

INVERNESS MEDICAL INNOVATIONS INC

Form 10-K/A

April 16, 2010

**Table of Contents**

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

**FORM 10-K/A  
(Amendment No. 2)**

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

**(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):

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the 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 March 31, 2010, the registrant had 83,964,221 shares of common stock, par value \$0.001 per share, outstanding.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

None.

---

**INVERNESS MEDICAL INNOVATIONS, INC.**

**FORM 10-K**

**For The Fiscal Year Ended December 31, 2009**

	<b>Page</b>
<b><u>PART I</u></b>	
<u>ITEM 1.</u> Business	3
<u>ITEM 1A.</u> Risk Factors	14
<u>ITEM 1B.</u> Unresolved Staff Comments	30
<u>ITEM 2.</u> Properties	30
<u>ITEM 3.</u> Legal Proceedings	31
<u>ITEM 4.</u> Submission of Matters to a Vote of Security Holders	31
<b><u>PART II</u></b>	
<u>ITEM 5.</u> Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	31
<u>ITEM 6.</u> Selected Consolidated Financial Data	34
<u>ITEM 7.</u> Management's Discussion and Analysis of Financial Condition and Results of Operations	36
<u>ITEM 7A.</u> Quantitative and Qualitative Disclosures About Market Risk	58
<u>ITEM 8.</u> Financial Statements and Supplementary Data	61
<u>ITEM 9.</u> Changes In and Disagreements With Accountants On Accounting and Financial Disclosure	63
<u>ITEM 9A.</u> Controls and Procedures	63
<b><u>PART III</u></b>	
<u>ITEM 10.</u> Directors, Executive Officers and Corporate Governance	67
<u>ITEM 11.</u> Executive Compensation	72
<u>ITEM 12.</u> Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	87
<u>ITEM 13.</u> Certain Relationships and Related Transactions, and Director Independence	90
<u>ITEM 14.</u> Principal Accounting Fees and Services	91
<b><u>PART IV</u></b>	
<u>ITEM 15.</u> Exhibits, Financial Statement Schedules	92
<u>Signatures</u>	97
<u>Ex-10.31</u>	
<u>EX-10.32</u>	
<u>EX-23.1</u>	
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</u>	

**Table of Contents**

**EXPLANATORY NOTE**

The purpose of this Amendment No. 2 to our Annual Report on Form 10-K/A is to amend Part III, Items 10 through 14 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2009, which was filed with the U.S. Securities and Exchange Commission on March 1, 2010 (as previously amended, the Original Report ), to include information previously omitted from the Original Report in reliance on General Instruction G to Form 10-K, which provides that registrants may incorporate by reference certain information from a definitive proxy statement filed with the SEC within 120 days after the end of the fiscal year.

We have made no other significant changes to the Original Report. In order to preserve the nature and character of the disclosures set forth in the Original Report, this report speaks as of the date of the filing of the Original Report, March 1, 2010, and we have not updated the disclosures in this report to speak as of a later date.

**Table of Contents**

**PART I**

*This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Readers can identify these statements by forward-looking words such as may, could, should, would, intend, will, expect, anticipate, believe, estimate, continue or similar words. Readers should carefully review statements that contain these words because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other forward-looking information. We caution investors that all such forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from any projected results or expectations that we discuss in this report. You should therefore carefully review the risk factors and uncertainties discussed in Item 1A entitled Risk Factors, which begins on page 14 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](http://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.

## **Table of Contents**

### **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.

## **Table of Contents**

*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<sup>®</sup> 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<sup>™</sup>, 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

## **Table of Contents**

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,

## **Table of Contents**

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

## **Table of Contents**

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

## **Table of Contents**

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.

## **Table of Contents**

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

## **Table of Contents**

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.

## **Table of Contents**

*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 31.

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 14 through 30 of this report.

## **Table of Contents**

### **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.

**Table of Contents**

**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 3 and 36 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

**Table of Contents**

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

## **Table of Contents**

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;

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

**Table of Contents**

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.

**Table of Contents**

**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.

**Table of Contents**

**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.

**Table of Contents**

**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.





**Table of Contents**

**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.

## **Table of Contents**

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.



**Table of Contents**

**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

## **Table of Contents**

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.

**Table of Contents**

**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;

**Table of Contents**

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 31. 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

## **Table of Contents**

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.

**Table of Contents**

**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.

**Table of Contents**

**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

**Table of Contents**

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.

## **Table of Contents**

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.

	<b>High</b>	<b>Low</b>
<b>Fiscal 2009</b>		
Fourth Quarter	\$ 44.01	\$ 37.02
Third Quarter	\$ 41.86	\$ 30.27
Second Quarter	\$ 35.99	\$ 25.80
First Quarter	\$ 28.93	\$ 18.59
<b>Fiscal 2008</b>		
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**

<b>Date</b>	<b>IMA</b>	<b>NYSE Composite Index</b>	<b>Dow Jones U.S. Healthcare Index</b>
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.

	<b>2009</b>	<b>For the Year Ended December 31,</b>			<b>2005</b>
		<b>2008</b>	<b>2007</b>	<b>2006</b>	
		<b>(in thousands, except per share data)</b>			
<b>Statement of Operations Data:</b>					
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

Edgar Filing: INVERNESS MEDICAL INNOVATIONS INC - Form 10-K/A

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)

**Table of Contents**

	<b>2009</b>	<b>For the Year Ended December 31,</b>			<b>2005</b>
		<b>2008</b>	<b>2007</b>	<b>2006</b>	
		<b>(in thousands, except per share data)</b>			
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)

**Table of Contents**

	2009	2008	December 31, 2007 (in thousands)	2006	2005
<b>Balance Sheet Data:</b>					
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 14 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

## **Table of Contents**

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

**Table of Contents**

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.

**Table of Contents**

**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%
--	--------------	------------	-----

*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.

## **Table of Contents**

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.

**Table of Contents**

**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.

**Table of Contents**

*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):

	<b>2008</b>	<b>2007</b>	<b>% Increase (decrease)</b>
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

**Table of Contents**

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):

	<b>2008</b>	<b>2007</b>	<b>% Increase (decrease)</b>
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.

**Table of Contents**

**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

**Table of Contents**

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,

**Table of Contents**

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.

## **Table of Contents**

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.



**Table of Contents**

*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

**Table of Contents**

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

**Table of Contents**

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

## **Table of Contents**

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.

## **Table of Contents**

### *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
<b>Total</b>	<b>\$ 2,850,874</b>	<b>\$ 206,394</b>	<b>\$ 222,364</b>	<b>\$ 1,231,954</b>	<b>\$ 1,190,162</b>

- (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.

## **Table of Contents**

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

## **Table of Contents**

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

## **Table of Contents**

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,

## **Table of Contents**

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

## **Table of Contents**

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.

## **Table of Contents**

### **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



**Table of Contents**

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

	<b>Interest Expense Increase</b>
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):

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

**Table of Contents****ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The financial statements and supplementary data, except for selected quarterly financial data which are summarized below, are listed under Item 15.(a) and have been filed as part of this 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):

	<b>2009</b>			
	<b>First Quarter(2)</b>	<b>Second Quarter(3)</b>	<b>Third Quarter(4)</b>	<b>Fourth Quarter(5)</b>
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)

**Table of Contents**

	<b>2008</b>			
	<b>First Quarter(6)</b>	<b>Second Quarter(7)</b>	<b>Third Quarter(8)</b>	<b>Fourth Quarter(9)</b>
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

**Table of Contents**

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

**Table of Contents**

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 65.

*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.

**Table of Contents**

**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

**Table of Contents**

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

**Table of Contents****PART III****ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE****Directors and Executive Officers**

The following biographical descriptions set forth certain information with respect to our directors and our executive officers who are not directors.

<b>Name</b>	<b>Age</b>	<b>Position</b>
Ron Zwanziger	56	Chairman of the Board, Chief Executive Officer and President
David Scott, Ph.D.	53	Director, Chief Scientific Officer
Jerry McAleer, Ph.D.	54	Director, Vice President, Research and Development and Vice President, Cardiology
Hilde Eylenbosch, M.D.	46	Senior Vice President, Marketing
David Toohey	53	President, Europe/Middle East
John Yonkin	50	Vice President, Operations
John Bridgen, Ph.D.	63	Senior Vice President, Business Development
David Teitel	46	Chief Financial Officer, Vice President & Treasurer
Jon Russell	45	Vice President, Finance
Michael K. Bresson	52	Vice President, Mergers & Acquisitions
Paul T. Hempel	61	Senior Vice President, Leadership Development and Special Counsel, Secretary
Ellen Chiniara	51	Vice President, General Counsel and Assistant Secretary
Tom Underwood	51	Chief Executive Officer, Alere Health, LLC
Emanuel Hart	60	Vice President, LAmARCIS
David Walton	56	Vice President, Asia Pacific
Eli Y. Adashi, M.D.	65	Director
Carol R. Goldberg	79	Director
Robert P. Khederian	58	Director
John F. Levy	63	Director
John A. Quelch	58	Director
James Roosevelt, Jr.	64	Director
Peter Townsend	75	Director

*Our Class III Directors Term Expiring 2010*

**Eli Y. Adashi, MD, MS, CPE, FACOG**, joined the Board on April 1, 2009. The outgoing Dean of Medicine and Biological Sciences and the Frank L. Day Professor of Biology at Brown University, Dr. Adashi Harvard-educated in Health Care Management (MS; 2005; HSPH) is presently a Professor of Medical Science at The Warren Alpert Medical School of Brown University and has been since 2004. A Physician-Scientist-Executive with over 25 years of experience in Health Care and in the Life Sciences. Dr. Adashi is a member of the Institute of Medicine of the National Academy of Sciences and of its Board on Health Sciences Policy. Dr. Adashi is the founder and former leader of the multidisciplinary Ovarian Cancer Program of the NCI-designated Huntsman Cancer Research Institute.



Dr. Adashi also served on sabbatical on the Quality Improvement Group of the Office of Clinical Standards and Quality, Centers for Medicare and Medicaid Services (CMS) and is a current *ad hoc* member of the Reproductive Health Drugs Advisory Committee of the U.S. Food & Drug Administration. A fellow of the American Association for the Advancement of Science and a member of the Association of American Physicians, Dr. Adashi is the author or co-author of over 250 peer-reviewed publications, over 120 book chapters/reviews, and 13 books focusing on ovarian biology, ovarian cancer and reproductive health. Dr. Adashi is a

**Table of Contents**

member of the Board's Compensation Committee. Dr. Adashi brings to our Board senior management experience and immense knowledge and experience in medicine and science from the provider perspective.

**Robert P. Khederian** has served on the Board since July 31, 2001. Mr. Khederian is the Chairman of Belmont Capital, a venture capital firm he founded in 1996, and Provident Corporate Finance, an investment banking firm he founded in 1998. From 1984 through 1996, he was founder and Chairman of Medical Specialties Group, Inc., a nationwide distributor of medical products which was acquired by Bain Capital. Mr. Khederian had been the Chairman of the Board of Cambridge Heart, Inc. from August 2006 to August 2008. Mr. Khederian also served as the interim CEO of Cambridge Heart, Inc. from December 2006 to December 2007. Mr. Khederian is a member of the Company Board's Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee. A former chief executive officer, Mr. Khederian has extensive knowledge of the capital markets and brings to the Board significant and valuable financial and investment expertise.

**David Scott, Ph.D.**, has served on the Board since July 31, 2001 and has served as our Chief Scientific Officer since our inception in May 2001. Dr. Scott served as Chairman of Inverness Medical Limited, a subsidiary of our predecessor company, Inverness Medical Technology, from July 1999 through November 2001, when that company was acquired by Johnson & Johnson, and as a managing director of Inverness Medical Limited from July 1995 to July 1999. Dr. Scott served as Managing Director of Great Alarm Limited, a consulting company, from October 1993 to April 1995. Between October 1984 and September 1993, he held several positions at MediSense UK, serving most recently as Managing Director, where he was responsible for managing product development, as well as the mass manufacture of one of its principal products, ExacTech. Dr. Scott's scientific and management background in our industry provides our Board with valuable general business and research and development expertise.

**Peter Townsend** has served on the Board since May 30, 2001. Mr. Townsend served as a director of our predecessor company, Inverness Medical Technology, from August 1996 through November 2001, when that company was acquired by Johnson & Johnson. From 1991 to 1995, when he retired, Mr. Townsend served as Chief Executive Officer and a director of Enviromed plc, a medical products company. Mr. Townsend is a member of the Board's Audit Committee. As a former chief executive officer of a medical products company, Mr. Townsend brings to the Board financial expertise, significant industry experience and an international business perspective.

*Our Class I Directors Term Expiring 2011*

**John A. Quelch** joined the Board on March 10, 2003. Since June 2001, Dr. Quelch has been a professor and Senior Associate Dean at the Harvard Business School. From July 1998 through June 2001, he was Dean of the London Business School. Dr. Quelch also serves as a director of WPP plc, the world's largest marketing and media services company, and as Chairman of the Massachusetts Port Authority. Dr. Quelch served as a director of Pepsi Bottling Group from 2005 to 2010 and of Gentiva Health Services, Inc. from 2006 to 2009. He is Chairperson of the Board's Nominating and Corporate Governance Committee. Through his general business experience and academic credentials, Dr. Quelch brings to our Board both industry and academic expertise in marketing and organizational management.

**John F. Levy** has served on the Board since May 30, 2001. Mr. Levy served as director of Inverness Medical Technology from August 1996 through November 2001, when that company was acquired by Johnson & Johnson. Since 1993, he has been an independent consultant. Mr. Levy served as President and Chief Executive Officer of Waban, Inc., a warehouse merchandising company, from 1989 to 1993. Mr. Levy is Chairperson of the Board's Audit Committee and is a member of the Board's Compensation Committee and Nominating and Corporate Governance Committee. A former chief executive officer, Mr. Levy brings to our Board financial expertise, investment experience and a knowledge of distribution systems.

***Jerry McAleer, Ph.D.***, joined the Board on March 10, 2003. Dr. McAleer has also served as our Vice President, Research and Development since our inception in May 2001 and has served as our Vice President, Cardiology since early 2006. Dr. McAleer served as Vice President of Research and Development of our predecessor company, Inverness Medical Technology, from 1999 through November 2001, when that company

**Table of Contents**

was acquired by Johnson & Johnson. From 1995 to 1999, Dr. McAleer served as Director of Development of Inverness Medical Limited, Inverness Medical Technology's primary research and development unit, where he headed the development of Inverness Medical Technology's electrochemical glucose strips. Prior to joining Inverness Medical Technology, Dr. McAleer held senior research and development positions at MediSense, a medical device company, and Ecossensors, Inc., an environmental research company. Dr. McAleer's scientific background in our industry provides our Board with valuable research and development expertise.

*Our Class II Directors Term Expiring 2012*

**Carol R. Goldberg** has served on the Board since May 30, 2001. Ms. Goldberg served as a director of our predecessor company, Inverness Medical Technology, from August 1992 through November 2001, when that company was acquired by Johnson & Johnson. Since December 1989, she has served as President of The AVCAR Group, Ltd., an investment and management consulting firm in Boston, Massachusetts. Ms. Goldberg is Chairperson of the Board's Compensation Committee and a member of the Board's Nominating and Corporate Governance Committee. As the former President and Chief Operating Officer of Stop & Shop Companies, Inc., Ms. Goldberg brings a wealth of financial, marketing and consumer expertise to the Board.

**James Roosevelt, Jr.** joined the Board on February 6, 2009. Mr. Roosevelt has served as the President and Chief Executive Officer of Tufts Health Plan since 2005. From 1999 to 2005, Mr. Roosevelt was Senior Vice President and General Counsel of Tufts Health Plan. Mr. Roosevelt also serves as Co-Chair of the Rules and By-laws Committee of the Democratic National Committee, Co-Chair of the Board of Directors for the Tufts Health Care Institute, and member of the Board of Directors at American Health Insurance Plans, Emmanuel College and PointRight Inc., where he serves as a member of the Compensation Committee. Mr. Roosevelt is a member of the Board's Nominating and Corporate Governance Committee. Mr. Roosevelt brings to our Board extensive senior management, policy-making and financial experience within the health insurance industry, which includes important customers of the Company and is a driving force behind the demand for control of healthcare costs, which is reshaping the diagnostic and health management industries in which we operate.

**Ron Zwanziger** has served as our Chairman, Chief Executive Officer and President since our inception on May 11, 2001. Mr. Zwanziger served as Chairman, Chief Executive Officer and President of our predecessor company, Inverness Medical Technology, from its inception in 1992 through November 2001 when that company was acquired by Johnson & Johnson. From 1981 to 1991, he was Chairman and Chief Executive Officer of MediSense, a medical device company. Mr. Zwanziger also serves as a director and Chairperson of the Nominating and Corporate Governance Committee of AMAG Pharmaceuticals, Inc., and served a portion of 2009 as a member of the Compensation Committee for AMAG Pharmaceuticals, Inc. As the Chief Executive Officer of the Company, as well as the founder and chief executive officer of two other successful medical diagnostic companies, Mr. Zwanziger brings strategic vision, leadership, extensive business and operating experience and an immense knowledge of our Company and the industry to the Board.

*Executive Officers Who Are Not Directors*

**Hilde Eylenbosch, M.D.**, recently assumed the title of Senior Vice President, Marketing, after serving as our Vice President, Marketing since April 1, 2009. Prior to that, she served as Chief Executive Officer of SPD Swiss Precision Diagnostics GmbH, our 50/50 joint venture with Proctor & Gamble, since its inception on May 18, 2007. Dr. Eylenbosch has also served as our President, Consumer Diagnostics since June 2006. Prior to assuming that title she served as Vice President, Consumer Diagnostics from July 2005 to June 2006, Vice President, Consumer Marketing from October 2004 to July 2005 and Vice President of International Women's Health from November 2001 to October 2004. Dr. Eylenbosch served in the same capacity for our predecessor company, Inverness Medical Technology, from August 2001 until that company was acquired by Johnson & Johnson in November 2001. Prior to

that, she held various positions at Inverness Medical Technology, including Director of U.S. Women's Health from September 1998 through October 2000. When she joined Inverness Medical Technology in January 1995, Dr. Eylembosch was responsible for marketing that company's women's health products in Europe. Before joining Inverness Medical Technology, Dr. Eylembosch was employed by Synthelabo, a French pharmaceutical company, where she held various marketing positions.

**Table of Contents**

**David Toohey** was appointed President, Europe/Middle East in January 2008. Prior to that, he served as President, Professional Diagnostics from December 2005, as Vice President, Professional Diagnostics from October 2002, as Vice President, European Operations from February 2002, and as Vice President, New Products from November 2001. He also served as Managing Director of our Unipath Limited subsidiary from December 2001 through October 2002. Mr. Toohey was employed by our predecessor company, Inverness Medical Technology, as its Vice President, New Products from May 2001 through November 2001, when that company was acquired by Johnson & Johnson. Prior to joining Inverness Medical Technology, Mr. Toohey served as Vice President of Operations at Boston Scientific Corporation's Galway, Ireland facility where he oversaw its growth, from a start-up to Boston Scientific Corporation's largest manufacturing facility, between 1995 and 2001. Prior to that time he held various executive positions at Bausch & Lomb, Inc., Digital Equipment Corp. and Mars, Inc.

**John Yonkin** was appointed Vice President, Operations in July 2009. Previously, he served as President, Inverness Medical Innovations North America, Inc. from January 2008. Prior to that, he served as President, U.S. Point of Care from June 2006. Mr. Yonkin also served as President, Nutritionals, a role he had from June 2006 until we sold that business in 2010. Prior to that, he served as our Vice President, Nutritionals from April 2005 to June 2006 and Vice President, U.S. Sales and Marketing from November 2001 to April 2005. Mr. Yonkin served as Vice President of U.S. Sales of our predecessor company, Inverness Medical Technology, from October 1998 through January 2000 and as its General Manager from January 2000 through November 2001, when that company was acquired by Johnson & Johnson. He also served as Manager of Product Development for Inverness Medical Technology from October 1997 until October 1998. From January 1995 to September 1997, Mr. Yonkin was Director of National Accounts for Genzyme Genetics, a subsidiary of Genzyme, Inc., a leader in genetic testing services for hospitals, physicians and managed healthcare companies.

**John Bridgen, Ph.D.**, recently assumed the title of Senior Vice President, Business Development, after serving as our Vice President, Business Development since June 2006. Prior to that he served as our Vice President, Strategy since September 2005. Dr. Bridgen joined our Company in September 2002 upon our acquisition of Wampole Laboratories, LLC. Dr. Bridgen served as President of Wampole from August 1984 until September 2005. Prior to joining Wampole, Dr. Bridgen had global sales and marketing responsibility for the hematology and immunology business units of Ortho Diagnostic Systems Inc., a Johnson & Johnson company.

**David Teitel** has served as our Chief Financial Officer and Treasurer since December 2006. Mr. Teitel has over 20 years of public and private company finance experience, including nine years of audit experience at Arthur Andersen and senior financial positions with Thermo Electron Corp., which is now Thermo Fisher Scientific Inc. and Deknatel Snowden Pencer Inc. Mr. Teitel joined the Company in December 2003 as Director of Finance Operations and assumed the title Vice President, Finance in December 2004.

**Jon Russell** has served as our Vice President, Finance since December 2006. In this role, Mr. Russell oversees financial systems management and integration and shares responsibility for external communications with the Chief Executive Officer. Previously, Mr. Russell was Chief Financial Officer of Wampole Laboratories, LLC. He has more than 20 years of experience in finance and operations management, including senior operational finance positions in North America and Europe with Precision Castparts Corporation, Vertex Interactive, Inc. and Genicom Corporation. Mr. Russell began his career at Ernst & Young LLP.

**Michael K. Bresson** rejoined us as Vice President, Mergers & Acquisitions, in January 2007 after serving as President of LifeTrac Systems Incorporated from February 2006 to December 2006. Previously, Mr. Bresson served as our Vice President, Business Development from May 2005 to February 2006. From 1998 until January 2005, he was employed at Apogent Technologies Inc. (now part of Thermo Fisher Scientific Inc.), last serving as Apogent's Executive Vice President Administration, General Counsel and Secretary. Prior to joining Apogent in 1998, Mr. Bresson was a partner at the law firm of Quarles & Brady LLP.

*Paul T. Hempel* served as our General Counsel and Secretary from our inception on May 11, 2001 until April 2006, when Mr. Hempel became Senior Vice President in charge of Leadership Development, while retaining

## **Table of Contents**

his role as Secretary. Mr. Hempel also retained oversight of our legal affairs until May 2007. Mr. Hempel served as General Counsel and Assistant Secretary of our predecessor company, Inverness Medical Technology, from October 2000 through November 2001, when that company was acquired by Johnson & Johnson. Prior to joining Inverness Medical Technology, he was a founding stockholder and Managing Director of Erickson Schaffer Peterson Hempel & Israel PC from 1996 to 2000. Prior to 1996, Mr. Hempel was a partner and managed the business practice at Bowditch & Dewey LLP.

**Ellen Chiniara** serves as Vice President, General Counsel and Assistant Secretary and is responsible for managing legal matters for our Company. Ms. Chiniara joined our Company in October 2006 as General Counsel of the Professional Diagnostics strategic business unit and became General Counsel of our Company in May 2007. From 2002 to 2006, Ms. Chiniara was Associate General Counsel, Neurology of Serono, Inc., a biopharmaceutical company. Previously, she served as General Counsel to a healthcare venture capital fund and a healthcare management services organization, where she also was Chief Operating Officer of its clinical trial site management division. From 1994 to 1997, Ms. Chiniara was Assistant General Counsel at Value Health, a specialty managed healthcare company. Prior to 1994, Ms. Chiniara was a corporate attorney in Boston with Hale and Dorr (now Wilmer Cutler Pickering Hale and Dorr LLP).

**Tom Underwood** has served as Chief Executive Officer of Alere Health, LLC since February 2010. Mr. Underwood served as President of the Technology Solutions Division of Alere from May 2008 and then as our Chief Information Officer since September 2009. Mr. Underwood served as President and Chief Operating Officer of Matria Healthcare from January 2008 until May 2008 when we acquired Matria. Prior to this role and since joining Matria Healthcare in June 2007, he served as Executive Vice President of Technology. Mr. Underwood came to Matria from First Consulting Group (FCG), where he last served as President of Global Shared Services. During his tenure with FCG, Mr. Underwood served in various executive leadership roles, including President of Global Shared Services, Executive Vice President of Healthcare, Executive Vice President of Government and Technology, and President of FCG Software Services. Previously, Mr. Underwood was Chief Executive Officer and President of Paragon Solutions, an offshore software development business that was acquired by FCG. Prior to his employment with Paragon and FCG, Mr. Underwood was the technology executive for IMNET Systems, an electronic medical record solutions company, which was acquired by McKesson HBOC. Earlier in his career, Mr. Underwood held numerous management and technology roles within Perceptics, a division of the Westinghouse Company, and AT&T Bell Laboratories.

**Emanuel Hart** served as Chief Executive Officer and President of Organics Ltd. (Israel), one of our subsidiaries, from July 1997 through 2007. Organics Ltd. includes manufacturing, research and development and marketing business units. In August 2007, Mr. Hart was appointed Vice President for International Business responsible for the Latin America, Africa, Russia, ex-Soviet Union countries and Israel territories (LAmARCIS) for all of our products.

**David Walton** serves as Vice President, Asia Pacific. Mr. Walton joined our Company in December 2001 when we acquired the Unipath business from Unilever, where he was previously International Director for the Consumer and Professional Diagnostic business units. Prior to this, Mr. Walton held various senior global sales and marketing roles in the Diagnostics Division of Eli Lilly based at Hybritech in San Diego, California and Liege, Belgium, Biorad U.K. and Corning Medical U.K.

## **Corporate Governance**

### *The Audit Committee*

The Company has a standing Audit Committee consisting of Mr. Levy, its Chairperson, Mr. Townsend and Mr. Khederian. Among other things, the Audit Committee oversees our accounting and financial reporting processes,



including the selection, retention and oversight of our independent registered public accountant and the pre-approval of all auditing and non-auditing services provided by the independent registered public accountant. The Board has determined that Mr. Levy is an audit committee financial expert, as defined by SEC rules adopted pursuant to the Sarbanes-Oxley Act.

## **Table of Contents**

### *Code of Ethics*

Our Board has adopted a code of ethics that applies to all of our employees and agents worldwide, including our chief executive officer, our chief financial officer, our controller, our other executive officers and the members of the Board. Known as The Inverness Medical Innovations Business Conduct Guidelines, this code of ethics is posted in its entirety on the Corporate Governance page of our website at [www.invmed.com](http://www.invmed.com).

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our officers and directors and persons who own more than 10% of our outstanding shares of common stock to file reports of ownership and changes in ownership with the Securities and Exchange Commission and the New York Stock Exchange. Such persons are required by applicable regulations to furnish us with copies of all reports filed pursuant to Section 16(a). To our knowledge, based solely on a review of the copies of such reports received by us and certain written representations that no other reports were required, we believe that for the fiscal year ended December 31, 2009, all Section 16(a) filing requirements applicable to our officers, directors and 10% beneficial owners were complied with.

## **ITEM 11. EXECUTIVE COMPENSATION**

### **Compensation Discussion and Analysis**

This Compensation Discussion and Analysis discusses the compensation paid to our key executives, our chief financial officer, or our CFO, and our three other most highly-compensated executive officers. These officers are collectively referred to as the named executive officers for purposes of this discussion. We refer to Ron Zwanziger, our Chief Executive Officer, or our CEO; David Scott, Ph.D., our Chief Scientific Officer; and Jerry McAleer, Ph.D., our Vice President, Research and Development, as our key executives.

### *Philosophy and Objectives*

The objective of our executive compensation program is to attract, retain and motivate the talented and dedicated executives who are critical to our goals of continued growth, innovation, increasing profitability and, ultimately, maximizing shareholder value. Specifically, we seek to attract and reward executives who display certain fundamental leadership characteristics for hiring and promotion that we have identified as consistent with our Company goals and culture. We provide these executives with what we believe to be a competitive total compensation package consisting primarily of base salary, long-term equity incentive compensation and a broad-based benefits program. Our compensation program is designed to reward each executive's individual performance by considering generally their past and potential contribution to our achievement of key strategic goals, such as revenue generation, margin improvement and the establishment and maintenance of key strategic relationships. Our executive compensation program aims to provide a risk-balanced compensation package which is competitive in our market sector and, more importantly, relevant to the individual executive.

Our policy for allocating between long-term and currently-paid compensation is to ensure adequate base compensation to attract and retain personnel, while providing incentives to maximize long-term value for our Company and our stockholders. Accordingly, (i) we provide cash compensation in the form of base salary to meet competitive cash compensation norms and (ii) we provide non-cash compensation, primarily in the form of stock-based awards, to reward superior performance against long-term strategic goals. Although we did grant cash bonuses during 2009, as discussed below, we do not provide a formal short-term incentive plan, as our strategic philosophy is to focus on the long-term goals discussed above. Because we do not have an annual cash incentive compensation plan, we set the base salaries for our named executive officers at a level higher than the average base

salaries for executives in similar positions with similar responsibilities at comparable companies. In general, we target our base salaries at the average of the range of annual cash compensation (base salary plus annual non-equity incentive compensation) for competitive positions. Our Compensation Committee believes this compensation structure focuses our executives' attention primarily on long-term stock price appreciation, rather than short-term results, and yet enables us to recruit and retain talented executives by ensuring that their annual cash compensation in the form of base salary is competitive with the aggregate annual cash compensation paid by other companies through base salaries and short-term cash incentive plans.

**Table of Contents**

*Executive Compensation Process*

The compensation of our named executive officers, as well as our other executive officers, is reviewed by our Compensation Committee at least annually for consistency with the objectives described above. Our management, including our CEO, participates in this review by making its own recommendations as to the compensation of our executive officers to the Compensation Committee. The Compensation Committee considers the recommendations of management in assessing executive compensation but also relies on other data and resources and may utilize the services of a compensation consultant in reviewing and determining executive compensation.

In reviewing executive compensation, the Compensation Committee and management also consider the practices of comparable companies of similar size, geographic location and market focus. In 2009, management and the Compensation Committee utilized the 2009 Radford Global Life Sciences Survey, or the 2009 Radford Survey, which provided comprehensive baseline compensation data on positions at the executive, management and professional levels, including salary, total cash compensation, options and equity compensation. Management and the Compensation Committee occasionally collect and analyze publicly available compensation data and other subscription compensation survey data. While benchmarking may not always be appropriate as a standalone tool for setting compensation due to the aspects of our business and objectives that may be unique to us, we generally believe that gathering this compensation information is an important part of our compensation-related decision-making process.

In addition, during 2009 the Compensation Committee engaged a compensation consultant, Aon Consulting's Radford Surveys + Consulting, or Radford, to assist the committee in assessing total compensation of our key executives. As part of its engagement, Radford assisted the Compensation Committee in selecting a new peer group to utilize in assessing the competitiveness of the compensation of our key executives. The peer group the Compensation Committee used in assessing 2008 compensation was considered out of date due to the fact that a number of the peer companies had been acquired, merged or no longer fit our peer criteria. The peer group selected by the Compensation Committee for purposes of evaluating 2009 executive compensation of the key executives consisted of nineteen publicly traded companies in a similar industry space and with similar revenues and market capitalizations. Of the 2009 peer group companies, 26% are health management companies and 74% are diagnostics/medical equipment companies. Specifically the peer group is comprised of the following companies:

Beckman Coulter, Inc.

Becton Dickinson and Company

Bio-Rad Laboratories, Inc.

Catalyst Health Solutions, Inc.

C.R. Bard, Inc.

Gen-Probe Incorporated

Healthways, Inc.

Hologic, Inc.

Hospira, Inc.

IDEXX Laboratories, Inc.

Kinetic Concepts, Inc.

Life Technologies Corporation

Lincare Holdings, Inc.

Magellan Health Services, Inc.

Myriad Genetics, Inc.

**Table of Contents**

PerkinElmer, Inc.

RehabCare Group, Inc.

St. Jude Medical, Inc.

Varian Medical Systems, Inc.

In connection with this engagement, Radford provided a detailed report, the 2009 Radford Report, which included summary observations and considerations regarding our compensation philosophy and methodology, as well as detailed competitive assessments of the cash and equity compensation of the key executives.

The Compensation Committee considered the 2009 Radford Survey and, in connection with the compensation of the key executives, the 2009 Radford Report, in its assessment of each element of 2009 executive compensation, as well as overall compensation.

In determining each component of an executive's compensation, numerous factors particular to the executive are considered, including:

The individual's particular background, including prior relevant work experience;

The demand for individuals with the executive's specific expertise and experience;

The individual's role with us and the compensation paid to similar persons determined through benchmark studies;

The individual's performance and contribution to our achievement of Company goals and objectives; and

Comparison to other executives within our Company.

*Elements of Compensation*

Executive compensation consists of the following elements:

*Base Salary.* Base salary is established based on the factors discussed above. Our general compensation philosophy, as described above, is to offer a competitive package of base salary plus long-term, equity-based incentive compensation. Because of this, we ensure that the cash compensation of our executives is competitive by targeting annual base salary for a particular individual near the average of the range of annual cash compensation (base salary plus annual non-equity incentive compensation) for executives in similar positions with similar responsibilities at comparable companies. Other elements of compensation, including past and present grants of stock-based awards, may also be considered. The Compensation Committee believes that a competitive base salary is necessary to attract and retain a management team with the requested skills to lead our Company. Despite this general philosophy, due to uncertainties facing the Company's businesses, including poor economic conditions and severe disruptions in the capital and credit markets stemming from the recent worldwide financial crisis, the Compensation Committee decided to freeze 2009 base salaries of the named executive officers, as well as the Company's other executive officers and most managers, at 2008 levels. As a result, the Compensation Committee anticipated that 2009 salaries might fall behind the targeted average levels.

*Bonuses.* Cash bonuses and non-equity incentive compensation are generally not a regular or important element of our executive compensation strategy, and we focus instead on stock-based awards designed to reward long-term performance. Consistent with this approach, the Compensation Committee did not implement any bonus or non-equity incentive plan for 2009. However, in light of the fact that no increases in base salary had been made for 2009 in anticipation of uncertain performance during the year, when the Company's financial performance for 2009 turned out to be significantly more positive than originally anticipated, our Compensation Committee decided in March 2010 to award discretionary, one-time cash bonuses to many of our executives for 2009. These discretionary, one-time bonuses, or the 2009 Bonuses, for which a total of \$4.0 million was reserved during the fourth quarter of 2009, were not part of any previously

**Table of Contents**

announced compensation plan or arrangement. The Compensation Committee's overall executive compensation strategy and philosophy continue to focus on base salary combined with long-term equity incentives.

The 2009 Bonuses were established based on an assessment of each executive's performance and contribution to our achievement of Company goals and objectives during the year. Twelve senior executives reviewed the list of approximately fifty executives (other than the key executives) and rated them on a scale as to their overall performance and leadership behaviors. Once completed, the CEO and the Senior Vice President of Leadership Development analyzed the results and submitted recommended bonus amounts intended to compensate for market comparisons, as well as performance, to the Compensation Committee, which ultimately approved all of the 2009 Bonuses.

In establishing the amount of the 2009 Bonuses, the Compensation Committee also considered the 2009 Radford Report for our key executives, the 2009 Radford Survey for our other executive officers and most other executives, and other regional data sources for certain executives. Generally, the total 2009 cash compensation for each executive awarded a bonus was targeted at the average of the range of total annual cash compensation for executives in similar positions with similar responsibilities at comparable companies, although comparison to other executives within our Company was also considered. In some cases, retention considerations were also considered.

The following named executive officers received 2009 Bonuses in the following amounts:

<b>Executive Officer</b>	<b>2009 Bonus</b>
Ron Zwanziger <i>Chairman, CEO and President</i>	\$ 250,000
David Scott, Ph.D. <i>Chief Scientific Officer</i>	\$ 125,000
Jerry McAleer, Ph.D. <i>Vice President, Research and Development</i>	\$ 125,000
David Teitel <i>Chief Financial Officer</i>	\$ 100,000
John Bridgen, Ph.D. <i>Senior Vice President, Business Development</i>	\$ 125,000
Tom Underwood <i>Chief Executive Officer, Alere Health, LLC.</i>	\$ 125,000

In determining Mr. Zwanziger's bonus, the Compensation Committee first considered that, prior to the bonus, Mr. Zwanziger's total cash compensation (which consisted of salary only) was significantly below the average range for total cash compensation within our peer group according to the 2009 Radford Report. Taking into consideration the information from 2009 Radford Report, coupled with the various factors described above, including Mr. Zwanziger's significant history and role in forming and leading our Company and in establishing and developing our core business strategy and direction, his expertise and experience as a successful chief executive and his performance and contribution to our overall goals and objectives, the Compensation Committee discussed and adopted the bonus described above in an effort to be more in line with our cash compensation objectives. While background, expertise and experience, and individual performance and contribution to our overall goals and objectives are all subjective measures, and are not based on any stated quantifiable objectives, they play an important role in the Compensation Committee's overall decision-making process. These subjective factors are considered in the aggregate and, accordingly, no specific factor played a greater role in determining the amount of Mr. Zwanziger's bonus.

In determining Dr. Scott's bonus, the Compensation Committee first considered that, prior to the bonus, Dr. Scott's total cash compensation (which consisted of salary only) was below the average range for total cash compensation within our peer group according to the 2009 Radford Report. Taking into consideration the information from the 2009 Radford Report, coupled with the various factors described above, including Dr. Scott's significant history with our company as a founder and as a driving force in developing and implementing our overall business strategy and technology initiatives, his expertise and experience in these areas and his performance and contribution to our overall



goals and objectives, the Compensation Committee discussed and adopted the bonus described above in an effort to be more in line with our cash compensation objectives. Because his salary was already closer to our targeted objective, the bonus awarded to Dr. Scott was less than that awarded to Mr. Zwanziger. While background, expertise and experience, and individual performance and contribution to our overall goals and objectives are all subjective measures, and are not based on any stated quantified objectives, they play an important role in the Compensation Committee's decision-

**Table of Contents**

making process. These subjective factors are considered in the aggregate and, accordingly, no specific factor played a greater role in determining the amount of Dr. Scott's bonus.

In determining Dr. McAleer's bonus, the Compensation Committee first considered that, prior to the bonus, Dr. McAleer's total cash compensation (which consisted of salary only) was below the average range for total cash compensation within our peer group according to the 2009 Radford Report. Taking into consideration the information from the 2009 Radford Report, coupled with the various factors described above, including Dr. McAleer's significant history with our company as a founder and as a driving force in developing and implementing our overall business strategy and technology initiatives, his expertise and experience in these areas and his performance and contribution to our overall goals and objectives, the Compensation Committee discussed and adopted the bonus described above in an effort to be more in line with our cash compensation objectives. Because his salary was already closer to our targeted objective, the bonus awarded to Dr. McAleer was less than that awarded to Mr. Zwanziger. While background, expertise and experience, and individual performance and contribution to our overall goals and objectives are all subjective measures, and are not based on any stated quantified objectives, they play an important role in the Compensation Committee's decision-making process. These subjective factors are considered in the aggregate and, accordingly, no specific factor played a greater role in determining the amount of Dr. McAleer's bonus.

As noted above, one of the subjective factors that played a role in determining each of the key executive's bonus award (as well as the option grants discussed below) was such person's performance and contribution to our overall goals and objectives. Generally, our overall goals and objectives are continued growth, innovation, increasing profitability and, ultimately, maximizing shareholder value. Our core strategy for achieving these goals is to lead the way in the convergence of rapid diagnostics with technology-driven health management programs focused on personal healthcare. By utilizing our innovative diagnostics in these programs we can enable consumers to gain greater control over their own health, as well as enable healthcare providers to improve clinical outcomes and lower costs. With respect to achievement of these goals, and implementation of our core strategy, over the last three years we have, through strategic acquisitions, established our Company as a leading supplier of cardiology diagnostic products, significantly enhanced our position in drugs of abuse testing, established a presence in oncology, continued to build a worldwide distribution network and become a leader in the growing health care management market. Through our research and development programs, we are developing new technology platforms that will facilitate our core strategy by moving testing out of the hospital and central laboratory and into the physician's office and ultimately the home. Additionally, through our strong pipeline of novel proteins or combinations of proteins that function as disease biomarkers, we are developing new tests targeted towards all of our areas of focus. Other achievements include continuing to consolidate certain of our higher-cost manufacturing operations into lower-cost facilities, continued progress with respect to business integration activities and consolidating sales processing and certain other back-office services from multiple U.S. operations into a shared services center.

Assessing each executive's contribution to achievement of these goals is a subjective analysis, as there are no stated quantified objectives on which compensation-related decisions are based, either at the company level or the individual level. In general, when making a compensation-related decision, the Compensation Committee considers, along with all of the other factors described above, the executive's role with us in light of these goals and our considerable achievements relative to these goals, as described above. As CEO, Mr. Zwanziger was evaluated with respect to establishing and developing our goals and our core strategy for achieving those goals, and our progress towards achieving our goals, particularly our progress as it relates to our acquisition strategy and our financial performance. As Chief Scientific Officer and as Vice President, Research and Development, respectively, Dr. Scott and Dr. McAleer were evaluated with respect to developing our core strategy, and our progress towards implementing this strategy, particularly our progress on technology initiatives supporting this strategy.

In determining Mr. Teitel's bonus, the Compensation Committee considered Mr. Teitel's performance, as rated by management in the manner described above, and his contribution to our achievement of company goals and objectives

during the year. In deciding to award Mr. Teitel a bonus the Compensation Committee determined, based upon the assessment and rating process described above, that his overall performance was rated as outstanding and considerably above expectations. This assessment of Mr. Teitel's performance was

**Table of Contents**

subjective in nature, and not based on any stated quantified objectives. Subjective factors are considered in the aggregate, and accordingly, no specific factor played a greater role in determining Mr. Teitel's bonus award. The Compensation Committee also considered that, prior to the bonus, Mr. Teitel's total cash compensation (which consisted of salary only) was significantly below the average range for total cash compensation for chief financial officers at comparable companies based on the 2009 Radford Survey.

In determining Dr. Bridgen's bonus, the Compensation Committee considered Dr. Bridgen's performance, as rated by management in the manner described above, and his contribution to our achievement of company goals and objectives during the year. In deciding to award Dr. Bridgen's bonus, the Compensation Committee determined, based upon the assessment and rating process described above, that his overall performance was rated as outstanding and considerably above expectations. This assessment of Dr. Bridgen's performance was subjective in nature, and not based on any stated quantified objectives. Subjective factors are considered in the aggregate, and accordingly, no specific factor played a greater role in determining Dr. Bridgen's bonus award. The Compensation Committee also considered that, prior to the bonus, Dr. Bridgen's total cash compensation (which consisted of salary only) was significantly below the average range for total cash compensation for heads of business development at comparable companies based on the 2009 Radford Survey.

In determining Mr. Underwood's bonus, the Compensation Committee considered Mr. Underwood's performance, as rated by management in the manner described above, and his contribution to our achievement of company goals and objectives during the year. In deciding to award Mr. Underwood a bonus, the Compensation Committee determined, based upon the assessment and rating process described above, that his overall performance was rated as outstanding and considerably above expectations and also considered the strategic importance of his new role as Chief Executive Officer of our Alere Health business unit. This assessment of Mr. Underwood's performance was subjective in nature, and not based on any stated quantified objectives. Subjective factors are considered in the aggregate and, accordingly, no specific factor played a greater role in determining Mr. Underwood's bonus award.

Mr. Geraty, who is expected to leave the Company in the near future, was not awarded a 2009 Bonus.

On November 18, 2009, we paid Tom Underwood a bonus of \$462,666 pursuant to a retention and severance agreement with Mr. Underwood dated the same day. This agreement, which provides for identical bonuses in 2010 and 2011 subject to continued employment, represents a restructuring of a change of control severance obligation under a 2007 agreement between Mr. Underwood and Matria Healthcare, Inc., a predecessor of Alere Health. The 2007 agreement predated our acquisition of Matria Healthcare and we viewed it as providing a potential disincentive to Mr. Underwood's continued employment.

*Stock Option and Stock-Based Awards.* We continue to believe long-term performance is best stimulated through an ownership culture that encourages such performance through the use of stock-based awards. The Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan, or the 2001 Option Plan, was established to provide certain of our employees, including our executive officers, with incentives to help align those employees' interests with the interests of stockholders and with our long-term success. The Compensation Committee believes that the use of stock options and other stock-based awards offers the best approach to achieving our long-term compensation goals. While the 2001 Option Plan allows our Compensation Committee to grant a number of different types of stock-based awards, other than one restricted stock grant made to Mr. Zwanziger in 2001, we have relied exclusively on stock options to provide equity incentive compensation. We believe that stock options most effectively focus the attention of our executives and management on long-term performance and stock price appreciation. Stock options granted to our executive officers have an exercise price equal to the fair market value of our common stock on the grant date, except that the options granted in February 2010, discussed below, as well as certain options granted to the key executives in July 2008, have a premium exercise price of \$61.49. Our stock options typically vest 25% per annum based upon continued employment over a four-year period, and generally expire ten years after the date of grant. Stock option

grants to our executive officers are made in connection with the commencement of employment, in conjunction with an annual review of total compensation and, occasionally, following a significant change in job responsibilities or to meet other special retention or performance objectives. Proposals to grant stock options to our executive officers are made by our CEO to the Compensation

## **Table of Contents**

Committee. With respect to proposals for grants made to our executive officers, the Committee generally reviews competitive compensation survey data and, if applicable, consultant reports, as discussed above, individual performance, the executive's existing compensation and other retention considerations. The Compensation Committee considers the estimated Black-Scholes valuation of each proposed stock option grant in determining the number of options subject to each grant. Generally, stock option grants for a particular individual are based on the factors discussed above and are intended to be valued near the average of the range of the value of long-term incentive awards for executives in similar positions with similar responsibilities at comparable companies, although other elements of compensation, including salary, may also be considered.

Generally, stock option grants to executive officers have been made in conjunction with meetings of the Board of Directors. During 2007, we adopted and currently have in force a stock option granting policy that includes the following elements:

Options to purchase shares of our common stock shall be granted effective as of the last day of the following months: February, April, June, August, October and December (each such date a "Grant Date");

For each employee (or prospective employee) that is not (or, upon hire, will not be) subject to Section 16 of the Exchange Act, the CEO shall have the authority to grant, in his sole discretion, an option or options to purchase up to an aggregate of 5,000 shares of common stock (on an annual basis); provided, however, that total number of shares of common stock underlying such options grants shall not exceed 150,000 per calendar year.

The Compensation Committee must approve all other stock option grants. Grants by the Compensation Committee must be approved only at a meeting of the Compensation Committee with and in consultation with the other independent directors and not by written consent.

Grants of options approved for existing employees, shall be effective as of, and the grant date thereof shall for all purposes be deemed to be, the Grant Date following the date of approval (except that any grants subject to stockholder approval shall be effective as of the date of stockholder approval).

Options approved for new hires, including those hired through acquisitions, shall be effective as of, and the grant date thereof shall for all purposes be deemed to be, the Grant Date following the later of (i) the date of such approval or (ii) the date on which the new hire's employment commences.

We have not adopted stock ownership guidelines.

During 2009, our Compensation Committee considered the fact that the value of the CEO's total long-term incentive awards trails the market at the 25th percentile and the value of the long-term incentive awards to our other key executives approximates the market at the 50th percentile. In February 2010, the Compensation Committee approved grants of stock options, or the February Grants, to purchase 250,000, 90,000 and 75,000 shares of common stock to Mr. Zwanziger, Dr. Scott and Dr. McAleer, respectively. While the closing price of our common stock on the date of grant was \$39.02, these options were granted with a premium exercise price of \$61.49, which was the offering price of a secondary offering of our common stock conducted by the Company in November 2007. Due to the premium exercise price and the fact that the price of our common stock would need to increase almost 65% in order for these option grants to even be in the money, the Compensation Committee considered these grants to be stronger long-term incentives than standard option grants and in the best interest of our stockholders.

In determining Mr. Zwanziger's February Grant, the Compensation Committee considered the analysis set forth in the 2009 Radford Report of the number of stock options required to deliver market competitive annual long-term incentives within the range of 2009 grants by our peer group. Taking that into consideration, coupled with the various

factors described above, including Mr. Zwanziger's cash compensation, prior equity grants, significant history and role in leading our company, his expertise and experience and his performance and contribution to our overall goals and objectives, as well as the fact that the exercise price of the grant would be at a significant premium to the then current trading price of our common stock, the Compensation Committee

**Table of Contents**

discussed and adopted the February Grant in an effort to meet our total compensation objectives. While background, expertise and experience, and individual performance and contribution to our overall goals and objectives are all subjective measures, and are not based on any stated quantifiable objectives, they play an important role in the Compensation Committee's overall decision-making process. These subjective factors are considered in the aggregate and, accordingly, no specific factor played a greater role in determining the grant.

In determining Dr. Scott's February Grant, the Compensation Committee considered the analysis set forth in the 2009 Radford Report of the number of stock options required to deliver market competitive annual long-term incentives within the range of 2009 grants by our peer group. Taking that into consideration, coupled with the various factors described above, including Dr. Scott's cash compensation, prior equity grants, significant history and role with our company, his expertise and experience and his performance and contribution to our overall goals and objectives, as well as the fact that the exercise price of the grant would be at a significant premium to the then current trading price of our common stock, the Compensation Committee discussed and adopted the February Grant in an effort to meet our total compensation objectives. While background, expertise and experience, and individual performance and contribution to our overall goals and objectives are all subjective measures, and are not based on any stated quantifiable objectives, they play an important role in the Compensation Committee's overall decision-making process. These subjective factors are considered in the aggregate and, accordingly, no specific factor played a greater role in determining the grant.

In determining Dr. McAleer's February Grant, the Compensation Committee considered the analysis set forth in the 2009 Radford Report of the number of stock options required to deliver market competitive annual long-term incentives within the range of 2009 grants by our peer group. Taking that into consideration, coupled with the various factors described above, including Dr. McAleer's cash compensation, prior equity grants, significant history and role with our company, his expertise and experience and his performance and contribution to our overall goals and objectives, as well as the fact that the exercise price of the grant would be at a significant premium to the then current trading price of our common stock, the Compensation Committee discussed and adopted the February Grant in an effort to meet our total compensation objectives. While background, expertise and experience, and individual performance and contribution to our overall goals and objectives are all subjective measures, and are not based on any stated quantifiable objectives, they played an important role in the Compensation Committee's overall decision-making process. These subjective factors are considered in the aggregate and, accordingly, no specific factor played a greater role in determining the grant.

As of June 30, 2009, Mr. Underwood, Mr. Teitel, Dr. Bridgen and Dr. Geraty were granted options to purchase 12,000, 23,581, 22,564 and 36,069 shares of common stock, respectively, at an exercise price of \$35.58 per share. In approving these grants, as well as other grants made to other officers, managers and employees of the Company as of the same date, the Compensation Committee considered the disincentive offered by underwater stock options held by each individual as a result of declines in the Company's stock price during 2008 and 2009 and determined the amount of the grants initially based upon a formula applied against all outstanding Company stock options. The Compensation Committee then adjusted the amount of each award after considering the various subjective factors previously described. With respect to these grants, the Compensation Committee considered each recipient's cash compensation, prior equity grants, role in leading our Company, expertise and experience, and performance and contribution to our overall goals and objectives. While background, expertise and experience, and individual performance and contribution to our overall goals and objectives are all subjective measures, and are not based on any stated quantified objectives, they play an important role in the Compensation Committee's decision-making process. These subjective factors are considered in the aggregate and, accordingly, none of these subjective factors played a greater role in determining the grants.

As of August 31, 2009, Mr. Underwood was granted options to purchase 40,000 shares of common stock at an exercise price of \$35.60 per share, in connection with Mr. Underwood's appointment as our Chief Information Officer.



The Compensation Committee considered this grant an appropriate incentive for Mr. Underwood in accepting this new role, which the committee expected would constitute a global, strategic leadership role once Mr. Underwood was able to transition into it. The Compensation Committee also considered an analysis of total compensation for comparable executives, the estimated Black-Scholes valuation of the proposed stock option grant, as well as Mr. Underwood's background, expertise and experience, and

## **Table of Contents**

individual performance and past contribution to our overall goals and objectives in approving this grant. While many of these factors are subjective measures, and are not based on any stated quantified objectives, they play an important role in the Compensation Committee's decision-making process. These subjective factors are considered in the aggregate and, accordingly, no specific factor played a greater role in determining the grant.

In addition, as of October 30, 2009, Mr. Teitel was granted options to purchase 10,000 shares of common stock at an exercise price of \$38.01 per share. The Compensation Committee considered an analysis of total compensation for comparable executives and determined that Mr. Teitel's long-term incentive compensation remained significantly lower than that of executives at comparable companies. In approving this grant, the Compensation Committee also considered the estimated Black-Scholes valuation of the proposed stock option grant, as well as Mr. Teitel's background, expertise and experience, and individual performance and past contribution to our overall goals and objectives. While many of these factors are subjective measures, and are not based on any stated quantified objectives, they play an important role in the Compensation Committee's decision-making process. These subjective factors are considered in the aggregate and, accordingly, no specific factor played a greater role in determining the grant.

*Other Compensation.* Other than as discussed below, our named executive officers do not have employment agreements. The named executive officers are not eligible to participate in, and do not have any accrued benefits under, any Company-sponsored defined benefit pension plan. They are eligible to, and in some case do, participate in defined contribution plans, such as a 401(k) plan, on the same terms as other employees. The terms of these defined contribution plans vary depending on the jurisdiction of employment of the executive. In addition, consistent with our compensation philosophy, we intend to continue to maintain our current benefits and perquisites for our executive officers; however, the Compensation Committee in its discretion may revise, amend or add to the officer's executive benefits and perquisites if it deems it advisable. We believe these benefits and perquisites are currently lower than median competitive levels for comparable companies. Finally, all of our executives are eligible to participate in our other employee benefit plans, including medical, dental, life and disability insurance.

### *Tax Implications*

Section 162(m) of the Internal Revenue Code of 1986, as amended, limits the deductibility on our tax return of compensation of over \$1,000,000 to certain of the named executive officers unless, in general, the compensation is paid pursuant to a plan which is performance-related, non-discretionary and has been approved by our stockholders. We periodically review the potential consequences of Section 162(m) and may structure the performance-based portion of our executive compensation to comply with the exemptions available under Section 162(m). We believe that options granted under the 2001 Option Plan will generally qualify as performance-based compensation under Section 162(m). However, we reserve the right to use our judgment to authorize compensation payments that do not comply with these exemptions when we believe that such payments are appropriate and in the best interest of the stockholders, after taking into consideration changing business conditions or the officer's performance.

## **Compensation Committee Report**

We, the Compensation Committee, have reviewed and discussed the Compensation Discussion and Analysis beginning on page 72 of this annual report with management.

Based on this review and discussion, we recommended to the Board of Directors that the Compensation Discussion and Analysis be included in this annual report.

### **THE COMPENSATION COMMITTEE**

Carol R. Goldberg, Chairperson

Eli Y. Adashi, Member

Robert P. Khederian, Member

**Table of Contents****Compensation of Executive Officers**

Set forth below is information regarding the compensation of our Chief Executive Officer, our Chief Financial Officer, our other key executives and our three other most highly-compensated executive officers for the fiscal year 2009. Such officers are collectively referred to as the named executive officers.

*Summary Compensation Table.* The following table sets forth information regarding the named executive officers compensation for fiscal years 2009, 2008 and 2007. For our named executive officers, the amount of salary and bonus represented between 45% and 100% of the named executive officers total compensation for 2009.

**Summary Compensation Table**

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Award (\$)(1)	Change in Pension Value and Non-Qualified Non-Equity Incentive Compensation		All Other Compensation (\$)(2)	Total (\$)
						(\$)	(\$)		
Ron Zwanziger <i>Chairman, Chief Executive Officer and President</i>	2009	\$ 900,000	\$ 250,000					\$ 713	\$ 1,150,713
	2008	\$ 824,423			\$ 1,366,500			\$ 778	\$ 2,191,701
	2007	\$ 750,000			\$ 6,024,000			\$ 990	\$ 6,774,990
David Teitel <i>Chief Financial Officer and Treasurer</i>	2009	\$ 300,000	\$ 100,000		\$ 490,566			\$ 8,063	\$ 898,629
	2008	\$ 299,808						\$ 7,678	\$ 307,486
	2007	\$ 241,250			\$ 477,400			\$ 7,601	\$ 726,251
David Scott, Ph.D.(3) <i>Chief Scientific Officer</i>	2009	\$ 550,306	\$ 125,000		\$				\$ 675,306
	2008	\$ 622,791			\$ 683,250				\$ 1,306,041
	2007	\$ 648,626			\$ 3,012,000				\$ 3,660,626
Jerry McAleer, Ph.D.(3) <i>Vice President, Research &amp; Development and Vice President, Cardiology</i>	2009	\$ 510,998	\$ 125,000		\$				\$ 635,998
	2008	\$ 553,581			\$ 592,150				\$ 1,145,731
	2007	\$ 540,521			\$ 2,510,000				\$ 3,050,521
John Bridgen, Ph.D.(4) <i>Senior Vice President, Business Development</i>	2009	\$ 428,600	\$ 125,000		\$ 324,922			\$ 8,063	\$ 886,585
Tom Underwood(4) <i>Chief Executive Officer, Alere Health, LLC</i>	2009	\$ 439,600	\$ 587,666		\$ 752,000			\$ 7,569	\$ 1,786,835

Edgar Filing: INVERNESS MEDICAL INNOVATIONS INC - Form 10-K/A

Ron Geraty, M.D.(5) <i>former Chief Executive Officer,</i> <i>Alere Health, LLC</i>	2009	\$ 550,008		\$ 519,394	\$ 8,063	\$ 1,077,465
	2008	\$ 498,022	\$ 165,871	\$ 774,000	\$ 7,786	\$ 1,445,679
	2007	\$ 41,921		\$ 2,035,133	\$ 6,677	\$ 2,083,731

- (1) These amounts represent the aggregate grant date fair value of stock option awards made during 2009, 2008 and 2007, respectively, calculated in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, Compensation – Stock Compensation (FASB ASC Topic 718, excluding estimated forfeitures). See Note 16 of the Notes to our consolidated financial statements included in our Annual Report on Form 10-K/A for the year ended December 31, 2009 for a discussion of the other relevant assumptions used in calculating these amounts.
- (2) The amounts in this column include for 2009: (a) matching contributions made by our Company to our defined contribution plans in the amount of \$7,350 on behalf of Mr. Teitel, Dr. Bridgen and Dr. Geraty and \$6,856 on behalf of Mr. Underwood and (b) life insurance premiums paid by our Company in the amount of \$713 on behalf of Mr. Zwanziger, Mr. Teitel, Dr. Bridgen, Mr. Underwood and Dr. Geraty. The amounts in this column include for 2008: (a) matching contributions made by our Company to our defined contribution plans in the amount of \$6,900 on behalf of Mr. Teitel and Dr. Geraty and (b) life insurance premiums paid by our Company in the amount of \$778 on behalf of Mr. Zwanziger and Mr. Teitel and \$886 on behalf of Dr. Geraty. The amounts in this column include for 2007: (a) matching contributions made by our Company to our defined contribution plans in the amount of \$6,750 on behalf of Mr. Teitel, (b) life insurance premiums paid by our Company in the amount of \$990 and \$851 on behalf of Mr. Zwanziger and Mr. Teitel, respectively, and (c) \$6,677 in commuting expenses for Dr. Geraty.

**Table of Contents**

- (3) Salary and other compensation paid in British pounds. British pounds were converted to U.S. dollars using the average exchange rate for the year reported.
- (4) Dr. Bridgen and Mr. Underwood were not named executive officers in 2008 or 2007.
- (5) Dr. Geraty joined the Company on November 16, 2007 when we acquired Alere Medical, Inc. The bonus earned by Dr. Geraty in 2008 was the last Management Incentive Plan bonus authorized by Alere, which was cancelled upon the acquisition of Alere.

*Grants of Plan-Based Awards.* The following table sets forth certain information with respect to options granted to the named executive officers in fiscal year 2009.

**Grants of Plan-Based Awards**

Name	Effective Grant Date (1)	Approval Date (1)	Compensation Committee	Estimated Future Payouts		Estimated Future Payouts		All Other Stock Awards:		All Other Option Awards:		Exercise or Base Price (4)	Grant Date Fair Value of Stock and Option Awards (5)
				Under Incentive Plan Awards	Under Non-Equity Incentive Plan Awards	Under Equity Incentive Plan Awards	Under Non-Equity Incentive Plan Awards	Number of Shares of Securities	Number of Securities				
				Threshold	Maximum	Threshold	Maximum	Units	Options	(#)(2)	(#)(3)		
David Teitel	6/30/09	5/21/09								23,581		\$ 35.58	\$ 339,566
	10/30/09	9/24/09								10,000		\$ 38.01	\$ 151,000
John Bridgen, Ph.D.	6/30/09	5/21/09								22,564		\$ 35.58	\$ 324,922
Tom Underwood	6/30/09	5/21/09								12,000		\$ 35.58	\$ 172,800
	8/31/09	7/24/09								40,000		\$ 35.60	\$ 579,200
Ron Geraty, M.D.	6/30/09	5/21/09								36,069		\$ 35.58	\$ 519,394

- (1) The grant date of the options for the named executive officers is in accordance with our stock option granting policy, in which grants of options approved by the Compensation Committee for existing employees shall be effective as of the next Grant Date following the date of approval (except that any grants subject to stockholder approval shall be effective as of the date of stockholder approval). Under this policy, Grant Date means the last day of the following months: February, April, June, August, October, and December.
- (2) All stock option awards were made under our 2001 Stock Option and Incentive Plan.
- (3) The terms of these options provide for vesting in four equal annual installments, commencing on the first anniversary of the date of grant and conditioned upon the recipient's continued employment with the Company on

the applicable vesting date. The options will expire on the tenth anniversary of the grant date or, if earlier, 90 days after the recipient's employment terminates.

- (4) The exercise price of the stock option awards to the named executive officers is equal to the closing price of the common stock on the applicable grant date.
- (5) These amounts represent the aggregate grant date fair value of stock option awards made during 2009 calculated in accordance with FASB ASC Topic 718, excluding estimated forfeitures. See Note 16 of the Notes to our consolidated financial statements included in our Annual Report on Form 10-K/A for the year ended December 31, 2009 for a discussion of the other relevant assumptions used in calculating these amounts.

**Table of Contents**

*Outstanding Equity Awards at Fiscal Year-End.* The following table sets forth certain information with respect to unexercised options held by the named executive officers at the end of fiscal year 2009.

**Outstanding Equity Awards at Fiscal Year-End**

Name	Option Awards				Stock Awards				
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (1) Unexercisable	Equity Incentive Awards: Number of Securities Underlying Unexercised Options (#)	Exercise Price (\$)	Option Expiration Date (2)	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Unearned Shares or Units of Stock That Have Not Vested (\$)	Number of Shares or Units of Other Rights That Have Not Vested (#)	Market Payout Value of Unearned Shares or Units of Other Rights That Have Not Vested (\$)
Ron Zwanziger	30,000			\$ 14.92	2-12-2011				
	65,000			\$ 17.15	12-20-2011				
	5,065			\$ 15.55	8-23-2012				
	7,576			\$ 21.78	12-31-2013				
	150,000	150,000		\$ 39.72	5-17-2017				
David Teitel	37,500	112,500		\$ 61.49	7-23-2018				
	10,000			\$ 21.38	12-11-2013				
	10,000			\$ 24.25	12-17-2014				
	3,750	1,250		\$ 34.40	10-4-2016				
	15,000	5,000		\$ 38.10	12-15-2016				
	10,000	10,000		\$ 48.14	8-31-2017				
David Scott, Ph.D.		23,581		\$ 35.58	6-30-2019				
		10,000		\$ 38.01	10-30-2019				
	24,000			\$ 14.92	2-12-2011				
	199,691			\$ 15.47	11-30-2011				
	2,284			\$ 15.60	9-3-2012				
Jerry McAleer, Ph.D.	5,252			\$ 21.78	12-31-2013				
	75,000	75,000		\$ 39.72	5-17-2017				
	18,750	56,250		\$ 61.49	7-23-2018				
	16,000		\$ 14.92	2-12-2011					



Edgar Filing: INVERNESS MEDICAL INNOVATIONS INC - Form 10-K/A

	189,706		\$ 15.47	11-30-2011
	129,413		\$ 16.76	12-2-2011
	1,805		\$ 15.60	9-3-2012
	4,656		\$ 21.78	12-31-2013
	62,500	62,500	\$ 39.72	5-17-2017
	16,250	48,750	\$ 61.49	7-23-2018
John Bridgen, Ph.D.	36,570		\$ 11.75	9-30-2012
	6,664		\$ 21.78	12-31-2013
	50,000		\$ 24.25	12-17-2014
	12,500	12,500	\$ 42.26	2-28-2017
	20,000	20,000	\$ 56.18	12-31-2017
		22,564	\$ 35.58	6-30-2019
Tom Underwood		25,000	\$ 33.17	6-30-2018
	250	750	\$ 18.91	12-31-2018
		12,000	\$ 33.58	6-30-2019
		40,000	\$ 35.60	8-31-2019
Ron Geraty, M.D.	35,000	35,000	\$ 56.18	12-31-2017
	7,500	22,500	\$ 33.17	6-30-2018
	7,500	22,500	\$ 35.52	8-29-2018
		36,069	\$ 35.58	6-30-2019

(1) Unless otherwise noted, options become exercisable in four equal annual installments beginning on the first anniversary of the date of grant.

**Table of Contents**

(2) Unless otherwise noted, the expiration date of each option occurs ten years after the date of grant of such option.

*Option Exercises and Stock Vested.* The following table sets forth certain information with respect to options exercised by the named executive officers in fiscal year 2009.

**Option Exercises and Stock Vested**

Name	Option Awards		Stock Awards	
	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise (\$)(1)	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting (\$)
Ron Zwanziger				
David Teitel				
David Scott, Ph.D.	50,000	\$ 1,540,245		
Jerry McAleer, Ph.D.	40,000	\$ 1,213,904		
John Bridgen, Ph.D.				
Tom Underwood				
Ron Geraty, M.D.				

(1) Represents the difference between the aggregate exercise price and the aggregate fair market value of the common stock on the dates of exercise.

*Non-qualified Defined Contribution and Other Non-qualified Deferred Compensation Plans.* Our named executive officers do not participate in any non-qualified defined contribution or other deferred compensation plans.

*Pension Benefits.* Our named executive officers do not participate in any plan that provides for specified retirement benefits, or payments and benefits that will be provided primarily following retirement, other than defined contribution plans such as our 401(k) savings plan.

*Employment Agreements and Potential Payments upon Termination or Change-in-Control.*

On November 18, 2009, we entered into a retention and severance agreement with Tom Underwood in order to restructure change of control severance obligations existing under a 2007 agreement between Mr. Underwood and Matria Healthcare, Inc., a predecessor to Alere Health. In addition to a bonus paid in 2009, Mr. Underwood's current retention and severance agreement provides for two further stay bonuses of \$462,666 payable November 18, 2010 and June 30, 2011, as well as severance payable in the event of involuntary termination without cause or voluntary termination with good reason. As consideration for these severance benefits, Mr. Underwood agreed that (i) for one year after his employment terminates if less than all of the stay bonuses have been paid, or (ii) for two years after his employment terminates if the full amount of all of the stay bonuses has been paid, he will not provide similar services to any business that competes with Alere Health in many states within the United States. As part of the agreement Mr. Underwood also entered into Alere Health's standard non-solicitation agreement.

Dr. Geraty, who is expected to leave the Company in the near future, has an employment agreement which provides for severance payments in the event of involuntary termination without cause or constructive termination. These payments will be triggered by his departure. Dr. Geraty has agreed not to engage in any business activity which is directly or indirectly in competition with us within the United States or to solicit our employees or customers for a period of one year following the date his employment terminates.

The table below sets forth the estimated payments and benefits that would be provided to the extent that payments under these agreements are triggered, or in the case of Dr. Geraty, the amount of the expected payment obligation that will be triggered when he leaves the Company.

**Table of Contents**

<b>Name and Position</b>	<b>Date of Termination</b>	<b>Severance Payments</b>	<b>Benefits</b>
Tom Underwood <i>Chief Executive Officer, Alere Health, LLC</i>	Prior to Nov. 18, 2010	\$ 925,332(1)	\$ 52,354(5)
	Nov. 18, 2010 through June 30, 2011	462,666(2)	52,354(5)
	After June 30, 2011	439,600(3)	14,072(6)
Ron Geraty, M.D. <i>former Chief Executive Officer, Alere Health, LLC</i>	Any	550,008(4)	0

- (1) Severance obligation is a lump-sum payment equal to the greater of (i) any unpaid stay bonuses, as discussed above, or (ii) 12 months of Mr. Underwood's then-current salary. Mr. Underwood is entitled to stay bonuses of \$462,666 each if he remains employed on November 18, 2010 and June 30, 2011, both of which would be accelerated and would, in the aggregate, exceed the value of 12 months of his current salary.
- (2) Represents June 30, 2011 stay bonus, which would be accelerated and would exceed the value of 12 months of Mr. Underwood's current salary.
- (3) Represents 12 months of Mr. Underwood's current salary.
- (4) Represents Dr. Geraty's current annual salary. Severance obligation is 12 months' continuation of Dr. Geraty's then-current salary.
- (5) Represents the current cost of continuation of all group benefits for which executives are eligible at the time of termination for two years, including cell phone and auto insurance, based on the assumptions used for financial reporting purposes under generally accepted accounting principles.
- (6) Represents the current cost of medical and dental insurance coverage for one year, based on the assumptions used for financial reporting purposes under generally accepted accounting principles.

Our named executive officers are otherwise employees-at-will and do not have employment contracts with us. Other than provisions in our 2001 Stock Option and Incentive Plan that provide for all stock options to automatically become fully exercisable and any stock awards to become vested and non-forfeitable in the event of a change of control as defined in the plan, there are no other contracts, agreements, plans or arrangements that provide for payments to our named executive officers at, following, or in connection with any termination of employment, change in control of our Company or a change in a named executive officer's responsibilities. All of the outstanding stock options held by our named executive officers reported above under Outstanding Equity Awards at Fiscal Year-End were issued under our 2001 Stock Option and Incentive Plan and are subject to accelerated exercisability upon a change of control. The table below sets forth the value attributable to such an acceleration of exercisability.

**Value Attributable to Acceleration of  
Exercisability  
of Stock Options upon a Change of Control(1)**

**Name**

Ron Zwanziger	\$	268,500
David Teitel	\$	200,773
David Scott, Ph.D.	\$	134,250
Jerry McAleer, Ph.D.	\$	111,875
John Bridgen, Ph.D.	\$	133,805
Tom Underwood	\$	557,010
Ron Geraty, M.D.	\$	536,314

(1) Assumes the occurrence of a change of control of the Company on December 31, 2009. The value attributable to the acceleration of stock options equals the difference between the applicable option exercise prices and the closing sale price of our common stock as reported by the New York Stock

**Table of Contents**

Exchange on December 31, 2009, which was \$41.51, multiplied by the number of shares underlying the options.

**Risk Related to Compensation Policies**

Our compensation policies and practices for our employees, including our executive compensation program described in our Compensation Discussion and Analysis, aim to provide a risk-balanced compensation package which is competitive in our market sectors and relevant to the individual executive. Generally, we provide cash compensation in the form of base salary to meet competitive cash compensation norms and non-cash compensation, primarily in the form of stock-based awards, to reward superior performance against long-term strategic goals. This focus on base salary supplemented by long-term, non-cash compensation discourages short-term risk taking and provides motivation for employees to pursue the same strategic goals, including increasing shareholder value. While we did provide one-time, discretionary bonuses to many of our executives and managers for 2009, as discussed in our Compensation Discussion and Analysis, and we do provide commission-based compensation to a limited number of sales personnel consistent with industry practices, we do not believe that these practices, or our compensation policies and practices considered as a whole, are reasonably likely to have a material adverse effect on us.

**Compensation of Directors**

The following table sets forth information regarding the compensation of our directors for fiscal year 2009.

**Director Compensation**

Name(1)	Fees Earned or Paid in Cash (\$)(2)	Stock Awards (\$)	Option Awards (\$)(3)	Change in Pension Value and Non-Qualified Non-Equity Deferred Incentive Plan Compensation			All Other Compensation (\$)	Total (\$)
				Earnings (\$)	Compensation (\$)	Other (\$)		
Eli Adashi, M.D.	\$ 56,250		\$ 104,880				\$ 161,130	
Carol R. Goldberg	\$ 85,500						\$ 85,500	
Robert P. Khederian								
John F. Levy								
John A. Quelch								
James Roosevelt, Jr.	\$ 75,000		\$ 71,360				\$ 146,360	
Peter Townsend	\$ 92,750						\$ 92,750	

(1) Ron Zwanziger, Jerry McAleer and David Scott are not included in this table as they are employees of our Company and, accordingly, receive no compensation for their services as directors. The compensation received by Mr. Zwanziger, Dr. McAleer and Dr. Scott as employees of our Company are shown in the Summary Compensation Table above.

- (2) Dr. Adashi received cash payments of \$18,750 each in June 2009, September 2009 and December 2009. Ms. Goldberg received a cash payment of \$85,500 in December 2009. Mr. Roosevelt received cash payments of \$18,750 each in April 2009, June 2009, September 2009 and December 2009. Mr. Townsend received a cash payment of \$92,750 in December 2009. The details of the cash compensation is described in more detail below.
- (3) These amounts represent the aggregate grant date fair value of stock option awards made during 2009 calculated in accordance with FASB ASC Topic 718, excluding estimated forfeitures. See Note 16 of the Notes to our consolidated financial statements included in our Annual Report on Form 10-K/A for the year ended December 31, 2009 for a discussion of the other relevant assumptions used in calculating these amounts. As of December 31, 2009, each director had the following number of options outstanding: Eli

**Table of Contents**

Adashi: 8,000; Carol R. Goldberg: 53,003; Robert P. Khederian: 26,484; John F. Levy: 76,850; John A. Quelch: 74,204; James Roosevelt, Jr.: 8,000; and Peter Townsend: 24,686.

We historically compensated our non-employee directors solely through option grants, consistent with our overall compensation philosophy of focusing on long-term performance and aligning the interests of our directors with the interests of stockholders. These option grants vest over a three-year period in order to compensate for three years of service. Employee directors do not receive compensation for their services as directors.

During 2007, the Compensation Committee engaged a compensation consultant, Pearl Meyer & Partners, to assist the committee in assessing non-employee director compensation. The Compensation Committee concluded that our non-employee directors' annual compensation should be based on the total annual compensation (combined cash and equity) reflected in the 75th percentile of the 2007 peer group data. Accordingly, effective October 31, 2007, the Compensation Committee granted a number of options to the non-employee directors, using a Black-Scholes valuation model, designed to compensate the directors on an annual basis within the 75th percentile of the peer group data. Consistent with past practice, such options vest over a three-year period and compensate the directors for three years of service (2008 through 2010). In this case, however, the non-employee directors were given the option to elect to receive a portion of such compensation in the form of cash (and forego a portion of the option grant of equal value). If a director exercised this option, he or she would receive annual cash payments during 2008, 2009 and 2010 based on the total annual cash compensation paid in the 75th percentile of the peer group data provided by our consultant and would receive a reduced option grant designed to compensate the director for three years of service based on the total equity compensation (rather than combined cash and equity) paid in the 75th percentile of same peer group data. Two directors, Carol R. Goldberg and Peter Townsend, opted to exercise this right. Accordingly, Ms. Goldberg and Mr. Townsend received cash payments of \$85,500 and \$92,750, respectively, in January 2008, December 2008 and December 2009. Upon their election to the Board during 2009, Dr. Adashi and Mr. Roosevelt were each awarded compensation for the first year of their service as a director of \$75,000, payable quarterly in arrears, and an option to purchase 8,000 shares of our common stock. This package of cash compensation and stock options was intended offer these new non-employee directors a similar level of total annual compensation to that awarded to our incumbent non-employee directors through the October 2007 grants.

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

**Security Ownership of Certain Beneficial Owners and Management**

The following table furnishes information as to shares of our common stock beneficially owned by:

each person or entity known by us to beneficially own more than five percent of our common stock;

each of our directors;

each of our named executive officers (as defined in Compensation of Executive Officers on page 81); and

all of our directors and executive officers as a group.

Unless otherwise stated, beneficial ownership is calculated as of April 1, 2010. For the purpose of this table, a person, group or entity is deemed to have beneficial ownership of any shares that such person, group or entity has the right to acquire within 60 days after such date through the exercise of options or warrants.





**Table of Contents**

<b>Name and Address of Beneficial Owner(1)</b>	<b>Common Stock Amount and Nature of Beneficial Ownership(2)</b>	<b>Percent of Class(3)</b>
FMR LLC(4)	8,882,827	10.58%
Capital Research Global Investors(5)	7,594,177	9.04%
Ron Zwanziger(6)	3,815,843	4.52%
David Scott, Ph.D.(7)	795,543	*
Jerry McAleer, Ph.D.(8)	708,694	*
David Teitel(9)	51,288	*
Ron Geraty, M.D.(10)	148,383	*
John Bridgen, Ph.D.(11)	134,617	*
Tom Underwood(12)	250	*
Eli Y. Adashi, M.D.(13)	2,667	*
Carol R. Goldberg(14)	122,197	*
Robert P. Khederian(15)	37,656	*
John F. Levy(16)	198,593	*
John A. Quelch(17)	66,136	*
James Roosevelt, Jr.(18)	2,667	*
Peter Townsend(19)	10,902	*
All executive officers and directors (23 persons)(20)	6,843,144	7.93%

\* Represents less than 1%

- (1) The address of each director or executive officer (and any related persons or entities) is c/o the Company at its principal office.
- (2) Unless otherwise indicated, the stockholders identified in this table have sole voting and investment power with respect to the shares beneficially owned by them.
- (3) The number of shares outstanding used in calculating the percentage for each person, group or entity listed includes the number of shares underlying options and warrants held by such person or group that were exercisable within 60 days from April 1, 2010, but excludes shares of stock underlying options and warrants held by any other person.
- (4) This information is based on information contained in a Schedule 13G/A filed with the SEC on February 16, 2010 by FMR LLC. Of this amount, FMR LLC has (i) sole voting power with respect to 589,881 shares and (ii) sole investment power with respect to 8,882,827 shares. The address provided therein for FMR LLC is 82 Devonshire Street, Boston, MA 02109.
- (5) This information is based on information contained in a Schedule 13G/A filed with the SEC on February 9, 2010 by Capital Research Global Investors, a division of Capital Research and Management Company. The address provided therein for Capital Research Global Investors is 333 South Hope Street, Los Angeles, CA 90071.

- (6) Consists of 3,408,908 shares of common stock and 406,935 shares of common stock underlying options and warrants exercisable within 60 days from April 1, 2010. Of the shares attributed to Mr. Zwanziger, 224,276 shares of common stock are owned by Orit Goldstein as Trustee of the Zwanziger Family 2004 Irrevocable Trust and 1,769,902 shares of common stock and 36,794 shares of common stock issuable upon the exercise of warrants are owned by Zwanziger Family Ventures, LLC, a limited liability company managed by Mr. Zwanziger and his spouse. Of the other shares attributed to him, Mr. Zwanziger disclaims beneficial ownership of (i) 2,600 shares owned by his wife, Janet M. Zwanziger, (ii) 9,450 shares owned by the Zwanziger Goldstein Foundation, a charitable foundation for which Mr. Zwanziger and his spouse, along with three others, serve as directors, (iii) 190,561 shares owned by Ron Zwanziger as Trustee of the Zwanziger 2004 Revocable Trust, and (iv) 191,830 shares owned by Orit Goldstein as the Trustee of the Zwanziger Family Trust.

**Table of Contents**

- (7) Consists of 433,066 shares of common stock and 362,477 shares of common stock underlying options exercisable within 60 days from April 1, 2010.
- (8) Consists of 257,114 shares of common stock and 451,580 shares of common stock underlying options exercisable within 60 days from April 1, 2010.
- (9) Consists of 2,538 shares of common stock and 48,750 shares of common stock underlying options exercisable within 60 days from April 1, 2010.
- (10) Consists of 98,383 shares of common stock and 50,000 shares of common stock underlying options exercisable within 60 days from April 1, 2010.
- (11) Consists of 2,633 shares of common stock and 131,984 shares of common stock underlying options exercisable within 60 days from April 1, 2010.
- (12) Consists of 250 shares of common stock underlying options exercisable within 60 days from April 1, 2010.
- (13) Consists of 2,667 of common stock underlying options exercisable within 60 days from April 1, 2010.
- (14) Consists of 74,645 shares of common stock and 47,552 shares of common stock underlying options exercisable within 60 days from April 1, 2010.
- (15) Consists of 20,000 shares of common stock and 17,656 shares of common stock underlying options exercisable within 60 days from April 1, 2010.
- (16) Consists of 126,302 shares of common stock, 4,391 shares of common stock issuable upon the exercise of warrants and 67,900 shares of common stock underlying options exercisable within 60 days from April 1, 2010. Mr. Levy disclaims beneficial ownership of 741 shares of common stock and 266 shares of common stock issuable upon the exercise of warrants owned by a charitable remainder unitrust.
- (17) Consists of 66,136 shares of common stock underlying options exercisable within 60 days from April 1, 2010.
- (18) Consists of 2,667 shares of common stock underlying options exercisable within 60 days from April 1, 2010.
- (19) Consists of 10,902 shares of common stock underlying options exercisable within 60 days from April 1, 2010.
- (20) Includes 2,293,645 shares of common stock underlying options or warrants exercisable within 60 days from April 1, 2010.

In addition, the Zwanziger Family Trust, a trust for the benefit of Mr. Zwanziger's children the trustee of which is Mr. Zwanziger's sister, and Mr. Underwood own, respectively, 11,984 shares and 4,104 shares of our Series B Preferred Stock. The shares of Series B Preferred Stock owned by the Zwanziger Family Trust and Mr. Underwood represent, both individually and in the aggregate, less than 1% of the outstanding shares of the Series B Preferred Stock. Mr. Zwanziger disclaims beneficial ownership of the Series B Preferred Stock owned by the Zwanziger Family Trust. We are not aware that any of our directors or executive officers beneficially own any other shares of Series B Preferred Stock.



**Table of Contents****Equity Compensation Plan Information**

The following table furnishes information with respect to compensation plans under which equity securities of the Company are authorized for issuance as of December 31, 2009.

<b>Plan Category</b>	<b>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights(1)</b> <b>(a)</b>	<b>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights</b> <b>(b)</b>	<b>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected In Column (a)(2))</b> <b>(c)</b>
Equity compensation plans approved by security holders	7,639,675	\$ 35.06	2,193,901(3)
Equity compensation plans not approved by security holders	75,000(4)	\$ 35.60	
<b>Total</b>	<b>7,714,675</b>	<b>\$ 35.07</b>	<b>2,193,901(3)</b>

- (1) This table excludes an aggregate of 2,123,450 shares issuable upon exercise of outstanding options assumed by the Company in connection with various acquisition transactions. The weighted average exercise price of the excluded acquired options is \$33.49.
- (2) In addition to being available for future issuance upon exercise of options that may be granted after December 31, 2009, 1,120,841 shares under the 2001 Stock Option and Incentive Plan may instead be issued in the form of restricted stock, unrestricted stock, performance share awards or other equity-based awards.
- (3) Includes 1,073,060 shares issuable under the Company's 2001 Employee Stock Purchase Plan (the "ESPP").
- (4) Represents shares issuable upon exercise of outstanding options issued as inducement grants in connection with our acquisition of Concateno, plc. These options have terms which are substantially the same as options granted under our 2001 Stock Option and Incentive Plan.

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

#### **Director Independence**

The Board has determined that the following directors are independent under the rules of the New York Stock Exchange: Dr. Adashi, Ms. Goldberg, Mr. Khederian, Mr. Levy, Dr. Quelch, Mr. Roosevelt and Mr. Townsend. The Board has an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee, each composed solely of directors who satisfy the applicable independence requirements of the New York Stock Exchange's listing standards.

**Policies and Procedures with Respect to Related Party Transactions**

Our Audit Committee Charter requires that members of the Audit Committee, all of whom are independent directors, conduct an appropriate review of, and be responsible for the oversight of, all related party transactions on an ongoing basis.

## **Table of Contents**

### **Investments by the Zwanziger Family Trust**

In November 2008, the Zwanziger Family Trust, a trust established for the benefit of the children of Ron Zwanziger, our Chairman, Chief Executive Officer and President, and the trustee of which is Mr. Zwanziger's sister, purchased certain of our securities from third parties in market transactions. The purchase consisted of approximately \$1.0 million of each of the following securities: our common stock, our Series B Convertible Perpetual Preferred Stock, our 3% senior subordinated convertible notes, interests (\$1.0 million face amount) in our first lien credit agreement and interests (\$1.0 million face amount) in our second lien credit agreement. To the extent we make principal and interest payments under the convertible notes and the credit facilities in accordance with their terms, the Zwanziger Family Trust, as a holder of convertible notes and as a lender under the credit facilities, will receive its proportionate share. In connection with its purchases of interests under our first lien credit agreement and second lien credit agreement, the Trust agreed that, whenever the consent or vote of the lenders is required under the credit facilities, it will vote the outstanding principal amount of its holdings in the same proportion as the votes cast by the other lenders under these credit facilities.

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

Our Audit Committee engaged BDO Seidman, LLP to serve as our independent registered public accountant during the fiscal year ended December 31, 2009. Our Audit Committee has selected BDO Seidman to serve as our independent registered public accountant for the current fiscal year.

#### **Audit Fees**

We have not received a final invoice from BDO Seidman for professional services rendered for the audit of our consolidated financial statements for fiscal year 2009. However, we expect aggregate audit fees billed by BDO Seidman for fiscal year 2009 to be approximately \$3,384,737, of which \$2,747,522 has been billed to date. This includes \$630,000 billed for professional services rendered in connection with the independent registered public accountant's audit of our internal control over financial reporting in connection with the 2009 audit. Audit fees also include fees billed in connection with the independent registered public accountant's review of our quarterly financial statements and audit services normally provided by the independent registered public accountant in connection with other statutory or regulatory filings. Aggregate audit fees billed by BDO Seidman for fiscal year 2008 were approximately \$3,246,668.

#### **Audit-Related Fees**

Aggregate audit-related fees billed in 2009 and 2008 by BDO Seidman were \$484,650 and \$515,473, respectively. Audit-related fees consist primarily of fees billed for professional services rendered by the independent registered public accountant for accounting consultations and services related to business acquisitions and financings.

#### **Tax Fees**

Aggregate tax fees billed in 2009 and 2008 by BDO Seidman were \$404,000 and \$347,000, respectively. Tax fees include fees billed for professional services rendered by the independent registered public accountant for tax compliance, tax advice and tax planning.

#### **All Other Fees**

During 2009 and 2008, no other fees were billed by BDO Seidman, LLP.



**Pre-approval Policies and Procedures**

The Audit Committee pre-approves all audit and non-audit services provided by the independent registered public accountant other than permitted non-audit services estimated in good faith by the independent registered public accountant and management to entail fees payable of \$25,000 or less on a project by project basis and which would otherwise qualify for exemption from the pre-approval requirements of the Securities Exchange Act of 1934, as amended (the Exchange Act ). This authority to pre-approve non-

**Table of Contents**

audit services may be delegated to one or more members of the Audit Committee, who shall present any services so pre-approved to the full Audit Committee at its next meeting.

**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:

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

**Table of Contents**

- 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)
- 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)



**Table of Contents**

- 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)
- 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)

**Table of Contents**

- 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)
- 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)





**Table of Contents**

- 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 June 26, 2007, filed on July 2, 2007)
- \*10.31 Employment Agreement, dated January 15, 2010, between Inverness Medical Innovations, Inc. and Ronald Geraty
- \*10.32 Retention and severance agreement, dated November 18, 2009, between Alere LLC and Thomas Underwood
- 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.

**Table of Contents**

**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: April 16, 2010

By:  
/s/ Ron Zwanziger

Ron Zwanziger  
Chairman, Chief Executive Officer and President

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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Ron Zwanziger Ron Zwanziger	Chief Executive Officer, President and Director (Principal Executive Officer)	April 16, 2010
/s/ David Teitel David Teitel	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	April 16, 2010
/s/ Eli Y. Adashi, MD Eli Y. Adashi, MD	Director	April 16, 2010
/s/ Carol R. Goldberg Carol R. Goldberg	Director	April 16, 2010
/s/ Robert P. Khederian Robert P. Khederian	Director	April 16, 2010
/s/ John F. Levy John F. Levy	Director	April 16, 2010
/s/ Jerry McAleer	Director	April 16, 2010

Edgar Filing: INVERNESS MEDICAL INNOVATIONS INC - Form 10-K/A

Jerry McAleer

/s/ John A. Quelch

Director

April 16, 2010

John A. Quelch

/s/ James Roosevelt, Jr.

Director

April 16, 2010

James Roosevelt, Jr.

/s/ David Scott

Director

April 16, 2010

David Scott

/s/ Peter Townsend

Director

April 16, 2010

Peter Townsend

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**

**CONSOLIDATED FINANCIAL STATEMENTS**

**Table of Contents**

	<b>Page</b>
<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

**Table of Contents**

**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)

	<b>2009</b>	<b>2008</b>	<b>2007</b>
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
<b>Net revenue</b>	<b>1,922,641</b>	<b>1,582,553</b>	<b>766,716</b>
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
<b>Cost of net revenue</b>	<b>868,419</b>	<b>729,035</b>	<b>379,955</b>
<b>Gross profit</b>	<b>1,054,222</b>	<b>853,518</b>	<b>386,761</b>
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)		
<b>Operating income (loss)</b>	<b>146,050</b>	<b>64,692</b>	<b>(174,792)</b>
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
<b>Income (loss) from continuing operations before provision (benefit) for income taxes</b>	<b>40,248</b>	<b>(38,247)</b>	<b>(248,355)</b>
Provision (benefit) for income taxes	15,627	(16,644)	(1,049)
<b>Income (loss) from continuing operations before equity earnings of unconsolidated entities, net of tax</b>	<b>24,621</b>	<b>(21,603)</b>	<b>(247,306)</b>
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)
<b>Net income (loss)</b>	<b>34,181</b>	<b>(21,601)</b>	<b>(243,352)</b>
Less: Net income attributable to non-controlling interests	465	167	1,401
	<b>33,716</b>	<b>(21,768)</b>	<b>(244,753)</b>

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

Preferred stock dividends		(22,972)	(13,989)	
<b>Net income (loss) available to common stockholders</b>	\$	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)**

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
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
<b>Total current assets</b>	<b>1,266,958</b>	<b>835,723</b>
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
<b>Total assets</b>	<b>\$ 6,943,992</b>	<b>\$ 5,955,360</b>
<b>LIABILITIES AND EQUITY</b>		
<b>Current liabilities:</b>		
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
<b>Total current liabilities</b>	<b>438,014</b>	<b>365,374</b>

<b>Long-term liabilities:</b>		
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
<b>Total long-term liabilities</b>	<b>2,977,089</b>	<b>2,310,279</b>
<b>Commitments and contingencies</b> (Notes 8, 9 and 11)		
<b>Stockholders equity:</b>		
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)
<b>Total stockholders equity</b>	<b>3,527,555</b>	<b>3,278,838</b>
Non-controlling interests	1,334	869
<b>Total equity</b>	<b>3,528,889</b>	<b>3,279,707</b>
<b>Total liabilities and equity</b>	<b>\$ 6,943,992</b>	<b>\$ 5,955,360</b>

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

Table of Contents

## 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 Number of Shares	Preferred Stock Amount	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Comprehensive Other (Loss)	Total Stockholders' Equity	Non-controlling Interest	Total Equity
		Number of Shares	Par Value \$0.001						
1,879	\$ 671,501	78,431	\$ 78	\$ 3,029,694	\$ (393,590)	\$ (28,845)	\$ 3,278,838	\$ 869	\$ 3,279,707
		3,431	4	117,815			117,819		117,819
		1,705	2	30,013			30,015		30,015
105	22,926			(23,079)			(153)		(153)
				2,881			2,881		2,881
				28,220			28,220		28,220
				9,828			9,828		9,828
						(1,137)	(1,137)		(1,137)

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)**

	<b>2009</b>	<b>2008</b>	<b>2007</b>
<b>Cash Flows from Operating Activities:</b>			
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
<b>Net cash provided by operating activities</b>	<b>287,531</b>	<b>147,844</b>	<b>88,755</b>
<b>Cash Flows from Investing Activities:</b>			
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
Cash received from (paid for) investments in minority interests and marketable Securities	12,560	12,133	(10,177)

Edgar Filing: INVERNESS MEDICAL INNOVATIONS INC - Form 10-K/A

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)
<b>Net cash used in investing activities</b>	<b>(583,727)</b>	<b>(713,332)</b>	<b>(1,786,530)</b>
<b>Cash Flows from Financing Activities:</b>			
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)	137,242	1,114,171
Tax benefit on exercised stock options	9,269	17,542	867
Principal payments of capital lease obligations	(798)	(958)	(94)
Other	(153)	(56)	
Net cash provided by continuing operations	633,866	298,111	2,032,926
Net cash used in discontinued operations	(12)	(342)	(542)
<b>Net cash provided by financing activities</b>	<b>633,854</b>	<b>297,769</b>	<b>2,032,384</b>
Foreign exchange effect on cash and cash equivalents	13,791	(5,689)	9,019
Net increase (decrease) in cash and cash equivalents	351,449	(273,408)	343,628
Cash and cash equivalents, beginning of period	141,324	414,732	71,104
<b>Cash and cash equivalents, end of period</b>	<b>\$ 492,773</b>	<b>\$ 141,324</b>	<b>\$ 414,732</b>

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

**Table of Contents**

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

By developing new capabilities in near-patient diagnosis, monitoring and health management, Inverness Medical Innovations, Inc. and subsidiaries enable individuals to take charge of improving their health and quality of life at home. 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.

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

On January 15, 2010, we completed the sale of our vitamins and nutritional supplements business (Note 24). The sale included our entire private label and branded nutritionals businesses and represents the complete divestiture of our entire vitamins and nutritional supplements business segment. The results of the vitamins and nutritional supplements business are included in income (loss) from discontinued operations, net of tax, for all periods presented. The assets and liabilities associated with the vitamins and nutritional supplements business have been reclassified to assets held for sale and liabilities related to assets held for sale as of December 31, 2009 and 2008 on our accompanying consolidated balance sheets.

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

Following the completion of our 50/50 joint venture with P&G on May 17, 2007, we ceased to consolidate the operating results of our consumer diagnostics business, which represented \$76.1 million of net product sales in 2007 (through the date the joint venture was formed), and instead account for our 50% interest in the results of the joint venture under the equity method of accounting. In our capacity as the manufacturer of products for the joint venture, we supply product to the joint venture and record revenue on those sales. No gain on the proceeds that we received from P&G through the formation of our joint venture will be recognized in our financial statements until P&G's option to require us to purchase its interest in the joint venture at market value expires after the fourth anniversary of the closing.

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

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

F-9

---

**Table of Contents**

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**

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

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

*(a) Use of Estimates*

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

*(b) Foreign Currencies*

In general, the functional currencies of our foreign subsidiaries are the local currencies. For purpose of consolidating the financial statements of our foreign subsidiaries, all assets and liabilities of the foreign subsidiaries are translated into U.S. dollars using the exchange rate at each balance sheet date while the stockholders' equity accounts are translated at historical exchange rates. Translation gains and losses that result from the conversion of the balance sheets of the foreign subsidiaries into U.S. dollars are recorded to cumulative translation adjustment which is a component of accumulated other comprehensive income within stockholders' equity (Note 17).

The revenue and expenses of our foreign subsidiaries are translated using the average rates of exchange in effect during each fiscal month during the year. Net realized and unrealized foreign currency exchange transaction gains of \$1.3 million during 2009, losses of \$0.5 million during 2008 and losses of \$2.0 million during 2007, are included as a component of other income (expense), net in the accompanying consolidated statements of operations.

*(c) Cash and Cash Equivalents*

We consider all highly-liquid investments purchased with original maturities of three months or less at the date of acquisition to be cash equivalents. Cash equivalents consisted of money market funds at December 31, 2009 and 2008.

*(d) Restricted Cash*

We had restricted cash of \$2.4 million and \$2.7 million as of December 31, 2009 and 2008, respectively.

*(e) Marketable Securities*

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

*(f) Inventories*

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

F-10

---

**Table of Contents**

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**

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

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

*(g) Property, Plant and Equipment*

We record property, plant and equipment at historical cost or, in the case of a business combination, at fair value on the date of the business combination. Depreciation is computed using the straight-line method based on the following estimated useful lives of the related assets: machinery, laboratory equipment and tooling, 2-21 years; buildings, 20-50 years; leasehold improvements, lesser of remaining term of lease or estimated useful life of asset; computer software and equipment, 1-5 years and furniture and fixtures, 2-15 years. Land is not depreciated. Depreciation expense related to property, plant and equipment amounted to \$54.3 million, \$49.7 million and \$25.4 million in 2009, 2008 and 2007, respectively. Expenditures for repairs and maintenance are expensed as incurred.

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

Goodwill and indefinite-lived intangible assets are required to be tested for impairment annually, in lieu of being amortized, using a fair value approach at the reporting unit level. Furthermore, testing for impairment is required on an interim basis if an event or circumstance indicates that it is more likely than not an impairment loss has been incurred. An impairment loss shall be recognized to the extent that the carrying amount of goodwill or any indefinite-lived intangible asset exceeds its implied fair value. Impairment losses shall be recognized in operating results.

Our valuation methodology for assessing impairment, using both the discounted cash flows approach and the market approach, requires management to make judgments and assumptions based on historical experience and projections of future operating performance. Our annual impairment review performed on September 30, 2009 did not indicate that goodwill or other indefinite-lived intangible assets related to our professional diagnostics, health management or our consumer diagnostics reporting units were impaired, 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.

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

We evaluate long-lived tangible and intangible assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indicators of impairment are present with respect to long-lived tangible and intangible assets used in operations and undiscounted future cash flows are not expected to be sufficient

to recover the assets carrying amount, additional analysis is performed as appropriate and the carrying value of the long-lived asset is reduced to the estimated fair value, if this is lower, and an impairment loss would be charged to expense in the period the impairment is identified. We believe that the carrying values of our other long-lived tangible and intangible assets were realizable as of December 31, 2009.

F-11

---



**Table of Contents**

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**

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

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

*(j) Business Acquisitions*

On January 1, 2009, we adopted a new accounting standard issued by the Financial Accounting Standards Board, or FASB, related to accounting for business combinations using the acquisition method of accounting (previously referred to as the purchase method). Among the significant changes, this standard requires a redefining of the measurement date of a business combination, expensing direct transaction costs as incurred, capitalizing in-process research and development costs as an intangible asset and recording a liability for contingent consideration at the measurement date with subsequent re-measurements recorded as general and administrative expense. This standard also requires costs for business restructuring and exit activities related to the acquired company to be included in the post-combination financial results of operations and also provides new guidance for the recognition and measurement of contingent assets and liabilities in a business combination. Acquisitions consummated prior to January 1, 2009 were accounted for in accordance with the previously applicable guidance. During 2009, we incurred \$15.9 million of acquisition-related costs, of which \$3.8 million was capitalized as of December 31, 2008.

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

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

*(k) Income Taxes*

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts that are expected more likely than not to be realized in the future (Note 18).

In 2006, the FASB issued a new accounting standard which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with income tax accounting. In accordance with this update, we recognize some or all of the benefit of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position (Note 18).

*(l) 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

F-12

---

**Table of Contents**

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**

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

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

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 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.

*(m) Employee Stock-Based Compensation Arrangements*

We account for share-based payments in accordance with Accounting Standards Codification, or ASC 718-10, *Compensation - Stock Compensation*. Compensation cost associated with stock options includes: (i) amortization related to the remaining unvested portion of all stock option awards granted prior to January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123, and (ii) amortization related to all stock option awards granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123-R. In addition, we record expense over the offering period in connection with shares issued under our employee stock purchase plan. Compensation expense for stock-based compensation awards includes an estimate for forfeitures and is recognized over the expected term of the options using the straight-line method.

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

*(n) Net Income (Loss) per Common Share*

Net income (loss) per common share is based upon the weighted average number of outstanding common shares and the dilutive effect of common share equivalents, such as options and warrants to purchase common stock, convertible preferred stock and convertible notes, if applicable, that are outstanding each year (Note 14).

*(o) Other Operating Expenses*

F-13

---

**Table of Contents**

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**

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

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

We expense advertising costs as incurred. In 2009, 2008 and 2007, advertising costs amounted to \$15.4 million, \$15.7 million and \$15.7 million, respectively, and are included in sales and marketing expenses in the accompanying consolidated statements of operations.

Shipping and handling costs are included in cost of net revenue in the accompanying consolidated statements of operations. Additionally, to the extent that we charge our customers for shipping and handling costs, these costs are recorded as product revenues.

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

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

At December 31, 2009, no one individual customer accounts receivable balance was in excess of 10%. At December 31, 2008, we had one individual customer accounts receivable balance outstanding that represented 15% of the gross accounts receivable balance. During 2009, 2008 and 2007, we had one customer that represented 15%, 23% and 17% of our net revenue, respectively, and purchased our professional diagnostics products.

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

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

Our primary financial instruments at December 31, 2009 and 2008 consisted of cash equivalents, restricted cash, marketable securities, accounts receivable, accounts payable, debt and our interest rate swap contract. We apply fair value measurement accounting to value our financial assets and liabilities. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. A fair value hierarchy requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The estimated fair value of these financial instruments approximates their carrying values at December 31, 2009 and 2008.

*(r) Recent Accounting Pronouncements*

Recently Issued Standards

In December 2009, the FASB issued Accounting Standards Update No. 2009-17, *Consolidations (Topic 810): Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities*, or ASU 2009-17. The amendments in this update replace the quantitative-based risks and rewards calculation for determining which reporting entity, if any, has a controlling financial interest in a variable interest entity with an approach focused on identifying which reporting entity has the power to direct the activities of a variable interest entity that most significantly impact the entity's economic performance and (1) the obligation to absorb losses of the entity or (2) the right to receive benefits from the entity. An approach that is expected to be primarily qualitative will be more effective for identifying which reporting entity has a controlling financial

**Table of Contents**

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**

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

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

interest in a variable interest entity. The amendments in this update also require additional disclosures about a reporting entity's involvement in variable interest entities, which will enhance the information provided to users of financial statements. This standard is effective for fiscal years beginning on or after December 15, 2009. We are currently evaluating the potential impact of this standard.

In December 2009, the FASB issued ASU No. 2009-16, *Transfers and Servicing (Topic 860): Accounting for Transfers of Financial Assets*, or ASU 2009-16. The amendments in this update improve financial reporting by eliminating the exceptions for qualifying special-purpose entities from the consolidation guidance and the exception that permitted sale accounting for certain mortgage securitizations when a transferor has not surrendered control over the transferred financial assets. In addition, the amendments require enhanced disclosures about the risks that a transferor continues to be exposed to because of its continuing involvement in transferred financial assets. Comparability and consistency in accounting for transferred financial assets will also be improved through clarifications of the requirements for isolation and limitations on portions of financial assets that are eligible for sale accounting. This standard is effective January 1, 2010. The adoption of this standard will not have any impact on our financial position, results of operations or cash flows.

In October 2009, the FASB issued ASU No. 2009-15, *Accounting for Own-Share Lending Arrangements in Contemplation of Convertible Debt Issuance or Other Financing*, or ASU 2009-15. ASU 2009-15 provides guidance on equity-classified share-lending arrangements on an entity's own shares when executed in contemplation of a convertible debt offering or other financing. This standard is effective for fiscal years beginning on or after December 15, 2009, and interim periods within those years for arrangements outstanding as of the beginning of those fiscal years. The adoption of this standard will not have any impact on our financial position, results of operations or cash flows.

In October 2009, the FASB issued ASU No. 2009-14, *Software (Topic 985): Certain Revenue Arrangements That Include Software Elements* a consensus of the FASB EITF, or ASU 2009-14. ASU 2009-14 changes the accounting model for revenue arrangements that include tangible products and software elements. The amendments of this update provide additional guidance on how to determine which software, if any, relating to the tangible product also would be excluded from the scope of the software revenue recognition guidance. The amendments in this update also provide guidance on how a vendor should allocate arrangement consideration to deliverables in an arrangement that includes both tangible products and software as well as arrangements that have deliverables both included and excluded from the scope of software revenue recognition guidance. This standard is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. We are currently evaluating the potential impact of this standard.

In October 2009, the FASB issued ASU No. 2009-13, *Revenue Recognition (Topic 650): Multiple-Deliverable Revenue Arrangements* a consensus of the FASB EITF, or ASU 2009-13. ASU 2009-13 will separate multiple-deliverable revenue arrangements. This update establishes a selling price hierarchy for determining the selling price of a deliverable. The amendments of this update will replace the term "fair value" in the revenue allocation guidance with "selling price" to clarify that the allocation of revenue is based on entity-specific assumptions rather than assumptions of a marketplace participant. The amendments of this update will eliminate the residual method of allocation and require that arrangement consideration be allocated at the inception of the arrangement to all

deliverables using the relative selling price method. The amendments in this update will require that a vendor determine its best estimated selling price in a manner consistent with that used to determine the price to sell the deliverable on a standalone basis. This standard is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. We are currently evaluating the potential impact of this standard.

Recently Adopted Standards

F-15

---



**Table of Contents**

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**

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

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

Effective December 31, 2009, we adopted ASU No. 2009-12, *Fair Value Measurements and Disclosure*, or ASU 2009-12. This standard provides additional guidance on using the net asset value per share, provided by an investee, when estimating the fair value of an alternate investment that does not have a readily determinable fair value and enhances the disclosures concerning these investments. Examples of alternate investments, within the scope of this standard, include investments in hedge funds and private equity, real estate and venture capital partnerships. The adoption of this standard did not have any impact on our financial position, results of operations or cash flows.

Effective October 1, 2009, we adopted ASU No. 2009-05, *Measuring Liabilities at Fair Value*, or ASU 2009-05. ASU 2009-05 amends Accounting Standards Codification, or the Codification, Topic 820, *Fair Value Measurements*. Specifically, ASU 2009-05 provides clarification that, in circumstances in which a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using one or more of the following methods: (i) a valuation technique that uses a) the quoted price of the identical liability when traded as an asset or quoted prices for similar liabilities or similar liabilities when traded as assets and/or (ii) a valuation technique that is consistent with the principles of Topic 820 of the Codification (e.g. an income approach or market approach). ASU 2009-05 also clarifies that when estimating the fair value of a liability, a reporting entity is not required to adjust to include inputs relating to the existence of transfer restrictions on that liability. The adoption of this standard did not have any impact on our financial position, results of operations or cash flows.

Effective July 1, 2009, we adopted *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*. This standard establishes only two levels of U.S. generally accepted accounting principles ( GAAP ), authoritative and non-authoritative. The FASB Codification became the source of authoritative, nongovernmental GAAP, except for rules and interpretive releases of the Securities Exchange Commission, or SEC, which are sources of authoritative GAAP for SEC registrants. All other non-grandfathered, non-SEC accounting literature not included in the Codification became non-authoritative. As the Codification was not intended to change or alter existing GAAP, it did not have any impact on the Company's consolidated financial statements.

Effective June 30, 2009, we adopted a new accounting standard for subsequent events. This standard establishes general guidance of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. In particular, this standard sets forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. The adoption of this standard did not have any impact on our financial position, results of operations or cash flows.

Effective June 30, 2009, we adopted three new accounting standards which provide additional application guidance and enhanced disclosures regarding fair value measurements and impairments of securities. They also provide additional guidelines for estimating fair value in accordance with fair value accounting. The first accounting standard provides additional guidelines for estimating fair value in accordance with fair value accounting. The second accounting standard changes accounting requirements for other-than-temporary-impairment for debt securities by replacing the current requirement that a holder have the positive intent and ability to hold an impaired security to recovery in order to conclude an impairment was temporary with a requirement that an entity conclude it does not

intend to sell an impaired security and it will not be required to sell the security before the recovery of its amortized cost basis. The third accounting standard increases the frequency of fair value disclosures. These standards were effective for fiscal years and interim periods ended

**Table of Contents**

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**

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

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

after June 15, 2009. The adoption of these accounting standards did not have any impact on our financial position, results of operation or cash flows.

Effective January 1, 2009, we adopted a new accounting standard which addresses the accounting for certain instruments as derivatives. Under this new standard, specific guidance is provided regarding requirements for an entity to consider embedded features as indexed to the entity's own stock. The adoption of this standard did not have any impact on our financial position, results of operations or cash flows.

Effective January 1, 2009, we adopted a new accounting standard for convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement). This standard specifies that issuers of such instruments should separately account for the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. This standard should be applied retrospectively for all periods presented. The adoption of this standard did not have any impact on our financial position, results of operations or cash flows.

Effective January 1, 2009, we adopted a new accounting standard related to fair value accounting for all non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis, at least annually. These include goodwill and other non-amortizable intangible assets. The adoption of this standard did not have a material impact on our financial position, results of operations or cash flows.

Effective January 1, 2009, we adopted a new accounting standard which amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset. The adoption of this standard did not have any impact on our financial position, results of operations or cash flows.

Effective January 1, 2009, we adopted a new accounting standard which requires entities that utilize derivative instruments to provide qualitative disclosures about their objectives and strategies for using such instruments, as well as any details of credit-risk-related contingent features contained within derivatives. It also requires entities to disclose additional information about the amounts and location of derivatives located within the financial statements and the impact that hedges have on an entity's financial position, financial performance and cash flows. As this standard only required additional disclosure, the adoption did not impact our consolidated results of operations, financial condition or cash flows.

Effective January 1, 2009, we adopted a new accounting standard for collaborative arrangements related to the development and commercialization of intellectual property. The standard concluded that a collaborative arrangement is one in which the participants are actively involved and are exposed to significant risks and rewards that depend on the ultimate commercial success of the endeavor. The nature and purpose of collaborative arrangements are to be disclosed along with the accounting policies and the classification and amounts of significant financial statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however required disclosure under this new standard applies to the entire collaborative agreement. This standard is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. The adoption of this standard did not have any impact on

our current or prior consolidated results of operations, financial condition or cash flows.

Effective January 1, 2009, we adopted a new accounting standard issued to establish accounting and reporting standards for the non-controlling interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a non-controlling interest in a subsidiary is an ownership interest in the consolidated entity and should therefore be reported as equity in the consolidated financial statements. The standard also establishes guidance for presentation and disclosure of the non-controlling results on the consolidated statement of

F-17

---

**Table of Contents****INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(2) Summary of Significant Accounting Policies (Continued)**

operations, on a retrospective basis. The adoption of this standard did not have a material impact on our financial position, results of operations or cash flows.

Effective January 1, 2009, we adopted a new accounting standard for business combinations. This standard requires an acquiring company to measure all assets acquired and liabilities assumed, including contingent considerations and all contractual contingencies, at fair value as of the acquisition date. In addition, an acquiring company is required to capitalize in-process research and development, or IPR&D, and either amortize it over the life of the product or write it off if the project is abandoned or impaired. The standard also amended accounting for uncertainty in income taxes as required by the Codification. Previously, accounting standards generally required post-acquisition adjustments related to business combination deferred tax asset valuation allowances and liabilities for uncertain tax positions to be recorded as an increase or decrease to goodwill. This new standard does not permit this accounting and, generally, requires any such changes to be recorded in current period income tax expense. Thus, all changes to valuation allowances and liabilities for uncertain tax positions established in acquisition accounting, whether the business combination was originally accounted for under this guidance or not, will be recognized in current period income tax expense. See Note 4 for further description of the impact of this new accounting standard.

Effective January 1, 2009, we adopted a new accounting standard which provides guidance on initial recognition and measurement, subsequent measurement and accounting, and disclosure of assets and liabilities arising from contingencies in a business combination. Early adoption of this statement was not permitted. The impact of adopting this accounting standard on our consolidated financial statements will depend on the economic terms of any future business combinations.

**(3) Other Balance Sheet Information**

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

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Inventories, net:</b>		
Raw materials	\$ 62,397	\$ 35,324
Work-in-process	56,338	33,346
Finished goods	102,804	104,915
	<b>\$ 221,539</b>	<b>\$ 173,585</b>
<b>Property, plant and equipment, net:</b>		
Machinery, laboratory equipment and tooling	\$ 183,490	\$ 135,667
Land and buildings	135,644	133,274
Leasehold improvements	22,841	18,995
Computer software and equipment	96,950	58,797

Edgar Filing: INVERNESS MEDICAL INNOVATIONS INC - Form 10-K/A

Furniture and fixtures	19,340	15,116
	458,265	361,849
Less: Accumulated depreciation and amortization	(133,877)	(87,371)
	\$ 324,388	\$ 274,478

F-18

---

**Table of Contents**

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**

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

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

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Accrued expenses and other current liabilities:</b>		
Compensation and compensation-related	\$ 76,360	\$ 60,495
Advertising and marketing	6,155	5,639
Professional fees	9,743	7,721
Interest payable	16,661	