

INVERNESS MEDICAL INNOVATIONS INC

Form 10-K

March 01, 2010

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

FORM 10-K

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

(Mark One)

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

For the fiscal year ended December 31, 2009

or

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

For the transition period from to

Commission file number 000-16789

INVERNESS MEDICAL INNOVATIONS, 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

New York Stock Exchange

Stock, \$0.001 per share par value

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting common stock held by non-affiliates of the registrant based on the closing price of the registrant's stock on the New York Stock Exchange on June 30, 2009 (the last business day of the registrant's most recently completed second fiscal quarter) was \$1,940,958,310.

As of February 24, 2010, the registrant had 83,874,282 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 annual meeting of shareholders currently scheduled to be held on June 30, 2010 are incorporated by reference into Part III of this Form 10-K.

INVERNESS MEDICAL INNOVATIONS, INC.

FORM 10-K

For The Fiscal Year Ended December 31, 2009

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PART I

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

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

ITEM 1. BUSINESS

GENERAL

Inverness Medical Innovations enables individuals to take charge of improving their health and quality of life at home by developing new capabilities in near-patient diagnosis, monitoring and health management. Our global leading products and services, as well as our new product development efforts, focus on cardiology, women's health, infectious disease, oncology and drugs of abuse. We are confident that our unique ability to offer rapid diagnostic tools combined with value-added healthcare services will improve care and lower healthcare costs for both providers and patients.

Inverness Medical Innovations, Inc., a Delaware corporation, 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. Our common stock is listed on the New York Stock Exchange under the symbol IMA. We have grown our businesses through strategic acquisitions, tactical use of our superior intellectual property portfolio and through organic growth.

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.invmed.com and we make available through 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. These reports may be accessed through our website's investor information page. We also make our code of ethics and certain other governance documents and policies available through this site.

Segments

Our major reportable operating segments are professional diagnostics, health management and consumer diagnostics. Financial information about our reportable segments is provided in Note 19 of the Notes to Consolidated Financial

Statements which are included elsewhere in this report.

On January 15, 2010, we completed the sale of our vitamins and nutritional supplements business. This business, which had been reported in prior periods as a separate operating segment, is now classified as discontinued operations. See Note 24 of the Notes to Consolidated Financial Statements.

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Products and Services

Professional Diagnostics. Professional diagnostics are generally designed to assist medical professionals in both preventative and interventional medicine, and include testing and monitoring performed in hospitals and doctors offices and, increasingly, testing and monitoring done at home at the direction of the medical professional, or through patient self-testing. Professional diagnostic products provide for qualitative or quantitative analysis of a patient's body fluids or tissue for evidence of a specific medical condition, disease state or toxicological state or to measure response to therapy. Within professional diagnostics, we focus on point-of-care, rapid diagnostic testing and health monitoring and the developing patient self-testing market. We distinguish the point-of-care and patient self-testing markets from clinical diagnostic markets consisting of large, centralized laboratories offering a wide range of highly-automated laboratory services in hospital or related settings. The point-of-care market for rapid diagnostic products consists primarily of small and medium size laboratories and testing locations, such as physician office laboratories, specialized mobile clinics, emergency rooms and some rapid-response laboratories in larger medical centers.

In the market for rapid diagnostic products, the ability to deliver faster, accurate results at reasonable prices generally drives demand. This means that, while there is certainly demand for faster, more efficient automated equipment from large hospitals and major reference testing laboratories, there is also growing demand by point-of-care facilities and smaller laboratories for fast, high-quality, less expensive, self-contained diagnostic kits. As the speed and accuracy of such products improve, we believe that these products will play an increasingly important role in achieving early diagnosis, timely intervention and therapy monitoring outside of acute medicine environments, especially where supplemented by the support and management services that we also provide.

Our current professional diagnostic products test for over 100 disease states and conditions and include point-of-care and laboratory tests in 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 80 million Americans alone have one or more types of cardiovascular disease. The worldwide cardiology diagnostic market, including the markets for heart failure diagnostics, coronary artery disease risk assessment, coagulation testing and acute coronary syndrome, exceeds \$1.5 billion. Our Triage, Cholestech LDX and INRatio products, all acquired through acquisitions in 2007, have established us as a leader in this market. The Triage system consists of a portable fluorometer that interprets consumable test devices for cardiovascular conditions, as well as the detection of certain drugs of abuse. The Triage cardiovascular tests include the following:

Triage BNP Test. An immunoassay that measures B-type Natriuretic Peptide (BNP) in whole blood or plasma, used as an aid in the diagnosis and assessment of severity of heart failure. The test is also used for the risk stratification of patients with acute coronary syndrome and heart failure. We also offer a version of the Triage BNP Test for use on Beckman Coulter lab analyzers.

Triage Cardiac Panel. An immunoassay for the quantitative determination of CK-MB, myoglobin and troponin I in whole blood or plasma, used as an aid in the diagnosis of acute myocardial infarction.

Triage CardioProfilER Panel. An immunoassay for use as an aid in the diagnosis of acute myocardial infarction, the diagnosis and assessment of severity of congestive heart failure, risk stratification of patients with acute coronary syndromes and risk stratification of patients with heart failure. This panel combines troponin I, CK-MB, myoglobin and BNP to provide rapid, accurate results in whole blood and plasma.

Triage Profiler Shortness of Breath (S.O.B.) Panel. An immunoassay for use as an aid in the diagnosis of myocardial infarction, the diagnosis and assessment of severity of congestive heart failure, the 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.

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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.

The Cholestech LDX System is a point-of-care monitor of blood cholesterol and related lipids which is used to test patients at risk of, or suffering from, heart disease and related conditions. The Cholestech LDX System makes it possible to provide a complete lipid profile with tests for total cholesterol (TC), HDL & LDL cholesterol, triglycerides, and glucose (GLU), as well as tests for ALT and AST (for liver enzyme monitoring), and high sensitivity C-reactive protein (hs-CRP). The Cholestech LDX System can also provide coronary heart disease risk assessment from the patient's results as measured on the lipid profile cassette. The Cholestech LDX System provides results in five minutes per test cassette (seven minutes for hs-CRP) and is CLIA-waived, meaning the United States Food and Drug Administration, or FDA, has waived the more stringent requirements for laboratory testing applicable to moderate or high complexity laboratories based on the Cholestech LDX System's ease of use and accuracy. This allows the Cholestech LDX System to be marketed to physicians' offices, rather than hospitals or larger laboratories, and it is present in approximately 12% of U.S. CLIA-waived physicians' office laboratories with an installed base of approximately 10,000 units in regular use.

The 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 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 with risk of blood clot formation are maintained within the therapeutic range with the proper dosage of oral anticoagulant therapy. The 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 INRatio System is targeted to both the professional, or point-of-care market, as well as the patient self-testing market. Recently we introduced the INRatio2 System, which targets the patient self-testing market and offers enhanced ease of use. Patient self-testing has gained significant momentum since March 2008 when Centers for Medicare & Medicaid Services expanded coverage of home INR monitoring to include chronic atrial fibrillation and venous thromboembolism patients on warfarin.

As of November 30, 2009, we also distribute the epoc[®] Blood Analysis System for blood gas and electrolyte testing pursuant to an agreement with Epocal, Inc., or Epocal. The epoc (enterprise point of care) platform is a point-of-care analysis system which provides wireless bedside blood gas and electrolyte measurement testing solutions and complements our Triage products in cardiology and emergency room settings. Utilizing easy to use, low-cost disposable Smart-Cards[™], the epoc System produces laboratory quality results in critical and acute care settings in about 30 seconds. The epoc System received FDA 510(k) clearance in 2006 for marketing in the U.S.

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

Women's Health. Since women's health and general sexual health issues are a global health concern, this remains a priority area for us. In the professional marketplace, we are a global leader in pregnancy fertility/ovulation testing and bone therapy (osteoporosis) monitoring. Our professional pregnancy tests are generally urine-based, CLIA-waived rapid tests in dipstick or cassette format.

Our professional women's health products also target diseases, such as rubella and Group B strep, which pose unique threats to unborn or newborn babies and, in addition, we market a portfolio of tests for sexually-transmitted diseases. Our women's health products are sold under our Acceava, Clearview, Sure-Step, Inverness Medical TestPack and

Osteomark brands.

Infectious Disease. We believe that the demand for infectious disease diagnostic products is growing faster than many other segments of the immunoassay market due to the increasing incidence of certain diseases or groups of diseases, including viral hepatitis, respiratory syncytial virus (RSV), influenza, tuberculosis, human immunodeficiency virus (HIV) / acquired immunodeficiency syndrome (AIDS), herpes

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and other sexually-transmitted diseases. To meet this demand, we have continued to expand our product offerings and now offer one of the world's largest infectious disease test menus. We develop and market a wide variety of point-of-care tests for Influenza A/B, strep throat, HIV, HSV-2, HCV, Malaria, C.difficile, infectious mononucleosis, Lyme disease, Chlamydia, H.pylori, RSV, Rubella and other infectious diseases. Our tests for infectious disease are sold under brand names which include Acceava, BinaxNOW, Clearview, Determine, Inverness Medical TestPack, DoubleCheckGold, Panbio and TECHLAB®. We have, as of February 2010, also acquired a majority interest in Standard Diagnostics, Inc., or Standard Diagnostics, whose SD branded rapid diagnostic tests, particularly its tests for HIV, malaria and influenza, have a strong presence in Asia, Africa and the Middle East.

In addition to point-of-care products, we also offer a line of indirect fluorescent antibody, or IFA, assays for over 20 viral, bacterial and autoimmune diseases, a full line of serology diagnostic products covering a broad range of disease categories and over 70 enzyme-linked immunosorbent assays (ELISA) tests for a wide variety of infectious and autoimmune diseases, as well as a full line of automated instrumentation for processing ELISA assays. 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, primarily 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 from year to year based in large part on the severity, length and timing of the onset of the cold and flu season. While we believe that the severity, length and timing of the onset of the cold and flu season will continue to impact sales of certain of our infectious disease products, there can be no assurance that our future sales of these products will necessarily follow historical patterns.

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

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 the second most common in women.

Drugs of Abuse. Drug abuse is a major global health problem, as well as a social and economic burden. In addition to being a primary cause of lost workforce productivity, family conflict and drug-related crime, drug abuse is linked to the spread of HIV/AIDS through contaminated needles. Drug abuse is one of the most costly health problems in the United States. As a result, employers, law enforcement officials and others expend considerable effort to be sure their employees and constituents are free of substance abuse, creating a significant market for simple, reliable tests to detect the most commonly abused substances. Additionally, physicians are increasingly utilizing drug testing to identify and address signs of prescription drug misuse. Urine-based screening 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 screening urine for drugs of abuse.

We offer one of the broadest and most comprehensive lines of drugs of abuse tests available today. We offer tests to detect alcohol, as well as the following illicit and prescription drugs of abuse: amphetamines/methamphetamines,

cocaine, opiates, phencyclidine, tetrahydrocannabinol, acetaminophen, barbiturates,

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benzodiazepines, methadone, propoxyphene and tricyclic antidepressants, using both urine and saliva body fluids.

Our rapid drugs of abuse tests are sold primarily under the brands Triage, iScreen, Concateno and SureStep. The TOX Drug Screen panel sold for use with our Triage system detects the presence of any illicit or 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 which displays results for the presence of up to six different drugs in under five minutes and two drugs in under 90 seconds.

We have recently expanded our drugs of abuse products and services significantly, particularly in the toxicology laboratory field. Our addition of Concateno plc, or Concateno, in August 2009, allows us to offer comprehensive lab-based testing services throughout Europe, and the acquisition of Kroll Laboratory Services, Inc., or Kroll, in February 2010, enables us to offer toxicology services through laboratories certified by the U.S. Substance Abuse and Mental Health Services Administration, or SAMHSA. Through our subsidiary Redwood Toxicology Laboratory, Inc., or Redwood, we also offer comprehensive, low-cost laboratory testing services to multiple domestic clients, including law enforcement agencies, penal systems, insurers and employers. Our comprehensive offerings deliver the certainty of science, the dependability of proven processes and the assurance of legally defensible results.

Health Management. We believe that by utilizing both existing professional diagnostic devices and new devices under development to enhance the delivery of health management and other services to healthcare providers, we can further facilitate cost containment and outcome-driven decision making. Our Alere health management business strives to empower participants of our programs and physicians so they can work together towards better health. We also provide services supporting home INR testing through Quality Assured Services, Inc., or QAS, and Tapestry Medical, Inc., or Tapestry.

Our expert-designed health management programs:

embrace the entire lifespan, from pre-cradle to end-of-life, and targeted health states, from wellness to prevention to total health management of the individual for those having various chronic illnesses.

target high-cost chronic conditions with programs designed to improve outcomes and reduce expenditures.

provide health coaches who engage and motivate participants during teachable moments.

help participants improve their health by supporting their individual health goals.

bring greater clarity to healthcare with empowering technologies that lead to better outcomes.

offer the expertise of 1,850 healthcare professionals who share a passion for patient and customer care.

Our key health management programs are:

Care. The Alere Disease Management Program provides technology-enabled, evidence-based solutions for managing chronic and high-cost conditions, improving productivity and reducing healthcare costs. The Alere Disease Management Program assists individuals with chronic diseases or conditions to better manage their care by increasing their knowledge about their illnesses, potential complications and the importance of medication and treatment plan compliance. Our highly-trained clinicians proactively contact participants to monitor their progress and ensure they are following the plan of care set by their physician. They work with participants to identify potential gaps in care, which occur when individuals do not receive national standards of care, or best practices, or when an individual fails

to comply with their treatment plan.

We offer a personal health support model of care. This model differs from providers of traditional, total population health models in several ways, including how individuals are selected, as well as a more disciplined approach to defining who can benefit from what kinds of touches and how these specific interactions are best accomplished. A second key differentiator is the use of the Alere DayLink Monitor for persons participating in higher risk health management programs. The DayLink Monitor records a participant s

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weight and/or answers to questions regarding their symptoms. This information is gathered daily and sent to our clinicians for review. The Alere Disease Management Program currently assists individuals with the following diseases or conditions: asthma, coronary artery disease, chronic obstructive pulmonary disease, diabetes, heart failure, pain, weight management and depression. In addition, we also offer Complex Care Management and Chronic Care Management for participants who require more attention and care than a traditional disease management program provides. What distinguishes our two programs is that Complex Care provides on-site care, and the Chronic Complex program involves telephone contact with Alere clinicians.

Patient Self-Testing Services. We also offer services designed to support anticoagulation management for patients at risk for stroke and other clotting disorders who can benefit from home INR monitoring. As mentioned, home INR monitoring has grown increasingly popular since the Centers for Medicare & Medicaid Services expanded coverage to include home INR monitoring of chronic atrial fibrillation and venous thromboembolism patients on warfarin. Our QAS and Tapestry businesses assist patients in acquiring home INR monitors, including our INRatio2 monitors, and seeking Medicare reimbursement and insurance coverage, while providing physicians with a comprehensive solution for incorporating home INR monitoring into their practice. Our CoagNow program includes our Face-2-Face patient training model, which utilizes experienced nurse educators; patient scheduling; collection and reporting of home testing results to the physician and CoagClinic, our sophisticated web-based application that provides healthcare professionals with real-time access to patient information.

Women's & Children's Health. Our Women's and Children's Health division delivers a total spectrum of obstetrical care services, ranging from a risk assessment to identify women at risk for preterm birth to a neonatal program for early infant care management. In between are first and second trimester genetic testing as well as home-based obstetrical programs to manage and monitor pregnant women who have medical or pregnancy-related problems that could harm the health of the mother or baby. We deliver telephonic and home-based nursing services that support physician and patient goals. We have developed and refined these services over the years to accommodate physician plans of care. We focus on assessment of patient data and providing education. Our high-risk pregnancy management program revenues tend to be seasonal. Revenues tend to decrease with the onset of the holiday season starting with Thanksgiving. As a result, first and fourth quarter revenues of each year tend to be lower than second and third quarter revenues.

Oncology. The Alere Oncology Program is the longest-running cancer management program (since 1994) in the nation. This program screens for and manages 62 types of cancer. Since the program's inception, we have managed more than 50,000 participants. Cancer continues to challenge employers and health plans as they search for tools to compassionately manage this condition among their population in the most cost-effective manner. By incorporating best of breed practices and coordinating with physicians and participants, we provide an integrated solution to proactively manage this expensive and debilitating disease.

Wellness. Wellness Solutions is a suite of integrated wellness programs and resources designed to help organizations reduce health risks and improve the health and productivity of their employees while reducing healthcare-related costs. Wellness programs include screening for risk factors associated with diabetes, cardiovascular heart disease, hypertension and obesity; screening for high-risk pregnancies; assessments of health risks for broad populations; programs that promote better health by encouraging sustainable changes in behavior and health coaching. In September 2009, we enhanced our wellness offerings through our acquisition of Free & Clear, Inc., or Free & Clear, the healthy behaviors company that specializes in web-based learning and phone-based cognitive behavioral coaching to help employers, health plans and state governments improve the overall health and productivity of their covered populations. Free & Clear's evidence-based programs address the four key modifiable health risks that contribute to chronic disease: tobacco use, poor nutrition, physical inactivity and stress.

Technology Solutions. Our technology solutions provide employers and health plans with a powerful portal or front door to our continuum of healthcare services and allow individuals to create a HIPAA Compliant, confidential on-line record of all of their personal healthcare data. On January 1, 2010, we launched our enhanced integrated health management portal, Apollo, with several large clients. Apollo will be rolled out to the remainder of Alere's existing clients throughout 2010 and 2011. The enhanced system provides the framework and supporting

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infrastructure for a series of significant enhancements to Alere's services, including a whole new dynamic, interactive and personalized experience for employees via an enhanced health portal and will provide us with an unparalleled ability to integrate data from a variety of sources, including health plans, pharmacy benefit managers and point of care devices.

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

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

a meaningful, engaging experience with content and activities presented based on their preferences, activities and personal health data, and

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

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

Consumer Diagnostics. On May 17, 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 with P&G, 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 drugs of abuse 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 alcohol abuse, cholesterol monitoring and colon cancer screening. Taking advantage of our leadership in the field of women's health, we also sell Balance Activ Vaginal Gel directly to consumers and health care professionals for the effective treatment of bacterial vaginosis without antibiotics.

Methods of Distribution and Customers

In the United States, Canada, the United Kingdom, Ireland, Germany, Italy, Spain, Switzerland, the Netherlands, Belgium, France, Austria, India, Japan, China, South Korea, Taiwan, Hong Kong, Australia, New Zealand, South Africa, Brazil, Argentina, Colombia and Israel, we distribute our professional diagnostic products to hospitals, reference laboratories, physicians' offices and other point-of-care settings through our own sales forces and distribution

networks. In these countries, as well as in all other major world markets, we also utilize third-party distributors to sell our products. Our QAS and Tapestry subsidiaries facilitate the distribution of our INRatio and INRatio2 coagulation monitors by contacting targeted customers and facilitating the Medicare reimbursement process for physicians and for patients monitoring at home.

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

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

Manufacturing

Our primary manufacturing facilities are located in Hangzhou and Shanghai, China; Matsudo, Japan; San Diego, California; and Scarborough, Maine. We are in the final stages of closing another significant facility in Bedford, England and transferring the manufacturing operations located there to our low cost production facilities mainly in China. We also manufacture products at a number of other facilities in the United States, the United Kingdom, Germany, Spain, Israel, Australia and South Africa. We recently acquired a majority interest in Standard Diagnostics, a manufacturer and distributor of professional diagnostic products, which has significant manufacturing facilities in Yongin, South Korea and Gurgaon, India.

Our primary manufacturing facilities are ISO certified and registered with the FDA. We manufacture substantially all of our consumable diagnostic products at these facilities. We also manufacture the consumable diagnostic devices containing the diagnostic chemistry or other proprietary diagnostic technology, which are used in conjunction with our diagnostic or monitoring systems, including our Triage system, our Cholestech LDX monitoring devices, our 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 which we sell, including our Triage[®] BNP Test for use on Beckman Coulter systems, a majority of our IFA and ELISA tests and our TECHLAB[®] products.

Research and Development

Our primary research and development centers are in Jena, Germany; Stirling, Scotland and San Diego, California. We also conduct research and development at various of our other facilities including facilities in the United States, the United Kingdom, Spain, Australia and Israel. Standard Diagnostics also has significant research and development operations. Our research and development programs currently focus on the development of cardiology, women's health, infectious disease, oncology and drugs of abuse products.

Global Operations

We are a global company with major manufacturing facilities in Hangzhou and Shanghai, China and Matsudo, Japan and significant research and development operations in Jena, Germany and Stirling, Scotland. Standard Diagnostics has significant operations in Yongin, South Korea and Gurgaon, India. Our distribution network supporting our professional diagnostics business includes offices in the United States, Canada, the United Kingdom, Germany, Italy, Spain, Switzerland, the Netherlands, Belgium, France, Austria, India, Japan, China, South Korea, Taiwan, Hong Kong, Australia, New Zealand, South Africa, Brazil, Argentina, Colombia and Israel.

Our professional diagnostic products are sold throughout the world. Our health management programs are offered almost exclusively in the United States. During 2009 and 2008, respectively, approximately 69% and 71% of our net revenue was generated from the United States, approximately 17% and 18% of our net revenue was generated from Europe, and approximately 14% and 11% of our net revenue was generated from customers located elsewhere.

Competition

Professional Diagnostics. The main competitors for our professional rapid diagnostic products are Becton Dickinson and Quidel Corporation, or Quidel. Some competitors in this market, such as Becton Dickinson, are large companies with substantial resources, while numerous smaller, yet aggressive companies are also competitors. Some automated immunoassay systems may be considered competitors when labor shortages force laboratories to automate or when the costs of such systems are lower. Such systems are provided by Abbott, Siemens AG, Beckman Coulter, Johnson & Johnson, Roche Diagnostics and other large diagnostic companies. In the infectious disease area, newer technologies utilizing amplification techniques for analyzing molecular DNA gene sequences, from companies such as Abbott, Becton Dickinson, Roche

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Diagnostics, Cepheid and Gen-Probe, are making in-roads into this market. Competition for rapid diagnostics is intense and is primarily based on price, breadth of product line and distribution capabilities.

Our competitors in the ELISA diagnostics market include the large diagnostics companies named above, which manufacture state-of-the-art automated immunoassay systems and a wide array of diagnostic products designed for processing on those systems. Other competitors in this market, DiaSorin and Diamedx, in particular, are smaller companies who 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 and our 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, The Binding Site, Trinity Biotech, Meridian Biosciences and DiaSorin. However, products in these categories also compete to a large extent against rapid membrane and ELISA products, which are often easier to perform and read and can be more precise.

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 of our Triage and LDX point-of-care testing systems, which consist of rapid diagnostic devices interpreted by portable electronic readers, are the large diagnostic companies identified above who produce automated immunoassay systems. We expect these large companies to continue to compete vigorously to maintain their dominance of the cardiology testing market. Although we offer our Triage BNP test for use on Beckman Coulter Immunoassay Systems, our other primary cardiology products are not currently designed for automated batch testing. Our Triage products face strong competition from Abbott Laboratories i-Stat hand-held system and our LDX system also faces direct competition from Abaxis Medical Diagnostics, which markets its point-of-care blood laboratory systems to physicians office laboratories, and Polymer Technology Systems, which sells a home cholesterol test system. The primary competitors for our INRatio coagulation monitoring system are Roche Diagnostics and International Technidyne Corporation, a division of Thoratec, who together currently account for approximately 75% of the domestic sales of PT/INR point-of-care and patient self-testing devices.

In oncology, our NMP-22 diagnostic products aid in diagnosing and monitoring bladder cancer patients, in conjunction with standard diagnostic procedures, and are based on our proprietary nuclear matrix protein technology. Our NMP-22 BladderChek Test is currently the only in-office test approved by the FDA as an aid in the diagnosis of bladder cancer. However, competition in the development and marketing of cancer diagnostics and therapeutics, using a variety of other technologies, is intense. Competing diagnostic products based on other technologies may be introduced by other companies and could adversely affect our competitive position. In a larger sense, our tests also compete with more invasive or expensive procedures, such as surgery, bone scans, magnetic resonance imaging and other in vivo imaging techniques. In the market for urine-based diagnostic tests, our NMP-22 tests also compete with existing cellular-based tests, such as the microscopic examination of suspicious cells and a test known as UroVysion™, which is a fluorescent in-situ hybridization test.

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

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

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Health Management. Competition for our health management services is also intense. Other health management service providers include Health Dialog and Healthways, Inc. 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 and self-insured employers. Some of these entities, health plans and self-insured employers in particular, may be customers or potential customers and may own, acquire or establish health management service providers or capabilities for the purpose of providing health management services in-house. Many of these competitors are considerably larger than us, with access to greater resources. We believe however that our ability to improve clinical and financial outcomes and our technology platforms, most notably our new Apollo system, will enable us to compete effectively.

Consumer Diagnostics. Our First Check tests compete against over-the-counter diagnostic tests sold primarily by Phamatech, Inc., 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 consisting of an increasing number of patents, patent applications and licensed patents which protect our vision of the technologies, products and services of the future. Our intellectual property portfolio consists of patents that we own and, in some cases, licenses to patents or other proprietary rights of third parties which may be limited in terms of field of use, transferability or may require royalty payments.

The medical products industry, including the diagnostic testing industry, historically has been characterized by extensive litigation regarding patents, licenses and other intellectual property rights. As the fact of our pending litigation with Healthways, Inc. and Robert Bosch North America Corp. and with Health Hero Network Inc. suggests, litigation relating to intellectual property rights is also a risk in the health management industry. For more information regarding these pending matters see Item 3 entitled "Legal Proceedings" beginning on page 30.

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

Finally, we believe that certain of our trademarks are valuable assets that are important to the marketing of both our products and services. Many of these trademarks have been registered with the United States Patent and Trademark Office or internationally, as appropriate.

The medical products industry, including the diagnostic testing industry, and the health management industry place considerable importance on obtaining and enforcing patent and trade secret protection for new technologies, products, services and processes. Trademark protection is an important factor in the success of certain of our product lines and health management programs. Our success therefore depends, in part, on our abilities to obtain and enforce the patents and trademark registrations necessary to protect our products, to preserve our trade secrets and to avoid or neutralize threats to our proprietary rights from third parties. We cannot, however, guarantee our success in enforcing or maintaining our patent rights; in obtaining future patents or licensed patents in a timely manner or at all; or as to the breadth or degree of protection that our patents or trademark registrations or other intellectual property rights might

afford us. For more information regarding the risks associated with our reliance on intellectual property rights see the risk factors discussed in Item 1A entitled "Risk Factors" on pages 13 through 29 of this report.

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Government Regulation

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

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably, all of our products sold in the United States are subject to the Federal Food, Drug and Cosmetic Act, or the FDCA, as implemented and enforced by the FDA. All of our diagnostic products sold in the United States require FDA clearance to market under Section 510(k) of the FDCA, which may require pre-clinical and clinical trials. Foreign countries may require similar or more onerous approvals to manufacture or market these products. The marketing of our consumer diagnostic products is also subject to regulation by the U.S. Federal Trade Commission, or the FTC. In addition, we are required to meet regulatory requirements in countries outside the United States, which can change rapidly with relatively short notice.

The Clinical Laboratory Improvement Act of 1967 and the Clinical Laboratory Improvement Amendments of 1988, or CLIA, extended federal oversight to many clinical laboratories, including certain of our drug testing laboratories in the United States, by requiring that they be certified to meet quality assurance, quality control and personnel standards. Laboratories also must undergo proficiency testing and are subject to inspections. Certain of our drug testing laboratories perform drug testing on employees of federal government contractors and certain other entities and are therefore regulated by the Substance Abuse and Mental Health Services Administration, or SAMHSA (formerly the National Institute on Drug Abuse), which has established detailed performance and quality standards that laboratories must meet to be approved to perform drug testing on employees of federal government contractors and certain other entities.

Certain of the clinicians, such as nurses, must comply with individual licensing requirements. All of our clinicians who are subject to licensing requirements are licensed in the state in which they are physically present, such as the location of the call center from which they operate and, if applicable, states in which they visit or interact with patients, to the extent such licensure is required. In the future, multiple state licensing requirements for healthcare professionals who provide services telephonically over state lines may require us to license more of our clinicians in more than one state. New judicial decisions, agency interpretations or federal or state legislation or regulations could increase the requirement for multi-state licensing of a greater number of our clinical staff, which would increase our administrative costs.

Certain aspects of our health management business are subject to unique licensing or permit requirements by state and local health agencies. In addition, our health management business is subject to the Health Insurance Portability and Accountability Act and its regulations, or HIPAA, and the Health Information Technology for Economic and Clinical Health (HITECH) Act. We are also required to obtain certification to participate in certain governmental payment programs, such as various state Medicaid programs. Some states have established Certificate of Need, or CON, programs regulating the expansion of healthcare operations. The failure to obtain, renew or maintain any of the required licenses, certifications or CONs could adversely affect our business.

Employees

As of January 31, 2010, we had approximately 11,300 employees, including temporary and contract employees, of which approximately 6,400 employees are located in the United States. In addition, we utilize consultants specializing

in areas such as research and development, risk management, regulatory compliance, strategic planning and marketing.

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ITEM 1A. RISK FACTORS

The risks described below may materially impact your investment in our company or may in the future, and, in some cases already do, materially affect us and our business, financial condition and results of operations. You should carefully consider these factors with respect to your investment in our securities. This section includes or refers to certain forward-looking statements; you should read the explanation of the qualifications and limitations on such forward-looking statements beginning on pages 2 and 35 of this report.

Disruptions in the capital and credit markets related to the current national and worldwide financial crisis, which may continue indefinitely or intensify, could adversely affect our results of operations, cash flows and financial condition, or those of our customers and suppliers.

The recent disruptions in the capital and credit markets may continue indefinitely or intensify, and adversely impact our results of operations, cash flows and financial condition, or those of our customers and suppliers. These disruptions could adversely affect our ability to draw on our bank revolving credit facility, which is dependent on the ability of the banks that are parties to the facility to meet their funding commitments. Those banks may not be able to meet their funding commitments to us if they experience shortages of capital and liquidity. Disruptions in the capital and credit markets as a result of uncertainty, changing or increased regulation, reduced alternatives or failures of significant financial institutions could adversely affect our access to liquidity needed to conduct or expand our businesses or conduct acquisitions or make other discretionary investments, as well as our ability to effectively hedge our currency exchange or interest rate risks. Such disruptions may also adversely impact the capital needs of our customers and suppliers, which, in turn, could adversely affect our results of operations, cash flows and financial condition.

Our business has substantial indebtedness, which 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.

We currently have, and will likely continue to have, a substantial amount of indebtedness. As of December 31, 2009, we had total debt outstanding of approximately \$2.1 billion, which included approximately \$1.1 billion in aggregate principal amount of indebtedness outstanding under our senior secured credit facility, \$250.0 million in aggregate principal amount of indebtedness outstanding under our junior secured credit facility, \$100.0 million in indebtedness under our outstanding September 2009 senior notes, \$150.0 million in indebtedness under our outstanding August 2009 senior notes, \$400.0 million in indebtedness under our outstanding May 2009 senior subordinated notes, and \$150.0 million in indebtedness under our outstanding May 2007 senior subordinated convertible notes.

Our substantial indebtedness could affect our future operations in important ways. For example, it could:

make it more difficult to satisfy our obligations under our senior notes, our senior subordinated notes, our senior subordinated convertible notes, our secured credit facilities and our other debt-related instruments;

require us to use a large portion of our cash flow from operations to pay principal and interest on our indebtedness, which would reduce the amount of cash available to finance our operations and service obligations, to delay or reduce capital expenditures or the introduction of new products and/or forego business opportunities, including acquisitions, research and development projects or product design enhancements;

limit our flexibility to adjust to market conditions, leaving us vulnerable in a downturn in general economic conditions or in our business and less able to plan for, or react to, changes in our business and the industries in

which we operate;

impair our ability to obtain additional financing;

place us at a competitive disadvantage compared to our competitors that have less debt; and

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expose us to fluctuations in the interest rate environment with respect to our indebtedness that bears interest at variable rates.

We expect to obtain the money to pay our expenses and to 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, which will be affected by financial, business, economic and other factors. We will not be able to control many of these factors, such as economic conditions in the markets in which we operate and pressure from competitors. We cannot be certain that our cash flow will be sufficient to allow us to pay principal and interest on our debt and meet our other obligations. If our cash flow and capital resources prove inadequate, we could face substantial liquidity problems and might be required to dispose of material assets or operations, restructure or refinance our debt, seek additional equity capital or borrow more money. We cannot guarantee that we will be able to do so on acceptable terms. In addition, the terms of existing or future debt agreements may restrict us from adopting 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, including the credit agreements governing our secured credit facilities and the indentures governing our senior notes, our senior subordinated notes and our senior subordinated convertible notes, subject us to various restrictions on our ability to engage in certain activities, including, among other things, our ability to:

incur additional debt;

pay dividends or make distributions or repurchase or redeem our stock or subordinated debt;

acquire other businesses;

make investments;

make loans to or extend credit for the benefit of third parties or their subsidiaries;

prepay indebtedness;

enter into transactions with affiliates;

raise additional capital;

make capital or finance lease expenditures;

dispose of or encumber assets; and

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

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

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

The agreements governing our secured credit facilities 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 leverage ratios and minimum consolidated interest coverage ratios. If we violate any of these covenants, we may suffer a material adverse effect. Most notably, our outstanding debt under our secured credit facilities 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 may be limited. Alternatively, we could be forced to refinance or renegotiate the terms and conditions of our secured credit

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facilities, including the interest rates, financial and restrictive covenants and security requirements of the secured credit facilities, 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, including the credit agreements governing our secured credit facilities and the indentures governing our senior notes, our senior subordinated notes and our senior subordinated convertible notes, 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 on commercially reasonable terms or 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 fundamental change or change of control, which could limit our opportunity to enter into a fundamental change or change of control transaction.

Upon the occurrence of a change of control or a fundamental change, as defined in the indentures governing our senior notes, our senior subordinated notes and our senior subordinated convertible notes, holders of notes will have the right to require us to purchase all or any part of such holders' notes at a price equal to either 100% (in the case of the senior subordinated convertible notes) or 101% (in the case of all other notes) of the principal amount thereof, plus accrued and unpaid interest, if any. The events that constitute a change of control under the indentures may also constitute a default under our secured credit facilities, which prohibit the purchase of the notes by us in the event of certain changes of control, unless and until our indebtedness under the secured credit facilities is repaid in full.

There can be no assurance that either we or our guarantor subsidiaries would have sufficient financial resources available to satisfy all of our or their obligations under the senior notes, the senior subordinated notes, the senior subordinated convertible notes, and the secured credit facilities in the event of such a change of control or fundamental change. Our failure to purchase notes as required under any of the indentures governing our outstanding senior notes, our senior subordinated notes or our senior subordinated convertible notes would result in a default under that indenture and under our secured credit facilities and could have a material adverse consequence for us and our stakeholders.

Our acquisitions may not be profitable, and the integration of these businesses may be costly and difficult and may cause disruption to our business.

Since commencing activities in November 2001, we have acquired and integrated into our operations numerous businesses. Since the beginning of 2007, we have acquired and integrated, or are in the process of integrating, Free & Clear; Concateno; the ACON second territory business; Matria Healthcare, Inc., or Matria; BBI Holdings Plc, or BBI; Panbio Limited, or Panbio; ParadigmHealth; Redwood; Alere Medical, Inc., or Alere Medical; HemoSense, Inc., or HemoSense; Cholestech Corporation, or Cholestech; Biosite Incorporated, or Biosite; and Instant Technologies, Inc., or Instant. We have also made a number of smaller acquisitions. The ultimate success of all of these acquisitions depends, in part, on our ability to realize the anticipated synergies, cost savings and growth opportunities from integrating these businesses or assets into our existing businesses. However, the successful integration of independent businesses or assets is a complex, costly and time-consuming process. The difficulties of integrating companies and acquired assets include, among others:

consolidating manufacturing, research and development operations and health management information technology platforms, where appropriate;

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

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coordinating sales, distribution and marketing functions and strategies, including the integration of our current health management 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;

minimizing the diversion of management's attention from ongoing business concerns; and

coordinating geographically separate organizations.

regulatory issues relating to the integration of acquisitions or of legacy entities.

We may not accomplish the integration of our acquisitions smoothly or successfully. The diversion of the attention of our management from current operations to integration efforts and any difficulties encountered in combining operations could prevent us from realizing the full benefits anticipated to result from these acquisitions and adversely affect our other businesses. Additionally, the costs associated with the integration of our acquisitions may be substantial. To the extent that we incur integration costs that are not anticipated when we finance our acquisitions, these unexpected costs could adversely impact our liquidity or force us to borrow additional funds. Ultimately, the value of any business or asset that we have acquired may not be greater than or equal to the purchase price of that business or asset.

If we choose to acquire or invest in new and complementary businesses, products or technologies rather than developing them internally, such acquisitions or investments could disrupt our business and, depending on how we finance these acquisitions or investments, could result in the use of significant amounts of cash.

Our success depends in part on our ability to continually enhance and broaden our product offerings in response to changing technologies, customer demands and competitive pressures. Accordingly, from time to time, we may seek to acquire or invest in businesses, products or technologies instead of developing them internally. Acquisitions and investments involve numerous risks, including:

the inability to complete the acquisition or investment;

disruption of our ongoing businesses and diversion of management attention;

difficulties in integrating the acquired entities, products or technologies;

difficulties in operating the acquired business profitably;

difficulties in transitioning key customer, distributor and supplier relationships;

difficulties in evaluating, integrating and retaining key management;

risks associated with entering markets in which we have no, or limited, prior experience; and

unanticipated costs.

In addition, any future acquisitions or investments may result in:

issuances of dilutive equity securities, which may be sold at a discount to market price;

use of significant amounts of cash;

the incurrence of debt;

the assumption of significant liabilities, including litigation;

unfavorable financing terms;

large one-time expenses; and

the creation of intangible assets, including goodwill, the write-down of which may result in significant charges to earnings.

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If we fail to complete strategic acquisitions or investments our ability to meet our goals may be compromised and our future business prospects may be limited.

We may be unable to come to terms on, or complete, potential acquisitions or investments in businesses we believe to be of strategic importance. This may occur for many reasons, including but not limited to:

we may not be able to agree on terms and conditions which we believe are reasonable;

we may be out bid by another party or parties;

we may not be able to finance the purchase price;

we may not have enough available stock to use as consideration;

a competitor may come to an agreement to acquire a targeted business before we are able to; or

antitrust or other laws or regulations may prohibit the acquisition or prevent us from completing the acquisition or investment in a manner which we believe would benefit us.

Our joint venture transaction with P&G may not realize all of its intended benefits.

In connection with SPD, our 50/50 joint venture with P&G, we may experience among other problems:

difficulties in integrating our corporate culture and business objectives with that of P&G into the joint venture;

diversion of our management's time and attention from other business concerns;

difficulties in retaining key employees who are necessary to manage the joint venture; or

difficulties in working with an entity based in Switzerland and thus remote or inconvenient to our Waltham, Massachusetts headquarters.

Moreover, 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.

For any of these reasons, or as a result of other factors, we may not realize the anticipated benefits of the joint venture and cash flow or profits derived from our ownership interest in SPD may be less than the cash flow or profits that could have been derived had we retained the transferred assets and continued to operate the consumer diagnostics business ourselves. P&G retains an option to require us to purchase P&G's interest in SPD at fair market value during the 60-day period beginning on May 17, 2011. Moreover, 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 the joint venture at fair market value less damages.

We may not be successful in conducting future joint venture transactions.

In addition to SPD, our 50/50 joint venture with P&G, we may enter into additional joint venture transactions in the future. We may experience unanticipated difficulties in connection with those joint venture transactions. We cannot assure you that any such joint venture transaction will be profitable or that we will receive any of the intended benefits

of such a transaction.

If goodwill and/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.

In connection with the accounting for our acquisitions we have recorded, or will 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. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings, which could materially adversely affect our reported results of operations in future periods.

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

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. In addition, our manufacturing processes often require complex and specialized equipment which can be expensive to repair or replace with required lead times of up to a year. Also, our private label consumer diagnostics business relies on operational efficiency to mass produce products at low margins per unit. We also rely on numerous third parties to supply production materials and, in some cases, there may not be alternative sources immediately available.

In recent years we have shifted production of several of our products to our manufacturing facilities in China and closed less efficient and more expensive facilities elsewhere. We expect to continue to shift production to China and other lower cost facilities as part of our continuing efforts to reduce costs, improve quality and more efficiently serve targeted markets. Moving the production of products is difficult and involves significant risk. Problems establishing relationships with local materials suppliers; acquiring or adapting the new facility and its equipment to the production of new products; hiring, training and retaining personnel; and establishing and maintaining compliance with governmental regulations and industry standards can cause delays and inefficiencies, which could have a material negative impact on our financial performance. We also currently rely on a number of significant third-party manufacturers to produce certain of our professional diagnostics products. Any event which negatively impacts our manufacturing facilities, our manufacturing systems or equipment, or our contract manufacturers or suppliers, including, among others, wars, terrorist activities, natural disasters and outbreaks of infectious disease, 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 or 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.

Even though we carry business interruption insurance policies, we may suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies.

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

We intend to continue to invest in product and technology development. The development of new or enhanced products or services is a complex and uncertain process. We may experience research and development, manufacturing, marketing and other difficulties that could delay or prevent our development, introduction or marketing of new products, services or enhancements. We cannot be certain that:

any of the products or services under development will prove to be effective in clinical trials;

any products or services under development will not infringe on intellectual property rights of others;

we will be able to obtain, in a timely manner or at all, regulatory approval to market any of our products or services that are in development or contemplated;

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.

The factors listed above, as well as manufacturing or distribution problems, or other factors beyond our control, could delay new product or service launches. In addition, we cannot assure you that the market will accept these products and services. Accordingly, there is no assurance that our overall revenue will increase if and when new products or services are launched.

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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 anticipated safety and effectiveness of those potential products, we may not be able to sell future products and our sales could be adversely affected.

Before we can sell certain of our products, we must conduct clinical studies intended to demonstrate that our potential products are safe and effective and perform as expected. The results of these clinical studies are used as the basis to obtain regulatory approval from government authorities such as the Food and Drug Administration, or FDA. Clinical studies are experiments conducted using potential products and 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 certain 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 potential product candidates altogether. Even if we successfully manage our clinical studies, we may not obtain favorable results and may not be able to 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 may not be able to sell future products and our sales could be adversely affected.

Our future performance depends on, among other matters, our estimates as to when and at what cost we will receive regulatory approval for new products. Regulatory approval can be a lengthy, expensive and uncertain process, making the timing, cost and ability to obtain approvals difficult to predict. 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, or 510(k), or through approval of a Premarket Approval, or PMA. To receive 510(k) clearance, a new product must be substantially equivalent to a medical device first marketed in interstate commerce prior to May 1976. The FDA may determine that a new product is not substantially equivalent to a device first marketed in interstate commerce prior to May 1976 or that additional information is needed before a substantial equivalence determination can be made. A not substantially equivalent determination, or a request for additional information, could prevent or delay the market introduction of new products that fall into this category. The 510(k) clearance and PMA review processes can be expensive, uncertain and lengthy. It generally takes from three to five months from submission to obtain 510(k) clearance, and from six to eighteen months from submission to obtain a PMA approval; however, it may take longer, and 510(k) clearance or PMA approval may never be obtained.

Modifications or enhancements that could significantly affect safety or effectiveness, or 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 by the FDA.

There is increased uncertainty due to the impending changes to the 510(k) and PMA process. These reforms may increase the time to receive clearance. The uncertainty of the requirements for approval may result in an increase in costs.

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

In addition to regulatory requirements in the United States, we are subject to the regulatory approval requirements for each foreign country to which we export our products. In the European Union, regulatory compliance requires affixing the CE mark to product labeling. Although our products are currently eligible for CE marking through self-certification, this process can be lengthy and expensive. In Canada, as another example, our products require approval by Health Canada prior to commercialization, along with International Standards Organization, or ISO, 13485/CMDCAS certification. It generally takes from three to six months from submission to obtain a Canadian Device License. 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.

Failure to comply with ongoing regulations applicable to our businesses 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 manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping. For example, our manufacturing facilities and those of our suppliers and distributors are, or can be, subject to periodic regulatory inspections. The FDA and foreign regulatory agencies may require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any product approvals that could restrict the commercial applications of those products. In addition, the subsequent discovery of previously unknown problems with a product may result in restrictions on the product, including withdrawal of the product from the market. We are also subject to routine inspection by the FDA and certain state agencies for compliance with the Quality System Regulation and Medical Device Reporting requirements in the United States and other applicable regulations worldwide, including but not limited to ISO requirements. CLIA extended 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 portions of our health management 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 Medicaid 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 certain of our health management services 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 such 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 management services. In such event, we may incur significant costs to comply with such laws and regulations. In addition, we are subject to numerous federal, state and local laws relating to such matters as privacy, healthcare kickbacks and false claims, 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, termination of our service agreements by our customers, disgorgement of money, operating

restrictions and criminal prosecution.

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New federal or state 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. In addition, the federal government recently enacted the Genetic Information Non-discrimination Act of 2008, or GINA, and we may incur additional costs in assisting our customers with their efforts to comply with GINA while continuing to offer certain of our services.

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

There are a number of initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States. These initiatives range from proposals to fundamentally change federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under governmental funded programs, to minor modifications to existing programs. In particular, federal legislation may reduce or significantly alter Medicare and Medicaid reimbursements. 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 federal healthcare spending. Other proposals include additional taxes on the sale of medical devices to fund a portion of the reform proposals. Legislative proposals are also pending that would impose federal reporting requirements regarding payments or relationships between manufacturers of covered drugs, devices or biological or medical supplies and physicians, among others. The ultimate content or timing of any future healthcare reform legislation, and its impact on us, is impossible to predict. If significant reforms are made to the healthcare system in the United States, or in other jurisdictions, those reforms may have an adverse effect on our financial condition and results of operations.

If we deliver products with defects, our credibility may be harmed, market acceptance of our products may decrease and we may be exposed to liability in excess of our product liability insurance coverage.

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 may cause the product to report inaccurate information, such as a false positive result, a false negative result or an error message. In addition, our product development and production are extremely complex and could expose our products to defects. Any defects could harm our credibility and decrease market acceptance of our products. In addition, our marketing of monitoring services may cause us to be subjected to various product liability claims, including, among others, claims that inaccurate monitoring results lead to injury or death. Potential product liability claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy. In the event that we are held liable for a claim for which we are not indemnified, or for damages exceeding the limits of our insurance coverage, that claim could materially damage our business and financial condition.

The effect of market saturation may negatively affect the sales of our products, including our Triage BNP tests.

Our meter-based Triage BNP test, launched domestically in January 2001, was the first blood test available to aid in the detection of heart failure and benefited from a first-to-market position until the entry of direct competition in June 2003. As the acute care and initial diagnosis market segment for BNP testing in the U.S. hospital setting becomes saturated, unless we are able to successfully introduce new products into the market and achieve market acceptance of those products in a timely manner, we expect the growth rates of sales unit volume for our Triage BNP tests and average selling prices in 2010 and future periods to be lower than the growth rates and selling prices experienced over the past several years, which may adversely impact our product sales, gross margins and our overall financial results. In addition, as the market for BNP testing matures and more competitive products become available, the average sales price for the Triage BNP tests is likely to decline.

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The health management business is a relatively new component of the overall healthcare industry.

The health management services provided by our Alere health management business and our subsidiaries QAS and Tapestry, are relatively new components of the overall healthcare industry. Accordingly, our health management customers have not had significant experience in purchasing, evaluating or monitoring such services, which can result in a lengthy sales cycle. The success of our health management business depends on a number of factors. These factors include:

our ability to differentiate our health management services from those of our 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 and engagement efforts with customers and their health plan participants;

our ability to sell and implement new and additional services beneficial to health plans and employers and their respective participants or employees;

our ability to achieve, measure and effectively communicate cost savings for health plans and employers through the use of our services; and

our ability to retain health plan and employee accounts as competition increases and as health plan customers may choose to provide health management services themselves.

Since the health management business is continually evolving, we may not be able to anticipate and adapt to the developing market. Moreover, we cannot predict with certainty the future growth rate or the ultimate size of the market.

Increasing health insurance premiums and co-pays 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 and co-pays have generally increased in recent years. Increased premiums may cause individuals to forgo health insurance, as well as medical attention. This may reduce demand for our point-of-care diagnostic products and also reduce the number of lives managed by our health management programs. Increased co-pays may cause insured individuals to forgo medical attention thereby reducing demand for our professional diagnostic tests, as well as revenues under certain health management programs.

Our health management business may be adversely affected by cost reduction pressures among our customers.

Additionally, our customers continue to face cost reduction pressures that may cause them to curtail their use of, or reimbursement for, health management services, to negotiate reduced fees or other concessions or to delay payment. In addition, the loss of jobs due to the recent economic crisis may cause the number of lives we manage to decrease. These financial pressures could have an adverse impact on our business.

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

Certain of our health management contracts provide reimbursement to us based on total relevant populations managed by health plans. As unemployment rates rise, certain of our revenues may be reduced under these contracts as managed lives may decrease. One of the primary collection risks of our health management 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 agreement, but patient responsibility amounts (deductibles and copayments) remain outstanding. As unemployment rates rise nationally, these uninsured and patient due accounts could make up a greater percentage of the health management business accounts receivable. Deterioration in the collectability of these accounts could

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adversely affect the health management business collection of accounts receivable, cash flows and results of operations.

If we are unable to retain and negotiate favorable contracts with managed care plans, our revenues may be reduced.

The ability of our health management business to obtain favorable contracts with health maintenance organizations, preferred provider organizations and other managed care plans significantly affects the revenues and operating results of our health management business. The business future success will depend, in part, on its ability to retain and renew its managed care contracts and to enter into new managed care contracts on terms favorable to us. If the health management business is unable to retain and negotiate favorable contracts with managed care plans, our revenues may be reduced.

A portion of our health management fees are contingent upon performance.

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

Many of our health management services are provided pursuant to long-term contracts that we may not be able to re-negotiate. If our costs increase, we may not be able to increase our prices, which would adversely affect results of operations. Accordingly, any increase in our costs could reduce our overall profit margin.

Demands of non-governmental payers may adversely affect our growth in 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 management business. These non-governmental payers increasingly are demanding discounted fee structures, and the trend toward consolidation among non-governmental payers tends to increase their bargaining power over fee structures. Reductions in price increases or the amounts received from managed care, commercial insurance or other payers could have a material, adverse effect on the financial position and results of operations of our health management business.

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

Our businesses, and in particular our health management business, are dependent on the effective use of information technology and, consequently, technology failure or obsolescence may negatively impact our businesses. In addition, data acquisition, data quality control, data security and data analysis, which are a cornerstone of our health management programs, are intense and complex processes subject to error. Untimely, incomplete or inaccurate data, flawed analysis of such data or our inability to properly integrate, implement and update systems could have a material adverse impact on our business and results of operations. In particular, we are relying on our recently launched healthcare portal, Apollo, to provide the framework and supporting infrastructure for significantly enhanced future health management programs and to provide a competitive advantage. Apollo is a new and unproven system

and may not provide these expected benefits or meet our needs or the needs of our customers or program participants.

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Our financial condition or 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 England, Scotland, Japan, China, Australia, Germany and Israel. Conducting business outside the United States subjects us to numerous risks, including:

- increased costs or reduced revenue as a result of movements in foreign currency exchange rates;
- decreased liquidity resulting from longer accounts receivable collection cycles typical of foreign countries;
- lower productivity resulting from difficulties managing sales, support and research and development operations across many countries;
- lost revenues resulting from difficulties associated with enforcing agreements and collecting receivables through foreign legal systems;
- lost revenues resulting from the imposition by foreign governments of trade protection measures;
- higher cost of sales resulting from import or export licensing requirements;
- lost revenues or other adverse effects as a result of economic or political instability in or affecting foreign countries in which we sell our products or operate; and
- adverse effects resulting from changes in foreign regulatory or other laws affecting the sales of our products or our foreign operations.

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. Three of our five largest manufacturing operations are conducted outside the United States in Hangzhou and Shanghai, China and Matsudo, Japan, and we also have manufacturing operations in the United Kingdom, Australia, South Africa and Israel. We also have significant research and development operations in Jena, Germany and Stirling, Scotland, as well as in the United Kingdom, Australia and Israel. In addition, for the year ended December 31, 2009, approximately 31% of our net revenue was derived from sales outside the United States. Because of our foreign operations and foreign sales, we face 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 and Japan. These exposures may change over time as business practices evolve and could result in increased costs or reduced revenue and could affect our actual cash flow.

Intense competition could reduce our market share or limit our ability to increase market share, which could impair the sales of our products and harm our financial performance.

The medical products industry is rapidly evolving, and developments are expected to continue at a rapid pace. Competition in this industry, which includes both our professional diagnostics and consumer diagnostics businesses, is intense and expected to increase as new products 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.

Our future success depends upon maintaining a competitive position in the development of products and technologies in our areas of focus. Our competitors may:

develop technologies and products that are more effective than our products or that render our technologies or products obsolete or noncompetitive;

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obtain patent protection or other intellectual property rights that would prevent us from developing potential products; or

obtain regulatory approval for the commercialization of our products more rapidly or effectively than we do.

Also, the possibility of patent disputes with competitors holding patent rights may limit or delay expansion possibilities for our diagnostic businesses and new product launches. In addition, many of our existing or potential competitors have or may have substantially greater research and development capabilities, clinical, manufacturing, regulatory and marketing experience and financial and managerial resources.

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

We are involved in various legal proceedings arising out of our businesses, including those matters discussed in Item 3 entitled Legal Proceedings beginning on page 30. 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, employment or investor matters, and we expect that this will continue to be the case in the future. Such lawsuits 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, have a material adverse effect on our sales, operations or financial performance. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties. These suits can be expensive and result in counterclaims challenging the validity of our patents and other rights. We cannot assure you that these lawsuits or any future lawsuits relating to our business will not have a material adverse effect on us.

The rights we rely upon to protect the intellectual property underlying our products may not be adequate, which could enable third parties to use our technology and would reduce our ability to compete in the market.

Our success will depend in part on our ability to develop or acquire commercially valuable patent rights and to protect our intellectual property. Our patent position is generally uncertain and involves complex legal and factual questions. The degree of present and future protection for our proprietary rights is uncertain and may be impacted by intellectual property law or legislation.

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;

claims of any patents which are issued may not provide meaningful protection;

our inability to develop additional proprietary technologies that are patentable;

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;

patents issued to other companies may harm our ability to do business;

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 may lose the competitive advantage which they provide.

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

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measures may not be adequate to safeguard the technology underlying our products. If these measures do not protect our rights, third parties could use our technology and our ability to compete 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 on any of our intellectual property rights, or design around our proprietary technologies.

Claims by others that our products infringe on 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 both the professional and consumer diagnostics industries. We expect that our products and services could be increasingly subject to third-party infringement claims, as the number of competitors grows and the functionality of products and technology in different industry segments overlaps. Third parties may currently have, or may eventually be issued, patents which our products and services or technology may infringe. Any of these third parties might make a claim of infringement 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 cause negative publicity, have an impact on prospective customers, cause product delays, require us to develop non-infringing technology, 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 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 have initiated, and may need to further 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 the market.

We rely on patents to protect a portion of our intellectual property and our competitive position. In order to protect or enforce our patent rights, we may initiate patent litigation against third parties, such as infringement suits or interference proceedings. Litigation may be necessary to:

assert claims of infringement;

enforce our patents;

protect our trade secrets or know-how; or

determine the enforceability, scope and validity of the proprietary rights of others.

Currently, we have initiated a number of lawsuits against competitors whom we believe to be selling products that infringe our proprietary rights. These current lawsuits and any other lawsuits that we initiate could be expensive, take significant time and divert management's attention from other business concerns. Litigation also puts 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.

Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in our industry are generally uncertain. We may not prevail in any of these suits 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 price of the notes may decline.

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Non-competition obligations and other restrictions will limit our ability to take full advantage of our management team, the technology we own or license and our research and development capabilities.

Members of our management team have had significant experience in the diabetes field. In addition, technology we own or license may have potential applications to this field and our research and development capabilities could be applied to this field. However, in conjunction with our split-off from Inverness Medical Technology, Inc., or IMT, we agreed not to compete with IMT and Johnson & Johnson in the field of diabetes through 2011. In addition, our license agreement with IMT prevents us from using any of the licensed technology in the field of diabetes. As a result of these restrictions, we are limited in our ability to pursue opportunities in the field of diabetes at this time.

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

Factors relating to our business make our future operating results uncertain and may cause them to fluctuate from period to period. Such factors include:

- the timing of new product announcements and introductions by us and our competitors;
- market acceptance of new or enhanced versions of our products;
- the extent to which our current and future products rely on rights belonging to third parties;
- changes in manufacturing costs or other expenses;
- competitive pricing pressures;
- changes in healthcare reimbursement policies and amounts;
- public health measures or changes in practices or conduct which may increase or decrease incidents of disease or the need for diagnostic testing
- regulatory changes;
- the gain or loss of significant distribution outlets or customers;
- increased research and development expenses;
- liabilities and costs associated with litigation;
- length of sales cycle and implementation process for new health management customers;
- the costs and timing of any future acquisitions;
- general economic conditions; or
- general stock market conditions or other economic or external factors.

Because our operating results may fluctuate from quarter to quarter, it may be difficult for us or our investors to predict future performance by viewing historical operating results.

Period-to-period comparisons of our operating results may not be meaningful due to our acquisitions.

We have engaged in a number of acquisitions in recent years, which makes it difficult to analyze our results and to compare them from period to period. Significant acquisitions since 2007 include our acquisitions of Instant in March 2007, Biosite in June 2007, Cholestech in September 2007, Matria in May 2008 and the ACON second territory business in April 2009. Period-to-period comparisons of our results of operations may not be meaningful due to these acquisitions and are not indications of our future performance. Any future acquisitions will also make our results difficult to compare from period to period in the future.

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

Our Series B Preferred Stock is convertible into common stock in certain circumstances. If the conditions to conversion were satisfied, then subject to adjustment, each of the approximately 2.0 million shares of Series B Preferred Stock outstanding as of December 31, 2009 could convert into 5.7703 shares of our common stock, or approximately 11.4 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 principal amount of senior subordinated convertible 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. Sales of a substantial number of shares of our common stock in the public market could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. We cannot predict the effect that future sales of our common stock or other equity-related securities would have on the market price of our common stock. The price of our common stock could be affected by possible sales of our common stock by holders of our Series B Preferred Stock or our senior subordinated convertible notes and by other hedging or arbitrage trading activity that may develop involving our common stock.

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

The current outstanding shares of our Series B Preferred Stock have an aggregate stated liquidation preference of approximately \$793.7 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 shares of common stock or additional shares of Series B Preferred Stock and in either case must satisfy the dividend obligation by issuing the requisite number of shares based upon market prices. Upon a liquidation of our company, the holders of shares of Series B Preferred Stock shall 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 but unpaid dividends. Because of the substantial liquidation preference to which the holders of the Series B Preferred Stock shall be 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.

There are provisions in our certificate of incorporation and bylaws that 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:

our certificate of incorporation provides for three classes of directors with the term of office of one class expiring each year, commonly referred to as a staggered board. By preventing stockholders from voting on the election of more than one class of directors at any annual meeting of stockholders, this

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provision 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;

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;

our certificate of incorporation prohibits our stockholders from filling board vacancies, calling special stockholder meetings or taking action by written consent;

our certificate of incorporation provides for the removal of a director only with cause and by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of directors; and

our bylaws require advance written notice of stockholder proposals and director nominations.

Additionally, we are subject to Section 203 of the Delaware General Corporation Law, which, in general, imposes restrictions upon acquirers of 15% or more of our stock. Finally, the 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 of control.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal corporate administrative office, together with the administrative office for most of our United States consumer operations, is located at 51 Sawyer Road, Waltham, Massachusetts. Our Alere health management business is headquartered in Atlanta, Georgia. 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. These key administrative facilities are leased from third parties.

We own approximately 26.1 acres of land in San Diego, California which houses one of our five primary manufacturing operations, as well as significant administrative and research and development operations for our professional diagnostics businesses. Our buildings on this property include 167,000 square feet of manufacturing space for professional diagnostic products. Our other primary manufacturing operations are in Hangzhou and Shanghai, China; Matsudo, Japan and Scarborough, Maine. We currently manufacture a portion of our consumer and professional diagnostics out of a manufacturing facility of approximately 300,000 square feet in Hangzhou, China, which we own. The majority of our consumer diagnostic products are manufactured out of approximately 54,000 square feet of space in Shanghai, China. In October 2009, we moved the manufacture of our Determine products to a leased space of approximately 35,000 square feet in Matsudo, Japan, which lease expires in December 2016. We will also continue to rent 16,000 square feet of space in Matsudo from Abbott Laboratories until June 2011. We manufacture certain professional diagnostic products out of a 64,000 square foot facility that we lease in Scarborough, Maine. We also continue to conduct some technical manufacturing and antibody production operations related to certain professional and consumer diagnostic products from a plant which we lease in Bedford, England. In addition, Standard Diagnostics manufactures its professional diagnostic products in facilities in Yongin, South Korea, which it owns, and Gurgaon, India, which it leases. The San Diego, Hangzhou and Scarborough facilities, as well as the Standard Diagnostics facilities, also house significant research and development operations which support our diagnostic businesses, as does a facility which we rent in Jena, Germany.

We rely increasingly on toxicology laboratories to provide reliable drugs of abuse testing results to customers. Redwood provides its laboratory testing services out of a leased facility in Redwood, California, while Concateno operates its primary laboratory out of a leased facility in Abingdon, England. We also recently acquired, and now own, two SAMHSA certified laboratories located in Gretna, Louisiana and Richmond, Virginia.

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We also have leases or other arrangements for other facilities in various locations worldwide, including smaller manufacturing operations and laboratories, administrative or sales offices, call centers and warehouses.

ITEM 3. LEGAL PROCEEDINGS

Healthways, Inc. and Robert Bosch North America Corp., v. Alere, Inc.

Healthways, Inc. and Robert Bosch North America Corp. filed a complaint in U.S. District Court in the Northern District of Illinois on November 5, 2008 against Alere Medical alleging infringement of 11 patents, licensed by Bosch from Healthways. Alere Medical answered the complaint and filed counterclaims seeking declarations that the patents are invalid and not infringed. The plaintiffs subsequently filed an amended complaint substituting Alere LLC, or Alere, our consolidated health management subsidiary, as the defendant in place of Alere Medical. On August 31, 2009, plaintiffs filed a motion to dismiss Alere's affirmative defense and counterclaim that the patents-in-suit are unenforceable due to inequitable conduct. Alere opposed the motion and filed a motion to amend the existing pleadings to include newly discovered facts of inequitable conduct. Neither a hearing for those motions nor a trial date has been scheduled. We believe that we have strong defenses to Healthways' allegations and we intend to defend them vigorously. However, a ruling against Alere could potentially have a material adverse impact on our sales, operations or financial performance or could limit our current or future business opportunities.

Claims in the Ordinary Course and Other Matters

We are not a party to any other pending legal proceedings that we currently believe could have a material adverse impact on our sales, operations or financial performance. However, because of the nature of our business, we may be subject at any particular time to commercial disputes, consumer product claims, negligence claims or various other lawsuits arising in the ordinary course of our business, including infringement, employment or investor matters, and we expect that this will continue to be the case in the future. Such lawsuits generally seek damages, sometimes in substantial amounts.

As an example, our subsidiary Alere Medical continues to defend infringement claims brought by Health Hero Network, Inc., a subsidiary of Robert Bosch North America Corp., which alleges to have patented certain processes related to home monitoring of patients. That matter has been stayed pending reexamination of the Health Hero patents by the U.S. Patent and Trademark Office. Also, Alere Medical continues to defend a previously disclosed class action lawsuit brought by the Estate of Melissa Prince Quisenberry which relates to the March 14, 2007 sale of Alere Medical to an unrelated entity. While we believe that we have strong defenses to the claims brought by Health Hero and Quisenberry, and we intend to defend them vigorously, these, or other claims, could potentially have a negative impact on our sales, operations or financial performance or could limit our existing or future business opportunities.

In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties. These suits can be expensive and result in counterclaims challenging the validity of our patents and other rights.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

PART II

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

Unregistered Sales of Equity Securities and Use of Proceeds

On December 22, 2009, we issued a total of 128,513 shares of common stock as contingent consideration in connection with our October 2009 acquisition of Mologic Limited. We relied on the exemption from registration provided by Regulation S under the Securities Act.

Table of Contents**Market Information**

Our common stock trades on the New York Stock Exchange (NYSE) under the symbol IMA. Prior to January 2009, our common stock traded on the American Stock Exchange. The following table sets forth the high and low sales prices of our common stock for each quarter during fiscal 2009 and 2008.

	High	Low
Fiscal 2009		
Fourth Quarter	\$ 44.01	\$ 37.02
Third Quarter	\$ 41.86	\$ 30.27
Second Quarter	\$ 35.99	\$ 25.80
First Quarter	\$ 28.93	\$ 18.59
Fiscal 2008		
Fourth Quarter	\$ 30.52	\$ 12.33
Third Quarter	\$ 36.42	\$ 28.10
Second Quarter	\$ 38.71	\$ 30.00
First Quarter	\$ 62.65	\$ 26.29

On February 25, 2010, there were 2,190 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 facilities and the indentures governing the terms of our notes currently restrict the payment of cash or stock dividends.

Table of Contents**Stock Performance Graph**

The following line graph compares the change in the cumulative total stockholder return on our common stock from December 31, 2004 through December 31, 2009. This graph assumes an investment of \$100.00 on December 31, 2004 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 currently pay no dividends on our common stock. 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, 2004 and the last trading day of each subsequent year end through December 31, 2009.

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	IMA	NYSE Composite Index	Dow Jones U.S. Healthcare Index
12/31/04	\$ 100.00	\$ 100.00	\$ 100.00
12/30/05	\$ 94.46	\$ 106.95	\$ 106.87
12/29/06	\$ 154.18	\$ 126.05	\$ 112.43
12/31/07	\$ 223.82	\$ 134.35	\$ 119.80
12/31/08	\$ 75.34	\$ 79.41	\$ 91.02
12/31/09	\$ 165.38	\$ 99.10	\$ 108.19

The performance graph above shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liability of that section. This graph will not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Table of Contents**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, 2009 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.

Our selected consolidated financial data for the years ended December 31, 2009, 2008 and 2007, and as of December 31, 2009 and 2008, have been derived from our consolidated financial statements which are included elsewhere in this Annual Report on Form 10-K and were audited by BDO Seidman, LLP, an independent registered public accounting firm. Our selected consolidated financial data for the years ended December 31, 2006 and 2005, and as of December 31, 2007, 2006 and 2005, have been derived from our consolidated financial statements not included herein, which were audited by BDO Seidman, LLP.

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 and Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations.

	2009	For the Year Ended December 31,			2005
		2008	2007	2006	
		(in thousands, except per share data)			
Statement of Operations Data:					
Net product sales	\$ 1,365,079	\$ 1,151,265	\$ 728,091	\$ 470,079	\$ 331,046
Services revenue	528,487	405,462	16,646		
Net product sales and services revenue	1,893,566	1,556,727	744,737	470,079	331,046
License and royalty revenue	29,075	25,826	21,979	17,324	15,393
Net revenue	1,922,641	1,582,553	766,716	487,403	346,439
Cost of net product sales	619,503	543,317	365,545	257,785	192,326
Cost of services revenue	240,026	177,098	5,261		
Cost of license and royalty revenue	8,890	8,620	9,149	5,432	4,539
Cost of net revenue	868,419	729,035	379,955	263,217	196,865

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Gross profit	1,054,222	853,518	386,761	224,186	149,574
Operating expenses:					
Research and development	112,848	111,828	69,547	48,706	30,992
Purchase of in-process research and development			173,825	4,960	
Sales and marketing	441,646	381,939	163,028	89,700	66,300
General and administrative	357,033	295,059	155,153	67,938	56,045
(Gain) loss on dispositions, net	(3,355)			3,498	
Operating income (loss)	146,050	64,692	(174,792)	9,384	(3,763)

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	2009	For the Year Ended December 31,			2005
		2008	2007	2006	
		(in thousands, except per share data)			
Interest expense and other expenses, net, including amortization of original issue discounts and write-off of deferred financing costs	(105,802)	(102,939)	(73,563)	(17,595)	(7,536)
Income (loss) from continuing operations before provision (benefit) for income taxes	40,248	(38,247)	(248,355)	(8,211)	(11,299)
Provision (benefit) for income taxes	15,627	(16,644)	(1,049)	5,712	6,971
Income (loss) from continuing operations before equity earnings of unconsolidated entities, net of tax	24,621	(21,603)	(247,306)	(13,923)	(18,270)
Equity earnings of unconsolidated entities, net of tax	7,626	1,050	4,372	336	
Income (loss) from continuing operations	32,247	(20,553)	(242,934)	(13,587)	(18,270)
Income (loss) from discontinued operations, net of tax	1,934	(1,048)	(418)	(3,255)	(939)
Net income (loss)	34,181	(21,601)	(243,352)	(16,842)	(19,209)
Less: Net income attributable to non-controlling interests	465	167	1,401		
Net income (loss) attributable to Inverness Medical Innovations, Inc. and subsidiaries	33,716	(21,768)	(244,753)	(16,842)	(19,209)
Preferred stock dividends	(22,972)	(13,989)			
Net income (loss) available to common stockholders(1)	\$ 10,744	\$ (35,757)	\$ (244,753)	\$ (16,842)	\$ (19,209)
Basic net income (loss) per common share attributable to Inverness Medical Innovations, Inc. and subsidiaries:					
Net income (loss) per common share from continuing operations(1)	\$ 0.11	\$ (0.45)	\$ (4.74)	\$ (0.39)	\$ (0.75)
Net income (loss) per common share from discontinued operations(1)	\$ 0.02	\$ (0.01)	\$ (0.01)	\$ (0.10)	\$ (0.04)
Net (loss) income per common share	\$ 0.13	\$ (0.46)	\$ (4.75)	\$ (0.49)	\$ (0.79)

Diluted net income (loss) per common share attributable to Inverness Medical Innovations, Inc. and subsidiaries:

Net income (loss) per common share from continuing operations(1)	\$	0.11	\$	(0.45)	\$	(4.74)	\$	(0.39)	\$	(0.75)
Net income (loss) per common share from discontinued operations(1)	\$	0.02	\$	(0.01)	\$	(0.01)	\$	(0.10)	\$	(0.04)
Net income (loss) per common share(1)	\$	0.13	\$	(0.46)	\$	(4.75)	\$	(0.49)	\$	(0.79)

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	2009	2008	December 31, 2007 (in thousands)	2006	2005
Balance Sheet Data:					
Cash and cash equivalents	\$ 492,773	\$ 141,324	\$ 414,732	\$ 71,104	\$ 34,270
Working capital	\$ 828,944	\$ 470,349	\$ 674,048	\$ 133,297	\$ 84,514
Total assets	\$ 6,943,992	\$ 5,955,360	\$ 4,880,759	\$ 1,085,771	\$ 791,166
Total debt	\$ 2,149,324	\$ 1,520,534	\$ 1,387,849	\$ 202,976	\$ 262,504
Total stockholders' equity	\$ 3,527,555	\$ 3,278,838	\$ 2,586,667	\$ 714,138	\$ 397,308

(1) Net income (loss) available to common stockholders and basic and diluted net income (loss) per common share are computed as described in Notes 2(n) and 14 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 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 in this Item 7 include, without limitation, statements regarding anticipated expansion and growth in certain of our product and service offerings, research and development expenditures, the impact of our research and development activities, potential new product and technology achievements, the impact of our global distribution network, our ability to improve our working capital and operating margins, our expectations with respect to Apollo, our new integrated health management 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 13 of this report, as well as those factors identified from time to time in our periodic filings with the Securities and Exchange Commission. We 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 charge of improving their health and quality of life at home by developing new capabilities in near-patient diagnosis, monitoring and health management. Our global, leading products and services, as well as our new product development efforts, currently focus on cardiology, women's health, infectious disease, oncology and drugs of abuse. We are continuing to expand our product and service offerings in all of these categories both through acquisitions and new product development.

Through our August 2009 acquisition of Concateno and our February 2010 acquisition of Kroll, we expanded the range of drugs of abuse testing products and services that we can offer the government, employers, health plans and healthcare professionals. Our February 2010 acquisition of a majority interest in Standard Diagnostics brought us a comprehensive range of rapid diagnostic products, with particular strength in the infectious disease category. In December 2009, we also entered into an agreement with Epocal Inc. to become the exclusive distributor of the epoc[®] point-of-care diagnostic system in the U.S. and other key

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markets. Over time, we expect this high-precision platform to support a broad menu of tests serving the critical care, point-of-care and, eventually, home settings. Within our health management segment, our September 2009 acquisition of Free & Clear brought us highly differentiated smoking cessation programs.

We have also continued to make progress toward our long-standing goal of strengthening our global network in order to efficiently distribute our current and future diagnostic products and, ultimately, our services, to customers around the globe. Our April 2009 acquisition of the remainder of ACON Laboratories' rapid diagnostics business greatly enhanced our presence in China. We also acquired smaller distributors in Switzerland, Ireland, South Korea, Taiwan and Argentina.

Our research and development efforts focus on developing technology platforms that will facilitate movement of testing from the hospital and central laboratory to the physician's office and, ultimately, the home. During the fourth quarter of 2009, we recognized our first commercial sales of the PIMA CD4 analyzer in Africa. Developed by our research team in Jena, Germany, this portable, point-of-care device provides laboratory quality results for determining patient therapy eligibility for HIV positive individuals and monitoring for patients on life-long therapy. Additionally, through our strong pipeline of novel proteins, or combinations of proteins that function as disease biomarkers, we are developing new point-of-care tests targeted toward all of our areas of focus. During the first quarter of 2009, we launched the Triage NGAL test outside of the U.S. Recent studies published on the NGAL marker can help identify patients at risk for acute kidney injury and we hope that the Triage NGAL test will eventually develop broad market appeal.

As a global, leading supplier of near-patient monitoring tools, as well as value-added healthcare services, we are uniquely positioned to improve care and lower healthcare costs for both providers and patients. Our rapidly growing home coagulation monitoring business, which supports doctors' and patients' efforts to monitor warfarin therapy using our INRatio blood coagulation monitoring system, represents an early example of the convergence of diagnostic devices with health management services. In November 2009, we supplemented our growing QAS home coagulation monitoring business by acquiring Tapestry whose strong management team and core strength in Medicare reimbursement will, along with QAS, provide us with a stable platform for growth in this significantly under-penetrated market. During 2009, we also invested heavily in our new integrated health management technology platform, called Apollo. Using a sophisticated data engine for acquiring and analyzing information, combined with a state of the art touch engine for communicating with individuals and their health partners, we expect Apollo to benefit healthcare providers, health insurers and patients alike by enabling more efficient and effective health management programs. We successfully launched Apollo on January 1, 2010.

2009 Financial Highlights

Net revenue in 2009 of \$1.9 billion increased by \$340.1 million, or 21%, from \$1.6 billion in 2008. Net revenue increased primarily as a result of our health management and professional diagnostics-related acquisitions which contributed \$233.2 million of the increase. Additionally, as a result of the H1N1 flu outbreak, revenues from our North American flu sales increased by approximately \$66.5 million, or 192%, in 2009, from \$34.6 million in 2008.

Gross profit increased by \$200.7 million, or 24%, to \$1.1 billion in 2009 from \$853.5 million in 2008, principally as a result of the increase in net product sales and services revenue resulting from acquisitions, an increase in flu-related sales associated with the H1N1 flu outbreak and organic growth from our professional diagnostics business segment. Gross profit was adversely impacted by \$9.5 million and \$17.9 million during 2009 and 2008, respectively, for restructuring charges related to the closure of various manufacturing and operating facilities.

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

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segment has been segregated from continuing operations and reflected as discontinued operations for all periods presented. See *Discontinued Operations* below. Our results of operations were as follows:

Year Ended December 31, 2009 Compared to Year Ended December 31, 2008

Net Product Sales and Services Revenue. Net product sales and services revenue increased by \$336.8 million, or 22%, to \$1.9 billion in 2009 from \$1.6 billion in 2008. Excluding the unfavorable impact of currency translation, net product sales and services revenue in 2009 grew by approximately \$363.8 million, or 23%, over 2008. Of the currency adjusted increase, revenue increased primarily as a result of our professional diagnostic-related acquisitions which contributed \$233.2 million of the increase. Additionally, as a result of the H1N1 flu outbreak, revenues from our North American flu sales increased by approximately \$66.5 million, or 192%, in 2009, from \$34.6 million in 2008.

Net Product Sales and Services Revenue by Business Segment. Net product sales and services revenue by business segment for 2009 and 2008 are as follows (in thousands):

	2009	2008	% Increase (decrease)
Professional diagnostics	\$ 1,238,251	\$ 1,029,528	20%
Health management	521,695	392,399	33%
Consumer diagnostics	133,620	134,800	(1)%
Net product sales and services revenue	\$ 1,893,566	\$ 1,556,727	22%

Professional Diagnostics

The increase in net product sales and services revenue from our professional diagnostics business segment was \$208.7 million, or 20%, resulting in \$1.2 billion of net product and services revenue in 2009. As a result of the H1N1 flu outbreak, revenues from our North American flu sales increased approximately \$66.5 million comparing 2009 to 2008. Additionally, net product sales and services revenue increased as a result of our acquisitions of: (i) the ACON Second Territory Business, in April 2009, which contributed \$38.3 million of net product sales and services revenue, (ii) Concateno, in August 2009, which contributed \$33.3 million of net product sales and services revenue, (iii) Prodimol Biotecnologia S.A., or Prodimol, in October 2008, which contributed additional net product sales and services revenue of \$6.4 million in excess of those earned in the prior year's comparative period, (iv) Vision Biotech Pty Ltd, or Vision, in September 2008, which contributed additional net product sales and services revenue of \$6.3 million in excess of those earned in the prior year's comparative period and (v) various less significant acquisitions, which contributed an aggregate of \$11.2 million of such increase.

Health Management

Our health management net product sales and services revenue increased \$129.3 million, or 33%, to \$521.7 million in 2009 from \$392.4 million in 2008. Of the increase, net product sales and services revenue increased primarily as a result of our acquisitions of: (i) Matria, in May 2008, which contributed additional net product sales and services revenue of \$103.0 million in excess of those earned in the prior year's comparative period, (ii) Free & Clear, in September 2009, which contributed \$14.3 million of net product sales and services revenue, (iii) CVS Caremark's common disease management program, or Accordant, in September 2009, which contributed \$11.5 million of net product sales and services revenue and (iv) various less significant acquisitions, which contributed an aggregate of

\$8.9 million of such increase.

Consumer Diagnostics

Our consumer diagnostics net product sales and services revenue decreased by \$1.2 million, or 1%, to \$133.6 million in 2009 from \$134.8 million in 2008. The decrease during the year ended December 31, 2009, as compared to the year ended December 31, 2008, was primarily driven by a decrease in net product sales and services revenue associated with our First Check at-home testing drugs of abuse business.

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Net Product Sales and Services Revenue by Geographic Location. Net product sales and services revenue by geographic location for 2009 and 2008 are as follows (in thousands):

	2009	2008	% Increase
United States	\$ 1,302,376	\$ 1,098,894	19%
Europe	315,130	283,552	11%
Other	276,060	174,281	58%
Net product sales and services revenue	\$ 1,893,566	\$ 1,556,727	22%

Net product sales and services revenue of \$1.3 billion and \$1.1 billion generated in the United States were approximately 69% and 71%, respectively, of total net product sales and services revenue for the year ended December 31, 2009 and 2008, 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 \$3.2 million, or 13%, to \$29.1 million in 2009, from \$25.8 million in 2008. The increase in license and royalty revenue during 2009, as compared to 2008, was primarily attributed to an increase in royalty payments received from Quidel under existing licensing agreements and a \$5.0 million royalty payment received in connection with a license arrangement in the field of animal health diagnostics.

Gross Profit and Margin. Gross profit increased by \$200.7 million, or 24%, to \$1.1 billion in 2009, from \$853.5 million in 2008. The increase in gross profit for 2009, as compared to 2008, was largely attributed to the increase in net product sales and services revenue resulting from acquisitions, an increase in flu-related sales associated with the H1N1 flu outbreak, and organic growth from our professional diagnostics business segment. Included in gross profit in 2009 were restructuring charges totaling \$9.5 million associated with the closure of various manufacturing and operating facilities and \$2.0 million of stock-based compensation expense. Included in gross profit in 2008 were restructuring charges totaling \$17.9 million associated with the closure of various manufacturing and operating facilities and \$1.5 million of stock-based compensation expense. Cost of net revenue included amortization expense of \$42.1 million and \$43.4 million in 2009 and 2008, respectively.

Overall gross margin was 55% in 2009, compared to 54% in 2008.

Gross Profit from Net Product Sales and Services Revenue by Business Segment. Gross profit from net product sales and services revenue increased by \$197.7 million to \$1.0 billion in 2009, from \$836.3 million in 2008. Gross profit from net product sales and services revenue by business segment for 2009 and 2008 is as follows (in thousands):

	2009	2008	% Increase (decrease)
Professional diagnostics	\$ 733,640	\$ 596,186	23%
Health management	280,547	214,356	31%
Consumer diagnostics	19,850	25,770	(23)%

Gross profit from net product sales and services revenue	\$ 1,034,037	\$ 836,312	24%
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Professional Diagnostics

Gross profit from our professional diagnostics net product sales and services revenue increased by \$137.5 million, or 23%, to \$733.6 million during 2009, compared to \$596.2 million during 2008, principally as a result of gross profit earned on revenue from acquired businesses, as discussed above. Reducing gross profit for 2009 and 2008 was \$8.6 million and \$17.9 million in restructuring charges, respectively.

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As a percentage of our professional diagnostics net product sales and services revenue, gross profit from our professional diagnostics business was 59% in 2009, compared to 58% in 2008.

Health Management

Gross profit from our health management net product sales and services revenue increased by \$66.2 million, or 31%, to \$280.5 million during 2009, compared to \$214.4 million during 2008. The increase in gross profit was largely attributed to gross margins earned on revenues from recent acquisitions, as discussed above. Reducing gross profit for 2009 was \$0.6 million in restructuring charges.

As a percentage of our health management net product sales and services revenue, gross profit from our health management business was 54% in 2009, compared to 55% in 2008.

Consumer Diagnostics

Gross profit from our consumer diagnostics net product sales and services revenue decreased \$5.9 million, or 23%, to \$19.8 million during 2009, compared to \$25.8 million during 2008. The decrease in gross profit is primarily a result of net product sales and services revenue mix during the year ended December 31, 2009, compared to the year ended December 31, 2008.

As a percentage of our consumer diagnostics net product sales and services revenue, gross profit from our consumer diagnostics business was 15% for 2009, compared to 19% in 2008.

Research and Development Expense. Research and development expense increased by \$1.0 million, or 1%, to \$112.8 million in 2009, from \$111.8 million in 2008. Included in research and development expense in 2009 is \$5.2 million of stock-based compensation expense, representing an increase of approximately \$0.6 million from 2008. Restructuring charges associated with our various restructuring plans to integrate our newly-acquired businesses totaling \$1.1 million were included in research and development expense during 2009, representing a decrease of approximately \$6.2 million from 2008. Amortization expense of \$3.7 million was included in research and development expense for both 2009 and 2008.

Research and development expense as a percentage of net revenue decreased to 6% for 2009, from 7% for 2008.

Sales and Marketing Expense. Sales and marketing expense increased by \$59.7 million, or 16%, to \$441.6 million in 2009, from \$381.9 million in 2008. Amortization expense of \$186.9 million and \$148.6 million was included in sales and marketing expense for 2009 and 2008, respectively. The remaining increase in sales and marketing expense primarily relates to additional spending related to newly-acquired businesses. Also included in sales and marketing expense is \$4.2 million of stock-based compensation expense, representing a decrease of approximately \$0.1 million from 2008. Restructuring charges associated with our various restructuring plans to integrate our newly-acquired businesses totaling \$1.9 million were included in sales and marketing expense during 2009, representing a decrease of approximately \$2.4 million from 2008.

Sales and marketing expense as a percentage of net revenue decreased to 23% for 2009, from 24% for 2008.

General and Administrative Expense. General and administrative expense increased by \$62.0 million, or 21%, to \$357.0 million in 2009, from \$295.1 million in 2008. The increase in general and administrative expense relates primarily to additional spending related to newly-acquired businesses. Contributing to the increase in general and administrative expense for 2009, as compared to 2008, was \$15.9 million for acquisition-related costs recorded in connection with our adoption of a new accounting standard for business combinations on January 1, 2009. Also

included in general and administrative expense is \$16.7 million of stock-based compensation expense, representing an increase of approximately \$0.7 million from 2008. Amortization expense of \$22.9 million and \$18.2 million was included in general and administrative expense for 2009 and 2008, respectively.

General and administrative expense as a percentage of net revenue was 19% for both 2009 and 2008.

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Interest Expense. Interest expense includes interest charges and the amortization of deferred financing costs. Interest expense in 2009 also includes the amortization of original issue discounts associated with certain debt issuances. Interest expense increased by \$5.7 million, or 6%, to \$106.8 million for the year ended December 31, 2009, from \$101.1 million for the year ended December 31, 2008. Such increase was principally due to additional interest expense incurred on our 9% subordinated notes and 7.875% senior notes, totaling \$32.3 million for the year ended December 31, 2009. Substantially offsetting this increase was lower interest expense incurred due to lower interest rates charged during the year ended December 31, 2009, compared to the year ended December 31, 2008.

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):

	2009	2008	Change
Interest income	\$ 2,342	\$ 6,566	\$ (4,224)
Foreign exchange gains (losses), net	1,267	(457)	1,724
Other	(2,613)	(7,916)	5,303
Other income (expense), net	\$ 996	\$ (1,807)	\$ 2,803

Other income (expense), net for 2009 increased by \$2.8 million as compared to 2008, and included a decrease in interest income of \$4.2 million which resulted from lower interest earned on available cash balances, \$1.9 million of expense associated with fully-vested compensation-related costs for certain executives incurred in connection with the acquisition of Concateno during the third quarter of 2009, a \$2.9 million realized foreign currency gain associated with restricted cash established in connection with the acquisition of Concateno, and \$0.6 million of stamp duty tax incurred during 2009 in connection with an incremental investment made in one of our foreign subsidiaries. Other income (expense), net, for 2008 includes a \$12.5 million charge associated with an arbitration decision, a \$1.7 million realized foreign currency loss associated with restricted cash established in connection with the acquisition of BBI partially offset by \$5.5 million of income associated with settlements of prior year's royalties during 2008.

Provision (Benefit) for Income Taxes. Provision (benefit) for income taxes increased by \$32.3 million, to a \$15.6 million provision in 2009, from a \$16.6 million benefit in 2008. The effective tax rate in 2009 was 39%, compared to 43% in 2008. The increase in the provision for income taxes from 2008 to 2009 is primarily related to increased income in foreign jurisdictions. The decrease in the effective tax rate between the two years primarily results from the mix of tax jurisdictions, along with the impact of increased U.S. R&D credits.

The primary components of the 2009 provision for income taxes relates to U.S. federal and state income taxes and taxes on foreign income. The primary components of the 2008 benefit for income taxes relates to U.S. federal and state income taxes, taxes on foreign income and the recognition of benefit on German and U.K. losses.

Discontinued Operations, Net of Tax. The results of the vitamins and nutritional supplements business are included in income (loss) from discontinued operations, net of tax, for all periods presented. For the year ended December 31, 2009, the discontinued operations generated net income of \$1.9 million, as compared to a net loss of \$1.0 million for the year ended December 31, 2008.

Net Income (Loss). For the year ended December 31, 2009, we generated net income of \$33.7 million, or \$0.13 per basic and diluted common share after preferred stock dividends, based on net income available to common

stockholders of \$10.7 million. For the year ended December 31, 2008, we generated a net loss of \$21.8 million, or \$0.46 per basic and diluted common share after preferred stock dividends, based on net loss available to common stockholders of \$35.8 million. The net income in 2009 and the net loss 2008 resulted from the various factors as discussed above. See Note 14 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for the calculation of net income (loss) per common share.

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Year Ended December 31, 2008 Compared to Year Ended December 31, 2007

Net Product Sales and Services Revenue. Net product sales and services revenue increased by \$812.0 million, or 109%, to \$1.6 billion in 2008 from \$744.7 million in 2007. Excluding the unfavorable impact of currency translation, net product sales and services revenue in 2008 grew by approximately \$812.3 million, or 109%, over 2007. Of the currency adjusted increase, revenue increased primarily as a result of our professional diagnostic-related acquisitions which contributed \$392.4 million of the increase. Organic growth, particularly from our professional infectious disease and drugs of abuse products also contributed to the growth.

Net Product Sales and Services Revenue by Business Segment. Net product sales and services revenue by business segment for 2008 and 2007 are as follows (in thousands):

	2008	2007	% Increase (decrease)
Professional diagnostics	\$ 1,029,528	\$ 565,265	82%
Health management	392,399	23,374	1,579%
Consumer diagnostics	134,800	156,098	(14)%
Net product sales	\$ 1,556,727	\$ 744,737	109%

Professional Diagnostics

The increase in net product sales and services revenue from our professional diagnostics business segment was \$464.3 million, or 82%, resulting in \$1.0 billion of net product sales and services revenue in 2008. Of the increase, net product sales and services revenue increased primarily as a result of our acquisitions of: (i) Biosite, in June 2007, which contributed additional net product sales and services revenue of \$161.7 million in excess of those earned in the prior year's comparative period, (ii) Cholestech, in September 2007, which contributed additional net product sales and services revenue of \$49.4 million in excess of those earned in the prior year's comparative period, (iii) Bio-Stat Healthcare Group, or Bio-Stat, in October 2007, which contributed additional net product sales and services revenue of \$21.6 million in excess of those earned in the prior year's comparative period, (iv) HemoSense, in November 2007, which contributed additional net product sales and services revenue of \$27.2 million in excess of those earned in the prior year's comparative period, (v) Redwood, in December 2007, which contributed additional net product sales and services revenue of \$52.4 million in excess of those earned in the prior year's comparative period, (vi) BBI, in February 2008, which contributed product revenue of \$32.4 million and (vii) various less significant acquisitions, which contributed an aggregate of \$47.6 million of such increase. Organic growth contributed to the increase in net revenue during the year ended December 31, 2008, as compared to the year ended December 31, 2007.

Health Management

The increase in net product sales and services revenue from our health management business segment was \$369.0 million, or 1,579%, resulting in \$392.4 million of net product sales and services revenue in 2008. Of the increase, net product sales and services revenue increased primarily as a result of our acquisitions of: (i) Matria, in May 2008, which contributed \$197.7 million of net product sales and services revenue, (ii) QAS, in June 2007, which contributed additional net product sales and services revenue of \$10.9 million in excess of those earned in the prior year's comparative period, (iii) Alere, in November 2007, which contributed additional net product sales and services revenue of \$79.6 million in excess of those earned in the prior year's comparative period and (iv) ParadigmHealth in

December 2007, which contributed additional net product sales and services revenue of \$69.4 million in excess of those earned in the prior year's comparative period.

Consumer Diagnostics

The decrease in net product sales and services revenue from our consumer diagnostics business segment was \$21.3 million, or 14%, resulting in \$134.8 million of net product sales and services revenue for 2008. The decrease was primarily driven by the completion of our 50/50 joint venture with P&G in May 2007 in which

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we transferred substantially all of the assets of our consumer diagnostics business, other than our manufacturing and core intellectual property assets. Upon completion of the arrangement to form the joint venture, we ceased to consolidate the operating results of our consumer diagnostics 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. Net product sales and services revenue from our consumer diagnostics business segment for 2008 and 2007 included \$103.0 million and \$65.0 million, respectively, of manufacturing revenue associated with our manufacturing agreement with SPD, whereby we manufacture and sell consumer diagnostics to the joint venture. Partially offsetting the impact of the joint venture was an increase \$13.5 million of net product sales and services revenue attributed to our acquisitions of: (i) First Check Diagnostics LLC, or First Check, in January 2007, which contributed additional net product sales and services revenue of \$1.1 million in excess of those earned in the prior year's comparative period, (ii) Bio-Stat, in October 2007, which contributed additional net product sales and services revenue of \$4.6 million in excess of those earned in the prior year's comparative period and (iii) BBI, in February 2008, which contributed net product sales and services revenue of \$7.8 million.

Net Product Sales and Services Revenue by Geographic Location. Net product sales and services revenue by geographic location for 2008 and 2007 are as follows (in thousands):

	2008	2007	% Increase (decrease)
United States	\$ 1,098,894	\$ 445,462	147%
Europe	283,552	192,593	47%
Other	174,281	106,682	63%
Net product sales and services revenue	\$ 1,556,727	\$ 744,737	109%

Net product sales and services revenue of \$1.1 billion and \$445.5 million generated in the United States were approximately 71% and 60%, respectively, of total net product sales and services revenue for the year ended December 31, 2008 and 2007, respectively. The growth in net product sales and services revenue in all geographic regions resulted from the various acquisitions discussed above and organic growth, partially offset by the decrease in revenue associated with the formation of our 50/50 joint venture with P&G in May 2007.

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 \$3.8 million, or 18%, to \$25.8 million in 2008, from \$22.0 million in 2007. License and royalty revenue for 2008 increased primarily as a result of our acquisition of Biosite in June 2007, which contributed an additional \$1.9 million of royalty revenue in excess of those earned in 2007. Additionally, incremental royalty revenue was derived from new royalty agreements entered into during 2008, along with increases associated with certain existing royalty agreements, partially offset by decreases in other royalty agreements.

Gross Profit and Margin. Gross profit increased by \$466.8 million, or 121%, to \$853.5 million in 2008, from \$386.8 million in 2007. Gross profit during 2008 benefited from higher than average margins earned on revenue from our recently acquired businesses and from the favorable impact of our low cost manufacturing facilities in China. Included in gross profit in 2008 were restructuring charges totaling \$17.9 million associated with the closure of various manufacturing and operating facilities, a \$2.0 million charge related to the write-up to fair market value of inventory acquired in connection with our first quarter acquisitions of BBI and Panbio, and \$1.5 million of stock-based compensation expense. Included in gross profit in 2007 were restructuring charges totaling \$2.0 million

associated with the closure of various manufacturing and operating facilities, an \$8.2 million charge related to the write-up to fair market value of inventory acquired in connection with our acquisitions of Biosite, Cholestech and HemoSense and \$0.6 million of stock-based compensation expense. Cost of net revenue included amortization expense of \$43.4 million and \$24.0 million in 2008 and 2007, respectively.

Overall gross margin was 54% in 2008, compared to 50% in 2007.

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Gross Profit from Net Product Sales and Services Revenue by Business Segment. Gross profit from net product sales and services revenue increased by \$462.4 million to \$836.3 million in 2008, from \$373.9 million in 2007. Gross profit from net product sales and services revenue by business segment for 2008 and 2007 is as follows (in thousands):

	2008	2007	% Increase (decrease)
Professional diagnostics	\$ 596,186	\$ 306,710	94%
Health management	214,356	11,979	1,689%
Consumer diagnostics	25,770	55,242	(53)%
Gross profit from net product sales	\$ 836,312	\$ 373,931	124%

Professional Diagnostics

Gross profit from our professional diagnostics net product sales and services revenue increased by \$289.5 million, or 94%, comparing 2008 to 2007, principally as a result of gross profit earned on revenue from acquired businesses, as discussed above, which contributed higher than average gross profits. The higher than average profits were partially offset by a \$2.0 million charge related to the write-up to fair market value of inventory acquired in connection with our acquisitions of BBI and Panbio and \$17.9 million in restructuring charges. Reducing gross profit for 2007 was an \$8.2 million charge related to the write-up to fair market value of inventory acquired in connection with our acquisitions of Biosite, Cholestech and HemoSense and \$0.5 million in restructuring charges.

As a percentage of our professional diagnostics net product sales and services revenue, gross profit from our professional diagnostics business was 58% in 2008, compared to 54% in 2007.

Health Management

Gross profit from our health management net product sales and services revenue increased by \$202.4 million, or 1,689%, comparing 2008 to 2007, principally as a result of gross profit earned on revenue from acquired businesses, as discussed above.

As a percentage of our health management net product sales and services revenue, gross profit from our health management business was 55% in 2008, compared to 51% in 2007.

Consumer Diagnostics

Gross profit from our consumer diagnostics net product sales and services revenue decreased \$29.5 million, or 53%, comparing 2008 to 2007. The decrease is primarily a result of the formation of our 50/50 joint venture with P&G for our consumer diagnostics business in May 2007, partially offset by the gross profit earned on net products sales and services revenue from acquired businesses, primarily our BBI acquisition and the manufacturing profit associated with products sold under our manufacturing agreement with the joint venture. Gross profit for 2007 was adversely impacted by restructuring charges totaling \$1.5 million related to the formation of the joint venture.

As a percentage of our consumer diagnostics net product sales and services revenue, gross profit from our consumer diagnostics business was 19% for 2008, compared to 35% in 2007. The decrease in gross margin percentage for 2008, as compared to 2007, is driven by the formation of our 50/50 joint venture with P&G in May 2007. As a result of the

joint venture, our consumer diagnostics net product sales and services revenue primarily consist of the manufacturing revenue associated with our manufacturing agreement with the joint venture, whereby we manufacture and sell consumer diagnostics to the joint venture.

Research and Development Expense. Research and development expense increased by \$42.3 million, or 61%, to \$111.8 million in 2008 from \$69.5 million in 2007. The year over year increase in research and development expense is primarily the result of increased spending related to our cardiology research programs, partially offset by the transition of our consumer-related research and development efforts into our 50/50 joint

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venture with P&G. Additionally, our funding relationship with ITI Scotland Limited was complete as of December 31, 2007 and, as such, no funding was earned during 2008. This funding relationship was reflected as an offset to research and development expense totaling \$18.5 million during 2007. Also included in research and development expense is \$4.6 million of stock-based compensation expense, representing an increase of approximately \$2.4 million from 2007. Restructuring charges associated with our various restructuring plans to integrate our newly-acquired businesses totaling \$7.2 million were included in research and development expense during 2008, representing an increase of approximately \$4.7 million from 2007. Amortization expense of \$3.7 million and \$2.9 million was included in research and development expense for 2008 and 2007, respectively.

Research and development expense as a percentage of net revenue decreased to 7% for 2008, from 9% for 2007.

Purchase of In-Process Research and Development (IPR&D). In connection with two of our acquisitions since 2007, we acquired various IPR&D projects. Substantial additional research and development will be required prior to any of our acquired IPR&D programs and technology platforms reaching technological feasibility. In addition, once research is completed, each product candidate acquired will need to complete a series of clinical trials and receive FDA or other regulatory approvals prior to commercialization. Our estimates of the time and investment required to develop these products and technologies may change depending on the different applications that we may choose to pursue. We cannot give assurances that these programs will ever reach technological feasibility or develop into products that can be marketed profitably. For example, we have discontinued funding certain of the programs listed below. In addition, we cannot guarantee that we will be able to develop and commercialize products before our competitors develop and commercialize products for the same indications. The following table sets forth IPR&D projects for companies and certain assets we have acquired since 2007 (in thousands):

Company/ Year Assets Acquired	Purchase Price	IPR&D(1)	Programs Acquired	Discount Rate Used in Estimating Cash Flows(1)	Year of Expected Launch	Estimated Cost to Complete
Diamics/2007	\$ 4,000	\$ 682	PapMap (Pap Screening Methods)	63%	2009-2010	
		1,049	C-Map (Automated Pap Screening)	63%	2009-2010	
		3,094	POC (Point of Care Systems)	63%	2009-2010	
		\$ 4,825				\$ 7,476
Biosite/2007	\$ 1,800,000	\$ 13,000	Triage Sepsis Panel	15%	2008-2010	
		156,000	Triage NGAL	15%	2008-2010	
		\$ 169,000				\$ 6,000

(1) Management assumes responsibility for determining the valuation of the acquired IPR&D projects. The fair value assigned to IPR&D for each acquisition is estimated by discounting, to present value, the cash flows expected

once the acquired projects have reached technological feasibility. The cash flows are probability adjusted to reflect the risks of advancement through the product approval process. In estimating the future cash flows, we also considered the tangible and intangible assets required for successful exploitation of the technology resulting from the purchased IPR&D projects and adjusted future cash flows for a charge reflecting the contribution to value of these assets.

Sales and Marketing Expense. Sales and marketing expense increased by \$218.9 million, or 134%, to \$381.9 million in 2008, from \$163.0 million in 2007. The increase in sales and marketing expense primarily relates to additional spending related to newly-acquired businesses. Also included in sales and marketing expense is \$4.3 million of stock-based compensation expense, representing an increase of approximately \$2.6 million from 2007. Partially offsetting the increases was the favorable impact of the formation of our 50/50 joint venture with P&G. Restructuring charges associated with our various restructuring plans to integrate our newly-acquired businesses totaling \$4.2 million were included in sales and marketing expense during 2008,

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representing an increase of approximately \$3.4 million from 2007. Amortization expense of \$148.6 million and \$34.5 million was included in sales and marketing expense for 2008 and 2007, respectively.

Sales and marketing expense as a percentage of net revenue increased to 25% for 2008, from 22% for 2007.

General and Administrative Expense. General and administrative expense increased by \$139.9 million, or 90%, to \$295.1 million in 2008, from \$155.2 million in 2007. The increase in general and administrative expense relates primarily to additional spending related to newly-acquired businesses. Legal spending increased by approximately \$9.4 million in 2008, as compared to 2007. Also included in general and administrative expense is \$16.0 million of stock-based compensation expense, representing a decrease of approximately \$36.9 million from 2007 which included a charge of \$45.2 million related to our acquisition of Biosite. Partially offsetting the increases was the favorable impact from the formation of our 50/50 joint venture with P&G. Amortization expense of \$18.2 million and \$0.1 million was included in general and administrative expense for 2008 and 2007, respectively.

General and administrative expense as a percentage of net revenue decreased to 19% for 2008, from 20% for 2007.

Interest Expense. Interest expense includes interest charges and the amortization of deferred financing costs associated with our debt issuances. Interest expense in 2007 also includes the write-off of deferred financing costs and early termination fees associated with the repayment of outstanding debt. Interest expense increased by \$18.1 million, or 22%, to \$101.1 million in 2008, from \$83.0 million in 2007. The increase in interest expense in 2008 was due to higher average outstanding borrowing balances in 2008 and \$6.6 million in interest expense related to the accelerated present value accretion of our lease restoration costs due to the early termination of our facility lease in Bedford, England recorded in connection with our 2008 restructuring plans. Also contributing to the increase in 2008 was \$0.8 million of interest expense recorded in connection with a legal settlement with one of our distributors in June 2008. Interest expense for 2007 included the write-off of \$15.6 million of deferred financing costs and prepayment premium related to the repayment of outstanding debt, in conjunction with our financing arrangements related to our Biosite acquisition.

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):

	2008	2007	Change
Interest income	\$ 6,566	\$ 11,286	\$ (4,720)
Foreign exchange gains (losses), net	(457)	(2,007)	1,550
Other	(7,916)	145	(8,061)
Other income (expense), net	\$ (1,807)	\$ 9,424	\$ (11,231)

Other income (expense), net, for 2008 includes a \$12.5 million charge associated with an arbitration decision, partially offset by \$5.5 million of income associated with settlements of prior year's royalties during 2008.

Other income (expense), net, for 2007 includes a foreign exchange gain of \$1.9 million realized on the settlement of intercompany notes and \$3.9 million in unrealized foreign currency loss associated with a cash escrow established in connection with the acquisition of BBI.

(Benefit) Provision for Income Taxes. (Benefit) provision for income taxes increased by \$15.6 million, to a \$16.6 million benefit in 2008, from a \$1.0 million benefit in 2007. The effective tax rate in 2008 was 43%, compared to 1.0% in 2007. The increase in the benefit for income taxes from 2007 to 2008 is primarily related to the recognition of the benefit of losses in Germany, Japan and the United Kingdom.

The primary components of the 2008 benefit for income taxes relates to U.S. federal and state income taxes, taxes on foreign income and the recognition of benefit on German and U.K. losses. The primary components of the 2007 provision for income taxes relates to the recognition of benefit on U.S. and U.K.

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losses, state income taxes and taxes on foreign income. We recognized the benefit of U.S. net operating loss, or NOL, carryforwards and other U.S. deferred tax assets due to the U.S. non-current deferred tax liabilities recorded in purchase accounting for 2007 acquisitions. During 2007, we released approximately \$83.0 million of valuation allowance for these pre-acquisition U.S. deferred tax assets, which was released to goodwill. Thereafter, we recognized a benefit or recorded a provision, as appropriate, for the current year U.S. losses.

Discontinued Operations, Net of Tax. The results of the vitamins and nutritional supplements business are included in income (loss) from discontinued operations, net of tax, for all periods presented. For the year ended December 31, 2008, the discontinued operations incurred a net loss of \$1.0 million as compared to a net loss of \$0.4 million for the year ended December 31, 2007.

Net Loss. We incurred a net loss of \$21.8 million in 2008, while we incurred a net loss of \$244.8 million in 2007. Net loss per common share available to common stockholders was \$0.46 per basic and diluted common share in 2008, as compared to net loss of \$4.75 per basic and diluted common share in 2007. The net loss in 2008 and 2007 resulted from the various factors as discussed above. See Note 14 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for the calculation of net loss per common share.

Liquidity and Capital Resources

Based upon our current working capital position, current operating plans and expected business conditions, we currently expect to fund our short and long-term working capital needs and other commitments primarily through our operating cash flow, and we expect our working capital position to improve as we improve our operating margins and grow our business through new product and service offerings and by continuing to leverage our strong intellectual property position. At this point in time, our liquidity has not been materially impacted by the recent and unprecedented disruption in the current capital and credit markets and we do not expect that it will be materially impacted in the near future. However, we cannot predict with certainty the ultimate impact of these events on us. We will therefore continue to closely monitor our liquidity and capital resources.

In addition, we may also utilize our revolving credit facility, or other sources of financing, to fund a portion of our capital needs and other future commitments, including future acquisitions. We utilized these resources to complete our recent acquisitions of Standard Diagnostics and Kroll. If the capital and credit markets continue to experience volatility and the availability of funds remains limited, we may incur increased costs associated with issuing commercial paper and/or other debt instruments. In addition, it is possible that our ability to access the capital and credit markets may be limited by these or other factors at a time when we would like, or need, to do so, which could have an 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 prosecuting and defending our existing lawsuits and/or unforeseen lawsuits against us, integrating the operations of newly-acquired companies and executing our cost savings strategies. 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 significant 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. If we decide to engage in such activities, or if our operating results fail to meet our expectations, we could be required to seek additional funding through public or private financings or other arrangements. In such event, adequate funds may not be available when needed, or, may be available only on terms which could have a negative impact on our business and results of operations. In addition, if we raise additional funds by issuing equity or convertible securities, dilution to then existing stockholders may result.

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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, we sold \$150.0 million aggregate principal amount of 7.875% senior notes in a public offering. Net proceeds from this offering amounted to approximately \$145.0 million, which was net of underwriters' commissions totaling \$2.2 million and original issue discount totaling \$2.8 million. The net proceeds were used to fund our acquisition of Concateno. At December 31, 2009, we had \$147.3 million in indebtedness under this issuance of our 7.875% senior notes.

On September 28, 2009, we sold \$100.0 million aggregate principal amount of 7.875% senior notes in a private placement to initial purchasers, who agreed to resell the notes only to qualified institutional buyers. We also agreed to file a registration statement with the Securities Exchange Commission, or SEC, so that the holders of these notes may exchange the notes for registered notes that have substantially identical terms as the original notes. Net proceeds from this offering amounted to approximately \$95.0 million, which was net of the initial purchasers' original issue discount totaling \$3.5 million and offering expenses totaling approximately \$1.5 million. The net proceeds were used to partially fund our acquisition of Free & Clear. At December 31, 2009, we had \$96.6 million in indebtedness under this issuance of our 7.875% senior notes.

The 7.875% senior notes were issued under an Indenture dated August 11, 2009, as amended or supplemented, the Indenture. The 7.875% senior notes accrue interest from the dates of their respective issuances at the rate of 7.875% per year. Interest on the notes are payable semi-annually on February 1 and August 1, commencing on February 1, 2010. The notes mature on February 1, 2016, unless earlier redeemed.

We may redeem the 7.875% senior notes, in whole or part, at any time on or after February 1, 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 3.938% during the twelve months on and after February 1, 2013 to 1.969% during the twelve months on and after February 1, 2014 to zero on and after February 1, 2015. At any time prior to August 1, 2012, we may redeem up to 35% of the aggregate principal amount of the 7.875% senior notes with money that we raise in certain equity offerings, so long as (i) we pay 107.875% 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 7.875% senior notes remains outstanding afterwards. In addition, at any time prior to February 1, 2013, we may redeem some or all of the 7.875% senior notes by paying the principal amount of the notes being redeemed plus the payment of 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 7.875% 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 7.875% senior notes equal to the excess net cash proceeds, subject to certain exceptions. The purchase price of the notes will be 100% of their principal amount, plus accrued and unpaid interest.

The 7.875% senior notes are unsecured and are equal in right of payment to all of our existing and future senior debt, including our borrowing under our secured credit facilities. Our obligations under the 7.875% senior notes and the Indenture are fully and unconditionally guaranteed, jointly and 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 28 for guarantor financial information.

The Indenture contains covenants that will 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

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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.

Interest expense related to our 7.875% senior notes for the year ended December 31, 2009, including amortization of deferred financing costs and original issue discounts, was \$7.3 million. As of December 31, 2009, accrued interest related to the senior subordinated notes amounted to \$7.8 million.

9% Senior Subordinated Notes

On May 12, 2009, we completed the sale of \$400.0 million aggregate principal amount of 9% senior subordinated notes due 2016, or the 9% subordinated notes, in a public offering. 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. The net proceeds are intended to be used for general corporate purposes. At December 31, 2009, we had \$388.3 million in indebtedness under our 9% subordinated notes.

The 9% subordinated notes, which were issued under an Indenture dated May 12, 2009, as amended or supplemented, the Indenture, accrue interest from the date of their issuance, or May 12, 2009, at the rate of 9% per year. Interest on the notes are payable semi-annually on May 15 and November 15, commencing on November 15, 2009. The notes mature on May 15, 2016, unless earlier redeemed.

We may redeem the 9% subordinated notes, in whole or part, at any time 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. At any time prior to May 15, 2012, we may redeem up to 35% of the aggregate principal amount of the 9% subordinated notes with money that we raise in certain equity offerings so long as (i) we pay 109% 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 9% subordinated notes remains outstanding afterwards. 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 the payment of 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 9% 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.

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 9% subordinated notes equal to the excess net cash proceeds, subject to certain exceptions. The purchase price of the notes will be 100% of their principal amount, plus accrued and unpaid interest.

The 9% subordinated notes are unsecured and are subordinated in right of payment to all of our existing and future senior debt, including our borrowing under our secured credit facilities. Our obligations under the 9% subordinated notes and the Indenture 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. See Note 28 for

guarantor financial information.

The Indenture contains covenants that will 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

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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.

Interest expense related to our 9% subordinated notes for the year ended December 31, 2009, including amortization of deferred financing costs and original issue discounts, was \$25.0 million. As of December 31, 2009, accrued interest related to the senior subordinated notes amounted to \$5.0 million.

Secured Credit Facility

As of December 31, 2009, we had approximately \$1.0 billion in aggregate principal amount of indebtedness outstanding under our First Lien Credit Agreement and \$250.0 million in aggregate principal amount of indebtedness outstanding under our Second Lien Credit Agreement (collectively, with the First Lien Credit Agreement, the secured credit facility). Included in the secured credit facility is a revolving line-of-credit of \$150.0 million, of which \$142.0 million was outstanding as of December 31, 2009.

Interest on our First Lien indebtedness, as defined in the credit agreement, is as follows: (i) in the case of 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 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 and changes on a periodic basis. The Eurodollar Rate is equal to the LIBOR rate and is set for a period of one to three months at our election. Applicable margin with respect to Base Rate Loans is 1.00% and with respect to Eurodollar Rate Loans is 2.00%. Applicable margin ranges for our revolving line-of-credit with respect to Base Rate Loans is 0.75% to 1.25% and with respect to Eurodollar Rate Loans is 1.75% to 2.25%.

The outstanding indebtedness under the Second Lien Credit Agreement includes term loans in the aggregate amount of \$250.0 million. Interest on these term loans, as defined in the credit agreement, is as follows: (i) in the case of 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 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 Base Rate Loans, as in effect from time to time. Applicable margin with respect to Base Rate Loans is 3.25% and with respect to Eurodollar Rate Loans is 4.25%.

For the year ended December 31, 2009, interest expense, including amortization of deferred financing costs, under the secured credit facility was \$64.3 million. As of December 31, 2009, accrued interest related to the secured credit facility amounted to \$0.9 million. As of December 31, 2009, we were in compliance with all debt covenants related to the secured credit facility, which consisted principally of maximum consolidated leverage and minimum interest coverage requirements.

In August 2007, we entered into interest rate swap contracts, with an effective date of September 28, 2007, that have a total notional value of \$350.0 million and have a maturity date of September 28, 2010. These interest rate swap contracts pay us variable interest at the three-month LIBOR rate, and we pay 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 the senior credit facility into fixed rate debt.

In January 2009, we entered into interest rate swap contracts, with an effective date of January 14, 2009, that have a total notional value of \$500.0 million and have a maturity date of January 5, 2011. These interest rate swap contracts pay us variable interest at the one-month LIBOR rate, and we pay the counterparties a

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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 loans under the secured credit facility into fixed rate debt.

3% Senior Subordinated Convertible Notes

In May 2007, we sold \$150.0 million aggregate principal amount of 3% senior subordinated convertible notes, or senior subordinated convertible notes. At December 31, 2009, we had \$150.0 million in indebtedness under our senior subordinated convertible notes. The senior subordinated convertible notes are convertible into 3.4 million shares of our common stock at a conversion price of \$43.98 per share.

Interest expense related to our senior subordinated convertible notes for the year ended December 31, 2009, including amortization of deferred financing costs, was \$5.1 million. As of December 31, 2009, accrued interest related to the senior subordinated convertible notes amounted to \$0.6 million.

Series B Convertible Perpetual Preferred Stock

As of December 31, 2009, we had approximately 2.0 million shares of our Series B preferred stock issued and outstanding. 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 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 these shares of Series B preferred stock, we may, at our option and in our sole discretion, satisfy the entire conversion obligation in cash, or through a combination of cash and common stock, to the extent permitted under our secured credit facilities and under Delaware law. There were no conversions as of December 31, 2009.

Summary of Changes in Cash Position

As of December 31, 2009, we had cash and cash equivalents of \$492.8 million, a \$351.4 million increase from December 31, 2008. Our primary sources of cash during the year ended December 31, 2009 included \$287.5 million generated by our operating activities, \$631.2 million of net proceeds from issuance of debt, of which \$387.5 million related to the issuance of our 9% subordinated notes and \$243.7 million related to the issuance of our 7.875% senior notes, a \$12.6 million return of capital, of which \$10.0 million was from our 50/50 joint venture with P&G, and \$30.0 million from common stock issuances under employee stock option and stock purchase plans. Our primary uses of cash during the year ended December 31, 2009 related to \$468.5 million net cash paid for acquisitions and transactional costs, \$99.8 million of capital expenditures, net of proceeds from the sale of equipment, \$11.0 million in repayment of long-term debt, \$17.9 million paid for financing costs principally related to the issuance of our 9% subordinated notes and 7.875% senior notes and \$8.0 million related to net repayments under our revolving lines-of-credit, other debt and capital lease obligations. Fluctuations in foreign currencies positively impacted our cash balance by \$13.8 million during the year ended December 31, 2009.

Operating Cash Flows

Net cash provided by operating activities during the year ended December 31, 2009 was \$287.5 million, which resulted from net income of \$34.2 million, \$347.2 million of non-cash items, offset by \$89.8 million of cash used to meet net working capital requirements during the period. The \$347.2 million of non-cash items included \$312.4 million related to depreciation and amortization, \$8.5 million related to the impairment of assets, \$28.2 million related to non-cash stock-based compensation expense and \$10.4 million of interest expense related to the amortization of deferred financing costs and original issue discounts, partially offset by a \$9.1 million decrease related to the recognition of a tax benefit for current year losses and tax loss carryforwards and \$7.6 million in equity earnings

in unconsolidated entities.

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Investing Cash Flows

Our investing activities during the year ended December 31, 2009 utilized \$583.7 million of cash, including \$468.5 million used for acquisitions and transaction-related costs, net of cash acquired, \$99.8 million of capital expenditures, net of proceeds from sale of equipment and a \$15.2 million increase in investments and other assets.

The acquisitions of Tapestry, Free & Clear, Concateno and the ACON Second Territory Business during 2009 accounted for approximately \$383.1 million of the \$468.5 million of cash used for acquisitions.

Financing Cash Flows

Net cash provided by financing activities during the year ended December 31, 2009 was \$633.9 million. Financing activities during the year ended December 31, 2009 primarily included \$631.2 million of net proceeds from the issuance of debt, of which \$387.5 million related to the issuance of our 9% subordinated notes and \$243.7 million related to the issuance of our 7.875% senior notes and \$30.0 million cash received from common stock issuances under employee stock option and stock purchase plans, offset by \$11.1 million in repayments of long-term debt, \$17.9 million paid for financing costs related to certain debt issuances and \$8.0 million related to net repayments under our revolving lines-of-credit, other debt and capital lease obligations.

As of December 31, 2009, we had an aggregate of \$1.8 million in outstanding capital lease obligations which are payable through 2014.

Income Taxes

As of December 31, 2009, we had approximately \$184.5 million of domestic NOL and capital loss carryforwards and \$33.5 million of foreign NOL and capital loss carryforwards, respectively, which either expire on various dates through 2028 or may be carried forward indefinitely. These losses are available to reduce federal, state and foreign taxable income, if any, in future years. These losses are also subject to review and possible adjustments by the applicable taxing authorities. In addition, the domestic NOL carryforward amount at December 31, 2009 included approximately \$143.3 million of pre-acquisition losses at Matria, QAS, ParadigmHealth, Biosite, Cholestech, Redwood, HemoSense, Inverness Medical Nutritionals Group, Ischemia, Inc. and Ostex International, Inc. 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 are subject to the Internal Revenue Service Code Section 382 limitation 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 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. We have recorded a valuation allowance against a portion of the deferred tax assets related to our NOLs 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, 2009.

Table of Contents**Contractual Obligations**

The following table summarizes our principal contractual obligations as of December 31, 2009 and the effects such obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

Contractual Obligations	Total	Payments Due by Period			Thereafter
		2010	2011-2012	2013-2014	
Long-term debt obligations(1)	\$ 2,165,248	\$ 18,970	\$ 22,754	\$ 1,064,005	\$ 1,059,519
Capital lease obligations(2)	1,857	920	837	100	
Operating lease obligations(3)	156,560	29,628	46,688	43,139	37,105
Long-term and other liabilities(4)	4,329	666	1,332	1,332	999
Minimum royalty obligations	220	220			
Acquisition-related obligations(5)	60,907	37,436	23,471		
Purchase obligations capital expenditure	19,085	19,085			
Purchase obligations other(6)	41,792	38,042	3,750		
Interest on debt(7)	400,876	61,427	123,532	123,378	92,539
Total	\$ 2,850,874	\$ 206,394	\$ 222,364	\$ 1,231,954	\$ 1,190,162

- (1) Includes original issue discounts associated with the 9% senior subordinated notes and 7.875% senior notes. See description of various financing arrangements in this section and 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) Included in long-term and other liabilities is \$4.3 million in pension obligations.
- (5) Includes \$44.3 million of deferred payments associated with the acquisition of the ACON Second Territory Business, \$15.0 million in deferred payments associated with the acquisition of Accordant common disease management programs, or Accordant, \$1.2 million in deferred payments associated with the acquisition of Biolinker S.A. and \$0.4 million in deferred payments associated with the acquisition of Jinsung Meditech, Inc.
- (6) Other purchase obligations relate to inventory purchases and other operating expense commitments.
- (7) Includes the 3% senior subordinated convertible notes and other non-variable interest-bearing debt. See description of various financing arrangements in this section and 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 terms related to the following acquisitions:

Accordant has a maximum earn-out of \$6.0 million that, if earned, will be paid in quarterly payments of \$1.5 million beginning in the fourth quarter of 2012.

Ameditech, Inc., or Ameditech, has a maximum earn-out of \$4.0 million that, if earned, will be paid during 2010 and 2011.

Binax Inc., or Binax, has a maximum remaining earn-out of \$3.7 million that, if earned, will be paid no later than 2010.

Free & Clear has a maximum earn-out of \$30.0 million that, if earned, will be paid in 2011.

Gabmed GmbH, or Gabmed, has a maximum remaining earn-out of 0.5 million that, if earned, will be paid in equal annual amounts during 2010 through 2012.

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JSM has a maximum earn-out of \$3.0 million that, if earned, will be paid in annual amounts during 2011 through 2013.

Mologic Limited, or Mologic, has a maximum earn-out of \$19.0 million that, if earned, will be paid in annual amounts during 2011 through 2012, payable in shares of our common stock.

Tapestry has a maximum earn-out of \$25.0 million that, if earned, will be paid in annual amounts during 2011 and 2013. The earn-out is to be paid in shares of our common stock, except in the case that the 2010 financial targets defined under the earn-out agreement are exceeded, in which case the seller may elect to be paid the 2010 earn-out in cash.

Vision has a maximum remaining earn-out of \$1.2 million that, if earned, will be paid in 2010.

Privately-owned health management business acquired in 2008 has an earn-out that, if earned, will be paid in 2011.

For further information pertaining to our contractual contingent consideration obligations see Note 11 of our accompanying consolidated financial statements.

Additionally, we have a contractual contingent obligation to pay £1.0 million in compensation to certain executives of Concateno in accordance with the acquisition agreement, that, if earned, 65.0% will be paid in 2010 and the balance in 2011. All payments vest in full on a change of control event.

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, 2009 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 and determinable and (4) collection is reasonably assured.

The majority of our revenue is derived from product revenue. 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.

Additionally, we generate services revenue in connection with contracts with leading healthcare organizations whereby we distribute 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 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

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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 fixed fee license and royalty agreements are 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 \$60.2 million, \$35.8 million and \$38.4 million, or 4%, 3% and 5%, respectively, of net product sales in 2009, 2008 and 2007, respectively, which have been recorded against product sales to derive our net product sales. Of these amounts, approximately \$9.3 million, \$9.3 million and \$18.8 million, for 2009, 2008 and 2007, 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 \$354.5 million and \$261.4 million, net of allowances for doubtful accounts of \$12.5 million and \$10.0 million, as of December 31, 2009 and December 31, 2008, respectively.

Additionally, we generate services revenue in connection with contracts with leading healthcare organizations, whereby we distribute 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 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. Our deferred revenue balance was \$24.0 million and \$22.0 million, as of December 31, 2009 and December 31, 2008, respectively.

Valuation of Inventories

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. 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

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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 \$221.5 million and \$173.6 million, net of a reserve for excess and obsolete inventory of \$12.6 million and \$9.6 million, as of December 31, 2009 and 2008, respectively.

Valuation of Goodwill and Other Long-Lived and Intangible Assets

Our long-lived assets include (1) property, plant and equipment, (2) goodwill and (3) other intangible assets. As of December 31, 2009, the balances of property, plant and equipment, goodwill and other intangible assets, net of accumulated depreciation and amortization, were \$324.4 million, \$3.5 billion and \$1.7 billion, respectively.

Goodwill and other intangible assets are initially created as a result of business combinations or acquisitions of intellectual property. The values we record for goodwill and other intangible assets represent fair values calculated by accepted valuation methods. Such valuations require us to provide significant estimates and assumptions which are derived from information obtained from the management of the acquired businesses and our business plans for the acquired businesses or intellectual property. Critical estimates and assumptions used in the initial valuation of goodwill and other intangible assets include, but are not limited to: (1) future expected cash flows from product sales, customer contracts and acquired developed technologies and patents, (2) expected costs to complete any in-process research and development projects and commercialize viable products and estimated cash flows from sales of such products, (3) the acquired companies' brand awareness and market position, (4) assumptions about the period of time over which we will continue to use the acquired brand and (5) discount rates. These estimates and assumptions may be incomplete or inaccurate because unanticipated events and circumstances may occur. If estimates and assumptions used to initially value goodwill and intangible assets prove to be inaccurate, ongoing reviews of the carrying values of such goodwill and intangible assets, as discussed below, may indicate impairment which will require us to record an impairment charge in the period in which we identify the impairment.

Where we believe that property, plant and equipment and intangible assets have finite lives, we depreciate and amortize those assets over their estimated useful lives. For purposes of determining whether there are any impairment losses, as further discussed below, our management has historically examined the carrying value of our identifiable long-lived tangible and intangible assets and goodwill, including their useful lives where we believe such assets have finite lives, when indicators of impairment are present. In addition, we conduct an impairment review on the carrying values of all goodwill on at least an annual basis. For all long-lived tangible and intangible assets and goodwill, if an impairment loss is identified based on the fair value of the asset, as compared to the carrying value of the asset, such loss would be charged to expense in the period we identify the impairment. Furthermore, if our review of the carrying values of the long-lived tangible and intangible assets with finite lives indicates impairment of such assets, we may determine that shorter estimated useful lives are more appropriate. In that event, we will be required to record higher depreciation and amortization in future periods, which will reduce our earnings.

Valuation of Goodwill

We perform an impairment review on the carrying value of goodwill at least annually, or more frequently if events occur or circumstances exist that indicate that a reporting unit's carrying value exceeds its fair value. We performed our annual impairment review as of September 30, 2009, using the market approach and the discounted cash flows approach and, based upon this review, we do not believe that the goodwill related to our professional diagnostics, health management and consumer diagnostics reporting units was impaired. Because future cash flows and operating

results used in the impairment review are based on management's projections and assumptions, future events can cause such projections to differ from those used at September 30, 2009,

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which could lead to significant impairment charges of goodwill in the future. As of December 31, 2009, we have goodwill balances related to our professional diagnostics, health management and consumer diagnostics reporting units, which amounted to \$2.0 billion, \$1.4 billion and \$52.2 million, respectively, with the fair value of our professional and consumer diagnostics segments exceeding their carrying value by greater than 10% and the fair value of our health management segment exceeding its carrying value by approximately 9%.

We based our fair value estimates on assumptions 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 environments for our business units. There can be no assurances that our estimates and assumptions made for purposes of our goodwill and identifiable intangible testing as of September 30, 2009 will prove accurate predictions in the future. If our assumptions regarding business plans, competitive environments or anticipated growth rates are not achieved or change, 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 outside of the timing of our next annual evaluation.

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. Although we believe that the carrying value of our long-lived tangible and intangible assets was realizable as of December 31, 2009, future events could cause us to conclude otherwise.

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 exercise 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 statement of operations is 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 us 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

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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 \$37.5 million as of December 31, 2009, 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. Included in this valuation allowance is \$8.9 million for deferred tax assets of acquired companies, the future benefits of which will be generally applied to reduce our income tax expense. This is an increase of \$24.8 million from the valuation allowance of \$12.7 million as of December 31, 2008. The increase is primarily related to domestic state NOLs and domestic state credits. The valuation allowance is based on our estimates of taxable income by jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods, we may need to establish an additional valuation allowance or reduce our current valuation allowance which could materially impact our tax provision.

We 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 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 titled Part I, Item 3, Legal Proceedings, we have reported on material legal proceedings. In addition, because of the nature of our business, we may from time to time be subject to commercial disputes, consumer product claims or various other lawsuits arising in the ordinary course of our business, including employment matters, and we expect this will continue to be the case in the future. These lawsuits generally seek damages, sometimes in substantial amounts, for commercial or personal injuries allegedly suffered and can include claims for punitive or other special damages. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties, which can be expensive and can result in counterclaims against us.

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(r) in the notes to 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.

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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.

Our investing strategy, to manage interest rate exposure, 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. Currently, our short-term investments are in money market funds with original maturities of 90 days or less. At December 31, 2009, our short-term investments approximated market value.

At December 31, 2009, we had term loans in the amount of \$951.0 million and a revolving line-of-credit available to us of up to \$150.0 million, of which \$142.0 million was outstanding as of December 31, 2009, under our First Lien Credit Agreement. Interest on these term loans, as defined in the credit agreement, is as follows: (i) in the case of 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 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 and changes on a periodic basis. The Eurodollar Rate is equal to the LIBOR rate and is set for a period of one to three months at our election. Applicable margin with respect to Base Rate Loans is 1.00% and with respect to Eurodollar Rate Loans is 2.00%. Applicable margin ranges for our revolving line-of-credit with respect to Base Rate Loans is 0.75% to 1.25% and with respect to Eurodollar Rate Loans is 1.75% to 2.25%.

At December 31, 2009, we also had term loans in the amount of \$250.0 million under our Second Lien Credit Agreement. Interest on these term loans, as defined in the credit agreement, is as follows: (i) in the case of 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 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 Base Rate Loans, as in effect from time to time. Applicable margin with respect to Base Rate Loans is 3.25% and with respect to Eurodollar Rate Loans is 4.25%.

In August 2007, we entered into interest rate swap contracts, with an effective date of September 28, 2007, that have a total notional value of \$350.0 million and a maturity date of September 28, 2010. These interest rate swap contracts pay us variable interest at the three-month LIBOR rate, and we pay 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 the senior credit facility into fixed rate debt.

In January 2009, we entered into interest rate swap contracts, with an effective date of January 14, 2009, that have a total notional value of \$500.0 million and a maturity date of January 5, 2011. These interest rate swap contracts pay us variable interest at the one-month LIBOR rate, and we pay 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 loans under the secured credit facility into fixed rate debt.

Assuming no changes in our leverage ratio and considering our interest rate swaps, which would affect the margin of the interest rates under the credit agreements, the effect of interest rate fluctuations on

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outstanding borrowings as of December 31, 2009 over the next twelve months is quantified and summarized as follows (in thousands):

	Interest Expense Increase
Interest rates increase by 100 basis points	\$ 4,930
Interest rates increase by 200 basis points	\$ 9,860

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 2009, the net impact of foreign currency changes on transactions was a gain of \$1.3 million. Historically, we have not used derivative financial instruments or other financial instruments with original maturities in excess of three months to hedge such economic exposures.

Gross margins of products we manufacture at our foreign plants and sell in U.S. dollars and manufacturing by our U.S. plants and sold 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 54.6% in 2009. If the U.S. dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during 2009, our gross margin on total net product sales would have been 54.7%, 54.9% and 55.1%, respectively.

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

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

	Approximate Decrease in Net Revenue	Approximate Decrease in Net Income
If, during 2009, the U.S. dollar was stronger by:		
1%	\$ 5,013	\$ 530
5%	\$ 25,050	\$ 2,650
10%	\$ 50,096	\$ 5,300

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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 report on the pages indicated.

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 financial statements and supplementary data below.

The following table presents selected quarterly financial data for each of the quarters in the years ended December 31, 2009 and 2008, (in thousands, except per share data):

	2009			
	First Quarter(2)	Second Quarter(3)	Third Quarter(4)	Fourth Quarter(5)
Net revenue	\$ 425,153	\$ 438,652	\$ 512,665	\$ 546,171
Gross profit	\$ 234,450	\$ 237,896	\$ 280,297	\$ 301,579
Income (loss) from continuing operations	\$ 7,738	\$ 4,886	\$ 19,870	\$ (247)
(Loss) income from discontinued operations	\$ (1,347)	\$ (166)	\$ 413	\$ 3,034
Net income (loss) available to common stockholders	\$ 771	\$ (1,197)	\$ 14,299	\$ (3,129)
Basic Income (loss) per common share attributable to Inverness Medical Innovations, Inc. and subsidiaries:				
Income (loss) per common share from continuing operations(1)	\$ 0.03	\$ (0.02)	\$ 0.17	\$ (0.08)
(Loss) income per common share from discontinued operations	\$ (0.02)	\$ 0.00	\$ 0.01	\$ 0.04
Net income (loss) per common share	\$ 0.01	\$ (0.02)	\$ 0.18	\$ (0.04)
Diluted Income (loss) per common share attributable to Inverness Medical Innovations, Inc. and subsidiaries:				
Income (loss) per common share from continuing operations(1)	\$ 0.03	\$ (0.02)	\$ 0.17	\$ (0.08)
(Loss) income per common share from discontinued operations	\$ (0.02)	\$ 0.00	\$ 0.00	\$ 0.04
Net income (loss) per common share	\$ 0.01	\$ (0.02)	\$ 0.17	\$ (0.04)

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	2008			
	First Quarter(6)	Second Quarter(7)	Third Quarter(8)	Fourth Quarter(9)
Net revenue	\$ 351,744	\$ 381,175	\$ 417,174	\$ 432,460
Gross profit	\$ 177,787	\$ 204,038	\$ 226,310	\$ 245,383
(Loss) income from continuing operations	\$ (4,471)	\$ (30,580)	\$ (3,231)	\$ 17,729
(Loss) income from discontinued operations	\$ (80)	\$ 291	\$ 57	\$ (1,316)
Net (loss) income available to common stockholders	\$ (4,174)	\$ (33,455)	\$ (9,052)	\$ 10,924
Basic (Loss) income per common share attributable to Inverness Medical Innovations, Inc. and subsidiaries:				
(Loss) income per common share from continuing operations(1)	\$ (0.05)	\$ (0.43)	\$ (0.12)	\$ 0.16
(Loss) income per common share from discontinued operations	\$ 0.00	\$ 0.00	\$ 0.00	\$ (0.02)
Net (loss) income per common share	\$ (0.05)	\$ (0.43)	\$ (0.12)	\$ 0.14
Diluted (Loss) income per common share attributable to Inverness Medical Innovations, Inc. and subsidiaries:				
(Loss) income per common share from continuing operations(1)	\$ (0.05)	\$ (0.43)	\$ (0.12)	\$ 0.16
(Loss) income per common share from discontinued operations	\$ 0.00	\$ 0.00	\$ 0.00	\$ (0.02)
Net (loss) income per common share	\$ (0.05)	\$ (0.43)	\$ (0.12)	\$ 0.14

- (1) Net income (loss) available to common stockholders and basic and diluted net income (loss) per common share are computed as consistent with the annual per share calculations described in Notes 2(n) and 14 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.
- (2) Included in net income for the first quarter of 2009 is \$5.4 million related to restructuring charges associated with the decision to close various facilities, a write-off in the amount of \$4.7 million for acquisition-related costs recorded in connection with the adoption of a ASC 805, *Business Combinations*, on January 1, 2009 and \$5.9 million of non-cash stock-based compensation expense.
- (3) Included in net income for the second quarter of 2009 is \$4.9 million related to restructuring charges associated with the decision to close various facilities, a write-off in the amount of \$1.7 million for acquisition-related costs recorded in connection with the adoption of ASC 805, *Business Combinations*, on January 1, 2009 and \$6.6 million of non-cash stock-based compensation expense.
- (4) Included in net income for the third quarter of 2009 is \$6.2 million related to restructuring charges associated with the decision to close various facilities, a write-off in the amount of \$0.7 million relating to an inventory write-up recorded in connection with the acquisition of Concateno during the third quarter of 2009, acquisition-related costs in the amount of \$5.1 million recorded in connection with the adoption of ASC 805, *Business Combinations*, on January 1, 2009, a \$3.4 million gain associated with management's decision to dispose of our Diamics, Inc. operations, a \$2.9 million net realized foreign currency gain associated with restricted cash

established in connection with the acquisition of Concateno, a \$1.9 million compensation-related charge recorded in connection with the acquisition of Concateno, a \$0.3 million loss recorded in connection with the deferred payment of a portion of the ACON Second Territory Business purchase price consideration to be paid with our common stock and \$7.8 million of non-cash stock-based compensation expense.

- (5) Included in net income for the fourth quarter of 2009 is \$6.9 million related to restructuring charges associated with the decision to close various facilities, a write-off in the amount of \$1.4 million relating to an inventory write-up recorded in connection with the acquisition of Concateno during the third quarter of 2009, acquisition-related costs in the amount of \$4.3 million recorded in connection with the adoption of ASC 805, *Business Combinations*, on January 1, 2009, \$1.8 million of expense recorded in connection with fair value adjustments to acquisition-related contingent consideration obligations in accordance with ASC 805, *Business Combinations*, a \$3.2 million fair value write-down recorded in connection with an

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idle facility, expenses of \$1.8 million (\$1.1 million, net of tax) incurred in connection with the sale of our vitamins and nutritional supplements business and \$7.9 million of non-cash stock-based compensation expense.

- (6) Included in net loss for the first quarter of 2008 is \$16.3 million related to restructuring charges associated with the decision to close various facilities, a write-off of \$1.7 million related to inventory write-ups recorded in connection with the acquisitions of Panbio and BBI, a \$1.7 million net realized foreign currency loss associated with a cash escrow established in connection with the acquisition of BBI, and \$5.6 million of non-cash stock-based compensation expense.
- (7) Included in net loss for the second quarter of 2008 is \$23.6 million related to restructuring charges associated with the decision to close various facilities, a write-off of \$0.3 million related to inventory write-ups recorded in connection with the acquisitions of Panbio Limited and BBI, and \$7.2 million of non-cash stock-based compensation expense.
- (8) Included in net loss for the third quarter of 2008 is \$5.8 million related to restructuring charges associated with the decision to close various facilities, and \$7.0 million of non-cash stock-based compensation expense.
- (9) Included in net income for the fourth quarter of 2008 is \$5.0 million related to restructuring charges associated with the decision to close various facilities and \$6.7 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 management, including the CEO and CFO, concluded that our disclosure controls and procedures were effective at that time. We and our management understand nonetheless that controls and procedures, no matter how well designed and operated, can provide only reasonable assurances of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating and implementing possible controls and procedures. In reaching their conclusions stated above regarding the effectiveness of our disclosure controls and procedures, our CEO and CFO concluded that such disclosure controls and procedures were effective as of such date at the reasonable assurance level.

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 company's internal control over financial reporting is a process designed under the supervision of the 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 receipts and

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expenditures of our company 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 the financial statements.

There are inherent limitations in the effectiveness of any internal control, including the possibility of human error and the circumvention or overriding of controls. Accordingly, even effective internal controls can provide only reasonable assurances with respect to financial statement preparation. 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 company's internal control over financial reporting as of December 31, 2009. 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 management's assessment and those criteria, management determined that the Company maintained effective internal control over financial reporting as of December 31, 2009.

In conducting management's evaluation of the effectiveness of our company's internal control over financial reporting, management excluded all 2009 acquisitions. The contribution from these acquisitions represented approximately 3% and 6% of total assets and net revenue, respectively, as of and for the year ended December 31, 2009. Refer to Note 4 of the accompanying consolidated financial statements for further discussion of our acquisitions and their impact on our consolidated financial statements.

Our independent registered public accounting firm, BDO Seidman, LLP, has issued an audit report on our internal controls over financial reporting, which appears on page 63.

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 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Inverness Medical Innovations, Inc.:

We have audited Inverness Medical Innovations, Inc. and Subsidiaries (the Company) internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit 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 audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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 (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 (3) 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 indicated in the accompanying Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A, management's assessment of and conclusion on the effectiveness of internal control over financial reporting excluded all 2009 business combinations which are all included in the consolidated financial statements of the Company as of and for the year ended December 31, 2009. The acquired entities which were excluded constituted 3% and 6% of total assets and net revenue, respectively, as of and for the year ended December 31, 2009. Management did not assess the effectiveness of internal control over financial reporting of these acquired entities because of the timing of the acquisitions which were completed in 2009. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of these 2009 acquisitions.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Inverness Medical Innovations, Inc. and Subsidiaries

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as of December 31, 2009 and 2008, and the related consolidated statements of operations, equity and comprehensive loss, and cash flows for each of the three years in the period ended December 31, 2009 and our report dated February 26, 2010 expressed an unqualified opinion thereon.

/s/ BDO Seidman, LLP

Boston, Massachusetts
February 26, 2010

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information regarding directors, executive officers and corporate governance included in our definitive Proxy Statement to be filed pursuant to Regulation 14A in connection with our 2010 Annual Meeting of Shareholders (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, FINANCIAL STATEMENT SCHEDULES

(a) 1. Financial Statements.

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

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Statements of Operations for the Years Ended December 31, 2009, 2008 and 2007</u>	F-3
<u>Consolidated Balance Sheets as of December 31, 2009 and 2008</u>	F-4
<u>Consolidated Statements of Equity and Comprehensive Income (Loss) for the Years Ended December 31, 2009, 2008 and 2007</u>	F-5
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2009, 2008 and 2007</u>	F-8
<u>Notes to Consolidated Financial Statements</u>	F-9

2. Financial Statement Schedules.

All schedules for which provision is made in the applicable accounting regulation 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 here in.

3. Exhibits.

- 2.1 Agreement and Plan of Merger, dated as of May 17, 2007 by and among Inverness Medical Innovations, Inc., Inca Acquisition, Inc. and Biosite Incorporated (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, event date May 17, 2007, filed on May 18, 2007)

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- 2.2 Agreement and Plan of Merger, dated January 27, 2008, between Inverness Medical Innovations, Inc., Milano MH Acquisition Corp., Milano MH Acquisition LLC and Matria Healthcare, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, event date January 28, 2008, filed on January 29, 2008)
- 2.3 Acquisition Agreement by and among Inverness Medical Innovations, Inc., ACON Laboratories, Inc., Azure Institute, Inc., Oakville Hong Kong Co., Ltd., ACON Biotech (Hangzhou) Co., Ltd., and Karsson Overseas Ltd. dated March 16, 2009 (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, event date April 30, 2009, filed on April 30, 2009)**
- 3.1 Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 3.2 First Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.4 to Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2007)
- 3.3 Second Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.3 to Company's Quarterly Report on Form 10-Q for the period ended June 30, 2008)
- 3.4 Certificate of Designation, Preferences and Rights of Series A Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K dated December 20, 2001)
- 3.5 Certificate of Designations of Series B Convertible Perpetual Preferred Stock of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, event date, May 9, 2008, filed on May 14, 2008)
- 3.6 Certificate of Elimination of Series A Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, event date, May 9, 2008, filed on May 14, 2008)
- 3.7 Certificate of Correction to the First Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.5 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2006)
- 3.8 Second Certificate of Correction to the First Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.5 to Company's Registration Statement on Form S-4, as amended (File 333-149259))
- 3.9 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 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 dated as of June 9, 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 4.4 to the Form 8-A of Matria of New York Inc., dated June 9, 2009, filed on June 9, 2009)

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- 4.5 Third Supplemental Indenture dated as of August 4, 2009 among Inverness Medical Innovations, Inc., as issuer, GeneCare Medical Genetics Center, Inc. and Alere CDM LLC, collectively 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 dated August 4, 2009)
- 4.6 Fourth Supplemental Indenture dated as of September 22, 2009 among Inverness Medical Innovations, Inc., as issuer, ZyCare, Inc., as guarantor, 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 dated September 24, 2009)
- 4.7 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)
- 4.8 First Supplemental Indenture dated as of August 11, 2009 among Inverness Medical Innovations, Inc., as issuer, the guarantor subsidiaries named therein, as guarantors, and The 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 August 11, 2009, filed on August 11, 2009)
- 4.9 Second Supplemental Indenture dated as of September 22, 2009 among Inverness Medical Innovations, Inc., as Issuer, the guarantor subsidiaries named therein, as guarantors, and The Bank of New York Mellon Trust Company, N.A., as Trustee (incorporated by reference to Exhibit 4.4 to the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2009)
- 4.10 Third Supplemental Indenture dated as of September 28, 2009 among Inverness Medical Innovations, Inc., as Issuer, the guarantor subsidiaries named therein, as guarantors, and The 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 September 28, 2009, filed on September 28, 2009)
- 4.11 Registration Rights Agreement dated as of September 28, 2009 among Inverness Medical Innovations, Inc., the Guarantors named therein, Jefferies & Company, Inc., Goldman Sachs & Co., and Wells Fargo Securities (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K, event date September 28, 2009, filed on September 28, 2009)
- +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 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 Option Agreement, dated as of May 17, 2007 among US CD LLC, SPD Swiss Precision Diagnostics GmbH, Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH, Procter & Gamble International Operations, SA and Procter & Gamble RHD, Inc. (incorporated by reference to Exhibit 10.13 to Company's Quarterly Report on Form 10-Q, for the period ended June 30, 2007)
- 10.4 Post-Closing Covenants Agreement, dated as of November 21, 2001, by and among Johnson & Johnson, IMT, the Company, certain subsidiaries of IMT and certain subsidiaries of the Company (incorporated by reference to Exhibit 10.1 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.5 Amended and Restated Investor Rights Agreement, effective as of April 30, 2009, by and among Inverness Medical Innovations, Inc., Ron Zwanziger, ACON Laboratories, Inc., AXURE Institute, Inc., LBI, Inc., Oakville Hong Kong Co., Ltd., ACON Biotech (Hangzhou) Co., Ltd., Karsson Overseas Ltd., Manfield Top Worldwide Ltd., Jixun Lin and Feng Lin (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K, event date April 30, 2009, filed on April 30, 2009)

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- 10.6 Lease between WE 10 Southgate LLC and Binax, Inc. dated as of August 26, 2004 (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2005)
- 10.7 Form of Warrant for the Purchase of Shares of Common Stock of the Company issued pursuant to the Note and Warrant Purchase Agreement dated as of December 14, 2001 (incorporated by reference to Exhibit 99.5 to the Company's Current Report on Form 8-K dated December 20, 2001)
- 10.8 Warrant for the Purchase of Shares of Common Stock of the Company, dated as of March 31, 2005, issued to Roger Piasio (incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 30, 2006)
- 10.9 Form of Warrant Agreement issued pursuant to the Note and Warrant Purchase Agreement (incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K dated January 4, 2002)
- 10.10 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)
- 10.11 Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.4 to Company's Quarterly Report on Form 10-Q for the period ended June 30, 2005) (relating to grants made prior to August 29, 2008)
- 10.12 Form of Non-Qualified Stock Option Agreement for Senior Executives under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.5 to Company's Quarterly Report on Form 10-Q for the period ended June 30, 2005) (relating to grants made prior to August 29, 2008)
- 10.13 Form of Incentive Stock Option Agreement for Senior Executives under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.6 to Company's Quarterly Report on Form 10-Q for the period ended June 30, 2005) (relating to grants made prior to August 29, 2008)
- 10.14 Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the year ended December 31, 2008) (relating to grants made on or after August 29, 2008)
- 10.15 Form of Non-Qualified Stock Option Agreement for U.S. Executives under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K for the year ended December 31, 2008) (relating to grants made on or after August 29, 2008)
- 10.16 Form of Non-Qualified Stock Option Agreement for Non-U.S. Executives under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K for the year ended December 31, 2008) (relating to grants made on or after August 29, 2008)
- 10.17 Form of Incentive Stock Option Agreement for Executives under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.33 to the Company's Annual Report on Form 10-K for the year ended December 31, 2008) (relating to grants made on or after August 29, 2008)
- 10.18 Rules of Inverness Medical Innovations, Inc. HM Revenue and Customs Share Option Plan (2007) (adopted as subplan to Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan) (incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K for the year ended December 31, 2008) (relating to grants made on or after August 29, 2008)
- 10.19 Rules of the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan for the Grant of Options to Participants in France (adopted as subplan to Inverness Medical Innovations, Inc. 2001 Stock

Option and Incentive Plan) (incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K for the year ended December 31, 2008)

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- 10.20 Rules of Inverness Medical Innovations, Inc. Inland Revenue Approved Option Plan (adopted as subplan to Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan) (incorporated by reference to Exhibit 10.2 to Company's Quarterly Report on Form 10-Q for the period ended June 30, 2005)
- 10.21 Rules of Inverness Medical Innovations, Inc. HM Revenue and Customs Approved Share Option Plan (2007) (adopted as subplan to Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan) (incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2007) (relating to grants made prior to August 29, 2008)
- 10.22 Inverness Medical Innovations, 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 April 30, 2009).
- 10.23 Underwriting Agreement dated as of May 7, 2009 among Inverness Medical Innovations, Inc., the subsidiary guarantors named therein, UBS Securities LLC, Goldman, Sachs & Co., and Banc of America Securities LLC, as representatives of the several underwriters named in the Underwriting Agreement (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K, event date May 12, 2009, filed on May 12, 2009)
- 10.24 Underwriting Agreement dated as of August 5, 2009 among Inverness Medical Innovations, Inc., the subsidiary guarantors named therein, Jefferies & Company, Inc., Goldman, Sachs & Co., and Wells Fargo Securities, LLC as representatives of the several underwriters named in the Underwriting Agreement (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K, event date August 11, 2009, filed on August 11, 2009)
- 10.25 Purchase Agreement dated as of September 23, 2009 among Inverness Medical Innovations, Inc., the Guarantors named therein, Jefferies & Company, Inc., Goldman, Sachs & Co., and Wells Fargo Securities, LLC (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K, event date September 28, 2009, filed on September 28, 2009)
- 10.26 \$1,050,000,000 First Lien Credit Agreement dated as of June 26, 2007 among IM US HOLDINGS, LLC, as Borrower, Inverness Medical Innovations, Inc. as Guarantor, The Lenders and L/C Issuers Party Hereto General Electric Capital Corporation, as Administrative Agent, Citizens Bank of Massachusetts, Fifth Third Bank and Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services, Inc., as Co-Documentation Agents and UBS Securities LLC, as Joint Lead Arranger and Syndication Agent (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, event date June 26, 2007, filed on July 2, 2007)
- 10.27 First Amendment to First Lien Credit Agreement dated as of November 15, 2007 among IM US Holdings, LLC, as Borrower, Inverness Medical Innovations, Inc., as a Guarantor, the Lenders signatory hereto and General Electric Capital Corporation, as collateral agent and administrative agent for the Lenders (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K dated November 20, 2007)
- 10.28 \$250,000,000 Second Lien Credit Agreement dated as of June 26, 2007 among IM US HOLDINGS, LLC, as Borrower, Inverness Medical Innovations, Inc., as a Guarantor, The Lenders General Electric Capital Corporation, as Administrative Agent and UBS Securities LLC, as Syndication Agent, Joint Lead Arranger and Sole Bookrunner (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, event date June 26, 2007, filed on July 2, 2007)
- 10.29 First Lien Guaranty And Security Agreement dated as of June 26, 2007 among IM US HOLDINGS, LLC, as Borrower, and Each Grantor 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 June 26, 2007, filed on July 2, 2007)
- 10.30 Second Lien Guaranty And Security Agreement dated as of June 26, 2007 among IM US HOLDINGS, LLC, as Borrower, and Each Grantor and General Electric Capital Corporation, as Administrative Agent (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, event date

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- 14.50 Inverness Medical Innovations Business Conduct Guidelines (incorporated by reference to Exhibit 14.50 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2006)
 - *21.1 List of Subsidiaries of the Company as of February 22, 2010
 - *23.1 Consent of BDO Seidman, 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
- * 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.

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SIGNATURES

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

INVERNESS MEDICAL INNOVATIONS, INC.

Date: February 26, 2010

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

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INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Inverness Medical Innovations, Inc.:

We have audited the accompanying consolidated balance sheets of Inverness Medical Innovations, Inc. and Subsidiaries (the Company) as of December 31, 2009 and 2008, and the related consolidated statements of operations, equity and comprehensive income (loss), and cash flows for each of the three years in the period ended December 31, 2009. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes 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, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Inverness Medical Innovations, Inc. and Subsidiaries at December 31, 2009 and 2008, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

As described in Note 4 of the financial statements, the Company adopted the accounting standards related to Business Combinations, effective for business combinations entered into after January 1, 2009.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated February 26, 2010, expressed an unqualified opinion thereon.

/s/ BDO Seidman, LLP

Boston, Massachusetts
February 26, 2010

Table of Contents**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS****(in thousands, except per share amounts)**

	2009	2008	2007
Net product sales	\$ 1,365,079	\$ 1,151,265	\$ 728,091
Services revenue	528,487	405,462	16,646
License and royalty revenue	29,075	25,826	21,979
Net revenue	1,922,641	1,582,553	766,716
Cost of net product sales	619,503	543,317	365,545
Cost of services revenue	240,026	177,098	5,261
Cost of license and royalty revenue	8,890	8,620	9,149
Cost of net revenue	868,419	729,035	379,955
Gross profit	1,054,222	853,518	386,761
Operating expenses:			
Research and development	112,848	111,828	69,547
Purchase of in-process research and development			173,825
Sales and marketing	441,646	381,939	163,028
General and administrative	357,033	295,059	155,153
Gain on disposition	(3,355)		
Operating income (loss)	146,050	64,692	(174,792)
Interest expense, including amortization of original issue discounts and write-off of deferred financing costs	(106,798)	(101,132)	(82,987)
Other income (expense), net	996	(1,807)	9,424
Income (loss) from continuing operations before provision (benefit) for income taxes	40,248	(38,247)	(248,355)
Provision (benefit) for income taxes	15,627	(16,644)	(1,049)
Income (loss) from continuing operations before equity earnings of unconsolidated entities, net of tax	24,621	(21,603)	(247,306)
Equity earnings of unconsolidated entities, net of tax	7,626	1,050	4,372
Income (loss) from continuing operations	32,247	(20,553)	(242,934)
Income (loss) from discontinued operations, net of tax	1,934	(1,048)	(418)
Net income (loss)	34,181	(21,601)	(243,352)
Less: Net income attributable to non-controlling interests	465	167	1,401
	33,716	(21,768)	(244,753)

Net income (loss) attributable to Inverness Medical Innovations, Inc. and subsidiaries

Preferred stock dividends		(22,972)	(13,989)	
Net income (loss) available to common stockholders	\$	10,744	\$ (35,757)	\$ (244,753)
Basic net income (loss) per common share attributable to Inverness Medical Innovations, Inc. and subsidiaries:				
Income (loss) from continuing operations	\$	0.11	\$ (0.45)	\$ (4.74)
Income (loss) from discontinued operations	\$	0.02	\$ (0.01)	\$ (0.01)
Net income (loss) per common share	\$	0.13	\$ (0.46)	\$ (4.75)
Diluted net income (loss) per common share attributable to Inverness Medical Innovations, Inc. and subsidiaries:				
Income (loss) from continuing operations	\$	0.11	\$ (0.45)	\$ (4.74)
Income (loss) from discontinued operations	\$	0.02	\$ (0.01)	\$ (0.01)
Net income (loss) per common share	\$	0.13	\$ (0.46)	\$ (4.75)
Weighted average common shares basic		80,572	77,778	51,510
Weighted average common shares diluted		81,967	77,778	51,510

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

Table of Contents**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****(in thousands, except par value amounts)**

	December 31,	
	2009	2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 492,773	\$ 141,324
Restricted cash	2,424	2,748
Marketable securities	947	1,763
Accounts receivable, net of allowances of \$12,462 and \$9,961 at December 31, 2009 and 2008, respectively	354,453	261,369
Inventories, net	221,539	173,585
Deferred tax assets	66,492	104,311
Income tax receivable	1,107	6,406
Receivable from joint venture, net		12,018
Prepaid expenses and other current assets	73,075	74,033
Assets held for sale	54,148	58,166
Total current assets	1,266,958	835,723
Property, plant and equipment, net	324,388	274,478
Goodwill	3,463,358	3,045,883
Other intangible assets with indefinite lives	43,644	42,909
Core technology and patents, net	421,719	459,307
Other intangible assets, net	1,264,708	1,166,536
Deferred financing costs, net, and other non-current assets	72,762	46,778
Investments in unconsolidated entities	63,965	68,832
Marketable securities	1,503	591
Deferred tax assets	20,987	14,323
Total assets	\$ 6,943,992	\$ 5,955,360
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ 18,970	\$ 19,058
Current portion of capital lease obligations	899	451
Accounts payable	126,322	96,582
Accrued expenses and other current liabilities	279,732	230,090
Payable to joint venture, net	533	
Liabilities related to assets held for sale	11,558	19,193
Total current liabilities	438,014	365,374

Long-term liabilities:		
Long-term debt, net of current portion	2,128,515	1,500,557
Capital lease obligations, net of current portion	940	468
Deferred tax liabilities	442,049	462,787
Deferred gain on joint venture	288,767	287,030
Other long-term liabilities	116,818	59,437
Total long-term liabilities	2,977,089	2,310,279
Commitments and contingencies (Notes 8, 9 and 11)		
Stockholders equity:		
Series B preferred stock, \$0.001 par value (liquidation preference, \$793,696 at December 31, 2009 and \$751,479 at December 31, 2008); Authorized: 2,300 shares; Issued and outstanding: 1,984 shares at December 31, 2009 and 1,879 shares at December 31, 2008	694,427	671,501
Common stock, \$0.001 par value; Authorized: 150,000 shares; Issued and outstanding: 83,567 at December 31, 2009 and 78,431 at December 31, 2008	84	78
Additional paid-in capital	3,195,372	3,029,694
Accumulated deficit	(359,874)	(393,590)
Accumulated other comprehensive loss	(2,454)	(28,845)
Total stockholders equity	3,527,555	3,278,838
Non-controlling interests	1,334	869
Total equity	3,528,889	3,279,707
Total liabilities and equity	\$ 6,943,992	\$ 5,955,360

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

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INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF EQUITY AND COMPREHENSIVE INCOME (LOSS)

(in thousands, except par value amounts)

	Preferred Stock \$0.001 Number of Par Shares	Common Stock \$0.001 Number of Par Shares	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity	Non-controlling Interest	Total Equity	Comprehensive Income
CE, BER 31,	\$	39,215	\$ 39	\$ 826,987	\$ (127,069)	\$ 14,181	\$ 714,138	\$ 170	\$ 714,308
of stock in on with ons and ferings, uance 44,204 of stock nd and ued mployee chase		35,204	35	1,859,985		1,860,020		1,860,020	
sed ation grants on stock		2,370	3	55,095		55,098		55,098	
e d with				57,480		57,480		57,480	
d in ons tion ax				135,022		135,022		135,022	
n iability nt				2,574		2,574		2,574	
					341	341		341	\$

Table of Contents**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF EQUITY AND COMPREHENSIVE INCOME (LOSS)**
(Continued)**(in thousands, except par value amounts)**

Preferred Stock		Common Stock		Additional	Accumulated	Accumulated	Total	Non-controlling	Total
Number of	Amount	Number of	\$0.001 Par						
Shares		Shares	Value	Capital	Deficit	(Loss)	Equity		Equity
	\$	76,789	\$ 77	\$ 2,937,143	\$ (371,822)	\$ 21,269	\$ 2,586,667	\$ 869	\$ 2,587,536
1,788	657,573						657,573		657,573
		580		20,945			20,945		20,945
		1,062	1	20,712			20,713		20,713
91	13,928			(14,026)			(98)		(98)
				20,973			20,973		20,973

Table of Contents**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF EQUITY AND COMPREHENSIVE INCOME (LOSS)****(Continued)****(in thousands, except par value amounts)**

	Preferred Stock		Common Stock		Additional	Accumulated	Accumulated	Total	Non-controlling	Total
	Number of Shares	Amount	Number of Shares	\$0.001 Par Value						
31,	1,879	\$ 671,501	78,431	\$ 78	\$ 3,029,694	\$ (393,590)	\$ (28,845)	\$ 3,278,838	\$ 869	\$ 3,279,707
n			3,431	4	117,815			117,819		117,819
h			1,705	2	30,013			30,015		30,015
e	105	22,926			(23,079)			(153)		(153)
k					2,881			2,881		2,881
n					28,220			28,220		28,220
ts					9,828			9,828		9,828
ck							(1,137)	(1,137)		(1,137)
y										

n						15,171	15,171		15,171	
)						11,389	11,389		11,389	
n										
ale						968	968		968	
n										
g								465	465	
					33,716		33,716		33,716	
e										
31,	1,984	\$ 694,427	83,567	\$ 84	\$ 3,195,372	\$ (359,874)	\$ (2,454)	\$ 3,527,555	\$ 1,334	\$ 3,528,889

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

Table of Contents**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENT OF CASH FLOWS****(in thousands)**

	2009	2008	2007
Cash Flows from Operating Activities:			
Net income (loss)	\$ 34,181	\$ (21,601)	\$ (243,352)
Income (loss) from discontinued operations, net of tax	1,934	(1,048)	(418)
Income (loss) from continuing operations	32,247	(20,553)	(242,934)
Adjustments to reconcile income (loss) from continuing operations to net cash provided by operating activities:			
Interest expense related to amortization of original issue discounts and write-off of deferred financing costs	10,423	5,930	10,963
Depreciation and amortization	312,435	265,654	97,982
Non-cash stock-based compensation expense	28,220	26,405	52,210
Charge for in-process research and development			173,825
Impairment of inventory	1,467	4,193	
Impairment of long-lived assets	6,983	20,031	3,872
Loss on sale of fixed assets	1,205	777	59
Equity earnings of unconsolidated entities, net of tax	(7,626)	(1,050)	(4,372)
Deferred and other non-cash income taxes	(9,124)	(41,714)	(28,008)
Other non-cash items	3,264	4,378	197
Changes in assets and liabilities, net of acquisitions:			
Accounts receivable, net	(36,455)	(39,546)	46,152
Inventories, net	(16,425)	(41,945)	(2,670)
Prepaid expenses and other current assets	9,081	(7,386)	15,196
Accounts payable	2,117	7,193	(2,156)
Accrued expenses and other current liabilities	(45,445)	(29,091)	(33,836)
Other non-current liabilities	(2,709)	3,400	1,783
Net cash provided by continuing operations	289,658	156,676	88,263
Net cash (used in) provided by discontinued operations	(2,127)	(8,832)	492
Net cash provided by operating activities	287,531	147,844	88,755
Cash Flows from Investing Activities:			
Purchases of property, plant and equipment	(100,606)	(65,699)	(35,831)
Proceeds from sale of property, plant and equipment	803	1,070	264
Cash paid for acquisitions and transactional costs, net of cash acquired	(468,527)	(649,899)	(2,036,116)
Cash received, net of cash paid, from formation of joint venture			324,170
	12,560	12,133	(10,177)

Cash received from (paid for) investments in minority interests and marketable Securities			
Increase in other assets	(27,720)	(10,500)	(28,373)
Net cash used in continuing operations	(583,490)	(712,895)	(1,786,063)
Net cash used in discontinued operations	(237)	(437)	(467)
Net cash used in investing activities	(583,727)	(713,332)	(1,786,530)
Cash Flows from Financing Activities:			
Proceeds from borrowing under long-term debt	631,177		
Decrease (increase) in restricted cash	418	139,204	(141,869)
Issuance costs associated with preferred stock		(350)	
Cash paid for financing costs	(17,756)	(1,401)	(40,675)
Proceeds from issuance of common stock, net of issuance costs	30,015	20,675	1,122,852
Repayments on long-term debt	(11,055)	(13,787)	(22,326)
Net (repayments) proceeds from revolving lines-of-credit	(7,251)		