are recorded along with product revenues.

*(q) Concentration of Credit Risk, Off-Balance Sheet Risks and Other Risks and Uncertainties*

Financial instruments that potentially subject us to concentration of credit risk primarily consist of cash and cash equivalents and accounts receivable. We invest our excess cash primarily in high quality securities and limit the amount of our credit exposure to any one financial institution. We do not require collateral or other securities to support customer receivables; however, we perform on-going credit evaluations of our customers and maintain allowances for potential credit losses.

At December 31, 2012 and 2011, no individual customer's accounts receivable balance was in excess of 10% of our aggregate accounts receivable. During 2012, 2011 and 2010, no one customer represented greater than 10% of our net revenue.

We rely on a number of third parties to manufacture certain of our products. If any of our third-party manufacturers cannot, or will not, manufacture our products in the required volumes, on a cost-effective basis, in a timely manner, or at all, we will have to secure additional manufacturing capacity. Any interruption or delay in manufacturing could have a material adverse effect on our business and operating results.

*(r) Financial Instruments and Fair Value of Financial Instruments*

Our primary financial instruments at December 31, 2012 and 2011 consisted of cash equivalents, restricted cash, marketable securities, accounts receivable, accounts payable and debt. We apply fair value measurement accounting to value our financial assets and liabilities. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(2) Summary of Significant Accounting Policies (Continued)**

advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. A fair value hierarchy requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value.

Described below are the three levels of inputs that may be used to measure fair value:

*Level 1* Quoted prices in active markets for identical assets or liabilities.

*Level 2* Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

*Level 3* Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

*(s) Software for Internal Use and for Resale*

We may capitalize certain costs associated with the development of internal-use software, including direct materials and services. Capitalized software is amortized on a straight-line basis over its estimated useful life and is included in computer software and equipment within property, plant and equipment.

We also develop software for resale or lease to external parties and expense the costs of developing software for resale or lease incurred before establishment of technological feasibility of the underlying software. The costs incurred from establishment of technological feasibility until general release of the software are capitalized, and the capitalized software is amortized over its estimated useful life. Capitalized software for resale or lease is included in computer software and equipment within property, plant and equipment.

*(t) Research and Development*

Our research and development programs focus on the development of cardiology, infectious disease, toxicology, diabetes, oncology and women's health products together with health information technologies that will facilitate connectivity and information and data management solutions. Research and development costs are expensed as incurred. Payments received from external parties to fund our research and development activities reduce the recorded research and development expenses.

*(u) Leases*

We lease certain facilities and equipment from external parties under operating leases. Rent expense related to operating leases is recorded in the income statement as incurred. We also lease machinery, laboratory equipment, tooling and other equipment under capital leases. In determining whether a lease is a capital or an operating lease, we estimate the expected term of the lease, which includes certain renewable options as required by lease accounting guidance. Rent deferrals, landlord incentives and rent escalations are included in calculation of minimum lease payments when performing the capital lease tests and when calculating the rent expense for operating leases.

Leased property, plant and equipment that meet the capital lease criteria are capitalized at the lower of the present value of the minimum lease payments or the fair value of the underlying asset at the inception date of the lease. Assets under capital leases are depreciated on a straight-line basis over the lease term.



**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(2) Summary of Significant Accounting Policies (Continued)**

Leasehold improvements are capitalized and amortized over the shorter of their estimated useful lives or the remainder of the expected term of the lease.

*(v) Recent Accounting Pronouncements*

*Recently Issued Standards*

In July 2012, the FASB issued Accounting Standards Update, or ASU, No. 2012-02, *Intangibles — Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment*, or ASU 2012-02. ASU 2012-02 allows an entity the option to first assess qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that the indefinite-lived intangible asset is impaired. If an entity concludes that it is not more likely than not that the indefinite-lived intangible asset is impaired, then the entity is not required to take further action. However, if an entity concludes otherwise, then it is required to determine the fair value of the indefinite-lived intangible asset and perform the quantitative impairment test by comparing the fair value with the carrying amount. An entity also has the option to bypass the qualitative assessment for any indefinite-lived intangible asset in any period and proceed directly to performing the quantitative impairment test. An entity will be able to resume performing the qualitative assessment in any subsequent period. ASU 2012-02 is effective for annual and interim impairment tests for fiscal years beginning after September 15, 2012. The adoption of this standard is not expected to have a material impact on our financial position, results of operations, comprehensive income or cash flows.

*Recently Adopted Standards*

Effective January 1, 2012, we adopted ASU No. 2011-08, *Intangibles — Goodwill and Other (Topic 350): Testing for Goodwill Impairment*, or ASU 2011-08. ASU 2011-08 allows an entity the option to first assess qualitative factors to determine whether it is necessary to perform the current two-step impairment test. If an entity believes, as a result of its qualitative assessment, that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, the quantitative two-step impairment test is required; otherwise, no further testing is required. This update does not change the current guidance for testing other indefinite-lived intangible assets for impairment. The adoption of this standard did not have an impact on our financial position, results of operations, comprehensive income or cash flows. Based upon a qualitative assessment, we performed Step 1 of the two-step impairment test on all of our reporting units in 2012.

Effective January 1, 2012, we adopted ASU No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income*, or ASU 2011-05. ASU 2011-05 (1) eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity; (2) requires the consecutive presentation of the statement of net income and other comprehensive income; and (3) requires an entity to present reclassification adjustments on the face of the financial statements from other comprehensive income to net income. This update does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The amendments do not affect how the earnings per share amounts are calculated or presented. Effective January 1, 2012, the FASB issued ASU No. 2011-12, *Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05*, or ASU 2011-12. As these accounting standards only require enhanced disclosure, the adoption of these standards did not impact our financial position, results of operations, comprehensive income or cash flows.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(2) Summary of Significant Accounting Policies (Continued)**

Effective January 1, 2012, we adopted ASU No. 2011-04, *Fair Value Measurements (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, or ASU 2011-04. ASU 2011-04 provides common requirements for measuring fair value and disclosing information about fair value measurements in accordance with U.S. GAAP.

**(3) Other Balance Sheet Information**

(a) *Components of selected captions in the consolidated balance sheets consist of (in thousands):*

	<u>December 31,</u>	
	<u>2012</u>	<u>2011</u>
<b>Inventories, net:</b>		
Raw materials .....	\$ 99,498	\$ 92,844
Work-in-process .....	89,895	72,939
Finished goods .....	147,728	154,486
	<u>\$ 337,121</u>	<u>\$ 320,269</u>
<b>Property, plant and equipment, net:</b>		
Machinery, laboratory equipment and tooling .....	\$ 416,311	\$ 340,750
Land and buildings .....	176,214	170,152
Leasehold improvements .....	45,654	38,767
Computer software and equipment .....	217,940	174,086
Furniture and fixtures .....	33,022	28,117
	<u>889,141</u>	<u>751,872</u>
Less: Accumulated depreciation and amortization .....	<u>(354,672)</u>	<u>(260,667)</u>
	<u>\$ 534,469</u>	<u>\$ 491,205</u>
<b>Accrued expenses and other current liabilities:</b>		
Compensation and compensation-related .....	\$ 93,467	\$ 77,656
Professional fees .....	12,152	9,171
Interest payable .....	18,074	27,137
Royalty obligations .....	26,171	29,085
Deferred revenue .....	38,188	33,407
Income taxes payable .....	29,733	50,134
Other taxes payable .....	23,038	29,245
Acquisition-related obligations .....	79,286	68,009
Other .....	91,810	71,729
	<u>\$ 411,919</u>	<u>\$ 395,573</u>

(b) *Note receivable from FGST Investments, Inc.*

In December 2012, we entered into an arrangement whereby we issued a \$40.0 million short-term note to an unrelated party, FGST Investments, Inc., or FGST, for the primary purpose of providing funding in connection with their acquisition of the Polymedica Corporation ("Liberty") line of business, a medical supply business, from a subsidiary of Express Scripts Holding Company. The note bears interest at a rate of 3.25% per annum and is collateralized by substantially all of the assets of FGST and its parent entity, ATLS. The \$40.0 million short-term note is classified within prepaid expenses and other current assets on our Consolidated Balance Sheet as of December 31, 2012. In connection with

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(3) Other Balance Sheet Information (Continued)**

the note, we obtained a call option on certain of the assets acquired by FGST, at a strike price of \$40.0 million. In lieu of repayment of the note, we may exercise the option by tendering the note to obtain those assets. If we do not exercise the option, \$10.0 million becomes repayable five days after the expiration of the option and \$30.0 million, plus accrued and unpaid interest, becomes repayable on the 60th day following the expiration of the option.

Upon evaluation of the significant terms of the note arrangement and the call option, we have concluded that the note and option represent a variable interest in FGST and, therefore, FGST is a variable interest entity. Further, we assessed whether we are the primary beneficiary in relation to FGST and concluded that we do not have power over the most significant activities of FGST, primarily operating decision making and that our obligation to absorb losses or receive benefits from FGST is limited to our note receivable from them. Given such, we have concluded that we are not the primary beneficiary and, therefore, we will not include the financial results of FGST in our consolidated financial statements. See also Note 25.

**(4) Business Combinations**

*(a) Acquisitions in 2012*

*(i) eScreen*

On April 2, 2012, we acquired eScreen, Inc., or eScreen, headquartered in Overland Park, Kansas, a technology-enabled provider of employment drug screening solutions for hiring and maintaining healthier and more efficient workforces. The preliminary aggregate purchase price was approximately \$295.0 million, which consisted of \$271.4 million in cash and a contingent consideration obligation with an aggregate acquisition date fair value of \$23.6 million. Included in our consolidated statements of operations for the year ended December 31, 2012 is revenue totaling approximately \$116.7 million related to eScreen. The operating results of eScreen are included in our professional diagnostics reporting unit and business segment. The amount allocated to goodwill from this acquisition is not deductible for tax purposes.

*(ii) Other acquisitions in 2012*

During 2012, we acquired the following businesses for a preliminary aggregate purchase price of \$199.4 million, which included cash payments totaling \$147.4 million and contingent consideration obligations with aggregate acquisition date fair values of \$52.0 million.

- Reatrol Comercializacao De Produtos De Saude, LDA, subsequently renamed Alere Lda, located in Vila Nova de Gaia, Portugal, a distributor of products for drugs of abuse testing (Acquired January 2012)
- Kullgren Holding AB, or Kullgren, located in Gensta, Sweden, a company that manufactures and distributes high-quality intimacy and pharmaceutical products (Acquired February 2012)
- Wellogic ME FZ-LLC, or Wellogic UAE, located in Dubai, United Arab Emirates, a company that provides development services to Alere Wellogic, LLC, which acquired the assets of Method Factory, Inc. (d/b/a Wellogic), or Wellogic, in December 2011 (Acquired February 2012)
- certain assets, primarily including customer and patient lists, of AmMed Direct LLC, or AmMed, located near Nashville, Tennessee, a privately-owned mail-order provider of home-diabetes testing products and supplies (Acquired March 2012)

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(4) Business Combinations (Continued)**

- MedApps Holding Company, Inc., or MedApps, headquartered in Scottsdale, Arizona, a developer of innovative remote health monitoring solutions that deliver efficient cost-effective connectivity between patient, care provider and electronic medical records (Acquired July 2012)
- Amedica Biotech, Inc., or Amedica, located in Hayward, California, a company focused on the development and manufacture of in vitro diagnostic tests (Acquired July 2012)
- DiagnosisOne, Inc., or DiagnosisOne, located in Lowell, Massachusetts, a software company that provides clinical analytics technology and data-driven content to hospitals, physician groups, insurers and governments (Acquired July 2012)
- Seelen Care Laege-og & Hospitalsartikler ApS, or Seelen, located in Holstebro, Denmark, a distributor of consumables, instruments and equipment to doctors, specialists and physiotherapists (Acquired August 2012)
- certain assets of Diagnostik Nord, or Diagnostik, located in Schwerin, Germany, a company focused on the sale of drug screening and in vitro diagnostic medical devices and a provider of diagnostic solutions (Acquired September 2012)
- Healthcare Connections Limited, or HCC, located in Buckinghamshire, United Kingdom, an occupational health provider specializing in employment medical programs, preventative health schemes and drug and alcohol sample collection services (Acquired November 2012)
- the diagnostic division of Medial spol. s.r.o., subsequently renamed Alere s.r.o., located in Prague, Czech Republic, a distributor of laboratory diagnostic devices, devices operating in the point-of-care testing regime, diagnostic kits and tests for biochemistry, hematology, and microbiology (Acquired November 2012)
- certain assets of Quantum Diagnostics, or Quantum Australia, located in Australia, an on-line medical supply company that provides a range of affordable drug and alcohol tests for personal, business and professional medical use. (Acquired November 2012)
- certain assets of NationsHealth, Inc., or NationsHealth, headquartered in Sunrise, Florida, a privately-owned mail-order provider of diabetes home-testing products and supplies, and a share acquisition of NationsHealth's subsidiary in the Philippines, or NationsHealth Philippines (Acquired December 2012)
- Branan Medical Corporation, or Branan, headquartered in Irvine, California, a manufacturer of drugs of abuse testing products (Acquired December 2012)

The operating results of Alere Lda, AmMed, MedApps, Amedica, Seelen, Diagnostik, HCC, Alere s.r.o., Quantum Australia, NationsHealth and Branan are included in our professional diagnostics reporting unit and business segment. The operating results of Wellogic UAE and DiagnosisOne are included in our health information solutions reporting unit and business segment. The operating results of Kullgren are included in our consumer diagnostics reporting unit and business segment.

Our consolidated statements of operations for the year ended December 31, 2012 included revenue totaling approximately \$44.6 million related to these businesses. Goodwill has been recognized in all of these acquisitions and amounted to approximately \$102.9 million. Goodwill related to the acquisitions of AmMed, Diagnostik and the US-based assets of NationsHealth, which totaled \$8.8 million, is deductible for tax purposes. The goodwill related to the remaining 2012 acquisitions is not deductible for tax purposes.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(4) Business Combinations (Continued)**

A summary of the preliminary fair values of the net assets acquired for the acquisitions consummated in 2012 is as follows (in thousands):

	<u>eScreen</u>	<u>Other</u>	<u>Total</u>
Current assets(1) .....	\$ 32,530	\$ 13,304	\$ 45,834
Property, plant and equipment .....	5,806	3,184	8,990
Goodwill .....	154,923	102,919	257,842
Intangible assets .....	204,000	121,223	325,223
Other non-current assets .....	481	221	702
Total assets acquired .....	<u>397,740</u>	<u>240,851</u>	<u>638,591</u>
Current liabilities .....	22,805	4,885	27,690
Non-current liabilities .....	79,945	36,520	116,465
Total liabilities assumed .....	<u>102,750</u>	<u>41,405</u>	<u>144,155</u>
Net assets acquired .....	294,990	199,446	494,436
Less:			
Contingent consideration .....	23,600	52,020	75,620
Cash paid .....	<u>\$271,390</u>	<u>\$147,426</u>	<u>\$418,816</u>

(1) Includes approximately \$4.0 million of acquired cash.

The following are the intangible assets acquired and their respective fair values and weighted-average useful lives (dollars in thousands):

	<u>eScreen</u>	<u>Other</u>	<u>Total</u>	<u>Weighted- average Useful Life</u>
Core technology and patents .....	\$ 93,200	\$ 54,903	\$148,103	18.7 years
Trademarks and trade names .....	17,300	2,090	19,390	18.3 years
Customer relationships .....	79,600	56,885	136,485	18.1 years
Non-competition agreements .....	—	1,118	1,118	5.1 years
Other .....	13,900	1,327	15,227	9.2 years
In-process research and development .....	—	4,900	4,900	N/A
Total intangible assets .....	<u>\$204,000</u>	<u>\$121,223</u>	<u>\$325,223</u>	

*(b) Acquisitions in 2011*

*(i) Arriva*

On November 23, 2011, we acquired Arriva Medical LLC, or Arriva, located in Coral Springs, Florida, a privately-owned mail-order provider of diabetes home-testing products and supplies. The aggregate purchase price was \$79.5 million, which consisted of a cash payment totaling \$64.4 million and 806,452 shares of our common stock with an aggregate fair value of \$15.2 million. Included in our consolidated statement of operations for the year ended December 31, 2011 is revenue totaling approximately \$5.3 million related to this acquired business. The operating results of Arriva are included in our professional diagnostics reporting unit and business segment. The amount allocated to goodwill from this acquisition is deductible for tax purposes.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(4) Business Combinations (Continued)**

(ii) Axis-Shield

On November 1, 2011, we acquired Axis-Shield, located in Dundee, Scotland, a U.K. publicly traded company focused on the development and manufacture of in vitro diagnostic tests for use in clinical laboratories and at the point of care. The aggregate purchase price was \$388.8 million, which consisted of cash payments totaling \$279.6 million and the fair value of previously-held investment totaling \$109.2 million. Included in our consolidated statement of operations for the year ended December 31, 2011 is revenue totaling approximately \$36.7 million, including \$1.8 million of license and royalty revenue, related to this acquired business. The operating results of Axis-Shield are included in our professional diagnostics reporting unit and business segment. We do not expect the amount allocated to goodwill to be deductible for tax purposes.

(iii) Avee

On October 3, 2011, we acquired Avee Laboratories Inc. and related companies, which we refer to collectively as Avee, located in Tampa, Florida, a privately-owned provider of drug testing services in the field of pain management. The aggregate purchase price was \$120.5 million, which was paid in cash. Included in our consolidated statement of operations for the year ended December 31, 2011 is revenue totaling approximately \$27.2 million related to this acquired business. The operating results of Avee are included in our professional diagnostics reporting unit and business segment. The amount allocated to goodwill from this acquisition is deductible for tax purposes.

(iv) Other acquisitions in 2011

During 2011, we acquired the following businesses for an aggregate purchase price of \$198.5 million, which included cash payments totaling \$139.3 million, a previously-held investment with a fair value totaling \$3.9 million, 25,463 shares of our common stock with an acquisition date fair value of \$1.0 million, contingent consideration obligations with an aggregate acquisition date fair value of \$48.7 million, deferred purchase price consideration with an acquisition date fair value of \$4.2 million and debt forgiveness with a fair value of \$1.5 million.

- 90% interest in BioNote, Inc., or BioNote, headquartered in South Korea, a manufacturer of diagnostic products for the veterinary industry (Acquired January 2011). We previously owned a 10% interest in BioNote.
- assets, including domain name, of Pregnancy.org, LLC, or Pregnancy.org, a U.S.-based company providing a website for preconception, pregnancy and newborn care content, tools and sharing (Acquired January 2011)
- Home Telehealth Limited, subsequently renamed Alere Connected Health Limited, or Alere Connected Health, located in Cardiff, Wales, a company that focuses on delivering integrated, comprehensive services and programs to health and social care providers and insurers (Acquired February 2011)
- Bioeasy Diagnostica Ltda., or Bioeasy, located in Belo Horizonte, Brazil, a company that markets and sells rapid diagnostic tests and systems for laboratory diagnosis, prevention and monitoring of immunological diseases and fertility (Acquired March 2011)
- 80.92% interest in Standing Stone, Inc., or Standing Stone, located in Westport, Connecticut, a company that focuses on disease state management by enhancing the quality of care provided to patients who require long-term therapy for chronic disease management (Acquired May 2011)



## ALERE INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### (4) Business Combinations (Continued)

- certain assets, rights, liabilities and properties of Drug Detection Devices, Inc., or 3DL, located in Alpharetta, Georgia, a distributor that promotes, markets, distributes and sells drugs of abuse diagnostic products, including consumables, point-of-care diagnostic kits and related products and services (Acquired July 2011)
- Colibri Medical AB, or Colibri, located in Helsingborg, Sweden, a distributor of point-of-care drugs of abuse diagnostic products primarily to the Scandinavian marketplace (Acquired July 2011)
- Laboratory Data Systems, Inc., or LDS, located in Tampa, Florida, a provider of healthcare software products, services, consulting and solutions (Acquired August 2011)
- certain assets, liabilities and properties of Abatek Medical LLC, or Abatek, located in Dover, New Hampshire, a distributor that promotes, markets, distributes and sells drugs of abuse diagnostic products, including consumables, point-of-care diagnostic kits and related products and services (Acquired September 2011)
- Forensics Limited, or ROAR, located in Worcestershire, England, a company that provides forensic quality toxicology services across the United Kingdom (Acquired September 2011)
- Mahsan Diagnostika Vertriebsgesellschaft mbH, or Mahsan, located in Reinbek, Germany, a distributor of in vitro diagnostic drugs of abuse products primarily to the German marketplace (Acquired October 2011)
- Medical Automation Systems Inc., or MAS, located in Charlottesville, Virginia, a provider of network-based software solutions for point-of-care testing (Acquired October 2011)
- certain assets and properties of 1 Medical Distribution, Inc., or 1 Medical, located in Worthington, Ohio, a distributor that promotes, markets, distributes and sells drugs of abuse diagnostic products, including consumables, point-of-care diagnostic kits and related products and services (Acquired November 2011)
- Method Factory, Inc. (d/b/a Wellogic), or Wellogic, headquartered in Waltham, Massachusetts, a provider of software solutions designed to connect the healthcare community (Acquired December 2011)

The operating results of BioNote, Bioeasy, 3DL, Colibri, LDS, Abatek, ROAR, Mahsan, MAS and 1 Medical are included in our professional diagnostics reporting unit and business segment. The operating results of Pregnancy.org, Alere Connected Health, Standing Stone and Wellogic are included in our health information solutions reporting unit and business segment.

Our consolidated statement of operations for the year ended December 31, 2011 included revenue totaling approximately \$21.1 million related to these businesses. Goodwill has been recognized in all of the acquisitions, with the exception of 1 Medical, and amounted to approximately \$131.3 million. Goodwill related to the acquisitions of Pregnancy.org, 3DL, Abatek, LDS and Wellogic, which totaled \$32.8 million, is expected to be deductible for tax purposes. The goodwill related to the remaining 2011 acquisitions is not expected to be deductible for tax purposes.

**ALERE INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(4) Business Combinations (Continued)**

A summary of the aggregate purchase price allocation for the acquisitions consummated in 2011 is as follows (in thousands):

	<u>Avee</u>	<u>Arriva</u>	<u>Axis-Shield</u>	<u>Other</u>	<u>Total</u>
Current assets(1) . . . . .	\$ 10,197	\$ 4,874	\$ 92,666	\$ 23,542	\$ 131,279
Property, plant and equipment . . . . .	5,411	524	50,719	11,820	68,474
Goodwill . . . . .	30,409	58,174	136,182	131,348	356,113
Intangible assets . . . . .	76,400	27,400	233,370	79,454	416,624
Other non-current assets . . . . .	—	1,196	18,512	13,009	32,717
Total assets acquired . . . . .	<u>122,417</u>	<u>92,168</u>	<u>531,449</u>	<u>259,173</u>	<u>1,005,207</u>
Current liabilities . . . . .	1,927	12,629	44,758	27,623	86,937
Non-current liabilities . . . . .	—	—	97,842	30,512	128,354
Total liabilities assumed . . . . .	<u>1,927</u>	<u>12,629</u>	<u>142,600</u>	<u>58,135</u>	<u>215,291</u>
Less:					
Fair value of non-controlling interest . . . . .	—	—	—	2,500	2,500
Net assets acquired . . . . .	<u>120,490</u>	<u>79,539</u>	<u>388,849</u>	<u>198,538</u>	<u>787,416</u>
Less:					
Contingent consideration . . . . .	—	—	—	48,685	48,685
Fair value of previously-held equity investment . . . . .	—	—	109,231	3,937	113,168
Fair value of common stock issued . . . . .	—	15,183	—	1,000	16,183
Loan forgiveness . . . . .	—	—	—	1,488	1,488
Deferred purchase price consideration . . . . .	—	—	—	4,170	4,170
Cash paid . . . . .	<u>\$120,490</u>	<u>\$64,356</u>	<u>\$279,618</u>	<u>\$139,258</u>	<u>\$ 603,722</u>

(1) Includes cash acquired of approximately \$23.2 million.

The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	<u>Avee</u>	<u>Arriva</u>	<u>Axis-Shield</u>	<u>Other</u>	<u>Total</u>	<u>Weighted-average Useful Life</u>
Core technology and patents . . . . .	\$ —	\$ —	\$ 56,919	\$ 19,740	\$ 76,659	10.1 years
Database . . . . .	—	—	—	64	64	3.0 years
Trademarks and trade names . . . . .	1,700	1,000	4,145	7,352	14,197	10.1 years
Customer relationships . . . . .	71,500	23,000	114,174	35,051	243,725	12.3 years
Non-compete agreements . . . . .	3,200	3,400	—	1,706	8,306	5.3 years
Software . . . . .	—	—	—	7,400	7,400	10.9 years
Other . . . . .	—	—	—	7,767	7,767	15.6 years
In-process research and development . . . . .	—	—	58,132	374	58,506	N/A
Total intangible assets . . . . .	<u>\$76,400</u>	<u>\$27,400</u>	<u>\$233,370</u>	<u>\$79,454</u>	<u>\$416,624</u>	

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(4) Business Combinations (Continued)**

*(c) Acquisitions in 2010*

(i) Immunalysis

On August 16, 2010, we acquired Diagnostix of California, Corp. (d/b/a Immunalysis Corporation), or Immunalysis, located in Pomona, California, a privately-owned manufacturer and marketer of abused and prescription drug screening solutions used by clinical reference and forensic/crime laboratories. The aggregate purchase price was \$56.2 million, which consisted of an initial cash payment totaling \$55.0 million and a contingent consideration obligation of up to \$5.0 million with an acquisition date fair value of \$1.2 million. Included in our consolidated statement of operations for the year ended December 31, 2010 is revenue totaling approximately \$7.9 million related to this acquired business. The operating results of this acquired operation are included in our professional diagnostics reporting unit and business segment. The amount allocated to goodwill from this acquisition is deductible for tax purposes.

(ii) Twist

On March 11, 2010, we acquired TwistDx, Inc., or Twist, headquartered in Cambridge, Massachusetts, a privately-owned research and development company with a research and development operation in the United Kingdom. The aggregate purchase price was \$70.8 million, which consisted of an initial cash payment totaling \$35.2 million and a contingent consideration obligation of up to \$125.0 million with an acquisition date fair value of \$35.6 million. Included in our consolidated statement of operations for the year ended December 31, 2010 is revenue totaling approximately \$0.2 million related to this acquired business. The operating results of this acquired operation are included in our professional diagnostics reporting unit and business segment. The amount allocated to goodwill from this acquisition is not deductible for tax purposes.

(iii) Alere Toxicology

On February 17, 2010, we acquired Kroll Laboratory Specialists, Inc., subsequently renamed Alere Toxicology Services, or Alere Toxicology, headquartered in Gretna, Louisiana, which provides forensic quality substance abuse testing products and services across the United States. The aggregate purchase price was \$109.5 million, which was paid in cash. Included in our consolidated statement of operations for the year ended December 31, 2010 is revenue totaling approximately \$31.3 million related to this acquired business. The operating results of Alere Toxicology are included in our professional diagnostics reporting unit and business segment. The amount allocated to goodwill from this acquisition is deductible for tax purposes.

(iv) Standard Diagnostics

On February 8, 2010, we acquired a 61.92% ownership interest in Standard Diagnostics via a tender offer for approximately \$162.1 million. On March 22, 2010, we acquired an incremental 13.37% ownership interest in Standard Diagnostics via a follow-on tender offer for approximately \$36.2 million. In June 2010, we acquired an incremental 2.84% ownership interest for approximately \$7.3 million, bringing our acquisition-related aggregate ownership interest in Standard Diagnostics to approximately 78.13%. Standard Diagnostics specializes in the medical diagnostics industry. Its main product lines relate to diagnostic reagents and devices for hepatitis, infectious diseases, tumor markers, fertility, drugs of abuse, urine strips and protein strips. The aggregate purchase price was \$205.6 million in cash. Included in our consolidated statement of operations for the year ended December 31, 2010 is revenue totaling approximately \$78.9 million related to Standard Diagnostics. The operating results of

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(4) Business Combinations (Continued)**

Standard Diagnostics are included in our professional diagnostics reporting unit and business segment. The amount allocated to goodwill from this acquisition is not deductible for tax purposes. During the fourth quarter of 2010, we acquired the remaining outstanding minority interests in Standard Diagnostics bringing our aggregate ownership interest to approximately 100% as of December 31, 2010. In connection with our purchase of shares from a certain minority shareholder, we incurred a compensation charge of \$60.1 million, as a result of the transition of the day-to-day management control of the business to us.

(v) Other acquisitions in 2010

During 2010, we acquired the following businesses for an aggregate purchase price of \$161.9 million, which consisted of initial cash payments totaling \$108.3 million, contingent consideration obligations with an acquisition date fair value of \$52.9 million and deferred purchase price consideration with an acquisition date present value of \$0.7 million.

- RMD Networks, Inc., or RMD, located in Denver, Colorado, a provider of clinical groupware software and services designed to improve communication and coordination of care among providers, patients, and payers in the healthcare environment (Acquired January 2010)
- certain assets of Streck, Inc., or Streck, located in Nebraska, a manufacturer of hematology, chemistry and immunology products for the clinical laboratory (Acquired January 2010)
- assets of the diagnostics division of Micropharm Ltd., or Micropharm, located in Wales, United Kingdom, an expert in high quality antibody production in sheep for both diagnostic and therapeutic purposes, providing antisera on a contract basis for U.K. and overseas companies and academic institutions, mainly for research, therapeutic and diagnostic uses (Acquired March 2010)
- Quantum Diagnostics Group Limited, or Quantum, headquartered in Essex, England, an independent provider of drug testing products and services to healthcare professionals across the U.K. and Europe (Acquired April 2010)
- assets of the workplace health division of Good Health Solutions Pty Ltd., subsequently renamed Alere Health Pty Ltd., located in East Sydney, Australia, an important player in the Australian health and wellness market, focusing on health screenings, health related consulting services, health coaching and fitness instruction (Acquired April 2010)
- certain assets of Unotech Diagnostics, Inc., or Unotech, located in California, a privately-owned company engaged in the development, formulation, manufacture, packaging, supply and distribution of our BladderCheck NMP22 lateral flow test and related lateral flow products (Acquired June 2010)
- Scipac Holdings Limited, or Scipac, headquartered in Kent, England, a diagnostic reagent company with an extensive product portfolio supplying purified human antigens, recombinant proteins and disease state plasma to a global customer base (Acquired June 2010)
- Ionian Technologies, Inc., or Ionian, located in San Diego, California (Acquired July 2010)
- AdnaGen AG, now known as AdnaGen GmbH, or AdnaGen, located in Langenhagen, Germany, a company that focuses on the development of innovative tumor diagnostics for the detection of rare cells (Acquired November 2010)

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(4) Business Combinations (Continued)**

- Medlab Produtos Medicos Hospitalares Ltda, now known as Alere S.A., located in San Paulo, Brazil, a distributor of medical instruments and reagents to public and private laboratories throughout Brazil and Uruguay (Acquired December 2010)
- Capital Toxicology, LLC, or Capital Toxicology, located in Austin, Texas, a privately-held toxicology business specializing in pain management services (Acquired December 2010)

The operating results of the acquired businesses mentioned above, except for RMD and Alere Health Pty Ltd., are included in our professional diagnostics reporting unit and business segment. The operating results of RMD and Alere Health Pty Ltd. are included in our health information solutions reporting unit and business segment. Our consolidated statement of operations for the year ended December 31, 2010 included revenue totaling approximately \$12.6 million related to these businesses. Goodwill has been recognized in all of the acquisitions, with the exception of Unotech and Micropharm, and amounted to approximately \$116.2 million. Goodwill related to the acquisition of Capital Toxicology, which totaled \$11.6 million, is deductible for tax purposes. Goodwill related to all other acquisitions is not deductible for tax purposes.

A summary of the aggregate purchase price allocation for the acquisitions consummated in 2010 is as follows (in thousands):

	<u>Immunoanalysis</u>	<u>Twist</u>	<u>Alere Toxicology</u>	<u>Standard Diagnostics</u>	<u>Other</u>	<u>Total</u>
Current assets(1) .....	\$ 6,933	\$ 373	\$ 6,044	\$ 51,056	\$ 20,829	\$ 85,235
Property, plant and equipment .....	1,076	152	3,300	18,580	13,149	36,257
Goodwill .....	18,234	61,463	53,435	33,798	116,186	283,116
Intangible assets .....	30,600	15,700	48,400	131,179	57,976	283,855
Other non-current assets .....	—	—	—	16,426	562	16,988
Total assets acquired .....	<u>56,843</u>	<u>77,688</u>	<u>111,179</u>	<u>251,039</u>	<u>208,702</u>	<u>705,451</u>
Current liabilities .....	569	731	1,640	13,389	14,749	31,078
Non-current liabilities .....	50	6,107	—	32,088	32,024	70,269
Total liabilities assumed .....	<u>619</u>	<u>6,838</u>	<u>1,640</u>	<u>45,477</u>	<u>46,773</u>	<u>101,347</u>
Net assets acquired .....	56,224	70,850	109,539	205,562	161,929	604,104
Less:						
Contingent consideration .....	1,200	35,600	—	—	52,908	89,708
Present value of deferred purchase price consideration .....	—	—	—	—	688	688
Cash paid .....	<u>\$55,024</u>	<u>\$35,250</u>	<u>\$109,539</u>	<u>\$205,562</u>	<u>\$108,333</u>	<u>\$513,708</u>

(1) Includes cash acquired of approximately \$22.9 million.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(4) Business Combinations (Continued)**

The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	<u>Immunalysis</u>	<u>Twist</u>	<u>Alere Toxicology</u>	<u>Standard Diagnostics</u>	<u>Other</u>	<u>Total</u>	<u>Weighted-average Useful Life</u>
Core technology and patents . . .	\$ 8,800	\$ 8,600	\$13,300	\$ 62,135	\$14,050	\$106,885	12.4 years
Quality systems . . . . .	—	—	—	—	153	153	5 years
Database . . . . .	—	—	—	—	654	654	3 years
Trademarks and trade names . .	800	—	—	9,350	1,504	11,654	6.3 years
License agreements . . . . .	—	—	—	—	459	459	5 years
Customer relationships . . . . .	19,900	—	35,100	45,754	24,578	125,332	14.3 years
Non-compete agreements . . . . .	300	—	—	255	2,095	2,650	4.2 years
Software . . . . .	—	—	—	—	5,000	5,000	7 years
Distribution agreement . . . . .	800	—	—	—	—	800	14 years
Manufacturing know-how . . . . .	—	—	—	—	3,683	3,683	10.5 years
In-process research and development . . . . .	—	7,100	—	13,685	5,800	26,585	N/A
Total intangible assets . . . . .	<u>\$30,600</u>	<u>\$15,700</u>	<u>\$48,400</u>	<u>\$131,179</u>	<u>\$57,976</u>	<u>\$283,855</u>	

**(5) Goodwill and Other Intangible Assets**

The following is a summary of goodwill and other intangible assets as of December 31, 2012 (dollars in thousands):

	<u>Gross Carrying Amount</u>	<u>Accumulated Amortization and Impairment Losses</u>	<u>Net Carrying Value</u>	<u>Weighted-average Useful Life</u>
<b>Amortized intangible assets:</b>				
Core technology and patents . . . . .	\$ 941,940	\$ 326,044	\$ 615,896	14.12 years
Other intangible assets:				
Supplier relationships . . . . .	18,629	15,862	2,767	9.25 years
Trademarks and trade names . . . . .	252,028	116,571	135,457	10.30 years
License agreements . . . . .	17,507	11,126	6,381	4.47 years
Customer relationships . . . . .	1,910,752	930,542	980,210	15.76 years
Manufacturing know-how . . . . .	15,332	9,607	5,725	12.21 years
Other . . . . .	199,880	112,091	87,789	7.41 years
Total other intangible assets . . . . .	<u>2,414,128</u>	<u>1,195,799</u>	<u>1,218,329</u>	
Total intangible assets with finite lives . . . . .	<u>\$3,356,068</u>	<u>\$1,521,843</u>	<u>\$1,834,225</u>	
<b>Intangible assets with indefinite lives:</b>				
Goodwill . . . . .	\$4,438,374	\$1,389,969	\$3,048,405	
Other intangible assets(1) . . . . .	62,935	26,484	36,451	
Total intangible assets with indefinite lives . .	<u>\$4,501,309</u>	<u>\$1,416,453</u>	<u>\$3,084,856</u>	

(1) Primarily includes an in-process research and development asset recorded in connection with certain acquisitions.



**ALERE INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(5) Goodwill and Other Intangible Assets (Continued)**

The following is a summary of goodwill and other intangible assets as of December 31, 2011 (dollars in thousands):

	Gross Carrying Amount	Accumulated Amortization and Impairment Losses	Net Carrying Value	Weighted- average Useful Life
<b>Amortized intangible assets:</b>				
Core technology and patents . . . . .	\$ 756,835	\$ 253,266	\$ 503,569	13.16 years
Other intangible assets:				
Supplier relationships . . . . .	18,652	14,709	3,943	9.19 years
Trademarks and trade names . . . . .	232,938	86,932	146,006	9.73 years
License agreements . . . . .	17,429	10,714	6,715	4.47 years
Customer relationships . . . . .	1,753,985	717,826	1,036,159	15.55 years
Manufacturing know-how . . . . .	10,996	6,139	4,857	12.70 years
Other . . . . .	168,005	83,329	84,676	7.90 years
Total other intangible assets . . . . .	<u>2,202,005</u>	<u>919,649</u>	<u>1,282,356</u>	
Total intangible assets with finite lives . . . . .	<u>\$2,958,840</u>	<u>\$1,172,915</u>	<u>\$1,785,925</u>	
<b>Intangible assets with indefinite lives:</b>				
Goodwill . . . . .	\$4,211,240	\$1,389,969	\$2,821,271	
Other intangible assets(1) . . . . .	76,686	7,140	69,546	
Total intangible assets with indefinite lives . . . . .	<u>\$4,287,926</u>	<u>\$1,397,109</u>	<u>\$2,890,817</u>	

(1) Primarily includes an in-process research and development asset recorded in connection with certain acquisitions.

The estimated useful lives of the individual categories of intangible assets were based on the nature of the applicable intangible assets and the expected future cash flows to be derived from those intangible assets. Amortization of intangible assets with finite lives is recognized over the shorter of the respective lives of the underlying license agreements, if applicable, or the period of time the assets are expected to contribute to future cash flows. We amortize our finite-lived intangible assets on patterns in which the economic benefits are expected to be realized. Amortization expense of intangible assets, which in the aggregate amounted to \$346.9 million, \$307.7 million and \$298.1 million in 2012, 2011 and 2010, respectively, is included in cost of net revenue, research and development, sales and marketing and general and administrative expenses in the accompanying consolidated statements of operations. The allocation of amortization expense to the expense categories is based on the intended usage and the expected benefits of the intangible assets in relation to the expense categories.

The following is a summary of estimated aggregate amortization expense of intangible assets for each of the five succeeding fiscal years as of December 31, 2012 (in thousands):

2013 . . . . .	\$299,473
2014 . . . . .	\$256,907
2015 . . . . .	\$232,489
2016 . . . . .	\$204,639
2017 . . . . .	\$163,382

During the fourth quarter, we perform our annual impairment tests of the carrying value of our goodwill by reporting unit. Our annual impairment review conducted during the fourth quarters of 2011 and 2010 indicated that a goodwill impairment charge was required in our health information solutions business segment and reporting unit. For further discussion see Note 2(h).

**ALERE INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(5) Goodwill and Other Intangible Assets (Continued)**

Goodwill amounts for our professional diagnostics, health information solutions and consumer diagnostics reporting units are summarized as follows (in thousands):

	<u>Professional Diagnostics</u>	<u>Health Information Solutions</u>	<u>Consumer Diagnostics</u>	<u>Total</u>
Goodwill at December 31, 2010 .....	\$2,326,114	\$ 452,962	\$52,224	\$2,831,300
Acquisitions(1) .....	352,986	31,043	—	384,029
Goodwill impairment charge(2) .....	—	(383,612)	—	(383,612)
Other(3) .....	(9,499)	(634)	(313)	(10,446)
Goodwill at December 31, 2011 .....	\$2,669,601	\$ 99,759	\$51,911	\$2,821,271
Acquisitions(1) .....	222,306	24,604	—	246,910
Fair value of non-controlling interest(4) .....	(36,040)	—	—	(36,040)
Other(3) .....	10,370	680	5,214	16,264
Goodwill at December 31, 2012 .....	<u>\$2,866,237</u>	<u>\$ 125,043</u>	<u>\$57,125</u>	<u>\$3,048,405</u>

- (1) Includes initial purchase price allocation, purchase accounting adjustments recorded to the acquired entities' opening balance sheet and additional payments made for earn-outs and milestones achieved.
- (2) We recorded a goodwill impairment charge of approximately \$383.6 million during 2011 related to our health information solutions business segment and reporting unit. 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.
- (3) These amounts relate primarily to adjustments resulting from fluctuations in foreign currency exchange rates.
- (4) This is the correction of a prior period balance sheet classification error which we do not believe is material to our 2011 or 2012 annual financial statements, or any previously reported quarterly financial statements, and represents the fair value of the non-controlling interest as of December 31, 2011 related to our acquisition of Axis-Shield.

We generally expense costs incurred for the internal development of intangible assets, except for costs that are incurred to establish patents and trademarks, such as legal fees for initiating, filing and obtaining the patents and trademarks. As of December 31, 2012 and 2011, we had approximately \$9.7 million and \$9.2 million, respectively, of costs capitalized, net of amortization, in connection with establishing patents and trademarks which are included in other intangible assets, net, in the accompanying consolidated balance sheets. Upon the initial filing of the patents and trademarks, we commence amortization of such intangible assets over their estimated useful lives. Costs incurred to maintain the patents and trademarks are expensed as incurred.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(6) Long-term Debt**

We had the following long-term debt balances outstanding (in thousands):

	<u>December 31,</u> <u>2012</u>	<u>December 31,</u> <u>2011</u>
A term loans(1)(2) .....	\$ 878,438	\$ 917,188
B term loans(1) .....	913,438	922,688
Incremental B-1 term loans(1) .....	247,500	250,000
Incremental B-2 term loans(1) .....	196,739	—
Revolving line of credit(1) .....	22,500	—
7.25% Senior notes .....	450,000	—
7.875% Senior notes .....	1,809	245,621
9% Senior subordinated notes .....	392,933	391,233
8.625% Senior subordinated notes .....	400,000	400,000
3% Convertible senior subordinated notes .....	150,000	150,000
Other lines of credit .....	31,957	19,603
Other .....	3,593	32,210
	<u>3,688,907</u>	<u>3,328,543</u>
Less: Current portion .....	(60,232)	(61,092)
	<u>\$3,628,675</u>	<u>\$3,267,451</u>

(1) Incurred under our secured credit facility.

(2) Includes “A” term loans and “Delayed Draw” term loans under our secured credit facility.

In connection with our significant long-term debt issuances, we recorded interest expense, including amortization and write-offs of deferred financing costs and original issue discounts, in our consolidated statements of operations for the years ended December 31, 2012, 2011 and 2010, respectively, as follows (in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Secured credit facility(1) .....	\$104,916	\$ 41,478	\$ —
Former secured credit facility(2) .....	—	53,841(3)	60,594
7.25% Senior notes .....	1,994	—	—
7.875% Senior notes .....	44,994(4)	22,291	21,300
9% Senior subordinated notes .....	41,474	40,248	38,337
8.625% Senior subordinated notes .....	37,096	36,437	9,892
3% Convertible senior subordinated notes .....	4,984	4,988	4,986
	<u>\$235,458</u>	<u>\$199,283</u>	<u>\$135,109</u>

(1) Includes “A” term loans, including the “Delayed-Draw” term loans; “B” term loans; “Incremental B-1” term loans; “Incremental B-2” term loans; and revolving line-of-credit loans. The amount includes \$5.0 million and \$2.9 million in 2012 and 2011, respectively, related to the amortization of fees paid for certain debt modifications.

(2) Consists of loans under our former First Lien Credit Agreement and Second Lien Credit Agreement.

(3) Amount includes approximately \$29.7 million recorded in connection with the termination of our former secured credit facility and related interest rate swap agreement, coupled with the amortization of fees paid for certain debt modifications.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(6) Long-term Debt (Continued)**

- (4) Amount includes approximately \$23.2 million loss recorded in connection with the repurchase of substantially all of our 7.875% senior notes. Included in the \$23.2 million is a \$12.3 million make-whole payment which has been classified within cash flow from financing activities in our consolidated statement of cash flows.

The following describes each of the debt instruments listed above:

*(a) Secured Credit Facility*

On June 30, 2011, we entered into a Credit Agreement, or secured credit facility, with certain lenders, General Electric Capital Corporation as administrative agent and collateral agent, and certain other agents and arrangers, and, along with certain of our subsidiaries, a related guaranty and security agreement. On December 7, 2011, we entered into an amendment to our secured credit facility to provide an additional term loan facility for the "Incremental B-1" term loans described below (all of which we borrowed on that date). On March 28, 2012, we entered into a further amendment to our secured credit facility to provide an additional term loan facility for the "Incremental B-2" term loans described below (all of which we borrowed on that date). The secured credit facility, as amended, provides for credit facilities totaling \$2.55 billion in the aggregate, consisting of term loans in the aggregate principal amount of \$2.3 billion (consisting of "A" term loans (including "Delayed Draw" term loans) in the aggregate principal amount of \$925.0 million, "B" term loans in the aggregate principal amount of \$925.0 million, "Incremental B-1" term loans in the aggregate principal amount of \$250.0 million and "Incremental B-2" term loans in the aggregate principal amount of \$200.0 million), all of which we have fully drawn, and, subject to our continued compliance with the secured credit facility, a \$250.0 million revolving line of credit (which includes a \$50.0 million sublimit for the issuance of letters of credit).

We must repay the "A" term loans (excluding the "Delayed Draw" term loans) in eighteen consecutive quarterly installments, which began on December 31, 2011 and continue through March 31, 2016, in the amount of \$7,812,500 each, and a final installment on June 30, 2016, in the amount of \$484,375,000; we must repay the "Delayed-Draw" term loans included within the "A" term loans in fifteen consecutive quarterly installments, which began on September 30, 2012 and continue through March 31, 2016, in the amount of \$3,750,000 each, and a final installment on June 30, 2016, in the amount of \$243,750,000. We must repay the "B" term loans in twenty-two consecutive quarterly installments, which began on December 31, 2011 and continue through March 31, 2017, in the amount of \$2,312,500 each, and a final installment on June 30, 2017, in the amount of \$874,125,000. We must repay the "Incremental B-1" term loans in twenty-one consecutive quarterly installments, which began on March 31, 2012 and continue through March 31, 2017, in the amount of \$625,000 each, and a final installment on June 30, 2017, in the amount of \$236,875,000. We must repay the "Incremental B-2" term loans in twenty consecutive quarterly installments, which began on June 30, 2012 and continue through March 31, 2017, in the amount of \$500,000 each, and a final installment on June 30, 2017, in the amount of \$190,000,000. We have paid in full all installments of all term loans due on or before December 31, 2012. We may repay any borrowings under the revolving line of credit at any time without premium or penalty, but we must repay all such borrowings in no event later than June 30, 2016. Notwithstanding the foregoing, and subject to certain exceptions provided for in the Credit Agreement, in the event that any of our existing 9% senior subordinated notes or existing 3% convertible senior subordinated notes remain outstanding on the date that is six months prior to the relevant maturity date thereof, respectively, then all of the term loans and revolving credit loans under the secured credit facility shall instead mature in full on the relevant prior date.

The "A" term loans (including the "Delayed Draw" term loans) and our borrowings under the revolving credit facility bear interest at a rate *per annum* of, at our option, either (i) the Base Rate, as

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(6) Long-term Debt (Continued)**

defined in the Credit Agreement, plus an applicable margin, which varies between 1.75% and 2.50% depending on our consolidated secured leverage ratio, or (ii) the Eurodollar Rate, as defined in the Credit Agreement, plus an applicable margin, which varies between 2.75% and 3.50% depending on our consolidated secured leverage ratio. The "B" term loans, the "Incremental B-1" term loans and the "Incremental B-2" term loans bear interest at a rate *per annum* of, at our option, either (i) the Base Rate, as defined in the Credit Agreement, plus an applicable margin, which varies between 2.50% and 3.25% depending on our consolidated secured leverage ratio, or (ii) the Eurodollar Rate, as defined in the Credit Agreement, plus an applicable margin, which varies between 3.50% and 4.25% depending on our consolidated secured leverage ratio. Interest on "B" term loans, "Incremental B-1" term loans and "Incremental B-2" term loans based on the Eurodollar Rate is subject to a 1.00% floor with respect to the base Eurodollar Rate. We are required to pay a fee on the unused portion of the revolving credit facility at a rate *per annum* of 0.50%. As of December 31, 2012, the "A" term loans (including the "Delayed-Draw" term loans), the "B" term loans, the "Incremental B-1" term loans, the "Incremental B-2" term loans and the revolving line of credit loans bore interest at rates of 3.21%, 4.75%, 4.75%, 4.75% and 3.21%, respectively, *per annum*.

As of December 31, 2012, we were in compliance with all financial covenants related to the above debt, which consisted principally of a maximum consolidated secured leverage ratio, a minimum consolidated interest coverage ratio and a limit on capital expenditures.

As of December 31, 2012, accrued interest related to the secured credit facility amounted to \$1.4 million.

*(b) First Lien Credit Agreement and Second Lien Credit Agreement*

In connection with entering into the secured credit facility on June 30, 2011, we repaid in full all outstanding indebtedness under and terminated our First Lien Credit Agreement, or senior secured credit facility, and our Second Lien Credit Agreement, or junior secured credit facility (and, collectively with the senior secured credit facility, our former secured credit facility), each dated June 26, 2007, with certain lenders, General Electric Capital Corporation, as administrative agent and collateral agent, and certain other agents and arrangers, and certain related guaranty and security agreements. The aggregate outstanding principal amount of the loans repaid under our former secured credit facility in connection with the termination thereof was approximately \$1.2 billion.

In August 2007, we entered into interest rate swap contracts, with an effective date of September 28, 2007, that had a total notional value of \$350.0 million and an original maturity date of September 28, 2010. These interest rate swap contracts paid us variable interest at the three-month LIBOR rate, and we paid the counterparties a fixed rate of 4.85%. In March 2009, we extended our August 2007 interest rate hedge for an additional two-year period commencing in September 2010 at a one-month LIBOR rate of 2.54%. These interest rate swap contracts were entered into to convert \$350.0 million of the \$1.2 billion variable rate term loans under our former secured credit facility into fixed rate debt. In connection with entering into the secured credit facility on June 30, 2011, we paid \$10.1 million to terminate these interest rate swap contracts which was recorded in interest expense, including amortization of original issue discounts and deferred financing costs, in our consolidated statements of operations.

In January 2009, we entered into interest rate swap contracts, with an effective date of January 14, 2009, that had a total notional value of \$500.0 million and a maturity date of January 5, 2011. These interest rate swap contracts paid us variable interest at the one-month LIBOR rate, and

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(6) Long-term Debt (Continued)**

we paid the counterparties a fixed rate of 1.195%. These interest rate swap contracts were entered into to convert \$500.0 million of the \$1.2 billion variable rate term loan under our former secured credit facility into fixed rate debt. We did not extend the terms of these interest rate swap contracts after January 5, 2011.

*(c) 7.25% Senior Notes*

On December 11, 2012, we sold a total of \$450.0 million aggregate principal amount of 7.25% senior notes due 2018, or the 7.25% senior notes, in a private placement to initial purchasers, who agreed to resell the notes only to qualified institutional buyers and to persons outside the United States; we sold the 7.25% senior notes at an initial offering price of 100%. Net proceeds from this offering amounted to \$443.2 million, which was net of the underwriters' commissions and offering expenses totaling \$6.8 million. We used \$267.4 million of the net proceeds to purchase \$248.2 million outstanding principal amount of the 7.875% senior notes as described below and \$170.0 million to pay down a portion of the outstanding balance under our revolving line of credit.

The 7.25% senior notes were issued under an indenture dated August 11, 2009, as amended or supplemented, the 7.25% Indenture. The 7.25% senior notes accrue interest at the rate of 7.25% per annum. Interest on the 7.25% senior notes is payable semi-annually on June 15 and December 15, beginning on June 15, 2013. The 7.25% senior notes mature on July 1, 2018, unless earlier redeemed.

We may redeem the 7.25% senior notes, in whole or part, at any time on or after December 15, 2015, by paying the principal amount of the notes being redeemed plus a declining premium, plus accrued and unpaid interest to, but excluding, the redemption date. The premium declines from 3.625% during the twelve months on and after December 15, 2015 to 1.813% during the six months on and after December 15, 2016 to zero on and after June 15, 2017. At any time prior to December 15, 2015, we may redeem up to 35% of the aggregate principal amount of the 7.25% senior notes with money that we raise in certain equity offerings, so long as (i) we pay 107.25% of the principal amount of the notes being redeemed, plus accrued and unpaid interest to, but excluding, the redemption date; (ii) we redeem the notes within 90 days of completing such equity offering; and (iii) at least 65% of the aggregate principal amount of the 7.25% senior notes remains outstanding afterwards. In addition, at any time prior to December 15, 2015, we may redeem some or all of the 7.25% senior notes by paying the principal amount of the notes being redeemed plus a make-whole premium, plus accrued and unpaid interest to, but excluding, the redemption date.

If a change of control occurs, subject to specified conditions, we must give holders of the 7.25% senior notes an opportunity to sell their notes to us at a purchase price of 101% of the principal amount of the notes, plus accrued and unpaid interest to, but excluding, the date of the purchase.

If we, or our subsidiaries, engage in asset sales, we, or they, generally must either invest the net cash proceeds from such sales in our or their businesses within a specified period of time, prepay certain indebtedness or make an offer to purchase a principal amount of the 7.25% senior notes equal to the excess net cash proceeds, subject to certain exceptions. The purchase price of the notes would be 100% of their principal amount, plus accrued and unpaid interest.

The 7.25% senior notes are unsecured and are equal in right of payment to all of our existing and future senior debt, including our borrowings under our secured credit facility. Our obligations under the 7.25% senior notes and the 7.25% Indenture are fully and unconditionally guaranteed, jointly and



**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(6) Long-term Debt (Continued)**

severally, on an unsecured senior basis by certain of our domestic subsidiaries, and the obligations of such domestic subsidiaries under their guarantees are equal in right of payment to all of their existing and future senior debt. See Note 24 for guarantor financial information.

The 7.25% Indenture contains covenants that limit our ability, and the ability of our subsidiaries, to, among other things, incur additional debt; pay dividends on capital stock or redeem, repurchase or retire capital stock or subordinated debt; make certain investments; create liens on assets; transfer or sell assets; engage in transactions with affiliates; create restrictions on our or their ability pay dividends or make loans, asset transfers or other payments to us or them; issue capital stock; engage in any business, other than our or their existing businesses and related businesses; enter into sale and leaseback transactions; incur layered indebtedness; and consolidate, merge or transfer all or substantially all of our, or their, assets, taken as a whole. These covenants are subject to certain exceptions and qualifications. The 7.25% Indenture contains customary events of default entitling the trustee or the holders of the 7.25% senior notes to declare all amounts owed pursuant to the 7.25% senior notes immediately payable if we violate certain of our obligations.

As of December 31, 2012, accrued interest related to the 7.25% senior notes amounted to \$1.9 million.

*(d) 7.875% Senior Notes*

During the third quarter of 2009, we sold a total of \$250.0 million aggregate principal amount of 7.875% senior notes due 2016, or the 7.875% senior notes, in two separate transactions on August 11, 2009 and September 28, 2009. Net proceeds from these offerings amounted to approximately \$240.0 million, which was net of underwriters' commissions totaling \$3.7 million and original issue discount totaling \$6.3 million. The 7.875% senior notes were issued under an indenture dated August 11, 2009, as amended or supplemented, the 7.875% Indenture. The 7.875% senior notes accrued interest from the dates of their respective issuances at the rate of 7.875% per annum. Interest on the notes was payable semi-annually on February 1 and August 1, commencing on February 1, 2010. The terms of the notes provided that they matured on February 1, 2016, unless earlier redeemed.

In December 2012, we used \$267.4 million of the net proceeds of our sale of the 7.25% senior notes to purchase \$248.2 million outstanding principal amount of the 7.875% senior notes. The purchased 7.875% senior notes represented 99.3% of the total then-outstanding principal amount of the 7.875% senior notes.

On February 13, 2013, we redeemed the remaining \$1.8 million outstanding principal amount of the 7.875% senior notes pursuant to our optional redemption right under the 7.875% Indenture, and we subsequently terminated the 7.875% Indenture.

As of December 31, 2012, accrued interest related to the 7.875% senior notes amounted to \$0.1 million.

*(e) Senior Subordinated Notes*

On May 12, 2009, we sold \$400.0 million aggregate principal amount of 9% senior subordinated notes due 2016, or the 9% subordinated notes, in a public offering at an initial offering price of 96.865%. Net proceeds from this offering amounted to \$379.5 million, which was net of underwriters' commissions totaling \$8.0 million and original issue discount totaling \$12.5 million.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(6) Long-term Debt (Continued)**

On September 21, 2010, we sold \$400.0 million aggregate principal amount of 8.625% senior subordinated notes due 2018, or the 8.625% subordinated notes, in a private placement to initial purchasers, who agreed to resell the notes only to qualified institutional buyers and to persons outside the United States; we sold the 8.625% subordinated notes at an initial offering price of 100%. Net proceeds from this offering amounted to \$393.0 million, which was net of underwriters' commissions totaling \$7.0 million. These notes were subsequently exchanged for new notes having substantially the same terms in an exchange offer registered under the Securities Act. We refer to the 9% subordinated notes and the 8.625% subordinated notes collectively as our senior subordinated notes.

The 9% subordinated notes, which were issued under an indenture dated May 12, 2009, as amended or supplemented, accrue interest from the date of their issuance, or May 12, 2009, at the rate of 9% *per annum*. Interest on the 9% subordinated notes is payable semi-annually on May 15 and November 15, beginning on November 15, 2009. The 9% subordinated notes mature on May 15, 2016, unless earlier redeemed. The 8.625% subordinated notes, which were issued under a supplemental indenture dated September 21, 2010, as amended or supplemented, accrue interest from the date of their issuance, or September 21, 2010, at the rate of 8.625% *per annum*. Interest on the 8.625% notes is payable semi-annually on April 1 and October 1, beginning on April 1, 2011. The 8.625% subordinated notes mature on October 1, 2018, unless earlier redeemed.

We may redeem the 9% subordinated notes, in whole or part, at any time (which may be more than once) on or after May 15, 2013, by paying the principal amount of the notes being redeemed plus a declining premium, plus accrued and unpaid interest to, but excluding, the redemption date. The premium declines from 4.50% during the twelve months after May 15, 2013 to 2.25% during the twelve months after May 15, 2014 to zero on and after May 15, 2015. In addition, at any time prior to May 15, 2013, we may redeem some or all of the 9% subordinated notes by paying the principal amount of the notes being redeemed plus a make-whole premium, plus accrued and unpaid interest to, but excluding, the redemption date.

We may redeem the 8.625% subordinated notes, in whole or part, at any time (which may be more than once) on or after October 1, 2014, by paying the principal amount of the notes being redeemed plus a declining premium, plus accrued and unpaid interest to, but excluding, the redemption date. The premium declines from 4.313% during the twelve months on and after October 1, 2014 to 2.156% during the twelve months on and after October 1, 2015 to zero on and after October 1, 2016. Prior to October 1, 2013, we may redeem, in whole or part, at any time (which may be more than once), up to 35% of the aggregate principal amount of the 8.625% subordinated notes with money that we raise in certain equity offerings so long as (i) we pay 108.625% of the principal amount of the notes being redeemed, plus accrued and unpaid interest to, but excluding, the redemption date; (ii) we redeem the notes within 90 days of completing such equity offering; and (iii) at least 65% of the aggregate principal amount of the 8.625% subordinated notes, including any 8.625% subordinated notes issued after September 21, 2010, remains outstanding afterwards. In addition, at any time prior to October 1, 2014, we may redeem some or all of the 8.625% subordinated notes by paying the principal amount of the notes being redeemed plus a make-whole premium, plus accrued and unpaid interest to, but excluding, the redemption date.

If a change of control occurs, subject to specified conditions, we must give holders of the senior subordinated notes an opportunity to sell their notes to us at a purchase price of 101% of the principal amount of the notes, plus accrued and unpaid interest to, but excluding, the date of the purchase.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(6) Long-term Debt (Continued)**

If we, or our subsidiaries, engage in asset sales, we, or they, generally must either invest the net cash proceeds from such sales in our or their businesses within a specified period of time, prepay senior debt or make an offer to purchase a principal amount of the senior subordinated notes (on a *pro rata* basis with respect to the 9% subordinated notes and the 8.625% subordinated notes) equal to the excess net cash proceeds, subject to certain exceptions. The purchase price of the senior subordinated notes would be 100% of their principal amount, plus accrued and unpaid interest.

The senior subordinated notes are unsecured and are subordinated in right of payment to all of our existing and future senior debt, including our borrowings under our secured credit facility and our senior notes, and equal in right of payment to our 3% convertible senior subordinated notes. Our obligations under the senior subordinated notes and the indentures under which they were issued are fully and unconditionally guaranteed, jointly and severally, on an unsecured senior subordinated basis by certain of our domestic subsidiaries, and the obligations of such domestic subsidiaries under their guarantees are subordinated in right of payment to all of their existing and future senior debt, including their guarantees with respect to our secured credit facility and our senior notes. See Note 24 for guarantor financial information.

The indentures under which the senior subordinated notes were issued contain covenants that limit our ability, and the ability of our subsidiaries, to, among other things, incur additional debt; pay dividends on capital stock or redeem, repurchase or retire capital stock or subordinated debt; make certain investments; create liens on assets; transfer or sell assets; engage in transactions with affiliates; create restrictions on our or their ability pay dividends or make loans, asset transfers or other payments to us or them; issue capital stock; engage in any business, other than our or their existing businesses and related businesses; enter into sale and leaseback transactions; incur layered indebtedness; and consolidate, merge or transfer all or substantially all of our, or their, assets, taken as a whole. These covenants are subject to certain exceptions and qualifications. These indentures contain customary events of default entitling the trustee or the holders of the relevant senior subordinated notes to declare all amounts owed pursuant the relevant senior subordinated notes immediately payable if we violate certain of our obligations with respect thereto.

As of December 31, 2012, accrued interest related to the 9% subordinated notes and the 8.625% subordinated notes amounted to \$4.5 million and \$8.6 million, respectively.

*(f) 3% Convertible Senior Subordinated Notes*

On May 14, 2007, we sold \$150.0 million principal amount of 3% convertible senior subordinated notes due 2016, or the 3% convertible senior subordinated notes, in a private placement to qualified institutional buyers, at an initial offering price of 100%. At the initial conversion price of \$52.30, the 3% convertible senior subordinated notes were convertible into an aggregate of 2.9 million shares of our common stock. The conversion price was subject to adjustment one year from the date of sale. Based upon the daily volume-weighted price per share of our common stock for the thirty consecutive trading days ending May 9, 2008, the conversion price decreased from \$52.30 to \$43.98 in May 2008. The decrease in conversion price resulted in additional shares of our common stock becoming issuable upon conversion of the 3% convertible senior subordinated notes. The 3% convertible senior subordinated notes are now convertible into 3.4 million shares of our common stock at a conversion price of \$43.98. Interest accrues at 3% *per annum*, compounded daily, on the outstanding principal amount of the 3% convertible senior subordinated notes and is payable in arrears on May 15th and November 15th of each year, beginning on November 15, 2007. We have paid in full all installments of interest on the 3% convertible senior subordinated notes due on or before December 31, 2012.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(6) Long-term Debt (Continued)**

We may not redeem the 3% convertible senior subordinated notes prior to their stated maturity. In the event of certain fundamental changes (as defined in the indenture governing the 3% convertible senior subordinated notes) or a termination of trading of our common stock (as described in such indenture), we may be required to repurchase the 3% convertible senior subordinated notes for cash at a price equal to 100% of the unconverted principal amount thereof plus any accrued but unpaid interest. The 3% convertible senior subordinated notes are unsecured and are subordinated in right of payment to all of our existing and future senior debt, including borrowings under our secured credit facility and our senior notes, and equal in right of payment to our senior subordinated notes. The indenture governing the 3% convertible senior subordinated notes contains customary events of default entitling the trustee or the holders thereof to declare all amounts owed pursuant to the 3% convertible senior subordinated notes immediately payable if we violate certain of our obligations with respect thereto.

As of December 31, 2012, accrued interest related to the 3% convertible senior subordinated notes amounted to \$0.6 million.

*(g) Lines of Credit*

Some of our subsidiaries maintain local lines of credit for short-term advances. Total available credit under the local lines of credit is approximately \$19.7 million, of which \$9.5 million was borrowed and outstanding as of December 31, 2012.

*(h) Other Debt*

Included in other debt for the year ended December 31, 2012 are borrowings by certain of our subsidiaries from various financial institutions. The borrowed funds are primarily used to fund capital expenditures and working capital requirements. Interest expense on these borrowings was \$5.1 million for the year ended December 31, 2012.

*(i) Maturities of Long-term Debt*

The following is a summary of the maturities of long-term debt outstanding on December 31, 2012 (in thousands):

2013 .....	\$ 60,232
2014 .....	48,745
2015 .....	49,304
2016 .....	1,380,335
2017 .....	1,304,904
Thereafter .....	854,251
	<u>3,697,771</u>
Less: Original issue discounts .....	(8,864)
	<u><u>\$3,688,907</u></u>

**ALERE INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(7) Fair Value Measurements**

The following tables present information about our assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2012 and 2011, and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value (in thousands):

<u>Description</u>	<u>December 31, 2012</u>	<u>Quoted Prices in Active Markets (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Unobservable Inputs (Level 3)</u>
<b>Assets:</b>				
Marketable securities .....	\$ 904	\$ 904	\$ —	\$ —
Total assets .....	<u>\$ 904</u>	<u>\$ 904</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Contingent consideration obligations(1) ...	\$176,172	\$ —	\$ —	\$176,172
Total liabilities .....	<u>\$176,172</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$176,172</u>

<u>Description</u>	<u>December 31, 2011</u>	<u>Quoted Prices in Active Markets (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Unobservable Inputs (Level 3)</u>
<b>Assets:</b>				
Marketable securities .....	\$ 3,340	\$ 3,340	\$ —	\$ —
Total assets .....	<u>\$ 3,340</u>	<u>\$ 3,340</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Contingent consideration obligations(1) ...	\$140,047	\$ —	\$ —	\$140,047
Foreign exchange forward contracts(2) ....	447	—	447	—
Total liabilities .....	<u>\$140,494</u>	<u>\$ —</u>	<u>\$ 447</u>	<u>\$140,047</u>

- (1) We determine the fair value of the contingent consideration obligations based on a probability-weighted approach derived from earn-out criteria estimates and a probability assessment with respect to the likelihood of achieving the various earn-out criteria. The measurement is based upon significant inputs not observable in the market. Significant increases or decreases in any of these inputs could result in a significantly higher or lower fair value measurement. Changes in the fair value of these contingent consideration obligations are recorded as income or expense within operating income in our consolidated statements of operations. See Note 11 for additional information on the valuation of our contingent consideration obligations.
- (2) The fair value of the foreign exchange forward contracts was measured using readily observable market inputs, such as quotations on forward foreign exchange points and foreign interest rates.

Changes in the fair value of our Level 3 contingent consideration obligations during the year ended December 31, 2012 were as follows (in thousands):

Fair value of contingent consideration obligations, January 1, 2012 .....	\$140,047
Acquisition date fair value of contingent consideration obligations recorded .....	75,620
Foreign currency adjustments .....	395
Payments .....	(33,211)
Present value accretion .....	19,230
Adjustments, net (income) expense .....	<u>(25,909)</u>
Fair value of contingent consideration obligations, December 31, 2012 .....	<u>\$176,172</u>

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(7) Fair Value Measurements (Continued)**

At December 31, 2012 and 2011, the carrying amounts of cash and cash equivalents, restricted cash, receivables, accounts payable and other current liabilities approximated their estimated fair values.

The carrying amount and estimated fair value of our long-term debt were \$3.7 billion at December 31, 2012. The carrying amount and estimated fair value of our long-term debt were \$3.3 billion at December 31, 2011. The estimated fair value of our long-term debt was determined using information derived from available market sources (Level 2 in the fair value hierarchy) and may not be representative of actual values that could have been or will be realized in the future.

**(8) Capital Leases**

The following is a schedule of the future minimum lease payments under capital leases, together with the present value of such payments as of December 31, 2012 (in thousands):

2013 .....	\$ 6,683
2014 .....	5,096
2015 .....	4,332
2016 .....	1,944
2017 .....	838
Thereafter .....	<u>708</u>
Total future minimum lease payments .....	19,601
Less: Imputed interest .....	<u>—</u>
Present value of future minimum lease payments .....	19,601
Less: Current portion .....	<u>(6,684)</u>
	<u>\$12,917</u>

At December 31, 2012, the capitalized amounts of the building, machinery and equipment and computer equipment under capital leases were as follows (in thousands):

Machinery, laboratory equipment and tooling .....	\$33,096
Computer equipment .....	633
Furniture and fixtures .....	210
Vehicles .....	39
Leasehold improvements .....	<u>—</u>
	33,978
Less: Accumulated amortization .....	<u>(4,351)</u>
	<u>\$29,627</u>

The amortization expense of assets recorded under capital leases is included in depreciation and amortization expense of property, plant and equipment.

**(9) Postretirement Benefit Plans**

*(a) Employee Savings Plans*

Our company and several of our U.S.-based subsidiaries sponsor various 401(k) savings plans, to which eligible domestic employees may voluntarily contribute a portion of their income, subject to



**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(9) Postretirement Benefit Plans (Continued)**

statutory limitations. In addition to the participants' own contributions to these 401(k) savings plans, we match such contributions up to a designated level. Total matching contributions related to employee savings plans were \$8.8 million, \$7.6 million and \$6.9 million in 2012, 2011 and 2010, respectively.

*(b) U.K. Pension Plans*

Changes in benefit obligations, plan assets, funded status and amounts recognized on the accompanying balance sheet as of and for the years ended December 31, 2012 and 2011, for our Defined Benefit Plan were as follows (in thousands):

	<u>2012</u>	<u>2011</u>
<b>Change in projected benefit obligation</b>		
Benefit obligation at beginning of year .....	\$14,966	\$14,391
Interest cost .....	742	773
Actuarial loss .....	2,211	274
Benefits paid .....	(417)	(260)
Foreign exchange impact .....	838	(212)
Benefit obligation at end of year .....	<u>\$18,340</u>	<u>\$14,966</u>
<b>Change in plan assets</b>		
Fair value of plan assets at beginning of year .....	\$11,272	\$10,855
Actual return on plan assets .....	1,634	(90)
Employer contribution .....	916	927
Benefits paid .....	(417)	(260)
Foreign exchange impact .....	638	(160)
Fair value of plan assets at end of year .....	<u>\$14,043</u>	<u>\$11,272</u>
<b>Funded status</b> .....	<u>\$ (4,297)</u>	<u>\$ (3,694)</u>
<b>Accumulated benefit obligation</b> .....	<u>\$18,340</u>	<u>\$14,966</u>

The net amounts recognized in the accompanying consolidated balance sheets are shown in current liabilities and were \$4.3 million and \$3.7 million for the years ended December 31, 2012 and 2011, respectively.

The following represents the amounts recognized in other comprehensive income (loss) for the year ended December 31, 2012:

Amortization of net loss .....	(114)
Amortization of prior service cost .....	(422)
New actuarial gains .....	1,212
Foreign exchange impact .....	419
Total .....	<u>\$1,095</u>

The amortization of prior service cost is expected to be approximately \$0.4 million in 2013.

Amounts recognized in accumulated other comprehensive income (loss) for the years ending December 31, 2012 and 2011 are as follows:

	<u>2012</u>	<u>2011</u>
Net actuarial loss .....	\$4,098	\$2,825
Prior service costs .....	4,754	4,932
Net amount recognized .....	<u>\$8,852</u>	<u>\$7,757</u>

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(9) Postretirement Benefit Plans (Continued)**

The measurement dates used to determine plan assets and benefit obligations for the Defined Benefit Plan were December 31, 2012 and 2011.

The following table provides the weighted-average actuarial assumptions:

	<u>2012</u>	<u>2011</u>
<b>Assumptions used to determine benefit obligations(1):</b>		
Discount rate .....	4.30%	4.90%
Rate of compensation increase .....	3.65%	3.75%
<b>Assumptions used to determine net periodic benefit cost(2):</b>		
Discount rate .....	4.90%	5.30%
Expected long-term return on plan assets .....	5.40%	6.40%
Rate of compensation increase .....	3.75%	4.15%

- (1) The actuarial assumptions used to compute the unfunded status for the plan are based upon information available as of December 31, 2012 and 2011.
- (2) The actuarial assumptions used to compute the net periodic pension benefit cost are based upon the information available as of the beginning of the presented year.

The actuarial assumptions are reviewed on an annual basis. The overall expected long-term rate of return on plan assets assumption was determined based on historical investment return rates on portfolios with a high proportion of equity securities.

The annual cost of the Defined Benefit Plan is as follows (in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Interest cost .....	\$ 742	\$ 773	\$ 717
Expected return on plan assets .....	(636)	(731)	(597)
Amortization of net loss .....	114	32	20
Amortization of prior service cost .....	422	427	—
Curtailment loss (gain) .....	—	—	—
Net periodic benefit cost .....	<u>\$ 642</u>	<u>\$ 501</u>	<u>\$ 140</u>

The plan assets of the Defined Benefit Plan comprise a mix of stocks and fixed income securities and other investments. At December 31, 2012, these stocks and fixed income securities represented 69% and 31%, respectively, of the market value of the pension assets. We expect to contribute approximately £0.6 million (or \$0.9 million at December 31, 2012) to the Defined Benefit Plan in 2013. We expect that the benefits to be paid to plan participants will range between approximately \$0.3 million and \$0.4 million per year for each of the next five years and that benefits totaling \$0.5 million will be paid annually for the five years thereafter.

Our overall investment strategy is to ensure the investments are spread across a range of investments varying by both investment class and geographical location which is achieved by investing largely in equity and fixed income funds. Spreading the investments in this manner reduces the risk of a decline in a particular market having a substantial impact on the whole fund. The target allocation for the plan assets is a 70% holding in equities (both in the U.K. and overseas), with the remaining assets invested in investment grade corporate bonds.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(9) Postretirement Benefit Plans (Continued)**

The fair values of our pension plan assets at December 31, 2012 and 2011 by asset category are presented in the following table (Level 2 in the fair value hierarchy).

<u>Asset Category</u>	<u>Plan Assets at December 31,</u>	
	<u>2012</u>	<u>2011</u>
Equity securities:		
U.K. equities .....	\$ 4,807	\$ 3,805
Overseas equities .....	2,532	1,993
U.S. equities .....	2,219	1,789
Debt securities — corporate bonds .....	4,286	3,450
Other — cash .....	198	235
Total plan assets .....	<u>\$14,042</u>	<u>\$11,272</u>

The table above presents the fair value of our plan's assets in accordance with the fair value hierarchy. The pension plan assets are measured using net asset value per share (or its equivalent) and are reported as a Level 2 investment above due to our ability to redeem the investment either at the balance sheet date or within limited time restrictions.

Unipath Limited, or Unipath, contributed \$0.4 million in 2012, \$0.3 million in 2011 and \$0.4 million in 2010 to a Defined Contribution Plan, which was recognized as an expense in the accompanying consolidated statement of operations.

**(10) Derivative Financial Instruments**

We may manage our economic and transaction exposure to certain market-based risks through the use of derivative instruments. Our objective for holding derivative instruments has been to reduce volatility of net earnings and cash flows associated with changes in interest rates and foreign currency exchange rates. We do not hold or issue derivative financial instruments for speculative purposes.

*(a) Interest Rate Risk*

We used interest rate swap contracts from time to time in the management of our interest rate exposure related to our former secured credit facility. On June 30, 2011, we entered into a new secured credit facility and, in connection therewith, repaid in full all outstanding indebtedness under and terminated our former secured credit facility and related interest rate swaps.

*(b) Foreign Currency Risk*

In connection with our acquisition of Axis-Shield, we acquired a number of foreign currency forward contracts. The specific risk hedged in these contracts was the undiscounted foreign currency spot rate risk on forecasted foreign currency revenue. As of December 31, 2012, all of the acquired foreign currency forward contracts were settled. As of December 31, 2011, the notional value of these contracts was \$16.6 million and CHF 5.4 million. We report the effective portion of the gain or loss on a cash flow hedge as a component of other comprehensive income, and it was subsequently reclassified into net earnings in the period in which the hedged transaction affected net earnings or the forecasted transaction was no longer probable of occurring.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(10) Derivative Financial Instruments (Continued)**

The following tables summarize the fair value of our derivative instruments and the effect of the derivative instruments on/in our accompanying consolidated balance sheets and consolidated statements of operations (in thousands):

<u>Derivative Instruments</u>	<u>Balance Sheet Caption</u>	<u>Fair Value at December 31, 2012</u>	<u>Fair Value at December 31, 2011</u>
Foreign currency forward contracts .....	Accrued expenses and other current liabilities	\$ —	\$ 447

<u>Derivative Instruments</u>	<u>Location of Gain (Loss) Recognized in Income</u>	<u>Amount of Gain (Loss) Recognized During the Year Ended December 31, 2012</u>	<u>Amount of Loss Recognized During the Year Ended December 31, 2011</u>
Foreign currency forward contracts .....	Other comprehensive income (loss)	\$ —	\$(1,187)
Total loss .....	Other comprehensive income (loss)	\$ —	\$(1,187)

**(11) Commitments and Contingencies**

*(a) Operating Leases*

We have operating lease commitments for certain of our facilities and equipment that expire on various dates through 2019. The following schedule outlines future minimum annual rental payments under these leases at December 31, 2012 (in thousands):

2013 .....	\$ 43,148
2014 .....	37,350
2015 .....	32,943
2016 .....	30,935
2017 .....	27,449
Thereafter .....	62,496
	<u>\$234,321</u>

Rent expense relating to operating leases was approximately \$51.2 million, \$42.3 million and \$39.0 million during 2012, 2011 and 2010, respectively.

*(b) Contingent Consideration Obligations*

We determine the acquisition date fair value of the contingent consideration obligations based on a probability-weighted approach derived from the overall likelihood of achieving the targets before the corresponding delivery dates. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement, as defined in fair value measurement accounting. The resultant probability-weighted milestone payments are discounted using a discount rate based upon the weighted-average cost of capital. At each reporting date, we revalue the contingent consideration obligations to the reporting date fair values and record increases and decreases in the fair values as income or expense in our consolidated statements of operations.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(11) Commitments and Contingencies (Continued)**

Increases or decreases in the fair values of the contingent consideration obligations may result from changes in discount periods and rates, changes in the timing and amount of earn-out criteria and changes in probability assumptions with respect to the likelihood of achieving the various earn-out criteria.

We have contractual contingent consideration obligations related to our acquisitions of Accordant, AdnaGen, Alere Healthcare, Alere S.A., Amedica, Bioeasy, Branana, Capital Toxicology, DiagnosisOne, Diagnostik, eScreen, HCC, Immunalysis, Ionian, LDS, MedApps, Mologic, NationsHealth, ROAR, Standing Stone, Twist, Wellogic and certain other small businesses.

- Accordant

With respect to Accordant, the terms of the acquisition agreement require us to pay an earn-out upon successfully meeting certain revenue and cash collection targets starting after the second anniversary of the acquisition date and completed prior to the third anniversary date of the acquisition. The maximum amount of the earn-out totaling \$6.0 million was achieved in 2012. A payment of \$1.5 million was made during the fourth quarter of 2012 and the remaining payments will be made in quarterly installments of \$1.5 million during 2013.

- AdnaGen

With respect to AdnaGen, the terms of the acquisition agreement require us to pay earn-outs upon successfully (i) meeting certain financial performance targets during the two years following the acquisition, (ii) achieving multiple product development milestones during the three years following the acquisition and (iii) creating pharmaceutical alliances during the six years following the acquisition. The maximum remaining amount of the earn-out payments is approximately \$42.0 million.

- Alere Healthcare

With respect to Alere Healthcare, the terms of the acquisition agreement require us to pay an earn-out upon successfully meeting certain revenue and operating income targets during each of the calendar years 2010 through 2012. The 2012 portion of the earn-out totaling approximately \$0.3 million was earned and accrued as of December 31, 2012. Payment of the 2012 earn-out is expected to be made during the second quarter of 2013.

- Alere S.A.

With respect to Alere S.A., the terms of the acquisition agreement require us to pay an earn-out upon successfully meeting certain revenue and EBITDA targets during each of the calendar years 2011 through 2016. The conditions of the 2012 and 2011 earn-outs were not achieved. The maximum remaining amount of the earn-out payments is approximately \$6.0 million.

- Amedica

With respect to Amedica, the terms of the acquisition agreement require us to make earn-out payments upon successfully meeting certain financial targets during each of the calendar years 2012 and 2013. The 2012 portion of the earn-out totaling approximately \$6.9 million was earned and accrued as of December 31, 2012. Payment of the 2012 earn-out is expected to be made during the second quarter of 2013. The maximum remaining amount of the earn-out payments is \$8.1 million.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(11) Commitments and Contingencies (Continued)**

- Bioeasy

With respect to Bioeasy, the terms of the acquisition agreement require us to pay earn-outs upon successfully meeting certain revenue and EBITDA targets during each of the calendar years 2011 through 2013. The 2011 and 2012 earn-outs were not achieved. The maximum remaining amount of the earn-out payments is approximately \$2.5 million.

- Branan

With respect to Branan, the terms of the acquisition agreement require us to pay earn-outs upon successfully achieving various regulatory product approval milestones by the second anniversary of the acquisition date. Four milestones were achieved during 2012 resulting in an accrual totaling approximately \$2.0 million as of December 31, 2012. Payment of the 2012 milestones is expected to be made during the first quarter of 2013. The maximum remaining amount of the earn-out payments is \$3.0 million.

- Capital Toxicology

The initial terms of the acquisition agreement for Capital Toxicology provided for an earn-out calculated based on the amount, if any, by which EBITDA derived from the acquired business exceeded specified targets during each of the calendar years 2011 and 2012. A portion of the earn-out for the 2011 calendar year totaling approximately \$2.1 million was earned and accrued as of December 31, 2011. During the first quarter of 2012, the acquisition agreement was modified to base the earn-out on the excess of actual cash collections from 2011 sales over 2011 expenses rather than EBITDA. This new criterion resulted in an incremental \$2.9 million accrual related to the earn-out for the 2011 calendar year based on cash collections through March 31, 2012. \$4.1 million was paid in respect of the earn-out for the 2011 calendar year during the second quarter of 2012. An additional payment of approximately \$1.5 million was made in the fourth quarter of 2012 for the incremental cash collections from 2011 sales received prior to August 31, 2012. The 2012 earn-out totaling \$5.0 million was achieved in 2012 and paid in the fourth quarter of 2012. No further contingent consideration obligations related to this acquisition exist as of December 31, 2012.

- DiagnosisOne

With respect to DiagnosisOne, the terms of the acquisition agreement require us to pay earn-outs upon successfully meeting certain financial targets within five years of the acquisition date. The maximum amount of the earn-out payments is \$33.0 million.

- Diagnostik

With respect to Diagnostik, the terms of the acquisition agreement require us to pay earn-outs upon successfully meeting certain financial targets within two years of the acquisition date. The maximum amount of the earn-out payments is approximately €1.4 million (approximately \$1.9 million at December 31, 2012).

- eScreen

With respect to eScreen, the terms of the acquisition agreement require us to pay earn-outs upon successfully meeting certain financial targets during calendar years 2012 through 2014. The 2012 portion of the earn-out was not achieved. The maximum remaining amount of the earn-out payments is \$70.0 million.



**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(11) Commitments and Contingencies (Continued)**

- HCC

With respect to HCC, the terms of the acquisition agreement require us to pay an earn-out upon successfully meeting certain EBITDA targets during calendar year 2013. The maximum amount of the earn-out payments is £3.5 million (approximately \$5.7 million at December 31, 2012).

- Immunalysis

With respect to Immunalysis, the terms of the acquisition agreement require us to pay earn-outs upon successfully meeting certain gross profit targets during each of the calendar years 2010 through 2012. Payment of the 2011 portion of the earn-out totaling approximately \$0.9 million was paid during the second quarter of 2012. The 2012 portion of the earn-out totaling approximately \$1.9 million was earned and accrued as of December 31, 2012, with payment expected to be made during the second quarter of 2013.

Additionally, we have a contractual contingent obligation to pay up to a total of \$3.0 million in compensation to certain executives of Immunalysis in accordance with the acquisition agreement that, if earned, will be paid out in connection with the contingent consideration payable to the former shareholders of Immunalysis, for each of the calendar years 2010, 2011 and 2012. Payment of the 2011 compensation totaling approximately \$1.0 million was made during the second quarter of 2012. The 2012 portion of the compensation totaling approximately \$1.0 million was earned and accrued as of December 31, 2012, with payment expected to be made during the second quarter of 2013.

- Ionian

With respect to our acquisition of Ionian, the terms of the acquisition agreement require us to pay earn-outs upon successfully meeting multiple product development milestones during the five years following the acquisition. The maximum amount of the earn-out payments is \$57.5 million.

- LDS

With respect to LDS, the terms of the acquisition agreement require us to pay an earn-out upon successfully meeting certain revenue and operating income targets during each of the twelve-month periods ending June 30, 2012 and 2013. During the third quarter of 2012, the acquisition agreement was modified to base the earn-out criteria on: revenue and operating income targets for the twelve-month period ending June 30, 2012, certain integration milestones to be achieved during 2012, and various product milestones to be achieved during 2012 and 2013. The portion of the earn-out related to revenue and operating income targets, totaling \$10.0 million was earned and paid during 2012. The portion of the earn-out related to the integration milestones and certain 2012 product milestones, totaling \$3.5 million, was earned and accrued as of December 31, 2012. The maximum remaining amount of the earn-out payments is \$7.5 million.

- MedApps

With respect to MedApps, the terms of the acquisition agreement require us to make earn-out payments upon achievement of certain technological and product development milestones through January 15, 2015. A portion of the earn-out, totaling \$0.8 million was earned and paid during the fourth quarter of 2012. The maximum remaining amount of the earn-out payments is \$21.2 million.

- Mologic

With respect to Mologic, the terms of the acquisition agreement require us to pay earn-outs, in shares of our common stock or cash, at our election, upon successfully meeting nine research and development project milestones during the five years following the acquisition. During 2012, a portion

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(11) Commitments and Contingencies (Continued)**

of the earn-out totaling approximately \$1.2 million was determined to have been achieved and was settled in shares of our common stock. The maximum remaining amount of the earn-out payments is \$14.8 million.

- NationsHealth

With respect to NationsHealth, the terms of the acquisition agreement require us to pay an earn-out upon successfully meeting certain operational targets within one year of the acquisition date. The maximum amount of the earn-out payment is \$8.0 million.

- ROAR

With respect to ROAR, the terms of the acquisition agreement require us to pay an earn-out upon successfully meeting certain EBITDA targets during 2012 through 2014. ROAR achieved approximately £1.2 million (approximately \$1.9 million at December 31, 2012) of earn-out payments in 2012 which were accrued for at December 31, 2012. Payment of this earn-out is expected to be made in the first quarter of 2013. The maximum remaining amount of the earn-out payments is £9.3 million (approximately \$15.2 million at December 31, 2012).

- Standing Stone

With respect to Standing Stone, the terms of the acquisition agreement require us to pay earn-outs and employee bonuses upon successfully meeting certain operational, product development and revenue targets during the period from the date of acquisition through calendar year 2013. An earn-out payment totaling approximately \$8.2 million and employee bonus payments totaling approximately \$0.4 million for the achievement of milestones were made during 2012. The maximum remaining amount of the earn-out payments is approximately \$2.8 million. The maximum remaining amount of the employee bonuses is \$0.1 million.

- Twist

With respect to our acquisition of Twist, the terms of the acquisition agreement require us to pay an earn-out upon successfully meeting certain revenue and product development targets. Approximately \$0.3 million in earn-out payments was paid during 2012. The maximum amount of the earn-out payments is \$125.0 million and, if earned, payments are expected to be made during the eight-year period following the acquisition date, but could extend thereafter.

- Wellogic

With respect to Wellogic, the terms of the acquisition agreement require us to pay an earn-out upon successfully meeting certain operational and profit targets during 2012 through 2019. The maximum remaining amount of the earn-out payments based upon operational targets is approximately \$49.8 million. The earn-out based on financial targets has no maximum.

*(c) Legal Proceedings*

*(i) 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

## ALERE INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### (11) Commitments and Contingencies (Continued)

products, which resulted in two recalls of certain Alere Triage products and revised release specifications for our Alere Triage meter-based products. On October 30, 2012, we responded to the warning letter and submitted evidence of our completion of most of the actions previously detailed in our prior response to the FDA Form 483. We have worked cooperatively with the FDA in an effort to fully address each of the inspectional observations and intend to continue to do so.

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

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

#### (ii) Class Action Litigation against Alere Home Monitoring

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

#### (iii) Claims in the Ordinary Course and Other Matters

Because of the nature of our business, we may be subject at any particular time to lawsuits or other claims arising in the ordinary course of our business, and we expect that this will continue to be the case in the future. Such lawsuits often seek damages, sometimes in substantial amounts.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(12) Net Loss Per Common Share**

The following tables set forth the computation of basic and diluted net loss per common share (in thousands, except per share amounts):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
<b>Basic and diluted net loss per common share:</b>			
<b>Numerator:</b>			
Loss from continuing operations .....	\$ (78,182)	\$ (133,542)	\$(1,028,707)
Preferred stock dividends .....	(21,293)	(22,049)	(24,235)
Preferred stock repurchase .....	—	23,936	—
Loss available to common stockholders from continuing operations .....	(99,475)	(131,655)	(1,052,942)
Income from discontinued operations .....	—	—	11,397
Net loss .....	<u>\$ (99,475)</u>	<u>\$ (131,655)</u>	<u>\$(1,041,545)</u>
<b>Denominator:</b>			
Weighted-average shares outstanding — basic and diluted .....	<u>80,587</u>	<u>83,128</u>	<u>84,445</u>
Loss per common share from continuing operations .....	\$ (1.23)	\$ (1.58)	\$ (12.47)
Income per common share from discontinued operations .....	—	—	0.14
Net loss per common share .....	<u>\$ (1.23)</u>	<u>\$ (1.58)</u>	<u>\$ (12.33)</u>

The following potential dilutive securities were not included in the calculation of diluted net loss per common share because the inclusion thereof would be antidilutive (in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
<b>Denominator:</b>			
Options to purchase shares of common stock .....	10,234	9,446	10,148
Warrants .....	4	162	242
Conversion shares related to 3% convertible senior subordinated notes .....	3,411	3,411	3,411
Conversion shares related to subordinated convertible promissory notes .....	27	27	27
Conversion shares related to Series B convertible preferred stock .....	10,239	10,239	12,063
Common stock equivalents related to the settlement of deferred purchase price consideration .....	—	142	306
Common stock equivalents related to the settlement of a contingent consideration obligation .....	—	—	28
Total number of antidilutive potentially issuable shares of common stock excluded from diluted common shares outstanding .....	<u>23,915</u>	<u>23,427</u>	<u>26,225</u>

**(13) Stockholders' Equity**

*(a) Common Stock*

As of December 31, 2012, we had 200.0 million shares of common stock, \$0.001 par value, authorized, of which 7.7 million shares were held in treasury and 80.9 million shares were outstanding, 11.8 million shares were reserved for issuance upon grant and exercise of equity awards under current

## ALERE INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### (13) Stockholders' Equity (Continued)

equity compensation plans, 1.0 million shares were reserved for issuance under our employee stock purchase plan and 4,000 shares were reserved for issuance upon exercise of outstanding warrants. We also had shares of common stock reserved for issuance upon conversion of the following securities outstanding on December 31, 2012: \$150.0 million in the aggregate principal amount of 3% convertible senior subordinated notes, convertible at \$43.98 per share into 3.4 million shares of our common stock; \$1.7 million of subordinated convertible promissory notes, convertible at \$61.49 per share into 27,647 shares of our common stock; and 1.8 million shares of our Series B convertible preferred stock, with an aggregate liquidation preference of approximately \$709.8 million, convertible under certain circumstances at \$69.32 per share into 10.2 million shares of our common stock.

#### *(b) Preferred Stock*

As of December 31, 2012, we had 5.0 million shares of preferred stock, \$0.001 par value, authorized, of which 2.3 million shares were designated as Series B Convertible Perpetual Preferred Stock, or Series B preferred stock. In connection with our acquisition of Matria, we issued shares of the Series B preferred stock and through June 30, 2011 paid all dividends on outstanding shares of Series B preferred stock in additional shares of Series B preferred stock. Subsequent to June 30, 2011 all dividends on outstanding shares of Series B preferred stock were paid in cash. At December 31, 2012, there were 1.8 million shares of Series B preferred stock outstanding with a fair value of approximately \$328.5 million.

Each share of Series B preferred stock, which has a liquidation preference of \$400.00 per share, is convertible, at the option of the holder and only upon certain circumstances, into 5.7703 shares of our common stock, plus cash in lieu of fractional shares. The initial conversion price is \$69.32 per share, subject to adjustment upon the occurrence of certain events, but will not be adjusted for accumulated and unpaid dividends. Upon a conversion of shares of the Series B preferred stock, we may, at our option, satisfy the entire conversion obligation in cash or through a combination of cash and common stock. Series B preferred stock outstanding at December 31, 2012 would convert into 10.2 million shares of our common stock, which are reserved. There were no conversions as of December 31, 2012.

Generally, the shares of Series B preferred stock are convertible, at the option of the holder, if during any calendar quarter beginning with the second calendar quarter after the issuance date of the Series B preferred stock, if the closing sale price of our common stock for each of 20 or more trading days within any period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter exceeds 130% of the conversion price per share of common stock in effect on the last trading day of the immediately preceding calendar quarter. In addition, the shares of Series B preferred stock are convertible, at the option of the holder, in certain other circumstances, including those relating to the trading price of the Series B preferred stock and upon the occurrence of certain fundamental changes or major corporate transactions. We also have the right, under certain circumstances relating to the trading price of our common stock, to force conversion of the Series B preferred stock. Depending on the timing of any such forced conversion, we may have to make certain payments relating to foregone dividends, which payments we can make, at our option, in the form of cash, shares of our common stock, or a combination of cash and shares of our common stock.

Each share of Series B preferred stock accrues dividends at \$12.00, or 3%, per annum, payable quarterly on January 15, April 15, July 15 and October 15 of each year, commencing following the first full calendar quarter after the issuance date. Dividends on the Series B preferred stock are cumulative

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(13) Stockholders' Equity (Continued)**

from the date of issuance. For the year ended December 31, 2012, Series B preferred stock dividends amounted to \$21.3 million, which reduced earnings available to common stockholders for purposes of calculating net loss per common share in 2011 (Note 12). Accrued dividends are payable only if declared by our board of directors and, upon conversion by the Series B preferred stockholder, holders will not receive any cash payment representing accumulated dividends. If our board of directors declares a dividend payable, we have the right to pay the dividends in cash, shares of common stock, additional shares of Series B preferred stock or a similar convertible preferred stock or any combination thereof.

The holders of Series B preferred stock have liquidation preferences over the holders of our common stock and other classes of stock, if any, outstanding at the time of liquidation. Upon liquidation, the holders of outstanding Series B preferred stock would receive an amount equal to \$400.00 per share of Series B preferred stock, plus any accumulated and unpaid dividends. As of December 31, 2012, the liquidation preference of the outstanding Series B preferred stock was \$709.8 million. The holders of the Series B preferred stock have no voting rights, except with respect to matters affecting the Series B preferred stock (including the creation of a senior preferred stock).

We evaluated the terms and provisions of our Series B preferred stock to determine if it qualified for derivative accounting treatment. Based on our evaluation, these securities do not qualify for derivative accounting.

*(c) Share Repurchases*

During the first quarter of 2011, we repurchased in the open market and privately-negotiated transactions 183,000 shares of our Series B preferred stock, which were convertible into approximately 1.1 million shares of our common stock, at a cost of approximately \$49.4 million, which we paid in cash. The repurchase of the preferred stock at an average cost of \$269.84 per preferred share, an amount less than the weighted-average fair value of the preferred shares at issuance, resulted in the allocation of \$13.7 million of income attributable to common stockholders. Also during the first quarter of 2011, and pursuant to the same repurchase program, we repurchased 16,700 shares of our common stock at a cost of approximately \$0.6 million, which we paid in cash.

During the second quarter of 2011, we repurchased in the open market and privately-negotiated transactions, 174,788 shares of our Series B preferred stock, which were convertible into approximately 1.0 million shares of our common stock, at a cost of approximately \$49.7 million, which we paid in cash. The repurchase of the preferred stock at an average cost of \$284.28 per preferred share, an amount less than the weighted-average fair value of the preferred shares at issuance, resulted in the allocation of \$10.2 million of income attributable to common stockholders. Also during the second quarter of 2011, and pursuant to the same repurchase program, we repurchased 8,300 shares of our common stock at a cost of approximately \$0.3 million, which we paid in cash.

During the third quarter of 2011, we repurchased approximately 7.6 million shares of our common stock at a cost of approximately \$183.9 million, which we paid in cash.

*(d) Stock Options and Awards*

In 2010, we adopted the Alere Inc. 2010 Stock Option and Incentive Plan, or the 2010 Plan, which replaced our 2001 Stock Option and Incentive Plan, or the 2001 Plan. The 2010 Plan currently allows

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(13) Stockholders' Equity (Continued)**

for the issuance of up to 5.2 million shares of common stock and other awards. The 2010 Plan is administered by the Compensation Committee of the Board of Directors, which selects the individuals eligible to receive awards, determines or modifies the terms and conditions of the awards granted, accelerates the vesting schedule of any award and generally administers and interprets the 2010 Plan. The 2010 Plan permits the granting of incentive and nonqualified stock options with terms of up to ten years and the granting of stock appreciation rights, restricted stock awards, unrestricted stock awards, performance share awards and dividend equivalent rights. The 2010 Plan also provides for option grants to non-employee directors and automatic vesting acceleration of all options and stock appreciation rights upon a change in control, as defined by the 2010 Plan. As of December 31, 2012 and 2011, there were 1.0 million and 1.1 million shares respectively, available for future grant under the 2010 Plan.

The following summarizes all stock option activity during the year ended December 31, 2012 (in thousands, except exercise price):

	<u>Options</u>	<u>Weighted- average Exercise Price</u>
Outstanding at January 1, 2012 .....	9,446	\$36.84
Granted .....	2,314	\$31.84
Exercised .....	(297)	\$18.79
Canceled/expired/forfeited. ....	<u>(813)</u>	<u>\$33.80</u>
Outstanding at December 31, 2012 .....	<u>10,650</u>	\$36.51
Exercisable at December 31, 2012 .....	<u>6,760</u>	\$38.66

The aggregate intrinsic value of the options outstanding at December 31, 2012 was \$0.6 million. The aggregate intrinsic value of the options exercisable at December 31, 2012 was \$0.6 million. The aggregate intrinsic value of stock options exercised during 2012, 2011 and 2010 was \$1.3 million, \$17.1 million, and \$6.9 million, respectively.

In addition, on December 30, 2012, we granted a restricted stock unit, or RSU, award to one of our executive employees in the amount of 110,000 units. The RSU award vests over a three-year period, however, if the executive's employment is involuntarily terminated, without cause, within three years, the RSU award will accelerate and fully vest. The RSU award will also accelerate and fully vest if the executive terminates his employment voluntarily after one year, other than in the presence of facts or circumstances which would constitute cause for termination by us. The fair value of the RSU award is \$18.37 per unit, calculated based on the closing market price of our common stock on the date of grant. The aggregate fair value of the RSU award is expensed on a straight-line basis over the recipient's service requirement completion period of one year. None of the units underlying the RSU award have vested or have been released as of December 31, 2012.

Based on equity awards outstanding as of December 31, 2012, there was \$29.6 million of unrecognized compensation costs related to unvested share-based compensation arrangements that are expected to vest. Such costs are expected to be recognized over a weighted-average period of 1.91 years.



**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(13) Stockholders' Equity (Continued)**

*(e) Warrants*

The following is a summary of all warrant activity during the three years ended December 31:

	Number of Shares <u>(in thousands)</u>	Exercise Price	Weighted- average Exercise Price
Warrants outstanding and exercisable, December 31, 2009 ..	461	\$ 3.81 - \$50.00	\$21.09
Exercised .....	(105)	\$ 3.81 - \$29.78	\$23.66
Cancelled .....	(113)	\$20.06 - \$29.78	\$29.62
Warrants outstanding and exercisable, December 31, 2010 ..	243	\$13.54 - \$50.00	\$16.00
Exercised .....	(81)	\$13.54 - \$24.00	\$19.15
Warrants outstanding and exercisable, December 31, 2011 ..	162	\$13.54 - \$50.00	\$14.44
Exercised .....	(158)	\$13.54	\$13.54
Warrants outstanding and exercisable, December 31, 2012 ..	<u>4</u>	\$50.00	\$50.00

The following table presents additional information related to warrants outstanding and exercisable at December 31, 2012:

<u>Exercise Price</u>	<u>Outstanding and Exercisable</u>		
	<u>Number of Shares (in thousands)</u>	<u>Weighted- average Remaining Contract Life</u>	<u>Weighted- average Exercise Price</u>
\$50.00 .....	<u>4</u>	3.50	\$50.00
	<u>4</u>	3.50	\$50.00

The warrants included in the table above were issued in connection with the acquisition of GeneCare. There were no warrants to purchase shares of our common stock outstanding that were issued to officers and directors of our company or entities controlled by these officers and directors at December 31, 2012. All outstanding warrants have been classified in equity.

*(f) Employee Stock Purchase Plan*

In 2001, we adopted the 2001 Employee Stock Purchase Plan, under which eligible employees are allowed to purchase shares of our common stock at a discount through periodic payroll deductions. Purchases may occur at the end of every six-month offering period at a purchase price equal to 85% of the market value of our common stock at either the beginning or end of the offering period, whichever is lower. We may issue up to 3.0 million shares of common stock under this plan. At December 31, 2012, 2.0 million shares had been issued under this plan.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(14) Stock-based Compensation**

We recorded stock-based compensation expense in our consolidated statements of operations for the years ended December 31, 2012, 2011 and 2010, respectively, as follows (in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Cost of net revenue .....	\$ 1,063	\$ 1,508	\$ 1,904
Research and development .....	3,150	3,862	7,087
Sales and marketing .....	3,464	4,267	4,161
General and administrative .....	<u>7,988</u>	<u>11,578</u>	<u>16,727</u>
	15,665	21,215	29,879
Benefit for income taxes .....	<u>(2,660)</u>	<u>(4,560)</u>	<u>(6,203)</u>
Stock-based compensation, net of tax .....	<u>\$13,005</u>	<u>\$16,655</u>	<u>\$23,676</u>

For the years ended December 31, 2012, 2011 and 2010, the presentation of our cash flows reports the excess tax benefits from the exercise of stock options as financing cash flows. For the years ended December 31, 2012, 2011 and 2010, excess tax benefits generated from option exercises amounted to \$0.5 million, \$3.4 million and \$1.7 million, respectively.

The following assumptions were used to estimate the fair value of options granted during the years ended December 31, 2012, 2011 and 2010, using a Black-Scholes option-pricing model:

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Risk-free interest rate .....	0.83%	1.31%	2.03%
Expected dividend yield .....	—	—	—
Expected life .....	5.60 years	5.46 years	5.34 years
Expected volatility .....	42%	43%	42%

The weighted-average fair value under a Black-Scholes option pricing model of options granted to employees during 2012, 2011 and 2010 was \$7.37, \$10.95 and \$13.54 per share, respectively. All options granted during these periods were granted at or above the fair market value on the date of grant.

For the year ended December 31, 2012, we recorded compensation expense of \$2.7 million related to our Employee Stock Purchase Plan. The fair value of the option component of the Employee Stock Purchase Plan shares was estimated at the date of grant using a Black-Scholes option pricing model and assumed an expected volatility of 44% and 47%, a risk-free interest rate of 0.06% and 0.15% and an expected life of 182 days and 184 days, for each of the two respective offering periods. In the first half of 2012 we had a second offering period to accommodate employees of a recent acquisition. The fair value of the option component of the Employee Stock Purchase Plans shares for this offering was estimated at the grant date of March 1, 2012 using a Black-Scholes option pricing model and assumed an expected volatility of 40%, a risk-free rate of 0.10%, and an expected life of 122 days. The 2012 charge is included in the employee's respective cost classification in the table above.

For the year ended December 31, 2011, we recorded compensation expense of \$2.5 million related to our Employee Stock Purchase Plan. The fair value of the option component of the Employee Stock Purchase Plan shares was estimated at the date of grant using a Black-Scholes option pricing model and assumed an expected volatility of 35% and 34%, a risk-free interest rate of 0.19% and 0.10% and an expected life of 181 days and 184 days, for each of the two respective offering periods. The 2011 charge is included in the employee's respective cost classification in the table above.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(14) Stock-based Compensation (Continued)**

For the year ended December 31, 2010, we recorded compensation expense of \$2.7 million related to our Employee Stock Purchase Plan. The fair value of the option component of the Employee Stock Purchase Plan shares was estimated at the date of grant using a Black-Scholes option pricing model and assumed an expected volatility of 39% and 45%, a risk-free interest rate of 0.18% and 0.22% and an expected life of 181 days and 184 days, for each of the two respective offering periods. The 2010 charge is included in general and administrative expense in the table above.

**(15) Accumulated Other Comprehensive Income (Loss)**

Accumulated other comprehensive income (loss) consisted of the following (in thousands):

	<u>Cumulative Translation Adjustment (Note 2(b))</u>	<u>Pension Liability Adjustment (Note 9(b))</u>	<u>Other(1)</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>
Balance at December 31, 2009 .....	\$ 12,915	\$(5,096)	\$(10,273)	\$ (2,454)
Period change .....	(210)	(113)	3,467	3,144
Balance at December 31, 2010 .....	12,705	(5,209)	(6,806)	690
Period change .....	(35,830)	(1,618)	6,488	(30,960)
Balance at December 31, 2011 .....	(23,125)	(6,827)	(318)	(30,270)
Period change .....	54,642	(756)	258	54,144
Balance at December 31, 2012 .....	<u>\$ 31,517</u>	<u>\$(7,583)</u>	<u>\$ (60)</u>	<u>\$ 23,874</u>

(1) Other represents unrealized gains (losses) on available-for-sale securities and hedging instruments.

**(16) Income Taxes**

Income (loss) before provision (benefit) for income taxes consists of the following (in thousands):

**Continuing Operations:**

	<u>2012</u>	<u>2011</u>	<u>2010</u>
United States .....	\$ (158,635)	\$ (493,073)	\$(1,078,981)
Foreign .....	37,164	327,026	11,195
	<u>\$ (121,471)</u>	<u>\$ (166,047)</u>	<u>\$(1,067,786)</u>

**Discontinued Operations:**

	<u>2012</u>	<u>2011</u>	<u>2010</u>
United States .....	\$ —	\$ —	\$ 16,973
Foreign .....	—	—	1,514
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 18,487</u>

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(16) Income Taxes (Continued)**

Our primary temporary differences that give rise to the deferred tax asset and liability are net operating loss, or NOL, carryforwards, nondeductible reserves, and accruals and differences in basis of the tangible and intangible assets. The income tax effects of these temporary differences are as follows (in thousands):

	<u>2012</u>	<u>2011</u>
NOL and capital loss carryforwards .....	\$ 117,091	\$ 161,312
Tax credit carryforwards .....	54,212	42,806
Nondeductible reserves .....	17,036	17,084
Nondeductible accruals .....	34,406	32,272
Difference between book and tax bases of tangible assets .....	1,059	159
Difference between book and tax bases of intangible assets .....	23,017	19,417
Deferred revenue .....	5,686	6,098
All other .....	30,071	27,113
Gross deferred tax asset .....	282,578	306,261
Less: Valuation allowance .....	(68,555)	(51,579)
Total deferred tax assets .....	<u>214,023</u>	<u>254,682</u>
Deferred tax liabilities:		
Difference between book and tax bases of tangible assets .....	42,835	52,303
Difference between book and tax bases of intangible assets .....	482,955	468,851
Debt .....	25,541	47,940
Other .....	15,525	15,173
Total deferred tax liability .....	<u>566,856</u>	<u>584,267</u>
Net deferred tax liability .....	<u>\$ 352,833</u>	<u>\$ 329,585</u>
Reported as:		
Deferred tax assets, current portion .....	\$ 67,722	\$ 42,975
Deferred tax assets, long-term .....	8,293	10,394
Deferred tax liabilities, current portion .....	(660)	(2,254)
Deferred tax liabilities, long-term .....	(428,188)	(380,700)
Net deferred tax liability .....	<u>\$(352,833)</u>	<u>\$(329,585)</u>

As of December 31, 2012, we had approximately \$60.6 million of domestic NOL and domestic capital loss carryforwards, approximately \$981.1 million of state NOL carryforwards and \$211.6 million of foreign NOL and foreign capital loss carryforwards, which either expire on various dates through 2032 or can be carried forward indefinitely. As of December 31, 2012, we had approximately \$57.7 million of domestic research and development, foreign tax and alternative minimum tax credits which either expire on various dates through 2031 or can be carried forward indefinitely. These loss carryforwards and tax credits may be available to reduce future federal, state and foreign taxable income, if any, and are subject to review and possible adjustment by the appropriate tax authorities. Section 382 imposes an annual limitation on the use of these losses to an amount equal to the value of the company at the time of the ownership change multiplied by the long-term tax exempt rate. Our domestic NOLs are subject to various Internal Revenue Service, or IRS, Code Section 382 limitations, however we forecast we will fully utilize the NOLs before their expiration. Section 383 imposes an annual limitation on the use of credits to an amount equal to the value of the company at the time of the ownership change multiplied by the long-term tax exempt rate. Our domestic credits are subject to various Internal Revenue Service, or IRS, Code Section 383 limitations. We forecast that some portion of these credits will expire before they are utilized and therefore has recorded a valuation allowance on these assets of \$0.9 million. The state NOL carryforwards are subject to various statutory limitations or require certain companies to realize taxable income in order to fully utilize the NOLs.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(16) Income Taxes (Continued)**

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

Our two China-based manufacturing subsidiaries qualify for a reduced income tax rate in 2012, 2011 and 2010. Both Chinese entities qualify as high technology status companies and the status is due to expire for one in 2013 and the other in 2014. The companies intend to file for a renewal of this status. The prescribed statutory rate for 2012 and 2011 is 25% and the reduced rate under the high technology status is 15%. In 2010, the companies qualified under the China Tax Reform Act and the income tax rate for one of the subsidiaries was 12.5% and 11% for the other. The reduced tax rate produced a tax expense of approximately \$1.0 million in 2012. In the absence of the reduced tax rate for 2012 a tax rate of 25% would have applied and would have resulted in a tax expense of approximately \$1.7 million in 2012. The earnings per common share effect of the reduced tax rate is \$0.01 for 2012. The reduced tax rate produced a tax expense of approximately \$0.5 million in 2011. In the absence of the reduced tax rate for 2011 a tax rate of 25% would have applied and would have resulted in a tax expense of approximately \$0.8 million in 2011. The earnings per common share effect of the reduced tax rate was \$0.01 for 2011. The reduced tax rate produced a tax expense of approximately \$1.3 million in 2010. In the absence of the reduced tax rate for 2010 a tax rate of 25% would have applied and would have resulted in a tax expense of approximately \$2.9 million in 2010. The earnings per common share effect of the reduced tax rate is \$0.02 for 2010.

The estimated amount of undistributed earnings of our foreign subsidiaries is \$654.2 million at December 31, 2012. No amount for U.S. income tax has been provided on undistributed earnings of our foreign subsidiaries because we consider such earnings to be indefinitely reinvested. In the event of distribution of those earnings we would be subject to both U.S. income tax and foreign withholding taxes, subject to possible offset by U.S. foreign tax credits. Determination of the amount of U.S. income tax liability that would be incurred is not practicable because of the complexities associated with this hypothetical calculation.

The following table presents the components of our benefit for income taxes (in thousands) for continuing operations:

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Current:			
Federal .....	\$ 11,794	\$ (1,229)	\$ (2,350)
State .....	9,500	4,193	5,285
Foreign .....	32,955	29,583	41,552
	<u>54,249</u>	<u>32,547</u>	<u>44,487</u>
Deferred:			
Federal .....	(58,292)	(27,109)	(40,154)
State .....	(15,087)	(23,720)	(12,695)
Foreign .....	(11,189)	(5,932)	(21,569)
	<u>(84,568)</u>	<u>(56,761)</u>	<u>(74,418)</u>
Total benefit for income taxes .....	<u><u>\$(30,319)</u></u>	<u><u>\$(24,214)</u></u>	<u><u>\$(29,931)</u></u>

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(16) Income Taxes (Continued)**

Benefit for income taxes in 2011 includes a benefit of \$7.0 million to correct items related to periods between 2007 and 2010. We do not believe that the corrected items are material to 2011 or any previously reported quarterly or annual financial statements. As a result, we have not restated our previously issued annual or quarterly financial statements.

The following table presents the components of our provision for income taxes (in thousands) for discontinued operations:

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Current:			
Federal .....	\$ —	\$ —	\$ —
State .....	—	—	(73)
Foreign .....	—	—	—
	<u>—</u>	<u>—</u>	<u>(73)</u>
Deferred:			
Federal .....	\$ —	\$ —	5,644
State .....	—	—	1,095
Foreign .....	—	—	424
	<u>—</u>	<u>—</u>	<u>7,163</u>
Total provision for income taxes .....	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 7,090</u>

The following table presents a reconciliation from the U.S. statutory tax rate to our effective tax rate:

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Statutory rate .....	35%	35%	35%
Effect of goodwill impairment charge .....	—	(75)	(31)
Stock-based compensation .....	(2)	(2)	—
Rate differential on foreign earnings .....	(2)	42	—
Research and development .....	—	1	—
State income taxes, net of federal benefit .....	3	8	1
Acquisition costs .....	(2)	(2)	(2)
Contingent consideration .....	6	4	—
Rate changes .....	(2)	3	—
Other permanent items .....	1	3	—
Change in valuation allowance .....	(9)	(2)	—
Uncertain tax positions .....	(3)	—	—
Effective tax rate .....	<u>25%</u>	<u>15%</u>	<u>3%</u>

The goodwill impairment charge created a deferred tax impact due to the existence of goodwill deductible for tax purposes. The deferred tax is calculated based on a methodology which allocates the goodwill impairment loss proportionally to the goodwill deductible for tax purposes compared to total goodwill. The goodwill impairment allocated to goodwill deductible for tax purposes created a deferred tax asset of \$35.3 million as of December 31, 2011. There has been no change to the goodwill impairment charge or the deferred tax asset in 2012.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(16) Income Taxes (Continued)**

During the year ended December 31, 2012, we increased the liability for income taxes associated with uncertain tax positions by \$3.2 million to a total of \$19.0 million at December 31, 2012. The primary reasons for the increase are foreign tax exposures associated with certain restructurings which increased the liability for income taxes associated with uncertain tax positions by \$4.8 million and decreased that liability by \$1.5 million primarily related to the reversal of domestic reserves no longer required due to audit settlements. We classify \$12.6 million of income tax liabilities as non-current income tax liabilities, \$0.9 million as income taxes payable and \$5.5 million of income tax liabilities as reserves net of long-term deferred tax assets which is not anticipated to be paid within one year of the balance sheet date. These non-current income tax liabilities are recorded in other long-term liabilities in our consolidated balance sheet at December 31, 2012. We anticipate an increase every quarter to the total amount of unrecognized tax benefits. We do not anticipate a significant increase or decrease of the total amount of unrecognized tax benefits within twelve months of the reporting date.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	<u>Amount</u>
Balances as of January 1, 2010 .....	\$ 4,905
Additions for tax positions in current and prior year acquisitions .....	2,070
Additions for tax positions taken during current year .....	263
Expiration of statutes of limitations or closure of tax audits .....	<u>(1,078)</u>
Balances as of December 31, 2010 .....	6,160
Additions for tax positions in current and prior year acquisitions .....	189
Additions for tax positions taken during current year .....	5,814
Reductions for tax positions taken during prior years .....	(26)
Reductions for tax positions in current and prior year acquisitions .....	(1,922)
Expiration of statutes of limitations or closure of tax audits .....	<u>(684)</u>
Balance as of December 31, 2011 .....	9,531
Previously recorded tax reserves not included in disclosure .....	6,236
Additions for tax positions in current and prior year acquisitions .....	1,852
Additions for tax positions taken during current year .....	2,922
Reductions for tax positions taken during prior years .....	(208)
Reductions for tax positions in current and prior year acquisitions .....	—
Expiration of statutes of limitations or closure of tax audits .....	<u>(1,328)</u>
Balance as of December 31, 2012 .....	<u><u>\$19,005</u></u>

Interest and penalties related to income tax liabilities are included in income tax expense. The interest and penalties recorded in 2012 amounted to \$0.5 million of income due to a reduction in the required accrual for interest. The balance of accrued interest and penalties recorded on the consolidated balance sheet at December 31, 2012 was \$0.4 million.

With limited exceptions, we are subject to U.S. federal, state and local or non-U.S. income tax audits by tax authorities for 2006 through 2011. We are currently under income tax examination by the IRS and a number of state and foreign tax authorities and anticipate these audits will be completed by the end of 2013. We cannot currently estimate the impact of these audits due to the uncertainties associated with tax examinations.



**ALERE INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(17) Financial Information by Segment**

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. Our chief operating decision-making group is composed of the chief executive officer and members of senior management. Our reportable operating segments are professional diagnostics, health information solutions, consumer diagnostics and corporate and other. Our operating results include license and royalty revenue which are allocated to Professional Diagnostics and Consumer Diagnostics on the basis of the original license or royalty agreement.

On January 15, 2010, we completed the sale of our vitamins and nutritional supplements business (Note 22). The sale included our private label and branded nutritional businesses and represents the complete divestiture of our entire vitamins and nutritional supplements business segment. The results of the entire vitamins and nutritional supplements business are included in income from discontinued operations, net of tax, in our consolidated financial statements.

The accounting policies of the segments are the same as those described in the summary of significant accounting policies. We evaluate performance of our operating segments based on revenue and operating income (loss). Revenues are attributed to geographic areas based on where the customer is located. Segment information for 2012, 2011 and 2010 is as follows (in thousands):

	<u>Professional Diagnostics</u>	<u>Health Information Solutions</u>	<u>Consumer Diagnostics</u>	<u>Corporate and Other</u>	<u>Total</u>
<b>2012</b>					
Net revenue . . . . .	\$2,189,892	\$535,422	\$ 93,511	\$ —	\$2,818,825
Operating income (loss) . . . . .	\$ 243,080	\$(73,432)	\$ 12,707	\$(73,223)	\$ 109,132
Depreciation and amortization . . . . .	\$ 355,957	\$ 96,427	\$ 3,455	\$ 1,008	\$ 456,847
Restructuring charge . . . . .	\$ 11,124	\$ 9,203	\$ —	\$ (2)	\$ 20,325
Stock-based compensation . . . . .	\$ —	\$ —	\$ —	\$ 15,665	\$ 15,665
Assets . . . . .	\$6,214,847	\$593,172	\$192,748	\$ 67,161	\$7,067,928
Expenditures for property, plant and equipment . . . . .	\$ 100,147	\$ 41,775	\$ 2,823	\$ 1,201	\$ 145,946
	<u>Professional Diagnostics</u>	<u>Health Information Solutions</u>	<u>Consumer Diagnostics</u>	<u>Corporate and Other</u>	<u>Total</u>
<b>2011</b>					
Net revenue . . . . .	\$1,756,509	\$ 534,514	\$ 95,504	\$ —	\$2,386,527
Operating income (loss) . . . . .	\$ 248,097	\$(439,872)	\$ 10,442	\$(71,522)	\$ (252,855)
Goodwill impairment charge . . . . .	\$ —	\$ 383,612	\$ —	\$ —	\$ 383,612
Depreciation and amortization . . . . .	\$ 283,112	\$ 108,383	\$ 5,375	\$ 716	\$ 397,586
Restructuring charge . . . . .	\$ 13,949	\$ 13,194	\$ (57)	\$ 1,196	\$ 28,282
Stock-based compensation . . . . .	\$ —	\$ —	\$ —	\$ 21,215	\$ 21,215
Assets . . . . .	\$5,826,756	\$ 624,305	\$199,422	\$ 22,218	\$6,672,701
Expenditures for property, plant and equipment . . . . .	\$ 81,774	\$ 46,850	\$ 2,676	\$ 1,232	\$ 132,532

**ALERE INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(17) Financial Information by Segment (Continued)**

<u>2010</u>	<u>Professional Diagnostics</u>	<u>Health Information Solutions</u>	<u>Consumer Diagnostics</u>	<u>Corporate and Other</u>	<u>Total</u>
Net revenue .....	\$1,459,492	\$ 598,819	\$ 97,036	\$ —	\$2,155,347
Operating income (loss) .....	\$ 134,687	\$(1,024,809)	\$ 11,310	\$(72,277)	\$(951,089)
Goodwill impairment charge .....	\$ —	\$ 1,006,357	\$ —	\$ —	\$1,006,357
Depreciation and amortization .....	\$ 246,080	\$ 120,617	\$ 5,439	\$ 654	\$ 372,790
Restructuring charge .....	\$ 7,941	\$ 7,249	\$ 77	\$ —	\$ 15,267
Stock-based compensation .....	\$ —	\$ —	\$ —	\$ 29,879	\$ 29,879
Assets .....	\$4,913,491	\$ 1,011,183	\$207,795	\$197,905	\$6,330,374
Expenditures for property, plant and equipment .....	\$ 43,364	\$ 48,410	\$ 4,314	\$ 153	\$ 96,241

The following tables summarize our net revenue from the professional diagnostics and health information solutions reporting segments by groups of similar products and services for 2012, 2011 and 2010 (in thousands):

**Professional Diagnostics Segment**

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Cardiology .....	\$ 503,534	\$ 518,746	\$ 488,497
Infectious disease .....	615,950	564,983	437,709
Toxicology .....	587,261	387,209	300,125
Diabetes .....	144,441	14,960	—
Other .....	314,030	250,274	214,387
Net product sales and services revenue ....	2,165,216	1,736,172	1,440,718
License and royalty revenue .....	24,676	20,337	18,774
Professional diagnostics net revenue .....	<u>\$2,189,892</u>	<u>\$1,756,509</u>	<u>\$1,459,492</u>

**Health Information Solutions Segment**

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Disease and case management .....	\$ 218,378	\$ 237,938	\$ 281,563
Women's & children's health .....	120,259	114,287	126,910
Wellness .....	104,634	104,868	103,343
Patient self-testing services .....	92,151	77,421	87,003
Health information solutions net revenue ...	<u>\$ 535,422</u>	<u>\$ 534,514</u>	<u>\$ 598,819</u>

The following tables summarize our net revenue by geographic area for 2012, 2011 and 2010, respectively, and our long-lived tangible assets by geographic area as of December 31, 2012 and 2011, respectively (in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
<b>Revenue by Geographic Area:</b>			
United States .....	\$1,724,704	\$1,453,160	\$1,380,314
Europe .....	483,857	396,480	361,810
Elsewhere .....	610,264	536,887	413,223
	<u>\$2,818,825</u>	<u>\$2,386,527</u>	<u>\$2,155,347</u>

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(17) Financial Information by Segment (Continued)**

	December 31,	
	2012	2011
<b>Long-lived Tangible Assets by Geographic Area:</b>		
United States .....	\$ 295,786	\$ 290,708
United Kingdom .....	37,928	27,515
China .....	31,277	29,563
Elsewhere .....	169,478	143,419
	\$ 534,469	\$ 491,205

**(18) Related Party Transactions**

In November 2008, the Zwanziger Family Trust, a trust established for the benefit of the children of Ron Zwanziger, our Chairman, Chief Executive Officer and President, and the trustee of which is Mr. Zwanziger's sister, purchased certain of our securities from third parties in market transactions. The purchase consisted of approximately \$1.0 million of each of the following of our outstanding securities: our common stock, our Series B Preferred Stock and our convertible notes. To the extent we make principal and interest payments under the convertible notes in accordance with their terms, the Zwanziger Family Trust, as a holder of convertible notes, will receive its proportionate share.

In May 2007, we completed the formation of SPD, our 50/50 joint venture with P&G, for the development, manufacturing, marketing and sale of existing and to-be-developed consumer diagnostic products, outside the cardiology, diabetes and oral care fields. Upon completion of the arrangement to form the joint venture, we ceased to consolidate the operating results of our consumer diagnostic products business related to the joint venture and instead account for our 50% interest in the results of the joint venture under the equity method of accounting.

At December 31, 2012 and 2011, we had a net receivable from the joint venture of \$2.3 million and \$2.5 million, respectively. Included in the \$2.3 million receivable balance as of December 31, 2012 is approximately \$1.6 million of costs incurred in connection with our 2008 SPD-related restructuring plans. Included in the \$2.5 million receivable balance as of December 31, 2011 is approximately \$1.5 million of costs incurred in connection with our 2008 SPD-related restructuring plans. We have also recorded a long-term receivable totaling approximately \$14.6 million and \$15.5 million as of December 31, 2012 and December 31, 2011, respectively, related to the 2008 SPD-related restructuring plans. Additionally, customer receivables associated with revenue earned after the formation of the joint venture was completed have been classified as other receivables within prepaid expenses and other current assets on our accompanying consolidated balance sheets in the amount of \$6.9 million and \$7.3 million as of December 31, 2012 and 2011, respectively. In connection with the joint venture arrangement, the joint venture bears the collection risk associated with these receivables. Sales to the joint venture under our manufacturing agreement totaled \$63.6 million, \$71.2 million and \$68.1 million during the years ended December 31, 2012, 2011 and 2010, respectively. Additionally, services revenue generated pursuant to the long-term services agreement with the joint venture totaled \$1.1 million, \$1.1 million and \$1.2 million during the years ended December 31, 2012, 2011 and 2010, respectively. Sales under our manufacturing agreement and long-term services agreement are included in net product sales and services revenue, respectively, in our accompanying consolidated statements of operations.

Under the terms of our product supply agreement, SPD purchases products from our manufacturing facilities in the U.K. and China. SPD in turn sells a portion of those tests back to us for

**ALERE INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(18) Related Party Transactions (Continued)**

final assembly and packaging. Once packaged, the tests are sold to P&G for distribution to third-party customers in North America. As a result of these related transactions, we have recorded \$7.3 million and \$8.9 million of trade receivables which are included in accounts receivable on our accompanying consolidated balance sheets as of December 31, 2012 and 2011, respectively, and \$21.3 million and \$19.3 million of trade accounts payable which are included in accounts payable on our accompanying consolidated balance sheets as of December 31, 2012 and 2011, respectively. During 2012 and 2010, we received \$11.2 million and \$8.8 million, respectively, in cash from SPD as a return on our investment.

The following table summarizes our related party balances with SPD within our consolidated balance sheets (in thousands):

<u>Balance Sheet Caption</u>	<u>As of December 31,</u>	
	<u>2012</u>	<u>2011</u>
Accounts receivable, net of allowances .....	\$ 7,317	\$ 8,931
Prepaid expenses and other current assets .....	\$ 9,161	\$ 9,775
Deferred financing costs, net, and other non-current assets .....	\$14,629	\$15,455
Accounts payable .....	\$21,258	\$19,273

In connection with the formation of SPD in May 2007, we entered into an option agreement with P&G, pursuant to which P&G had the right, for a period of 60 days commencing on May 17, 2011, to require us to acquire all of P&G's interest in SPD at fair market value, and P&G had the right, upon certain material breaches by us of our obligations to SPD, to acquire all of our interest in SPD at fair market value. On July 16, 2011, P&G's option to require us to acquire its interest in SPD at fair market value expired. In connection with the expiration of the option, we recognized a gain in the amount of approximately \$288.9 million during the third quarter of 2011.

**(19) Valuation and Qualifying Accounts**

We have established reserves against accounts receivable for doubtful accounts, product returns, discounts and other allowances. The activity in the table below includes all accounts receivable reserves. Provisions for doubtful accounts are recorded as a component of general and administrative expenses. Provisions for returns, discounts and other allowances are charged against net product sales. The following table sets forth activities in our accounts receivable reserve accounts (in thousands):

	<u>Balance at Beginning of Period</u>	<u>Provision</u>	<u>Amounts Charged Against Reserves</u>	<u>Balance at End of Period</u>
Year ended December 31, 2010 .....	\$12,462	\$14,021	\$ (6,102)	\$20,381
Year ended December 31, 2011 .....	\$20,381	\$23,614	\$(19,418)	\$24,577
Year ended December 31, 2012 .....	\$24,577	\$43,731	\$(31,912)	\$36,396

**ALERE INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(19) Valuation and Qualifying Accounts (Continued)**

We have established reserves against obsolete and slow-moving inventories. The activity in the table below includes all inventory reserves. Provisions for obsolete and slow-moving inventories are recorded as a component of cost of net product sales. The following table sets forth activities in our inventory reserve accounts (in thousands):

	<u>Balance at Beginning of Period</u>	<u>Provision</u>	<u>Amounts Charged Against Reserves</u>	<u>Balance at End of Period</u>
Year ended December 31, 2010 .....	\$12,632	\$ 6,269	\$(6,593)	\$12,308
Year ended December 31, 2011 .....	\$12,308	\$ 6,144	\$(4,843)	\$13,609
Year ended December 31, 2012 .....	\$13,609	\$13,587	\$(5,374)	\$21,822

**(20) Restructuring Activities**

The following table sets forth aggregate restructuring charges recorded in our consolidated statements of operations for the years ended December 31, 2012, 2011 and 2010 (in thousands):

<u>Statement of Operations Caption</u>	<u>2012</u>	<u>2011</u>	<u>2010</u>
Cost of net revenue .....	\$ 3,113	\$ 2,915	\$ 3,896
Research and development .....	1,278	433	488
Sales and marketing .....	2,504	4,954	1,539
General and administrative .....	13,430	19,980	9,344
Total operating expenses .....	20,325	28,282	15,267
Interest expense, including amortization of original issue discounts and deferred financing costs .....	277	280	348
Other income, net .....	—	—	(3,494)
Equity earnings of unconsolidated entities, net of tax .....	—	580	3,009
Total charges .....	<u>\$20,602</u>	<u>\$29,142</u>	<u>\$15,130</u>

*(a) 2012 Restructuring Plans*

In 2012, management developed cost reduction plans within our professional diagnostics business segment, including the integration of our business in Brazil, Europe and the United States. Additionally, management developed new plans to continue our efforts to reduce costs within our health information solutions business segment, including the impairment of fixed assets and intangibles associated with terminated projects. The following table summarizes the restructuring activities related to our 2012 restructuring plans for the year ended December 31, 2012 (in thousands):

	<u>Professional Diagnostics</u>	<u>Health Information Solutions</u>	<u>Total</u>
Severance-related costs .....	\$4,732	\$3,045	\$ 7,777
Facility and transition costs .....	119	1,234	1,353
Other exit costs .....	—	15	15
Cash charges .....	4,851	4,294	9,145
Fixed asset and inventory impairments .....	304	2,689	2,993
Intangible asset impairments .....	—	2,988	2,988
Other non-cash charges .....	—	(31)	(31)
Total charges .....	<u>\$5,155</u>	<u>\$9,940</u>	<u>\$15,095</u>

**ALERE INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(20) Restructuring Activities (Continued)**

We anticipate incurring approximately \$2.2 million in additional severance and facility costs under these plans related to our health information solutions business segment through 2014, as well as \$0.3 million in additional severance and facility costs under these plans related to our professional diagnostics business segment in 2013. As of December 31, 2012, \$3.4 million in severance and exit costs under these plans remain unpaid.

*(b) 2011 Restructuring Plans*

In 2011, management executed a company-wide cost reduction plan, which impacted our corporate and other business segment, as well as the health information solutions and professional diagnostics business segments. Management also developed plans within our professional diagnostics business segment to consolidate operating activities among certain of our U.S., European and Asia Pacific subsidiaries, including transferring the manufacturing of our Panbio products from Australia to our Standard Diagnostics facility in South Korea and eliminating redundant costs among our newly acquired Axis-Shield subsidiaries. Additionally, within our health information solutions business segment, management executed plans to further reduce costs and improve efficiencies, as well as cease operations at our GeneCare Medical Genetics Center, Inc., or GeneCare, facility in Chapel Hill, North Carolina and transfer the majority of our Quality Assured Services, Inc. operation in Orlando, Florida to our facility in Livermore, California. The following table summarizes the restructuring activities related to our 2011 restructuring plans for the years ended December 31, 2012 and 2011 (in thousands):

	<b>Professional Diagnostics</b>		
	<u>2012</u>	<u>2011</u>	<u>Since Inception</u>
Severance-related costs .....	\$ 3,161	\$12,047	\$15,208
Facility and transition costs .....	1,599	361	1,960
Cash charges .....	4,760	12,408	17,168
Fixed asset and inventory impairments .....	704	659	1,363
Total charges .....	<u>\$ 5,464</u>	<u>\$13,067</u>	<u>\$18,531</u>
	<b>Health Information Solutions</b>		
	<u>2012</u>	<u>2011</u>	<u>Since Inception</u>
Severance-related costs .....	\$ —	\$ 2,254	\$ 2,254
Facility and transition costs .....	(723)	6,341	5,618
Other exit costs .....	78	94	172
Cash charges .....	(645)	8,689	8,044
Fixed asset and inventory impairments .....	85	864	949
Intangible asset impairments .....	—	2,935	2,935
Other non-cash charges .....	—	761	761
Total charges .....	<u>\$ (560)</u>	<u>\$13,249</u>	<u>\$12,689</u>
	<b>Corporate and Other</b>		
	<u>2012</u>	<u>2011</u>	<u>Since Inception</u>
Severance-related costs .....	\$ (3)	\$ 1,193	\$ 1,190
Cash charges .....	(3)	1,193	1,190
Fixed asset and inventory impairments .....	—	3	3
Total charges .....	<u>\$ (3)</u>	<u>\$ 1,196</u>	<u>\$ 1,193</u>

**ALERE INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(20) Restructuring Activities (Continued)**

We anticipate incurring approximately \$1.8 million in additional costs under these plans related to our professional diagnostics business segment, primarily related to severance and facility exit costs, and may also incur impairment charges on assets as plans are finalized. We anticipate incurring minimal additional costs under these plans related to our health information solutions business segment, primarily related to imputed interest on facility lease obligations. As of December 31, 2012, \$1.5 million in cash charges remain unpaid.

*(c) 2010 Restructuring Plans*

In 2010, management developed several plans to reduce costs and improve efficiencies within our health information solutions and professional diagnostics business segments. The following table summarizes the restructuring activities related to the 2010 restructuring plans for the years ended December 31, 2012, 2011 and 2010 and since inception (in thousands):

	<b>Professional Diagnostics</b>			
	<u>2012</u>	<u>2011</u>	<u>2010</u>	<u>Since Inception</u>
Severance-related costs .....	\$ —	\$ 74	\$2,406	\$2,480
Facility and transition costs .....	—	174	812	986
Other exit costs .....	—	—	10	10
Cash charges .....	—	248	3,228	3,476
Fixed asset and inventory impairments .....	—	—	126	126
Total charges .....	<u>\$ —</u>	<u>\$ 248</u>	<u>\$3,354</u>	<u>\$3,602</u>
	<b>Health Information Solutions</b>			
	<u>2012</u>	<u>2011</u>	<u>2010</u>	<u>Since Inception</u>
Severance-related costs .....	\$ —	\$ —	\$4,647	\$4,647
Facility and transition costs (recoveries) .....	(84)	40	2,436	2,392
Other exit costs .....	52	98	190	340
Cash charges (recoveries) .....	(32)	138	7,273	7,379
Fixed asset and inventory impairments .....	—	—	165	165
Total charges (recoveries) .....	<u>\$ (32)</u>	<u>\$ 138</u>	<u>\$7,438</u>	<u>\$7,544</u>

We do not anticipate incurring significant additional charges under these plans. As of December 31, 2012, \$0.7 million in facility-related costs remain unpaid.



**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(20) Restructuring Activities (Continued)**

*(d) 2008 Restructuring Plans*

In May 2008, management decided to close our facility located in Bedford, England and initiated steps to cease operations at this facility and transition the manufacturing operations principally to our manufacturing facilities in Shanghai and Hangzhou, China. The following table summarizes the restructuring activities under this plan for the years ended December 31, 2012, 2011 and 2010 and since inception (in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>	<u>Since Inception</u>
Severance-related costs (recoveries) . . . . .	\$ (16)	\$ (74)	\$ 154	\$ 3,364
Facility and transition costs (recoveries) . . .	(32)	577	1,644	4,180
Other exit costs (recoveries) . . . . .	—	—	(3,443)	3,842
Cash charges (recoveries) . . . . .	(48)	503	(1,645)	11,386
Fixed asset and inventory impairments (recoveries) . . . . .	—	(125)	399	5,796
Total charges (recoveries) . . . . .	<u>\$ (48)</u>	<u>\$ 378</u>	<u>\$(1,246)</u>	<u>\$17,182</u>

During the year ended December 31, 2010, we recorded net recoveries of \$3.4 million in other exit costs as a result of a settlement of the facility restoration and lease costs with the landlord of the Bedford facility. The costs incurred for the years ended December 31, 2012, 2011 and 2010 were included in our professional diagnostics business segment.

In addition to the restructuring charges discussed above, certain charges associated with the Bedford facility closure were borne by SPD, our 50/50 joint venture with P&G. Of the restructuring charges recorded by SPD, 50% has been included in equity earnings of unconsolidated entities, net of tax, in our consolidated statements of operations. The following table summarizes the 50% portion of the restructuring charges borne by SPD and included in equity earnings of unconsolidated entities, net of tax, for the years ended December 31, 2011 and 2010 and since inception (in thousands):

	<u>2011</u>	<u>2010</u>	<u>Since Inception</u>
Severance-related costs . . . . .	\$ 30	\$ 747	\$ 5,797
Facility and transition costs . . . . .	479	2,364	5,396
Other exit costs . . . . .	—	145	283
Cash charges . . . . .	509	3,256	11,476
Fixed asset and inventory impairments (recoveries) . . .	71	(247)	4,635
Total charges included in equity earnings of unconsolidated entities, net of tax . . . . .	<u>\$ 580</u>	<u>\$3,009</u>	<u>\$16,111</u>

As of December 31, 2012, all cash charges have been paid and we do not anticipate incurring significant additional restructuring charges under this plan.

**ALERE INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(20) Restructuring Activities (Continued)**

Additionally, in 2008, management developed and initiated plans to transition the businesses of Cholestech and HemoSense, Inc., or HemoSense, to our San Diego, California facility. Restructuring charges under these plans related to our professional diagnostics business segment. The following table summarizes the restructuring activities for these plans for the years ended December 31, 2012, 2011 and 2010 and since inception (in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>	<u>Since Inception</u>
Severance-related costs .....	\$ —	\$ —	\$ 158	\$ 4,505
Facility and transition costs .....	554	198	1,358	5,267
Other exit costs .....	132	88	97	698
	<u>686</u>	<u>286</u>	<u>1,613</u>	<u>10,470</u>
Cash charges .....			912	5,011
Fixed asset and inventory impairments ...	—	—	912	5,011
	<u>—</u>	<u>—</u>	<u>912</u>	<u>5,011</u>
Total charges .....	<u>\$ 686</u>	<u>\$ 286</u>	<u>\$2,525</u>	<u>\$15,481</u>

We anticipate incurring an additional \$0.1 million in facility lease obligation charges through March 2017. As of December 31, 2012, \$0.6 million in facility-related costs remain unpaid.

*(f) Restructuring Reserves*

The following table summarizes our restructuring reserves related to the plans described above, of which \$5.0 million is included in accrued expenses and other current liabilities and \$1.2 million is included in other long-term liabilities on our consolidated balance sheets (in thousands):

	<u>Severance- related Costs</u>	<u>Facility and Transition Costs</u>	<u>Other Exit Costs</u>	<u>Total</u>
Balance, December 31, 2009 .....	\$ 8,426	\$ 3,630	\$ 6,850	\$ 18,906
Cash charges (recoveries) .....	7,408	6,257	(3,146)	10,519
Cash charges borne by SPD(1) .....	1,494	4,728	290	6,512
Payments .....	(14,995)	(10,183)	(380)	(25,558)
Currency adjustments .....	(346)	(174)	(156)	(676)
Balance, December 31, 2010 .....	1,987	4,258	3,458	9,703
Cash charges .....	15,494	7,691	280	23,465
Cash charges borne by SPD(1) .....	60	958	—	1,018
Payments .....	(13,923)	(7,592)	(3,133)	(24,648)
Currency adjustments .....	(238)	(100)	(12)	(350)
Balance, December 31, 2011 .....	3,380	5,215	593	9,188
Cash charges .....	10,919	2,667	277	13,863
Payments .....	(11,118)	(5,469)	(248)	(16,835)
Currency adjustments .....	(14)	16	—	2
Balance, December 31, 2012 .....	<u>\$ 3,167</u>	<u>\$ 2,429</u>	<u>\$ 622</u>	<u>\$ 6,218</u>

(1) Amounts represent 100% of the charges borne by SPD.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(21) Equity Investments**

We account for the results from our equity investments under the equity method of accounting in accordance with ASC 323 *Investments — Equity Method and Joint Ventures*, based on the percentage of our ownership interest in the business. Our equity investments primarily include the following:

(i) Axis-Shield

During the third quarter of 2011, we acquired, in various transactions, approximately 15.0 million shares of Axis-Shield, which represented a 29.9% ownership interest in Axis-Shield as of September 30, 2011. During the fourth quarter of 2011, we acquired a controlling interest of Axis-Shield (Note 4). Our equity earnings attributable to this investment during 2011 were immaterial.

(ii) SPD

In May 2007, we completed the formation of SPD, our 50/50 joint venture with P&G for the development, manufacturing, marketing and sale of existing and to-be-developed consumer diagnostic products, outside the cardiology, diabetes and oral care fields. Upon completion of the arrangement to form SPD, we ceased to consolidate the operating results of our consumer diagnostics business related to SPD. For the years ended December 31, 2012, 2011 and 2010, we recorded earnings of \$10.7 million, \$5.9 million and \$8.5 million, respectively, in equity earnings of unconsolidated entities, net of tax, in our accompanying consolidated statements of operations, which represented our 50% share of SPD's net income for the respective periods.

(iii) TechLab

In May 2006, we acquired 49% of TechLab, Inc., or TechLab, a privately-held developer, manufacturer and distributor of rapid non-invasive intestinal diagnostics tests in the areas of intestinal inflammation, antibiotic-associated diarrhea and parasitology. For the years ended December 31, 2012, 2011 and 2010, we recorded earnings of \$2.3 million, \$2.0 million and \$1.9 million, respectively, in equity earnings of unconsolidated entities, net of tax, in our accompanying consolidated statements of operations, which represented our minority share of TechLab's net income for the respective period.

Summarized financial information for the P&G joint venture and TechLab on a combined basis is as follows (in thousands):

*Combined condensed results of operations:*

	<u>For The Years Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Net revenue . . . . .	<u>\$212,955</u>	<u>\$232,857</u>	<u>\$224,193</u>
Gross profit . . . . .	<u>\$139,694</u>	<u>\$146,466</u>	<u>\$142,159</u>
Net income after taxes . . . . .	<u>\$ 26,056</u>	<u>\$ 15,922</u>	<u>\$ 20,913</u>

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(21) Equity Investments (Continued)**

*Combined condensed balance sheets:*

	<b>As of December 31,</b>	
	<b>2012</b>	<b>2011</b>
Current assets .....	\$ 79,842	\$ 84,376
Non-current assets .....	38,991	37,659
Total assets .....	<b>\$118,833</b>	<b>\$122,035</b>
Current liabilities .....	\$ 45,084	\$ 49,453
Non-current liabilities .....	6,791	6,326
Total liabilities .....	<b>\$ 51,875</b>	<b>\$ 55,779</b>

**(22) Discontinued Operations**

On January 15, 2010, we completed the sale of our vitamins and nutritional supplements business for a purchase price of approximately \$62.6 million in cash, which is net of the final working capital adjustment. The sale included our entire private label and branded nutritional businesses and represents the complete divestiture of our entire vitamins and nutritional supplements business segment. We recognized a gain of approximately \$18.7 million (\$11.6 million, net of tax) during 2010. The results of the vitamins and nutritional supplements business, which represents our entire vitamins and nutritional supplements business segment, are included in income from discontinued operations, net of tax, in our consolidated financial statements.

The following summarized financial information related to the vitamins and nutritional supplements businesses has been segregated from continuing operations and reported as discontinued operations through the date of disposition (in thousands).

	<b>For The Year Ended December 31, 2010</b>
Net revenue .....	\$ 4,362
Income from discontinued operations before income taxes .....	\$18,487
Provision for income taxes .....	\$ 7,090
Net income from discontinued operations .....	\$11,397

**(23) Supplemental Cash Flow Information**

*Cash Paid for Interest and Income Taxes:*

During 2012, 2011 and 2010, we made cash payments for interest totaling \$205.0 million, \$164.7 million and \$117.1 million, respectively.

During 2012, 2011 and 2010, total net cash paid for income taxes was \$31.9 million, \$47.8 million and \$31.1 million, respectively.

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(23) Supplemental Cash Flow Information (Continued)**

*Non-cash Investing Activities:*

During 2011, we issued shares of our common stock in connection with certain acquisitions (dollars in thousands):

<u>Company Acquired</u>	<u>Date of Acquisition</u>	<u>Common Stock Issued</u>	
		<u>Number of Shares</u>	<u>Fair Value of Shares</u>
Arriva Medical LLC .....	November 23, 2011	806,452	\$15,183
Pregnancy.org, LLC .....	January 28, 2011	25,463	\$ 1,000

*Non-Cash Financing Activities:*

During 2011 and 2010, we recorded non-cash income (expense) to accumulated other comprehensive income (loss) of \$7.3 million and \$2.4 million, respectively, representing the change in fair market value of our interest rate swap agreement.

During 2012, we issued shares of our common stock in connection with the settlement of an acquisition-related contingent consideration obligation (dollars in thousands):

<u>Contingent Consideration Obligation</u>	<u>Common Stock Issued</u>	
	<u>Number of Shares</u>	<u>Fair Value of Shares</u>
Mologic .....	66,666	\$1,243

**(24) Guarantor Financial Information**

Our 7.25% senior notes due 2018, our 7.875% senior notes due 2016, our 9% senior subordinated notes due 2018, and our 8.625% senior subordinated notes due 2018 are guaranteed by certain of our consolidated wholly owned subsidiaries, or the Guarantor Subsidiaries. The guarantees are full and unconditional and joint and several. The following supplemental financial information sets forth, on a consolidating basis, audited balance sheets as of December 31, 2012 and 2011, the related statements of operations, statements of comprehensive income (loss) and cash flows for each of the three years in the period ended December 31, 2012, respectively, for Alere Inc., the Guarantor Subsidiaries and our other subsidiaries, or the Non-Guarantor Subsidiaries. The supplemental financial information reflects the investments of Alere Inc. and the Guarantor Subsidiaries in the Guarantor and Non-Guarantor Subsidiaries using the equity method of accounting.

We have extensive transactions and relationships between various members of the consolidated group. These transactions and relationships include intercompany pricing agreements, intellectual property royalty agreements and general and administrative and research and development cost-sharing agreements. Because of these relationships, it is possible that the terms of these transactions are not the same as those that would result from transactions among wholly unrelated parties.

For comparative purposes, certain amounts for prior periods have been reclassified to conform to the current period classification.

ALERE INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(24) Guarantor Financial Information (Continued)

CONSOLIDATING STATEMENT OF OPERATIONS  
For the Year Ended December 31, 2012

	Issuer	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	\$ —	\$ 849,786	\$1,207,822	\$(143,877)	\$1,913,731
Services revenue	—	592,511	284,007	—	876,518
Net product sales and services revenue	—	1,442,297	1,491,829	(143,877)	2,790,249
License and royalty revenue	—	18,629	18,177	(8,230)	28,576
<b>Net revenue</b>	<b>—</b>	<b>1,460,926</b>	<b>1,510,006</b>	<b>(152,107)</b>	<b>2,818,825</b>
Cost of net product sales	6,040	405,685	654,921	(134,496)	932,150
Cost of services revenue	—	320,148	136,910	(6,059)	450,999
Cost of net product sales and services revenue	6,040	725,833	791,831	(140,555)	1,383,149
Cost of license and royalty revenue	—	—	15,583	(8,229)	7,354
<b>Cost of net revenue</b>	<b>6,040</b>	<b>725,833</b>	<b>807,414</b>	<b>(148,784)</b>	<b>1,390,503</b>
<b>Gross profit (loss)</b>	<b>(6,040)</b>	<b>735,093</b>	<b>702,592</b>	<b>(3,323)</b>	<b>1,428,322</b>
Operating expenses:					
Research and development	24,593	66,929	91,479	—	183,001
Sales and marketing	4,414	304,548	334,461	—	643,423
General and administrative	52,079	208,981	231,706	—	492,766
<b>Operating income (loss)</b>	<b>(87,126)</b>	<b>154,635</b>	<b>44,946</b>	<b>(3,323)</b>	<b>109,132</b>
Interest expense, including amortization of original issue discounts and deferred financing costs	(236,320)	(39,292)	(13,362)	48,414	(240,560)
Other income (expense), net	(16,655)	40,476	34,550	(48,414)	9,957
<b>Income (loss) before provision (benefit) for income taxes</b>	<b>(340,101)</b>	<b>155,819</b>	<b>66,134</b>	<b>(3,323)</b>	<b>(121,471)</b>
Provision (benefit) for income taxes	(111,595)	48,904	33,327	(955)	(30,319)
<b>Income (loss) before equity earnings of unconsolidated entities, net of tax</b>	<b>(228,506)</b>	<b>106,915</b>	<b>32,807</b>	<b>(2,368)</b>	<b>(91,152)</b>
Equity in earnings (losses) of subsidiaries, net of tax	148,394	(1,574)	—	(146,820)	—
Equity earnings of unconsolidated entities, net of tax	2,205	—	10,952	88	13,245
<b>Net income (loss)</b>	<b>(77,907)</b>	<b>105,341</b>	<b>43,759</b>	<b>(149,100)</b>	<b>(77,907)</b>
Less: Net income attributable to non-controlling interests	—	—	275	—	275
<b>Net income (loss) attributable to Alere Inc. and Subsidiaries</b>	<b>(77,907)</b>	<b>105,341</b>	<b>43,484</b>	<b>(149,100)</b>	<b>(78,182)</b>
Preferred stock dividends	(21,293)	—	—	—	(21,293)
<b>Net income (loss) available to common stockholders</b>	<b>\$ (99,200)</b>	<b>\$ 105,341</b>	<b>\$ 43,484</b>	<b>\$(149,100)</b>	<b>\$ (99,475)</b>

**ALERE INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(24) Guarantor Financial Information (Continued)**

**CONSOLIDATING STATEMENT OF OPERATIONS**

For the Year Ended December 31, 2011

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	\$ —	\$ 896,069	\$ 914,885	\$(127,822)	\$1,683,132
Services revenue	—	582,924	96,998	—	679,922
Net product sales and services revenue	—	1,478,993	1,011,883	(127,822)	2,363,054
License and royalty revenue	—	9,504	19,928	(5,959)	23,473
<b>Net revenue</b>	—	1,488,497	1,031,811	(133,781)	2,386,527
Cost of net product sales	3,651	408,742	512,712	(129,681)	795,424
Cost of services revenue	—	306,635	31,597	—	338,232
Cost of net product sales and services revenue	3,651	715,377	544,309	(129,681)	1,133,656
Cost of license and royalty revenue	—	—	12,995	(5,959)	7,036
<b>Cost of net revenue</b>	3,651	715,377	557,304	(135,640)	1,140,692
<b>Gross profit (loss)</b>	(3,651)	773,120	474,507	1,859	1,245,835
Operating expenses:					
Research and development	20,182	66,283	63,700	—	150,165
Sales and marketing	4,091	325,022	236,470	—	565,583
General and administrative	48,891	222,958	127,481	—	399,330
Goodwill impairment charge	—	383,612	—	—	383,612
<b>Operating income (loss)</b>	(76,815)	(224,755)	46,856	1,859	(252,855)
Interest expense, including amortization of original issue discounts and deferred financing costs	(156,948)	(100,575)	(8,795)	62,347	(203,971)
Other income (expense), net	(8,813)	54,197	18,846	(62,347)	1,883
Gain on sale of joint venture interest	16,309	—	272,587	—	288,896
<b>Income (loss) from continuing operations before provision (benefit) for income taxes</b>	(226,267)	(271,133)	329,494	1,859	(166,047)
Provision (benefit) for income taxes	(67,482)	17,411	27,813	(1,956)	(24,214)
<b>Income (loss) from continuing operations before equity earnings of unconsolidated entities, net of tax</b>	(158,785)	(288,544)	301,681	3,815	(141,833)
Equity in earnings of subsidiaries, net of tax	23,524	1,530	—	(25,054)	—
Equity earnings of unconsolidated entities, net of tax	1,952	—	6,503	69	8,524
<b>Net income (loss)</b>	(133,309)	(287,014)	308,184	(21,170)	(133,309)
Less: Net income attributable to non-controlling interests	—	—	233	—	233
<b>Net income (loss) attributable to Alere Inc. and Subsidiaries</b>	(133,309)	(287,014)	307,951	(21,170)	(133,542)
Preferred stock dividends	(22,049)	—	—	—	(22,049)
Preferred stock repurchase	23,936	—	—	—	23,936
<b>Net income (loss) available to common stockholders</b>	<u>\$(131,422)</u>	<u>\$(287,014)</u>	<u>\$ 307,951</u>	<u>\$ (21,170)</u>	<u>\$ (131,655)</u>



**ALERE INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(24) Guarantor Financial Information (Continued)**

**CONSOLIDATING STATEMENT OF OPERATIONS**

**For the Year Ended December 31, 2010**

**(in thousands)**

	<u>Issuer</u>	<u>Guarantor Subsidiaries</u>	<u>Non-Guarantor Subsidiaries</u>	<u>Eliminations</u>	<u>Consolidated</u>
Net product sales .....	\$ —	\$ 843,542	\$740,371	\$(111,510)	\$ 1,472,403
Services revenue .....	—	608,482	53,703	—	662,185
Net product sales and services revenue ..	—	1,452,024	794,074	(111,510)	2,134,588
License and royalty revenue .....	—	9,032	17,138	(5,411)	20,759
<b>Net revenue</b> .....	<b>—</b>	<b>1,461,056</b>	<b>811,212</b>	<b>(116,921)</b>	<b>2,155,347</b>
Cost of net product sales .....	166	396,325	403,098	(111,264)	688,325
Cost of services revenue .....	—	304,269	21,017	—	325,286
Cost of net product sales and services revenue .....	166	700,594	424,115	(111,264)	1,013,611
Cost of license and royalty revenue .....	—	66	12,494	(5,411)	7,149
<b>Cost of net revenue</b> .....	<b>166</b>	<b>700,660</b>	<b>436,609</b>	<b>(116,675)</b>	<b>1,020,760</b>
<b>Gross profit (loss)</b> .....	<b>(166)</b>	<b>760,396</b>	<b>374,603</b>	<b>(246)</b>	<b>1,134,587</b>
Operating expenses:					
Research and development .....	20,936	67,438	44,904	—	133,278
Sales and marketing .....	3,001	316,884	179,239	—	499,124
General and administrative .....	46,982	233,978	165,957	—	446,917
Goodwill impairment charge .....	—	1,006,357	—	—	1,006,357
<b>Operating loss</b> .....	<b>(71,085)</b>	<b>(864,261)</b>	<b>(15,497)</b>	<b>(246)</b>	<b>(951,089)</b>
Interest expense, including amortization of original issue discounts and deferred financing costs .....	(76,179)	(135,312)	(10,430)	82,486	(139,435)
Other income (expense), net .....	10,304	69,938	24,982	(82,486)	22,738
<b>Loss from continuing operations before provision (benefit) for income taxes</b> ...	<b>(136,960)</b>	<b>(929,635)</b>	<b>(945)</b>	<b>(246)</b>	<b>(1,067,786)</b>
Provision (benefit) for income taxes .....	(58,592)	9,363	19,298	—	(29,931)
<b>Loss from continuing operations before equity earnings of unconsolidated entities, net of tax</b> .....	<b>(78,368)</b>	<b>(938,998)</b>	<b>(20,243)</b>	<b>(246)</b>	<b>(1,037,855)</b>
Equity in losses of subsidiaries, net of tax ...	(940,121)	—	—	940,121	—
Equity earnings of unconsolidated entities, net of tax .....	2,023	—	8,680	(137)	10,566
Loss from continuing operations .....	(1,016,466)	(938,998)	(11,563)	939,738	(1,027,289)
Income from discontinued operations, net of tax .....	574	9,727	1,096	—	11,397
<b>Net loss</b> .....	<b>(1,015,892)</b>	<b>(929,271)</b>	<b>(10,467)</b>	<b>939,738</b>	<b>(1,015,892)</b>
Less: Net income attributable to non- controlling interests .....	—	—	1,418	—	1,418
<b>Net loss attributable to Alere Inc. and Subsidiaries</b> .....	<b>(1,015,892)</b>	<b>(929,271)</b>	<b>(11,885)</b>	<b>939,738</b>	<b>(1,017,310)</b>
Preferred stock dividends .....	(24,235)	—	—	—	(24,235)
<b>Net loss available to common stockholders</b> .....	<b>\$(1,040,127)</b>	<b>\$ (929,271)</b>	<b>\$(11,885)</b>	<b>\$ 939,738</b>	<b>\$(1,041,545)</b>

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(24) Guarantor Financial Information (Continued)**

**CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME (LOSS)**  
**For the Year Ended December 31, 2012**  
**(in thousands)**

	<u>Issuer</u>	<u>Guarantor Subsidiaries</u>	<u>Non-Guarantor Subsidiaries</u>	<u>Eliminations</u>	<u>Consolidated</u>
<b>Net income (loss)</b> .....	\$(77,907)	\$105,341	\$43,759	\$(149,100)	\$(77,907)
Other comprehensive income, before tax:					
Changes in cumulative translation adjustment .....	(834)	(302)	53,654	2,124	54,642
Unrealized gains (losses) on available for sale securities .....	(221)	—	5	—	(216)
Unrealized gains on hedging instruments .....	16	—	372	—	388
Minimum pension liability adjustment .....	—	—	(1,042)	—	(1,042)
Other comprehensive income (loss), before tax .....	(1,039)	(302)	52,989	2,124	53,772
Income tax benefit related to items of other comprehensive income (loss) .....	(86)	—	(286)	—	(372)
Other comprehensive income (loss), net of tax .....	(953)	(302)	53,275	2,124	54,144
<b>Comprehensive income (loss)</b> .....	(78,860)	105,039	97,034	(146,976)	(23,763)
Less: Comprehensive income attributable to non-controlling interests .....	—	—	275	—	275
<b>Comprehensive income (loss) attributable to Alere Inc. and Subsidiaries</b> .....	<u>\$(78,860)</u>	<u>\$105,039</u>	<u>\$96,759</u>	<u>\$(146,976)</u>	<u>\$(24,038)</u>

**ALERE INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(24) Guarantor Financial Information (Continued)**

**CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME (LOSS)**

**For the Year Ended December 31, 2011**

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
<b>Net income (loss)</b> .....	\$(133,309)	\$(287,014)	\$308,184	\$(21,170)	\$(133,309)
Other comprehensive income (loss), before tax:					
Changes in cumulative translation adjustment .....	(417)	342	(37,825)	2,070	(35,830)
Unrealized losses on available for sale securities .....	(33)	—	(438)	—	(471)
Unrealized gains (losses) on hedging instruments .....	11,952	—	(448)	—	11,504
Minimum pension liability adjustment .....	—	—	(3,070)	—	(3,070)
Other comprehensive income (loss), before tax .....	11,502	342	(41,781)	2,070	(27,867)
Income tax provision (benefit) related to items of other comprehensive income (loss) .....	4,650	—	(1,557)	—	3,093
Other comprehensive income (loss), net of tax .....	6,852	342	(40,224)	2,070	(30,960)
<b>Comprehensive income (loss)</b> .....	(126,457)	(286,672)	267,960	(19,100)	(164,269)
Less: Comprehensive income attributable to non-controlling interests .....	—	—	233	—	233
<b>Comprehensive income (loss) attributable to Alere Inc. and Subsidiaries</b> .....	<u><u>\$ (126,457)</u></u>	<u><u>\$ (286,672)</u></u>	<u><u>\$ 267,727</u></u>	<u><u>\$ (19,100)</u></u>	<u><u>\$ (164,502)</u></u>

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(24) Guarantor Financial Information (Continued)**

**CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME (LOSS)**  
**For the Year Ended December 31, 2010**  
**(in thousands)**

	<u>Issuer</u>	<u>Guarantor Subsidiaries</u>	<u>Non-Guarantor Subsidiaries</u>	<u>Eliminations</u>	<u>Consolidated</u>
<b>Net loss</b> .....	\$(1,015,892)	\$(929,271)	\$(10,467)	\$939,738	\$(1,015,892)
Other comprehensive income (loss), before tax:					
Changes in cumulative translation adjustment .....	(1,553)	(160)	3,632	(2,129)	(210)
Unrealized gains on available for sale securities .....	804	—	347	—	1,151
Unrealized gains on hedging instruments .....	3,965	—	—	—	3,965
Minimum pension liability adjustment .....	—	—	(113)	—	(113)
Other comprehensive income (loss), before tax .....	3,216	(160)	3,866	(2,129)	4,793
Income tax provision related to items of other comprehensive income (loss) .....	1,649	—	—	—	1,649
Other comprehensive income (loss), net of tax .....	1,567	(160)	3,866	(2,129)	3,144
<b>Comprehensive loss</b> .....	(1,014,325)	(929,431)	(6,601)	937,609	(1,012,748)
Less: Comprehensive income attributable to non-controlling interests .....	—	—	1,418	—	1,418
<b>Comprehensive loss attributable to Alere Inc. and Subsidiaries</b> .....	<u>\$(1,014,325)</u>	<u>\$(929,431)</u>	<u>\$ (8,019)</u>	<u>\$937,609</u>	<u>\$(1,014,166)</u>

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(24) Guarantor Financial Information (Continued)**

**CONSOLIDATING BALANCE SHEET**  
**December 31, 2012**  
**(in thousands)**

	<u>Issuer</u>	<u>Guarantor Subsidiaries</u>	<u>Non-Guarantor Subsidiaries</u>	<u>Eliminations</u>	<u>Consolidated</u>
<b>ASSETS</b>					
<b>Current assets:</b>					
Cash and cash equivalents	\$ 3,623	\$ 60,385	\$ 264,338	\$ —	\$ 328,346
Restricted cash	—	1,579	1,497	—	3,076
Marketable securities	—	787	117	—	904
Accounts receivable, net of allowances	—	193,598	330,734	—	524,332
Inventories, net	—	140,840	204,803	(8,522)	337,121
Deferred tax assets	12,193	39,003	13,736	2,790	67,722
Prepaid expenses and other current assets	(20,636)	86,562	79,343	(33)	145,236
Intercompany receivables	298,812	1,205,509	119,762	(1,624,083)	—
<b>Total current assets</b>	<b>293,992</b>	<b>1,728,263</b>	<b>1,014,330</b>	<b>(1,629,848)</b>	<b>1,406,737</b>
Property, plant and equipment, net	2,679	267,466	264,876	(552)	534,469
Goodwill	—	1,522,226	1,526,179	—	3,048,405
Other intangible assets with indefinite lives	—	7,100	29,351	—	36,451
Finite-lived intangible assets, net	24,701	851,278	958,246	—	1,834,225
Deferred financing costs, net and other non-current assets	78,522	6,369	24,037	(71)	108,857
Investments in subsidiaries	4,114,478	142,768	3,813	(4,261,059)	—
Investments in unconsolidated entities	33,979	—	56,512	—	90,491
Deferred tax assets	—	782	7,511	—	8,293
Intercompany notes receivable	1,724,650	722,552	1,278	(2,448,480)	—
<b>Total assets</b>	<b>\$6,273,001</b>	<b>\$5,248,804</b>	<b>\$3,886,133</b>	<b>\$(8,340,010)</b>	<b>\$7,067,928</b>
<b>LIABILITIES AND EQUITY</b>					
<b>Current liabilities:</b>					
Current portion of long-term debt	\$ 45,000	\$ —	\$ 15,232	\$ —	\$ 60,232
Current portion of capital lease obligations	—	2,787	3,897	—	6,684
Accounts payable	7,993	65,878	96,103	—	169,974
Accrued expenses and other current liabilities	(388,830)	519,914	280,861	(26)	411,919
Intercompany payables	557,578	814,111	252,394	(1,624,083)	—
<b>Total current liabilities</b>	<b>221,741</b>	<b>1,402,690</b>	<b>648,487</b>	<b>(1,624,109)</b>	<b>648,809</b>
<b>Long-term liabilities:</b>					
Long-term debt, net of current portion	3,617,068	—	11,607	—	3,628,675
Capital lease obligations, net of current portion	—	4,399	8,518	—	12,917
Deferred tax liabilities	(5,329)	250,962	182,642	(87)	428,188
Other long-term liabilities	17,678	40,346	108,682	(71)	166,635
Intercompany notes payables	241,421	1,498,342	708,717	(2,448,480)	—
<b>Total long-term liabilities</b>	<b>3,870,838</b>	<b>1,794,049</b>	<b>1,020,166</b>	<b>(2,448,638)</b>	<b>4,236,415</b>
<b>Stockholders' equity</b>	<b>2,180,422</b>	<b>2,052,065</b>	<b>2,215,198</b>	<b>(4,267,263)</b>	<b>2,180,422</b>
Non-controlling interests	—	—	2,282	—	2,282
<b>Total equity</b>	<b>2,180,422</b>	<b>2,052,065</b>	<b>2,217,480</b>	<b>(4,267,263)</b>	<b>2,182,704</b>
<b>Total liabilities and equity</b>	<b>\$6,273,001</b>	<b>\$5,248,804</b>	<b>\$3,886,133</b>	<b>\$(8,340,010)</b>	<b>\$7,067,928</b>

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(24) Guarantor Financial Information (Continued)**

**CONSOLIDATING BALANCE SHEET**  
**December 31, 2011**  
**(in thousands)**

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
<b>ASSETS</b>					
<b>Current assets:</b>					
Cash and cash equivalents	\$ 12,451	\$ 85,838	\$ 200,884	\$ —	\$ 299,173
Restricted cash	—	1,591	7,396	—	8,987
Marketable securities	—	770	316	—	1,086
Accounts receivable, net of allowances	—	199,547	276,277	—	475,824
Inventories, net	—	136,091	189,886	(5,708)	320,269
Deferred tax assets	10,912	22,813	7,266	1,984	42,975
Prepaid expenses and other current assets	(74,078)	140,630	78,861	—	145,413
Intercompany receivables	397,914	426,136	27,871	(851,921)	—
<b>Total current assets</b>	<b>347,199</b>	<b>1,013,416</b>	<b>788,757</b>	<b>(855,645)</b>	<b>1,293,727</b>
Property, plant and equipment, net	2,542	274,588	214,206	(131)	491,205
Goodwill	—	1,530,324	1,295,791	(4,844)	2,821,271
Other intangible assets with indefinite lives	—	7,100	62,446	—	69,546
Finite-lived intangible assets, net	28,685	1,011,852	745,388	—	1,785,925
Deferred financing costs, net, and other non-current assets	88,153	5,532	19,556	—	113,241
Investments in subsidiaries	3,586,625	32,512	3,005	(3,622,142)	—
Investments in unconsolidated entities	29,021	—	56,117	—	85,138
Marketable securities	2,254	—	—	—	2,254
Deferred tax assets	—	—	10,394	—	10,394
Intercompany notes receivable	1,934,366	(196,820)	—	(1,737,546)	—
<b>Total assets</b>	<b>\$6,018,845</b>	<b>\$3,678,504</b>	<b>\$3,195,660</b>	<b>\$(6,220,308)</b>	<b>\$6,672,701</b>
<b>LIABILITIES AND EQUITY</b>					
<b>Current liabilities:</b>					
Current portion of long-term debt	\$ 43,000	\$ —	\$ 18,092	\$ —	\$ 61,092
Current portion of capital lease obligations	—	1,550	4,533	—	6,083
Short-term debt	6,240	—	—	—	6,240
Accounts payable	6,704	53,978	94,782	—	155,464
Accrued expenses and other current liabilities	(259,010)	455,366	199,217	—	395,573
Intercompany payables	429,644	104,257	318,018	(851,919)	—
<b>Total current liabilities</b>	<b>226,578</b>	<b>615,151</b>	<b>634,642</b>	<b>(851,919)</b>	<b>624,452</b>
<b>Long-term liabilities:</b>					
Long-term debt, net of current portion	3,243,341	—	24,110	—	3,267,451
Capital lease obligations, net of current portion	—	2,175	10,454	—	12,629
Deferred tax liabilities	(25,936)	303,837	102,730	69	380,700
Other long-term liabilities	24,407	47,135	81,856	—	153,398
Intercompany notes payables	321,221	658,573	754,650	(1,734,444)	—
<b>Total long-term liabilities</b>	<b>3,563,033</b>	<b>1,011,720</b>	<b>973,800</b>	<b>(1,734,375)</b>	<b>3,814,178</b>
<b>Redeemable non-controlling interest</b>	<b>—</b>	<b>—</b>	<b>2,497</b>	<b>—</b>	<b>2,497</b>
<b>Stockholders' equity</b>					
Non-controlling interests	2,229,234	2,051,633	1,582,381	(3,634,014)	2,229,234
	—	—	2,340	—	2,340
<b>Total equity</b>	<b>2,229,234</b>	<b>2,051,633</b>	<b>1,584,721</b>	<b>(3,634,014)</b>	<b>2,231,574</b>
<b>Total liabilities and equity</b>	<b>\$6,018,845</b>	<b>\$3,678,504</b>	<b>\$3,195,660</b>	<b>\$(6,220,308)</b>	<b>\$6,672,701</b>

**ALERE INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(24) Guarantor Financial Information (Continued)**

**CONSOLIDATING STATEMENT OF CASH FLOWS  
For the Year Ended December 31, 2012  
(in thousands)**

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
<b>Cash Flows from Operating Activities:</b>					
Net income (loss)	\$ (77,907)	\$ 105,341	\$ 43,759	\$(149,100)	\$ (77,907)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:					
Equity in earnings (losses) of subsidiaries, net of tax	(148,394)	1,574	—	146,820	—
Non-cash interest expense, including amortization of original issue discounts and deferred financing costs	21,213	277	—	—	21,490
Depreciation and amortization	7,961	225,845	223,062	(21)	456,847
Non-cash charges for sale of inventories revalued at the date of acquisition	—	1,400	3,281	—	4,681
Non-cash stock-based compensation expense	4,247	5,486	5,932	—	15,665
Impairment of inventory	—	5	290	—	295
Impairment of long-lived assets	—	2,903	586	—	3,489
Impairment of intangible assets	—	2,988	—	—	2,988
(Gain) loss on sale of fixed assets	4	(2,664)	509	—	(2,151)
Gain on sales of marketable securities	(751)	—	—	—	(751)
Equity earnings of unconsolidated entities, net of tax	(2,205)	—	(10,952)	(88)	(13,245)
Deferred income taxes	20,500	(71,531)	(32,575)	(962)	(84,568)
Other non-cash items	22,234	908	7,429	—	30,571
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net	—	5,949	(28,114)	—	(22,165)
Inventories, net	—	(6,604)	(13,089)	2,902	(16,791)
Prepaid expenses and other current assets	(454,780)	367,746	(10,579)	95,087	(2,526)
Accounts payable	1,289	14,429	(25,845)	—	(10,127)
Accrued expenses and other current liabilities	335,600	(247,710)	56,622	(95,081)	49,431
Other non-current liabilities	(12,373)	(3,080)	(20,020)	(70)	(35,543)
Intercompany payable (receivable)	413,479	(368,161)	(44,156)	(1,162)	—
<b>Net cash provided by operating activities</b>	<b>130,117</b>	<b>35,101</b>	<b>156,140</b>	<b>(1,675)</b>	<b>319,683</b>
<b>Cash Flows from Investing Activities:</b>					
Decrease in restricted cash	—	12	5,899	—	5,911
Purchases of property, plant and equipment	(2,061)	(78,295)	(122,999)	65,962	(137,393)
Proceeds from sale of property, plant and equipment	—	22,330	66,277	(66,217)	22,390
Cash paid for acquisitions, net of cash acquired	(403,552)	—	(21,034)	—	(424,586)
Proceeds from sales of marketable securities	2,784	58	214	—	3,056
Net cash received from equity method investments	1,470	—	11,237	—	12,707
Decrease in other assets	(53,189)	(2,516)	(641)	70	(56,276)
<b>Net cash used in investing activities</b>	<b>(454,548)</b>	<b>(58,411)</b>	<b>(61,047)</b>	<b>(185)</b>	<b>(574,191)</b>
<b>Cash Flows from Financing Activities:</b>					
Cash paid for financing costs	(10,139)	—	—	—	(10,139)
Cash paid for contingent purchase price consideration	(20,116)	(788)	(60)	—	(20,964)
Cash paid for dividends	(21,293)	—	—	—	(21,293)
Proceeds from issuance of common stock, net of issuance costs	14,924	—	—	—	14,924
Proceeds from issuance of long-term debt	648,000	—	535	—	648,535
Payments on short-term debt	(6,240)	—	—	—	(6,240)
Payments on long-term debt	(300,155)	—	(11,457)	—	(311,612)
Net proceeds (payments) under revolving credit facilities	22,500	—	(8,228)	—	14,272
Excess tax benefits on exercised stock options	176	303	25	—	504
Principal payments on capital lease obligations	—	(2,132)	(4,871)	—	(7,003)
Purchase of non-controlling interest	—	—	(2,972)	—	(2,972)
Other	(12,267)	—	—	—	(12,267)
<b>Net cash provided by (used in) financing activities</b>	<b>315,390</b>	<b>(2,617)</b>	<b>(27,028)</b>	<b>—</b>	<b>285,745</b>
Foreign exchange effect on cash and cash equivalents	213	474	(4,611)	1,860	(2,064)
Net increase (decrease) in cash and cash equivalents	(8,828)	(25,453)	63,454	—	29,173
Cash and cash equivalents, beginning of period	12,451	85,838	200,884	—	299,173
<b>Cash and cash equivalents, end of period</b>	<b>\$ 3,623</b>	<b>\$ 60,385</b>	<b>\$ 264,338</b>	<b>\$ —</b>	<b>\$ 328,346</b>



ALERE INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(24) Guarantor Financial Information (Continued)

CONSOLIDATING STATEMENT OF CASH FLOWS

For the Year Ended December 31, 2011

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
<b>Cash Flows from Operating Activities:</b>					
Net income (loss)	\$ (133,309)	\$ (287,014)	\$ 308,184	\$(21,170)	\$ (133,309)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:					
Equity in earnings of subsidiaries, net of tax	(23,524)	(1,530)	—	25,054	—
Non-cash interest expense, including amortization of original issue discounts and deferred financing costs	13,671	23,473	446	—	37,590
Depreciation and amortization	3,842	250,832	137,340	(438)	391,576
Non-cash charges for sale of inventories revalued at date of acquisition	—	—	6,010	—	6,010
Non-cash stock-based compensation expense	5,776	8,390	7,049	—	21,215
Impairment of inventory	—	172	273	—	445
Impairment of long-lived assets	3	1,331	215	—	1,549
Impairment of goodwill	—	383,612	—	—	383,612
Impairment of intangible assets	—	2,935	3	—	2,938
Gain on sale of joint venture interest	(16,309)	—	(272,587)	—	(288,896)
(Gain) loss on sale of fixed assets	75	1,655	(153)	—	1,577
Gain on sales of marketable securities	—	—	(840)	—	(840)
Equity earnings of unconsolidated entities, net of tax	(1,952)	—	(6,503)	(69)	(8,524)
Deferred income taxes	35,012	(78,248)	(11,569)	(1,956)	(56,761)
Other non-cash items	(4,286)	3,971	(11,932)	—	(12,247)
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net	—	2,143	(41,551)	—	(39,408)
Inventories, net	—	(9,490)	(9,002)	(1,907)	(20,399)
Prepaid expenses and other current assets	72,955	(109,813)	(16,257)	—	(53,115)
Accounts payable	(233)	(10,278)	17,496	—	6,985
Accrued expenses and other current liabilities	(231,949)	199,110	47,121	—	14,282
Other non-current liabilities	35,109	4,301	(22,437)	—	16,973
Intercompany payable (receivable)	(1,512,567)	857,634	654,933	—	—
<b>Net cash provided by (used in) operating activities</b>	<b>(1,757,686)</b>	<b>1,243,186</b>	<b>786,239</b>	<b>(486)</b>	<b>271,253</b>
<b>Cash Flows from Investing Activities:</b>					
(Increase) decrease in restricted cash	—	148	(6,554)	—	(6,406)
Purchases of property, plant and equipment	20	(63,369)	(69,614)	431	(132,532)
Proceeds from sale of property, plant and equipment	—	292	655	—	947
Proceeds from disposition of business	—	—	11,491	—	11,491
Cash paid for acquisitions, net of cash acquired	(37,644)	(8,688)	(584,979)	—	(631,311)
Proceeds from sales of marketable securities	—	145	9,057	—	9,202
Net cash paid for equity method investments	(2,430)	—	(119,473)	—	(121,903)
(Increase) decrease in other assets	(24,997)	(7,781)	6,248	(1,154)	(27,684)
<b>Net cash used in investing activities</b>	<b>(65,051)</b>	<b>(79,253)</b>	<b>(753,169)</b>	<b>(723)</b>	<b>(898,196)</b>
<b>Cash Flows from Financing Activities:</b>					
Cash paid for financing costs	(73,876)	(804)	—	—	(74,680)
Cash paid for contingent purchase price consideration	(28,305)	—	—	—	(28,305)
Cash paid for dividends	(5,425)	—	—	—	(5,425)
Proceeds from issuance of common stock, net of issuance costs	37,886	—	—	—	37,886
Repurchase of preferred stock	(99,070)	—	—	—	(99,070)
Proceeds from issuance of long-term debt	2,100,000	937	(4,660)	—	2,096,277
Payments on long-term debt	(10,125)	(1,192,344)	(4,985)	—	(1,207,454)
Net proceeds under revolving credit facilities	—	—	10,715	—	10,715
Repurchase of common stock	(184,867)	—	—	—	(184,867)
Excess tax benefits on exercised stock options	1,357	414	1,652	—	3,423
Principal payments on capital lease obligations	—	(2,372)	(1,791)	—	(4,163)
Other	(4,053)	—	(204)	—	(4,257)
<b>Net cash provided by (used in) financing activities</b>	<b>1,733,522</b>	<b>(1,194,169)</b>	<b>727</b>	<b>—</b>	<b>540,080</b>
Foreign exchange effect on cash and cash equivalents	—	(38)	(16,441)	1,209	(15,270)
Net increase (decrease) in cash and cash equivalents	(89,215)	(30,274)	17,356	—	(102,133)
Cash and cash equivalents, beginning of period	101,666	116,112	183,528	—	401,306
<b>Cash and cash equivalents, end of period</b>	<b>\$ 12,451</b>	<b>\$ 85,838</b>	<b>\$ 200,884</b>	<b>\$ —</b>	<b>\$ 299,173</b>

**ALERE INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(24) Guarantor Financial Information (Continued)**

**CONSOLIDATING STATEMENT OF CASH FLOWS**  
**For the Year Ended December 31, 2010**  
**(in thousands)**

	<u>Issuer</u>	<u>Guarantor Subsidiaries</u>	<u>Non-Guarantor Subsidiaries</u>	<u>Eliminations</u>	<u>Consolidated</u>
<b>Cash Flows from Operating Activities:</b>					
Net loss	\$ (1,015,892)	\$ (929,271)	\$ (10,467)	\$ 939,738	\$ (1,015,892)
Income from discontinued operations, net of tax	574	9,727	1,096	—	11,397
Loss from continuing operations	(1,016,466)	(938,998)	(11,563)	939,738	(1,027,289)
Adjustments to reconcile loss from continuing operations to net cash provided by (used in) operating activities:					
Equity in earnings of subsidiaries, net of tax	940,121	—	—	(940,121)	—
Non-cash interest expense, including amortization of original issue discounts and write-off of deferred financing costs	6,311	6,279	1,168	—	13,758
Depreciation and amortization	663	266,152	99,852	(479)	366,188
Non-cash charges for sale of inventories revalued at date of acquisition	—	—	6,602	—	6,602
Non-cash stock-based compensation expense	9,498	9,648	10,733	—	29,879
Impairment of inventory	—	261	587	—	848
Impairment of long-lived assets	—	1,473	(62)	—	1,411
Impairment of goodwill	—	1,006,357	—	—	1,006,357
Loss on sale of fixed assets	—	719	279	—	998
Gain on sale of marketable securities	(4,190)	—	(314)	—	(4,504)
Equity earnings of unconsolidated entities, net of tax	(2,023)	—	(8,680)	137	(10,566)
Deferred income taxes	3,340	(55,333)	(22,425)	—	(74,418)
Other non-cash items	(981)	3,608	1,175	—	3,802
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net	—	(4,281)	(5,079)	—	(9,360)
Inventories, net	—	(2,012)	(21,297)	464	(22,845)
Prepaid expenses and other current assets	(80)	4,473	3,917	—	8,310
Accounts payable	4,358	(1,548)	(11,898)	—	(9,088)
Accrued expenses and other current liabilities	(60,601)	64,708	18,095	—	22,202
Other non-current liabilities	(5)	(269)	(27,178)	—	(27,452)
Intercompany payable (receivable)	(296,816)	(140,254)	437,070	—	—
Net cash provided by (used in) continuing operations	(416,871)	220,983	470,982	(261)	274,833
Net cash provided by (used in) discontinued operations	849	(258)	—	—	591
<b>Net cash provided by (used in) operating activities</b>	<b>(416,022)</b>	<b>220,725</b>	<b>470,982</b>	<b>(261)</b>	<b>275,424</b>
<b>Cash Flows from Investing Activities:</b>					
(Increase) decrease in restricted cash	—	(163)	22	—	(141)
Purchases of property, plant and equipment	(82)	(56,922)	(39,498)	261	(96,241)
Proceeds from sale of property, plant and equipment	—	73	722	—	795
Cash paid for acquisitions, net of cash acquired	(184,975)	(33,146)	(305,386)	—	(523,507)
Proceeds from (purchases) of marketable securities	4,190	—	(1,008)	—	3,182
Net cash received from equity method investments	1,316	44	10,994	—	12,354
Increase in other assets	(5,600)	(695)	(6,605)	—	(12,900)
Net cash used in continuing operations	(185,151)	(90,809)	(340,759)	261	(616,458)
Net cash provided by (used in) discontinued operations	(849)	61,445	2,000	—	62,596
<b>Net cash used in investing activities</b>	<b>(186,000)</b>	<b>(29,364)</b>	<b>(338,759)</b>	<b>261</b>	<b>(553,862)</b>
<b>Cash Flows from Financing Activities:</b>					
Cash paid for financing costs	(9,552)	(3,493)	—	—	(13,045)
Proceeds from issuance of common stock, net of issuance costs	19,024	—	—	—	19,024
Proceeds from issuance of long-term debt	400,000	—	—	—	400,000
Payments on long-term debt	—	(9,750)	—	—	(9,750)
Net payments under revolving credit facilities	—	(144,181)	(2,600)	—	(146,781)
Excess tax benefits on exercised stock options	1,030	264	389	—	1,683
Principal payments on capital lease obligations	—	(1,501)	(366)	—	(1,867)
Purchase of non-controlling interest	—	—	(52,864)	—	(52,864)
Other	(141)	—	—	—	(141)
<b>Net cash provided by (used in) financing activities</b>	<b>410,361</b>	<b>(158,661)</b>	<b>(55,441)</b>	<b>—</b>	<b>196,259</b>
Foreign exchange effect on cash and cash equivalents	—	—	(9,288)	—	(9,288)
Net increase (decrease) in cash and cash equivalents	(191,661)	32,700	67,494	—	(91,467)
Cash and cash equivalents, beginning of period	293,327	83,412	116,034	—	492,773
<b>Cash and cash equivalents, end of period</b>	<b>\$ 101,666</b>	<b>\$ 116,112</b>	<b>\$ 183,528</b>	<b>\$ —</b>	<b>\$ 401,306</b>

**ALERE INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(25) Subsequent Events**

*(a) Epocal*

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

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

*(b) Short-Term Note*

In December 2012, we made a \$40.0 million secured loan to a third party (the Short-Term Note) (Note 3 (b)) in connection with a potential acquisition. As of December 31, 2012, the loan is included at face value in prepaid expenses and other current assets on our Consolidated Balance Sheet. In February 2013, the issuer of the Short-Term Note filed for protection under Chapter 11 of the U.S. Bankruptcy Code. The Bankruptcy Court subsequently granted us "continuing, valid, binding, enforceable and perfected first priority liens and security interests" in all of the post-petition collateral of the debtor to the "same extent, priority and enforceability" held on pre-petition collateral, in order to secure any and all obligations of the debtor to us under the Short-Term Note, and other related agreements. The Bankruptcy Court further directed the debtor to pay us post-petition interest at the contractual default rate and at the times set forth in the Short-Term Note.

We have assessed our Short-Term Note for impairment and considered the following factors: we have a perfected first priority lien in all of the post-petition collateral of the debtor, and the value of the available collateral, as represented by the debtor to the Bankruptcy Court, significantly exceeds the amount that is owed to us under the Short-Term Note. Based on these factors, along with the protections afforded to us as a secured creditor under bankruptcy law, we have determined that the Short-Term Note is fully realizable and, accordingly, we have not recorded a reserve against the amount receivable as of December 31, 2012. The bankruptcy process is inherently complicated and subject to uncertainties and future changes in circumstances and there can be no certainty as to the outcome of these proceedings.

## NOTES

NOTES

## NOTES



## MANAGEMENT

### **Ron Zwanziger**

*Chairman of the Board,  
Chief Executive Officer  
and President*

### **David Scott, Ph.D.**

*Chief Scientific Officer*

### **Jerry McAleer, Ph.D.**

*Senior Vice President,  
Research and Development*

### **Namal Nawana**

*Chief Operating Officer*

### **John Bridgen, Ph.D.**

*Senior Vice President,  
Business Development*

### **David Teitel**

*Chief Financial Officer,  
Vice President and Treasurer*

### **John O'Rourke**

*Chief Information Officer*

### **Hilde Eylenbosch, M.D.**

*President, Alere  
International Limited*

### **Robert Hargadon**

*Vice President,  
Human Resources*

### **Nigel Lindner**

*Vice President,  
Research and Development*

### **Robert Di Tullio**

*Vice President,  
Global Regulatory  
and Clinical Affairs*

### **Paul T. Hempel**

*Senior Vice President,  
Chief Ethics and  
Compliance Officer,  
Assistant Secretary*

### **Ellen Chiniara**

*Vice President, General  
Counsel and Secretary*

### **Melissa Guerdan**

*Vice President,  
Global Quality Assurance*

### **James Post**

*Global President,  
Acute Care*

### **Sanjay Malkani**

*Global President,  
Toxicology*

### **Michael Cotton**

*Global President,  
Health Information  
Solutions*

### **Daniella Cramp**

*Global President,  
Chronic Care*

### **Avi Pelossof**

*Global President,  
Infectious Disease*

### **Kate Torchilin, Ph.D.**

*Vice President and  
General Manager,  
Connected Health*

## DIRECTORS

### **Eli Y. Adashi, M.D., M.S., CPE, F.A.C.O.G.<sup>1</sup>**

*Professor of Medical  
Science,  
The Warren Alpert  
Medical School,  
Brown University*

### **Carol R. Goldberg<sup>1</sup>**

*President,  
The AVCAR Group, Ltd.*

### **Robert P. Khederian<sup>1,2</sup>**

*Chairman,  
Belmont Capital*

### **John F. Levy<sup>2,3</sup>**

*formerly President and  
Chief Executive Officer,  
Waban, Inc.*

### **Jerry McAleer, Ph.D.**

*Senior Vice President,  
Research and Development,  
Alere Inc.*

### **John A. Quelch, D.B.A.<sup>3</sup>**

*Professor of Business  
Administration,  
Harvard Business School*

### **James Roosevelt, Jr.<sup>3</sup>**

*President and Chief  
Executive Officer,  
Tufts Health Plan*

### **David Scott, Ph.D.**

*Chief Scientific Officer,  
Alere Inc.*

### **Peter Townsend<sup>2</sup>**

*formerly Chief Executive  
Officer,  
Enviromed plc*

### **Ron Zwanziger**

*Chairman of the Board,  
Chief Executive  
Officer and President,  
Alere Inc.*

## SHAREHOLDER INFORMATION

INDEPENDENT REGISTERED  
PUBLIC ACCOUNTING FIRM

### **PricewaterhouseCoopers LLP**

*125 High Street  
Boston, MA 02110*

TRANSFER AGENT

### **Computershare**

*P.O. Box 43078  
Providence, RI 02940-3078  
1-877-282-1168*

LEGAL COUNSEL

### **Foley Hoag LLP**

*Seaport West  
155 Seaport Boulevard  
Boston, MA 02210-2600*

ANNUAL MEETING

*Wednesday, August 7, 2013  
At 12:30 P.M.*

### **Emerging Enterprise Center at Foley Hoag LLP**

*1000 Winter Street  
Suite 4000  
Waltham, Massachusetts  
02451*

<sup>1</sup> Member of the  
Compensation Committee

<sup>2</sup> Member of the Audit  
Committee

<sup>3</sup> Member of the Nominating  
and Corporate Governance  
Committee



Notes & Disclaimers

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The Company's common stock is traded on the New York Stock Exchange under the symbol ALR.

Please visit the Company website at [www.alere.com](http://www.alere.com) for current news and information.

This Annual Report and the attached Annual Report on Form 10-K contain 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. A number of important factors could cause actual results of Alere Inc. and its subsidiaries to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, our ability to successfully acquire and integrate our acquisitions and to recognize the expected benefits of restructuring and new business activities; our exposure to changes in interest rates and foreign currency exchange rates; our ability to successfully develop and commercialize products and services; our ability to develop enhanced health information solutions through the integrated use of innovative diagnostic and monitoring devices and to recognize the expected benefits of this strategy; the impact of healthcare reform legislation, as well as future initiatives; the content and timing of regulatory decisions and actions, including the impact of the FDA warning letter and the OIG subpoena, as well as the impact of changes in reimbursement policy, and budgetary constraints, both in the United States and abroad; the effect of pending and future legal proceedings on our financial performance, as well as other risk factors detailed in the attached Annual Report on Form 10-K and other risk factors identified from time to time in our periodic filings with the Securities and Exchange Commission. Readers should carefully review the factors discussed in the section entitled "Risk Factors" beginning on page 17 in the attached Annual Report on Form 10-K and should not place undue reliance on our forward-looking statements. These forward-looking statements were based on information, plans and estimates at the date of this report. We undertake no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes.



Shareholder Relations – Alere Inc.

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