INVERNESS MEDICAL INNOVATIONS INC
Form 10-K
March 02, 2009

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

FORM 10-K

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

(Mark One)

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

For the fiscal year ended December 31, 2008

or

o 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	**04-3565120**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
51 Sawyer Road, Suite 200, Waltham, Massachusetts	**02453**
(Address of principal executive offices)	(Zip Code)

(781) 647-3900
(Registrant s telephone number, including area code)

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $0.001 per share par value	New York Stock Exchange

Series B Convertible Perpetual Preferred Stock, $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 þ No o

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 o No þ

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

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. o

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

Large accelerated filer þ Accelerated filer o Non-accelerated filer o Smaller reporting company o
(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 o No þ

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 American Stock Exchange on June 30, 2008 (the last business day of the registrant s most recently completed second fiscal quarter) was $1,824,439,990.

As of February 25, 2009, the registrant had 78,626,101 shares of common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive proxy statement to be filed in connection with the registrant s annual meeting of shareholders currently scheduled to be held on May 21, 2009 are incorporated by reference into Part III of this Form 10-K.

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PART I

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

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

ITEM 1. BUSINESS

GENERAL

Inverness Medical Innovations enables individuals to take charge of improving their health and quality of life at home by developing new capabilities in near-patient diagnosis, monitoring and health management. Our global leading products and services, as well as our new product development efforts, focus on cardiology, women s health, infectious disease, oncology and drugs of abuse. Inverness Medical Innovations, Inc., a Delaware corporation, was formed to acquire the women s health, nutritional supplements and professional diagnostics businesses of its predecessor, Inverness Medical Technology, Inc., through a split-off and merger transaction, which occurred in November 2001. We became an independent, publicly-traded company immediately after the split-off and our common stock was listed on the American Stock Exchange under the symbol IMA. We are now listed on the New York Stock Exchange under the symbol IMA. Since the split-off, we have grown our businesses through strategic use of our superior intellectual property portfolio and through strategic acquisitions. Our Alere health management business, which represents the union of Matria Healthcare, LLC, or Matria, acquired in 2008; Alere Medical, Inc., or Alere Medical, and ParadigmHealth, Inc., or ParadigmHealth, each acquired during 2007, is a leading provider of health management services to insurers and employers and 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.

Our principal executive offices are located at 51 Sawyer Road, Suite 200, Waltham, Massachusetts 02453 and our telephone number is (781) 647-3900. Our website is www.invmed.com and we make available through this site, free of charge, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and Amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the Securities and Exchange Commission, or the SEC. These reports may be accessed through our website s investor information page. We also make our code of ethics and certain other governance documents and policies available through this site.

Segments

Our major reportable operating segments are professional diagnostics, health management, consumer diagnostics and vitamins and nutritional supplements. Below are discussions of each of these reportable segments. Financial information about our reportable segments is provided in Note 20 of the Notes to Consolidated Financial Statements, which are included elsewhere in this report.

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Products and Services

Professional Diagnostics. Professional diagnostics are generally designed to assist medical professionals in both preventative and interventional medicine, and includes testing or monitoring performed in hospitals and doctors offices and, increasingly, testing or 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 or disease state or to measure response to therapy. Within professional diagnostics, we focus on point-of-care, rapid diagnostic testing and the developing patient self-testing 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 (one out of every three) American adults 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 and, in the near-patient categories where we focus, annual growth is estimated at 15% to 20%. Our Biosite Triage, Cholestech LDX and HemoSense INRatio products, all acquired through acquisitions in 2007, have established us as a leader in this market. Our Triage system is used in approximately 63% of U.S. hospitals and in over 50 countries worldwide. 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 Biosite 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

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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.

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 CRP) and is CLIA-waived, meaning that 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 HemoSense 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 HemoSense 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.

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, acquired immunodeficiency

syndrome (AIDS), herpes and other sexually-transmitted diseases. To meet this demand, we have continued to expand our product offerings and now offer one of the world s largest infectious disease test menus. We develop and market a wide variety of point-of-care tests for Influenza A/B, strep throat, HIV, HSV-2, 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

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include Acceava, BinaxNOW, Clearview, Determine, Inverness Medical TestPack, DoubleCheckGold, Panbio and TECHLAB®.

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. 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, 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 and SureStep. The TOX Drug Screen panel sold for use with the Biosite Triage System detects the presence of any illicit or prescription drugs listed above at the point-of-care in approximately 15 minutes.

Through our subsidiary Redwood Toxicology Laboratories, or Redwood, we also offer comprehensive, low-cost laboratory testing services. Through its laboratory services, Redwood offers its clients, including law

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enforcement agencies, penal systems, insurers and employers, 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. Accordingly, during 2007, we entered the growing health management marketplace with our acquisitions of Alere Medical and ParadigmHealth, and in May 2008 we acquired Matria. Combined as Alere, our health management business strives to empower participants of our programs and physicians so that they can work together towards better health. Our expert-designed programs:

Embrace the entire lifespan, from pre-cradle to end-of-life, and targeted health states, from wellness to prevention to complex care

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 2,200+ healthcare professionals who share a passion for excellence in everything we do

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. Alere s 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. Alere offers 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 weight and/or answers to questions regarding their symptoms. This information is gathered daily and sent to Alere 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, Alere also offers 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.

Women s & Children s Health. Alere s 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 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.

Alere delivers telephonic and home-based nursing services that support physician and patient goals. Alere has 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.

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Oncology. The Alere Oncology Program is the most comprehensive, experienced and long-running cancer management program in the nation, managing 122 cancer types, covering more than eight million lives and effectively managing 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, Alere provides 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 addition, the Alere Health Portal provides employers and health plans with a powerful front door to Alere s continuum of healthcare services and the Alere Personal Health Record allows individuals to create a completely confidential on-line record of all of their personal healthcare data.

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 marijuana, cocaine, methamphetamines and opiates, 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 alike for the effective treatment of bacterial vaginosis without antibiotics.

Vitamins and Nutritional Supplements. We also market a wide variety of vitamins and nutritional supplements primarily within the United States. Most growth in this market is attributed to new products that generate attention in the marketplace. Well-established market segments, where competition is greater and media commentary less frequent, are generally stable. Slow overall growth in the industry has resulted in retailers reducing shelf space for nutritional supplements and has forced many under-performing items out of distribution, including several broad product lines. Sales growth of private label products has generally outpaced the overall industry growth, as retailers continue to add to the number of private label nutritional products on their shelves.

Our subsidiary, Inverness Medical Nutritionals Group, or IMN, is a national supplier of private label vitamins and nutritional products for major drug and food chains and also manufactures bulk vitamins, minerals, nutritional supplements and over-the-counter drug products under contract for unaffiliated brand name distributors. IMN also

manufactures an assortment of vitamin, mineral and nutritional supplement products for sale under Inverness Medical brand names.

Our Inverness Medical branded nutritional products are high-quality products sold at moderate prices through national and regional drug stores, groceries and mass merchandisers. These branded products include

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Stresstabs, a B-complex vitamin with added antioxidants; Ferro-Sequels, a time-release iron supplement; and Posture-D, a calcium supplement.

Methods of Distribution and Customers

In the United States, Canada, the United Kingdom, Germany, Italy, Spain, the Netherlands, France, Austria, India, Japan, China, Australia, South Africa, Brazil, 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. In the United States, we have distribution relationships with all of the major distributors to hospitals and reference laboratories, as well as with the major distributors serving physicians offices and other non-hospital, point-of-care settings. One of our distributors of cardiology and other professional diagnostic products, Thermo Fisher Scientific, accounted for 22% of our consolidated net revenue in 2008. Our Quality Assured Services, Inc., or QAS subsidiary facilitates the distribution of our HemoSense INRatio and INRatio2 coagulation monitors by contacting targeted customers and facilitating the Medicare reimbursement process for physicians and for patients monitoring at home. Under the terms of our acquisition of our Determine products from Abbott Laboratories in June 2005, Abbott distributes a portion of our Determine products, which are sold outside of the United States, in certain countries where we do not currently have suitable distribution capabilities. We also sell these products to Abbott as the exclusive supplier of its global Access to HIV Care program, through which Abbott provides free or low-cost testing products for HIV testing in underdeveloped countries around the world.

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.

We market and sell our First Check consumer drug testing products in the United States and Canada 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 print advertising.

We primarily market and sell our vitamins and nutritional supplements in the United States through private label arrangements with retail drug stores, groceries, mass merchandisers and warehouse clubs who sell our products under their store brands. We also sell a variety of branded products to the retail drug stores, groceries and mass merchandisers.

Manufacturing

We have major manufacturing facilities are located in Hangzhou and Shanghai, China; Matsudo, Japan; and San Diego, California. We are in the process 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 and in the United Kingdom, as well as in Israel, Australia and South Africa. All of our important manufacturing facilities are ISO certified and registered with the FDA. We manufacture substantially all of our consumable diagnostic products and nutritional 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 Biosite 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.

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We manufacture substantially all of our vitamin and nutritional products at IMN s facilities in Freehold and Irvington, New Jersey. IMN internally manufactures substantially all of its softgel requirements at the Irvington facility. Both facilities manufacture to the Good Manufacturing Practices, or GMP, standards.

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 in Bedford and Cambridge, England; Hangzhou, China; Scarborough, Maine; Hayward, California; Brisbane, Australia; and Yavne, Israel; and, to a lesser extent, at certain of our other facilities. Our research and development programs currently focus on the development of cardiology, infectious disease, oncology, HIV and women s health diagnostic products.

Our facility in Stirling, Scotland was formed in connection with a February 2005 co-development agreement with ITI Scotland Limited, or ITI, whereby ITI agreed to provide us with approximately £30.0 million over three years to partially fund research and development programs and we agreed to invest at least £37.5 million in these programs over three years. The funding arrangement with ITI, as well as our investment commitments related thereto, expired during the first quarter of 2008.

Global Operations

We are a global company. We have major manufacturing facilities in San Diego, California; Hangzhou and Shanghai, China and Matsudo, Japan and significant research and development operations in Jena, Germany and Stirling, Scotland. Our distribution network supporting our professional diagnostics business includes offices in the United States, Canada, England, France, Spain, Germany, Italy, Switzerland, Austria, Australia, New Zealand, Japan, South Africa, Israel, India, Brazil and Colombia.

Our professional diagnostic products are sold throughout the world. Our health management programs are offered almost exclusively in the United States and our vitamins and nutritional supplements are sold primarily in the United States and, to a lesser extent, in Canada. During 2008 and 2007, respectively, approximately 72% and 63% of our net revenues were generated from the United States, approximately 17% and 24% of our net revenues were generated from Europe, and approximately 11% and 13% of our net revenues were generated from customers located elsewhere. Revenues from the United States increased during 2008 due the disproportionate impact of our newly-established health management business and, in particular, our acquisition of Matria in May 2008.

Competition

Professional Diagnostics. The main competitors for our professional rapid diagnostic products are Becton Dickinson and 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 can 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, new technologies utilizing amplification techniques for analyzing molecular DNA gene sequences, from companies such as Abbott, Roche 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.

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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 handheld 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 over 75% of the domestic sales of PT/INR point-of-care and patient self-testing devices.

In oncology, our Matritech 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.

Health Management. Competition for our health management services is also intense. Other health management service providers include Health Dialog and Healthways. 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 highly-regarded technology platforms will enable us to compete effectively.

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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.

Vitamins and Nutritional Supplements. The market for private label vitamins and nutritional supplements is extremely price sensitive, with quality, customer service and marketing support also being important. Many of the companies that mass market branded vitamins and nutritionals, including U.S. Nutrition and Pharmavite, also sell to private label customers and constitute our major competitors for private label business. In addition, there are several companies, such as Perrigo Company, that compete only in the private label business.

In the branded nutritional supplements industry, competition is based upon brand name recognition, price, quality, customer service and marketing support. There are many companies, both small and large, selling vitamin products to retailers. A number of these companies, particularly manufacturers of nationally advertised brand name products, are substantially larger than we are and have greater financial resources. Among the major competitors of our branded products that are sold through groceries and other mass retailers are U.S. Nutrition, Wyeth, Pharmavite and GlaxoSmithKline.

Patents and Proprietary Technology; Trademarks

We have built a strong intellectual property portfolio in the area of lateral flow immunoassays, the technology which underlies many rapid diagnostic test formats, including most one-step home pregnancy and fertility/ovulation tests and most of our rapid membrane products for the point-of-care marketplaces that we serve. We believe that our intellectual property rights in the major patent families in this area of technology give us a distinct advantage and underpin our continuing success in this area. In addition, our intellectual property portfolio also includes an increasing number of other patents, patent applications and licensed patents protecting our vision of the technologies and products 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 prevalent in the health management industry. For more information regarding these pending matters see Item 3 entitled Legal Proceedings beginning on page 30.

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

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

The medical products industry, including the diagnostic testing industry, and the health management industry place considerable importance on obtaining and enforcing patent and trade secret protection for new technologies, products, services and processes. Trademark protection is an important factor in the success of certain of our product lines and health management programs. Our success therefore depends, in part, on our abilities to obtain and enforce the patents and trademark registrations necessary to protect our products, to preserve our trade secrets and to avoid or neutralize threats to our proprietary rights from third parties. We

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cannot, however, guarantee our success in enforcing or maintaining our patent rights; in obtaining future patents or licensed patents in a timely manner or at all; or as to the breadth or degree of protection that our patents or trademark registrations or other intellectual property rights might afford us. For more information regarding the risks associated with our reliance on intellectual property rights see the risk factors discussed in Item 1A. entitled Risk Factors on pages 13 through 29 of this report.

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 manufacturing, processing, formulation, packaging, labeling and advertising of our nutritional supplements are subject to regulation by one or more federal agencies, including the FDA, the Drug Enforcement Administration, the FTC and the Consumer Product Safety Commission. These activities are also regulated by various agencies of the states, localities and foreign countries in which our nutritional supplements are now sold or may be sold in the future. In particular, the FDA regulates the safety, manufacturing, labeling and distribution of dietary supplements, including vitamins, minerals and herbs, as well as food additives, over-the-counter and prescription drugs and cosmetics. The GMP standards promulgated by the FDA are different for nutritional supplement, drug and device products. In addition, the FTC has jurisdiction along with the FDA to regulate the promotion and advertising of dietary supplements, over-the-counter drugs, cosmetics and foods.

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. In the future, multiple state licensing requirements for healthcare professionals who provide services telephonically over state lines may require us to license some 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 heath agencies. In addition, our health management business is subject to the security regulations of the Health Insurance Portability and Accountability Act (HIPAA). We may also be required to obtain certification to participate in governmental payment programs, such as 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, 2009, we had approximately 8,300 employees, including temporary and contract employees, of which approximately 5,900 employees are located in the United States. In addition, we utilize

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

ITEM 1A. RISK FACTORS

The risks described below may materially impact your investment in our company or may in the future, and, in some cases already do, materially affect us and our business, financial condition and results of operations. You should carefully consider these factors with respect to your investment in our securities. This section includes or refers to certain forward-looking statements; you should read the explanation of the qualifications and limitations on such forward-looking statements beginning on pages 2 and 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 current 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 or interest rate. 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, 2008, in addition to other indebtedness, we had approximately $1.1 billion in aggregate principal amount of indebtedness outstanding under our senior secured credit facility, or the senior secured facility, $250.0 million in aggregate principal amount of indebtedness outstanding under our junior secured credit facility, or the junior secured facility (collectively with the senior secured facility, the secured credit facilities), and $150.0 million in indebtedness under our outstanding 3% senior subordinated convertible notes, or the senior subordinated convertible notes. The term loan under the senior secured facility bears interest at a rate per annum of LIBOR plus 2.00%, while the revolving line-of-credit under the senior secured facility, which provides up to $150.0 million of borrowing availability, is expected to bear interest at a rate per annum of LIBOR plus between 1.75% and 2.25%, depending on our consolidated leverage ratio. The junior secured facility bears interest at a rate per annum of LIBOR plus 4.25%. Our ability to incur additional indebtedness is subject to restrictions under our secured credit facilities and the 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 the 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;

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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

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 the senior subordinated convertible notes, our secured credit facilities and our other debt from cash flow from our operations and potentially from other debt or equity offerings. Accordingly, our ability to meet our expenses 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, including the notes, 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, including the credit agreements governing our secured credit facilities and the indenture governing the senior subordinated convertible notes, may restrict us from adopting any of these alternatives.

We have entered into agreements governing our indebtedness that 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 indenture governing the 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 indebtedness;

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

acquire other businesses;

make investments;

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

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 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 these 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 covenants with which we must comply on an on-going or periodic basis. These include covenants pertaining to capital expenditures, interest coverage ratios, leverage ratios and minimum cash requirements. If we violate any of

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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 facilities, including the interest rates, financial and restrictive covenants and security requirements of the 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 indenture governing the 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 fundamental change, as defined in the indenture governing the senior subordinated convertible notes, each holder of our senior subordinated convertible notes will have the right to require us to purchase the notes at a price equal to 100% of the principal amount, together with any accrued and unpaid interest. A fundamental change includes, among other things, the acquisition of more than 50% of our common stock by any person or group, the sale of all or substantially all of the our assets or a recapitalization or similar transaction involving us. Our failure to purchase, or give notice of purchase of, the senior subordinated convertible notes would be a default under the indenture, which would in turn be a default under our secured credit facilities. In addition, the occurrence of a change of control, as defined in the credit agreements governing our secured credit facilities, will constitute an event of default under the secured credit facilities. A default under our secured credit facilities would result in an event of default under our senior subordinated convertible notes and, if the lenders accelerate the debt under our secured credit facilities and/or under the indenture governing the senior subordinated convertible notes, this may result in the acceleration of our other indebtedness outstanding at the time. As a result, if we do not have enough cash to repay all of our indebtedness or to repurchase all of the senior subordinated convertible notes, we may be limited in the fundamental change or change of control transactions that we may pursue.

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 2006, we have acquired and integrated, or are in the process of integrating the rapid diagnostics business that we acquired from ACON Laboratories, Inc., or the Innovacon business; Instant Technologies, Inc., or Instant; Biosite Incorporated, or Biosite; Cholestech Corporation, or Cholestech; HemoSense, Inc., or HemoSense; Alere Medical; Redwood; ParadigmHealth; Panbio Limited, or Panbio; BBI Holdings Plc, or BBI; and Matria. We have also made a number of smaller acquisitions. The ultimate success of all of these acquisitions depends, in part, on our ability to realize the anticipated synergies, cost savings and growth opportunities from integrating these businesses or assets into our existing businesses. However, the successful integration of independent businesses or assets is a complex, costly and time-consuming process. The difficulties of integrating companies and acquired assets include, among others,:

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

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

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

establishing or expanding manufacturing, sales, distribution and marketing functions in order to accommodate newly-acquired businesses or product lines or rationalizing these functions to take advantage of synergies;

preserving the important licensing, research and development, manufacturing and supply, distribution, marketing, customer and other relationships;

minimizing the diversion of management s attention from on-going business concerns; and

coordinating geographically separate organizations.

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 on-going 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;

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

unanticipated costs.

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

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

use of significant amounts of cash;

the incurrence of debt;

the assumption of significant liabilities, including litigation;

unfavorable financing terms;

large one-time expenses; and

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

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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:

- difficulties in integrating our corporate culture and business objectives with that of P&G into the joint venture;
- difficulties or delays in transitioning clinical studies;
- diversion of our management s time and attention from other business concerns;
- higher than anticipated costs of integration at the joint venture;
- 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.

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.

We may experience manufacturing problems or delays, which could result in decreased revenue or increased costs.

Many of our manufacturing processes are complex and require specialized and expensive equipment. Replacement parts for our specialized equipment can be expensive and, in some cases, can require lead times of up to a year to acquire. In addition, our private label consumer diagnostics business, and our private label and bulk nutritional supplements business in particular, rely 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 addition, during 2008, we began the process of closing the manufacturing operations that we acquired with Cholestech and shifting the production of products from these facilities to our San Diego campus. We also began the process of closing our manufacturing facility in Bedford, England, and shifting the production of units manufactured there to China and to other lower-cost facilities. We have previously shifted the production of other products to our manufacturing facilities in China. 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. Any event which negatively impacts our manufacturing facilities, our manufacturing systems or equipment, or our contract manufacturers or suppliers, including, among others,

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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 it is able to restore its production processes or 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.

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

Before we can sell our products, we must conduct clinical studies intended to demonstrate that our potential products perform as expected. The results of these clinical studies are used as the basis to obtain regulatory approval from government authorities such as the 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, our 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.

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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 approval. 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 PMA s. 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.

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 on-going regulation 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 Quality System Requirement and Medical Device Reporting requirements in the United States and other applicable regulations worldwide, including but not limited to ISO regulations. 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

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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.

New federal or state laws may be enacted, or regulatory agencies may also impose new or enhanced standards that would increase our costs as well as the risks associated with non-compliance. For example, our manufacturing facilities for nutritional supplements will be subject to new GMP standards starting mid-2009. While our manufacturing facilities for nutritional supplements have been subjected to, and passed, third-party inspections against GMP standards, the on-going compliance required in order to meet GMP standards could involve additional costs and could present new risks associated with any failure to comply with the regulations in the future. In addition, the federal government recently enacted the Genetic Information Non-discrimination Act of 2008 (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.

In recent years, there have been numerous 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 have ranged 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 has reduced or significantly altered 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. 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. 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 and vitamins and nutritional supplements may cause us to be subjected to various product liability claims, including, among others, claims that inaccurate monitoring results lead to injury or death or that the vitamins and nutritional supplements have inadequate warnings concerning side effects and interactions with other substances. 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.

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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 natriuretic 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 in 2009 and future periods to be lower than the growth rates experienced over the past several years. 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, which will adversely impact our product sales, gross margins and our overall financial results.

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

The health management services provided by Alere and QAS 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.

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.

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 collectibility of uninsured accounts and patient due accounts and/or reduce total health plan populations.

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

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

Additionally, 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.

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 significant 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 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 nongovernmental 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.

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Our sales of branded nutritional supplements have been trending downward since 1998 due to the maturity of the market segments they serve and the age of that product line, and we may experience further declines in sales and/or profitability of those products.

Our aggregate sales of all of our brand name nutritional products, including, among others, Ferro-Sequels, Stresstabs, Protegra, Posture, SoyCare, ALLBEE and Z-BEC, have declined each year since 1998 through the year 2008, except in 2002 when they increased slightly as compared to 2001. We believe that these products have under-performed because they are, for the most part, aging brands with limited brand recognition that face increasing private label competition. The overall age of this product line means that we are subject to future distribution loss for under-performing brands, while its opportunities for new distribution on the existing product lines are limited. As a result, we do not expect significant sales growth of our existing brand name nutritional products, and we may experience further declines in overall sales of our brand name nutritional products in the future.

Our sales of specific vitamins and nutritional supplements could be negatively affected by media attention or other news developments that challenge the safety and effectiveness of those specific vitamins and nutritional supplements.

Most growth in the vitamin and nutritional supplement industry is attributed to new products that tend to generate greater attention in the marketplace than do older products. Positive media attention resulting from new scientific studies or announcements can spur rapid growth in individual segments of the market, and also affect individual brands. Conversely, news that challenges individual segments or products can have a negative impact on the industry overall, as well as on sales of the challenged segments or products. Most of our vitamin and nutritional supplement products serve well-established market segments and, absent unforeseen new developments or trends, are not expected to benefit from rapid growth. A few of our vitamin and nutritional supplement products are newer products that are more likely to be the subject of new scientific studies or announcements, which could be either positive or negative. News or other developments that challenge the safety or effectiveness of these products could negatively affect the profitability of our vitamin and nutritional supplements business.

Because sales of our private label nutritional supplements are generally made at low margins, the profitability of these products may suffer significantly as a result of relatively small increases in raw material or other manufacturing costs.

Sales of our private label nutritional supplements, which for the years ended December 31, 2008 and 2007 provided approximately 6% and 7%, respectively, of our net product sales, generate low profit margins. We rely on our ability to efficiently mass produce nutritional supplements in order to make meaningful profits from these products. Changes in raw material or other manufacturing costs can drastically cut into or eliminate the profits generated from the sale of a particular product. For the most part, we do not have long-term supply contracts for our required raw materials and, as a result, our costs can increase with little notice. The private label nutritional supplements business is also highly competitive, such that our ability to raise prices as a result of increased costs is limited. Customers generally purchase private label products via purchase order, not through long-term contracts, and they often purchase these products from the lowest bidder on a product by product basis. The internet has enhanced price competition among private label manufacturers through the advent of on-line auctions, where customers will auction off the right to manufacture a particular product to the lowest bidder.

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,

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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 four 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, approximately 28% 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;

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.

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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.

The market for the sale of vitamins and nutritional supplements is also highly competitive. This competition is based principally upon price, quality of products, customer service and marketing support. There are numerous companies in the vitamins and nutritional supplements industry selling products to retailers, such as mass merchandisers, drug store chains, independent drug stores, supermarkets, groceries and health food stores. As most of these companies are privately-held, we are unable to obtain the information necessary to assess precisely the size and success of these competitors. However, we believe that a number of our competitors, particularly manufacturers of nationally-advertised brand name products, are substantially larger than we are and have greater financial resources.

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

We are involved in various legal proceedings arising out of our businesses, including those matters discussed in Item 3 entitled Legal Proceedings beginning on page 30. Because of the nature of our business, we may be subject at any particular time to commercial disputes, product liability claims, negligence claims or various other lawsuits arising in the ordinary course of our business, including infringement, employment or investor matters, and we expect that this will continue to be the case in the future. Such lawsuits generally seek damages, sometimes in substantial amounts, for commercial or personal injuries allegedly suffered and can include claims for punitive or other special damages. An adverse ruling or rulings in one or more such lawsuits could, individually or in the aggregate, have a material adverse effect on our sales, operations or financial performance. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties. These suits can be expensive and result in counterclaims challenging the validity of our patents and other rights. We cannot assure you that these lawsuits or any future lawsuits relating to our businesses 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.

The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

- the 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;
- the claims of any patents which are issued may not provide meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;
- the 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; and

other companies may design around technologies we have patented, licensed or developed.

In addition to patents, we rely on a combination of trade secrets, non-disclosure agreements and other contractual provisions and technical measures to protect our intellectual property rights. Nevertheless, these measures may not be adequate to safeguard the technology underlying our products. If these measures do not

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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, our stock price could decline.

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

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

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

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

- the timing of new product announcements and introductions by us and our competitors;
- market acceptance of new or enhanced versions of our products;
- the extent to which our current and future products rely on rights belonging to third parties;
- changes in manufacturing costs or other expenses;
- competitive pricing pressures;
- changes in healthcare reimbursement policies and amounts;
- 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 2006 include our acquisitions of the Innovacon business in March 2006, Instant in March 2007, Biosite in June 2007, Cholestech in September 2007 and Matria in May 2008. 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.

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 1.9 million shares of Series B Preferred Stock outstanding as of December 31, 2008 could convert into 5.7703 shares of our common stock, or approximately 10.8 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

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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 3,410,641 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 $751.5 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 50% 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 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;

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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 housed in approximately 22,600 square feet of leased space located at 51 Sawyer Road, Waltham, Massachusetts. Our lease of this facility expires on May 31, 2013.

Our largest Alere health management business office is currently located in Marietta, Georgia in 77,705 square feet of leased office space, which currently expires on February 28, 2010. A new lease was recently signed in anticipation of consolidating the current Marietta office and an Atlanta area call center into one facility located in Atlanta, Georgia and comprising approximately 107,790 square feet. The move into the new space may occur as early as the second quarter of 2009, and the lease will expire in 2020.

We also own approximately 26.1 acres of land in San Diego, California which houses our Biosite operation, including significant administrative, research and manufacturing operations for certain professional diagnostics. Our buildings on this property currently consist of approximately 110,000 square feet of office space, 53,000 square feet of laboratory space and 167,000 square feet of manufacturing space.

During the second quarter of 2008, we commenced operations of a shared services center in Orlando, Florida and moved certain back-office and sales operations from seven of our U.S. companies to this center. Our lease of this facility, which is approximately 57,300 square feet, expires on January 31, 2013.

Our European operations are currently administered from a 130,000 square foot facility located in Bedford, England. We also manufacture products for consumer and professional diagnostics businesses and conduct research and development activity at the Bedford facility, although we are in the process of closing the Bedford manufacturing operations, which would move to our low cost production facilities mainly in China.

Our other primary manufacturing operations are in Hangzhou and Shanghai, China and Matsudo, Japan. We currently manufacture a portion of our consumer and professional diagnostics out of a newly-constructed manufacturing facility of approximately 300,000 square feet in Hangzhou, China, which we own. We currently manufacture the remainder of our consumer diagnostics out of approximately 54,000 square feet of space in Shanghai, China made available by our joint venture partner. Our Determine products are currently manufactured by us in Matsudo, Japan in 19,000 square feet of space rented from Abbott Laboratories and we are currently in the process of transferring those operations to a new leased facility, also in Matsudo, providing approximately 35,000 square feet of floor space.

We also have important manufacturing operations in Scarborough, Maine, and Freehold and Irvington, New Jersey. We manufacture certain of our professional diagnostics out of a 64,000 square foot facility that we lease in Scarborough, Maine. These facilities also include significant administrative and laboratory space. We also own a 160,000 square foot manufacturing facility in Freehold, New Jersey and lease a 35,000 square foot facility in Irvington, New Jersey. These New Jersey facilities manufacture our vitamin and nutritional supplement products.

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We also have leases or other arrangements for smaller manufacturing facilities, as well as administrative or sales offices, call centers, laboratory space and warehouses in various locations worldwide.

ITEM 3. LEGAL PROCEEDINGS

Estate of Melissa Prince Quisenberry v. Alere Medical, Inc., TA Associates, Inc., Covington Associates, et al.

On September 19, 2008, the Estate of Melissa Prince Quisenberry filed a class action complaint in the Superior Court of California on behalf of herself and others similarly situated against Alere Medical Inc., or Alere Medical, and Agora Parent, Inc., both of which are wholly-owned subsidiaries; Ronald D. Geraty, MD, chief executive officer of Alere Medical and certain other individuals who were executive officers, directors and/or significant shareholders of Alere Medical; as well as certain other unaffiliated entities. Plaintiff and class owned common and/or preferred stock in Alere Medical and allege that the defendants forced them to tender their stock in connection with the March 14, 2007 sale of Alere Medical to an unaffiliated entity at a price which was substantially lower than the price at which we bought Alere Medical in November 2007. Plaintiff also alleges that the individual defendants breached fiduciary duties of good faith, fair dealing, loyalty and candor; and that Alere Medical and certain unaffiliated entities aided, abetted and substantially participated in the breach of fiduciary duty. We believe that we have strong defenses to all of the allegations made by the class and we intend to defend the claims vigorously. However, an outcome against Alere Medical could potentially have a material adverse impact on our sales, operations or financial performance.

Healthways, Inc. and Robert Bosch North America Corp. v. Alere Medical, 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. 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, as we have previously reported, in April 2008, Pyramid Holdings Inc., a purchaser in our November 2007 public offering of our common stock, filed a putative securities class action against us, Ron Zwanziger, our chairman, chief executive officer and president, and David Teitel, our chief financial officer, in the United States District Court for the District of Massachusetts, alleging that the prospectus supplement and registration statement with respect to the November 2007 public offering were inaccurate and misleading and omitted to state material facts. The plaintiffs have subsequently filed their amended class action complaint, adding as defendants each of our then current directors, a former director, and a former chief financial officer. We believe that the allegations are baseless, and we intend to defend against them vigorously.

Also, 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.

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While we believe that we have strong defenses to the claims brought by Pyramid Holdings and Health Hero 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.

Finally, we were recently notified by the SEC that its 2005 formal order of investigation in connection with the previously disclosed revenue recognition matter at one of our diagnostic divisions has been completed and that the SEC does not intend to recommend any enforcement actions against us.

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

None.

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PART II

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

UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On October 31, 2008, we issued a total of 53,372 shares of common stock, as contingent consideration in connection with our July 2007 acquisition of Spectral Diagnostics Private Limited and Source Diagnostics (India) Private Limited, pursuant to an exemption afforded by Section 4(2) of the Securities Act of 1933, as amended.

On November 20, 2008, we issued approximately 112,158 shares of common stock as contingent consideration payable under the share purchase agreement governing our acquisition of Clondiag GmbH in February 2006 as a result of Clondiag achieving certain development milestones. We relied on the exemption from registration provided by Regulation S under the Securities Act.

Market Information

In January 2009, our common stock began trading on the New York Stock Exchange (NYSE) under the symbol IMA. Prior to that, our common stock traded on the American Stock Exchange (AMEX) under the symbol IMA. The following table sets forth the high and low sales prices of our common stock on AMEX for each quarter during fiscal 2008 and 2007.

	High	Low
Fiscal 2008		
Fourth Quarter	$ 30.52	$ 12.33
Third Quarter	$ 36.42	$ 28.10
Second Quarter	$ 38.71	$ 30.00
First Quarter	$ 62.65	$ 26.29
Fiscal 2007		
Fourth Quarter	$ 65.00	$ 52.38
Third Quarter	$ 55.79	$ 44.17
Second Quarter	$ 53.85	$ 38.00
First Quarter	$ 44.72	$ 36.90

On February 25, 2009, there were 2,325 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 indenture governing the terms of the senior subordinated convertible notes currently prohibit the payment of cash or stock dividends.

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Stock Performance Graph

The following line graph compares the change in the cumulative total stockholder return on our common stock from December 31, 2003 through December 31, 2008. This graph assumes an investment of $100.00 on December 31, 2003 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, 2003 and the last trading day of each subsequent year end through December 31, 2008.

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

Current Indices

Date	IMA	NYSE Composite Index	Dow Jones U.S. Healthcare Index
12/31/03	$ 100.00	$ 100.00	$ 100.00
12/31/04	$ 115.24	$ 112.16	$ 103.53
12/30/05	$ 108.86	$ 119.96	$ 110.64
12/29/06	$ 177.69	$ 141.38	$ 116.39
12/31/07	$ 257.94	$ 150.69	$ 124.03
12/31/08	$ 86.82	$ 89.06	$ 94.23

In prior years, we compared our cumulative total stockholder return to the AMEX U.S. Total Return Index and the AMEX Health Products & Services Total Return Index (the Old Indices). However, we have been informed that, following the acquisition of AMEX by the NYSE in October 2008, the Old Indices are no longer available. In addition, in January 2009, we transferred the listing of our common stock from AMEX to the NYSE. Accordingly, as a result of these events, this year we compared, for the first time, our cumulative total stockholder return to the Current Indices, which we believe will provide a more meaningful comparison of stock performance going forward. Because the Old Indices are no longer available, we cannot also provide a concurrent comparison to such indices.

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.

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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, 2008 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, 2008, 2007 and 2006, and as of December 31, 2008 and 2007, 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, 2005 and 2004, and as of December 31, 2006, 2005 and 2004, have been derived from our consolidated financial statements not included herein, which were audited by BDO Seidman, LLP.

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.

	For the Year Ended December 31,				
	2008	2007	2006	2005	2004
	(in thousands, except per share data)				
Statement of Operations Data:					
Net product sales	$ 1,240,138	$ 800,915	$ 552,130	$ 406,457	$ 365,432
Services revenue	405,462	16,646			
Net product sales and services revenue	1,645,600	817,561	552,130	406,457	365,432
License and royalty revenue	25,826	21,979	17,324	15,393	8,559
Net revenue	1,671,426	839,540	569,454	421,850	373,991
Cost of net product sales	624,654	431,403	334,799	264,999	223,669
Cost of services revenue	177,098	5,261			
Cost of license and royalty revenue	9,115	9,149	5,432	4,539	3,318
Cost of net revenue	810,867	445,813	340,231	269,538	226,987
Gross profit	860,559	393,727	229,223	152,312	147,004
Operating expenses:					
Research and development	111,828	69,547	48,706	30,992	31,954
Purchase of in-process research and development		173,825	4,960		
Sales and marketing	386,284	167,770	94,445	72,103	57,957
General and administrative	298,595	158,438	71,243	59,990	52,707
Loss on dispositions, net			3,498		

Operating income (loss)	63,852	(175,853)	6,371	(10,773)	4,386
Interest expense and other expenses, net, including amortization of original issue discounts and write-off of deferred financing costs	(103,356)	(74,251)	(17,822)	(1,617)	(18,707)
Loss before (benefit) provision for income taxes	(39,504)	(250,104)	(11,451)	(12,390)	(14,321)
(Benefit) provision for income taxes	(16,686)	(979)	5,727	6,819	2,275
Equity earnings of unconsolidated entities, net of tax	1,050	4,372	336		
Net loss	(21,768)	(244,753)	(16,842)	(19,209)	(16,596)
Preferred stock dividends	(13,989)				

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	For the Year Ended December 31,				
	2008	2007	2006	2005	2004
	(in thousands, except per share data)				
Net loss available to common stockholders(1)	$ (35,757)	$ (244,753)	$ (16,842)	$ (19,209)	$ (17,345)
Net loss per common share basic and diluted(1)	$ (0.46)	$ (4.75)	$ (0.49)	$ (0.79)	$ (0.87)

	December 31,				
	2008	2007	2006	2005	2004
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$ 141,324	$ 414,732	$ 71,104	$ 34,270	$ 16,756
Working capital	$ 457,198	$ 674,066	$ 133,313	$ 84,523	$ 62,615
Total assets	$ 5,955,360	$ 4,880,759	$ 1,085,771	$ 791,166	$ 568,269
Total debt	$ 1,520,534	$ 1,387,849	$ 202,976	$ 262,504	$ 191,224
Total stockholders equity	$ 3,278,838	$ 2,586,667	$ 714,138	$ 397,308	$ 271,416

(1) Net loss available to common stockholders and basic and diluted net loss per common share are computed as described in Notes 2(n) and 15 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

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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 in certain of our product categories, research and development expenditures, the impact of our research and development activities, potential new product and technology achievements, the impact of our worldwide distribution network, our ability to improve our margins through consolidation of certain of our higher cost manufacturing operations into lower cost facilities, our ability to achieve further synergies within expected timelines, our expectations with respect to our SPD joint venture with P&G, the growth prospects of the health management market, our ability to improve care and lower healthcare costs for both providers and patients, and our funding plans for our future working capital needs and commitments. Actual results or developments could differ materially from those projected in such statements as a result of numerous factors, including, without limitation, those risks and uncertainties set forth in Item 1A entitled Risk Factors, which begins on page 13 of this report, as well as those factors identified from time to time in our periodic filings with the Securities and Exchange Commission. We do not undertake any obligation to update any forward-looking statements. This report and, in particular, the following discussion and analysis of our financial condition and results of operations, should be read in light of those risks and uncertainties and in conjunction with our accompanying consolidated financial statements and notes thereto.

Overview

We enable individuals to take charge of improving their health and quality of life at home by developing new capabilities in near patient diagnosis, monitoring and health management. Our global leading products and services, as well as our new product development efforts, focus on cardiology, women s health, infectious disease, oncology, and drugs of abuse. With our 2007 acquisitions of Biosite, Cholestech, and HemoSense, we established our company as a leading supplier of cardiology diagnostic products. Our acquisitions of Biosite, Instant and Redwood during 2007 and Ameditech, Inc., or Ameditech, in 2008 enhanced our position in drugs of abuse testing. Additionally, with our December 2007 acquisition of Matritech, Inc., or Matritech, we also established a presence in oncology, by acquiring the unique NMP-22 ELISA and rapid point-of-care tests for the screening and monitoring of bladder cancer in conjunction with standard diagnostic procedures. We expect to continue to expand in all of these product categories through focused research and development projects and further development of our distribution capabilities.

During 2007 and 2008, we entered the growing health management market with our acquisitions of Alere Medical, ParadigmHealth and more recently, Matria. With the acquisition of Matria, we are now a leader in this field offering a broad range of services aimed at lowering costs for health plans, hospitals, employers and patients. Our health management services are focused in the areas of women s and children s health, cardiology and oncology. We are confident that our ability to offer near patient monitoring tools combined with value-added healthcare services will improve care and lower healthcare costs for both providers and patients. During the third quarter of 2008, we began efforts to consolidate the health management businesses under a single brand. Today, Matria, ParadigmHealth and Alere Medical, each a leader in their respective areas, are united as one business under the name Alere. Also, during the third quarter of 2008, we acquired an overseas health management business enabling us to establish a presence in

the newly-developing international health management market.

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Our research and development programs have two general focuses. We are developing new technology platforms that will facilitate our primary objective of enabling individuals to take charge of improving their health and quality of life 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.

We continue to advance toward our goal of establishing a worldwide distribution network that will allow us to bring both our current and future diagnostic products to the global professional market. In addition, we continue to focus on improving our margins through consolidation of certain of our higher cost manufacturing operations into lower cost facilities, including our 300,000 square foot manufacturing facility located in Hangzhou, China, as well as our jointly-owned facility in Shanghai, China, and we are already seeing improved margins on some of our existing products that we have moved to these facilities. Our business integration activities remain on track and we have seen positive results from the integrations completed to date and as we continue to aggressively integrate acquired operations in order to achieve further synergies within expected timelines. During the second half of 2007, we began implementation of a plan to consolidate sales processing and certain other back-office services from seven of our U.S. operations into a shared services center, located in Orlando, Florida. This shared services center commenced operations at the beginning of the second quarter of 2008.

2008 Financial Highlights

Net revenue in 2008 of $1.7 billion increased by $831.9 million, or 99%, from $839.5 million in 2007. Net revenue increased primarily as a result of our professional diagnostics-related acquisitions which contributed $397.8 million of the increase. Additionally, net revenue increased as a result of our newly-formed health management segment which provided $357.6 million of incremental revenue and primarily included the activities of our recent acquisitions of QAS, Alere Medical, ParadigmHealth and Matria. Partially offsetting the increased revenue as a result of acquisitions was the decrease in revenue associated with the completion of our 50/50 joint venture (SPD) with P&G in May 2007 in which 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 in accordance with Accounting Principles Board (APB) Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock.* Organic growth, particularly from our professional cardiology, infectious disease and drugs of abuse products, also contributed to the revenue growth, as well as higher license and royalty revenue.

Gross profit increased by $466.8 million, or 119%, to $860.6 million in 2008 from $393.7 million in 2007, principally as a result of gross profit earned on incremental revenue from acquired businesses, primarily in our professional diagnostics and health management businesses, as well as increased license and royalty revenue. Offsetting these increases was a decrease in our consumer diagnostics business gross margin, principally as a result of the formation of our 50/50 joint venture with P&G in May 2007. During 2008, gross profit was adversely impacted by a $17.9 million restructuring charge related to the closure of various manufacturing and operating facilities and a charge of $2.0 million associated with the write-up of inventory acquired to fair value in connection with two of our 2008 acquisitions. Gross profit in 2007 was adversely impacted by a $2.0 million charge associated with our various restructuring plans and a charge of $8.2 million associated with the write-up of inventory acquired to fair value in connection with three of our 2007 acquisitions.

We continue to invest aggressively in research and development of new products and technologies as evidenced by our increased research and development expense of $111.8 million in 2008, from $69.5 million in 2007. Expenditures in 2007 are reported net of $18.5 million arising from the co-development funding arrangement that we entered into with ITI, in February 2005. Research and development expense before considering the co-development funding was

$88.0 million in 2007. The increase in spending resulted principally from expenditures related to our cardiology research programs. Offsetting these increases was the

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favorable impact of the 50/50 joint venture with P&G. Our co-development funding arrangement with ITI expired in the first quarter of 2008. The final payment under this agreement was received and earned in the fourth quarter of 2007, and as such, no funding was earned in 2008.

Results of Operations

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

Net Product Sales. Net product sales increased by $439.2 million, or 55%, to $1.2 billion in 2008 from $800.9 million in 2007. Excluding the unfavorable impact of currency translation, net product sales in 2008 grew by approximately $439.5 million, or 55%, over 2007. Of the currency adjusted increase, revenue increased primarily as a result of our professional diagnostic-related acquisitions which contributed $363.8 million of the increase. Organic growth, particularly from our professional infectious disease, drugs of abuse products and vitamin and nutritional supplements, also contributed to the growth.

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

	2008	2007	% Increase (decrease)
Professional diagnostics	$ 1,000,190	$ 565,265	77%
Health management	18,632	9,210	102%
Consumer diagnostics	132,443	153,616	(14)%
Vitamins and nutritional supplements	88,873	72,824	22%
Net product sales	$ 1,240,138	$ 800,915	55%

Professional Diagnostics

The increase in net product sales from our professional diagnostics business segment was $434.9 million, or 77%, resulting in $1.0 billion of net product sales in 2008. Of the increase, revenue increased primarily as a result of our acquisitions of: (i) Biosite, in June 2007, which contributed additional product 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 product 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 product 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 product 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 product revenue of $23.9 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, particularly from our professional infectious disease products, also contributed to the growth. The currency adjusted organic growth for our professional diagnostics net product sales, excluding the impact of acquisitions, was 13%.

Health Management

Our health management net product sales increased $9.4 million, or 102%, to $18.6 million in 2008. The increase in net product sales represents additional sales related to our acquisition of QAS in June 2007.

Consumer Diagnostics

The decrease in net product sales from our consumer diagnostics business segment was $21.2 million, or 14%, resulting in $132.4 million of net product sales for 2008. The decrease was primarily driven by the completion of our 50/50 joint venture with P&G in May 2007 in which we transferred substantially all of the assets of our consumer diagnostics business, other than our manufacturing and core intellectual property

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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 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 attributed to our acquisitions of: (i) First Check Diagnostics LLC, or First Check, in January 2007, which contributed additional product 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 product 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 product revenue of $7.8 million.

Vitamins and Nutritional Supplements

Our vitamins and nutritional supplements net product sales increased by $16.0 million, or 22%, to $88.9 million in 2008. The increase is primarily a result of increased private label nutritional sales to our existing and new customers.

Services Revenue. Services revenue was $405.5 million in 2008, as compared to $16.6 million in 2007. Services revenue is principally related to our newly-formed health management business segment which primarily includes our recent acquisitions of QAS, Alere Medical, ParadigmHealth and Matria. In addition to the services revenue generated by our health management businesses, services revenue also includes revenue generated by our professional drugs of abuse testing and screening business, along with revenue associated with our long-term services agreement related to our consumer diagnostics joint venture formed with P&G in May 2007, pursuant to which we provide certain operational support services to the joint venture.

Services Revenue by Business Segment. Services revenue by business segment for 2008 and 2007 are as follows (in thousands):

	2008	2007
Professional diagnostics	$ 29,338	$
Health management	373,767	14,164
Consumer diagnostics	2,357	2,482
Total services revenue	$ 405,462	$ 16,646

Professional Diagnostics

Services revenue provided by our professional diagnostics business segment of $29.3 million in 2008 represents revenue related to the laboratory-based professional drugs of abuse testing and screening business at Redwood, which was acquired in December 2007.

Health Management

Services revenue provided by our newly-formed health management business segment was $373.8 million in 2008, with Matria contributing services revenue of $197.7 million, Alere Medical contributing services revenue of $91.2 million, ParadigmHealth contributing services revenue of $71.3 million and QAS contributing services revenue

of $12.1 million.

Consumer Diagnostics

Services revenue provided by our consumer diagnostics business segment decreased by $0.1 million, or 5%, to $2.4 million in 2008. Services revenue provided by our consumer diagnostics business segment represents revenue related to our long-term services agreements with our 50/50 joint venture with P&G formed in May 2007, pursuant to which we provide certain operational support services to the joint venture.

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

	2008	2007	% Increase (decrease)
United States	$ 1,186,583	$ 511,941	132%
Europe	283,552	196,379	44%
Other	175,465	109,241	61%
Net product sales and services revenue	$ 1,645,600	$ 817,561	101%

Net product sales and services revenue of $1.2 billion and $511.9 million generated in the United States were approximately 72% and 63%, 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 119%, to $860.6 million in 2008, from $393.7 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 52% in 2008, compared to 47% in 2007.

Gross Profit from Net Product Sales by Business Segment. Gross profit from net product sales represents total gross profit less gross profit associated with services revenue and license and royalty revenue. Gross profit from net product sales increased by $246.0 million to $615.5 million in 2008, from $369.5 million in 2007. Gross profit from net product sales by business segment for 2008 and 2007 is as follows (in thousands):

			% Increase

	2008	2007	(decrease)
Professional diagnostics	$ 581,806	$ 306,710	90%
Health management	2,729	3,076	(11)%
Consumer diagnostics	23,413	52,760	(56)%
Vitamins and nutritional supplements	7,536	6,966	8%
Gross profit from net product sales	$ 615,484	$ 369,512	67%

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Professional Diagnostics

Gross profit from our professional diagnostics net product sales increased by $275.1 million, or 90%, 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, 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 decreased by $0.3 million, or 11%, to $2.7 million during 2008, compared to $3.1 million during 2007.

As a percentage of our health management net product sales, gross profit from our health management business was 15% in 2008, compared to 33% in 2007.

Consumer Diagnostics

Gross profit from our consumer diagnostics net product sales decreased $29.3 million, or 56%, 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 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, gross profit from our consumer diagnostics business was 18% for 2008, compared to 34% 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 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.

Vitamins and Nutritional Supplements

Gross profit from our vitamins and nutritional supplements net product sales increased $0.6 million, or 8%, comparing 2008 to 2007. The increase is primarily the result of higher private label sales.

As a percentage of our vitamin and nutritional supplements net product sales, gross profit from our vitamins and nutritional supplements business was 9% in 2008, compared to 10% in 2007.

Gross Profit from Services Revenue. Gross profit from services revenue primarily represents gross profit related to our newly-formed health management business segment which includes our recent acquisitions of QAS, Alere Medical, ParadigmHealth and Matria. In addition to the gross profit from services revenue generated by our health management businesses, gross profit from services revenue also includes gross profit generated by our professional drugs of abuse testing and screening business, along with gross profit associated with our long-term services

agreement related to our consumer diagnostics joint venture formed with P&G in May 2007, pursuant to which we provide certain operational support services to the joint venture. Our gross profit from services revenue was $228.4 million in 2008 as compared to $11.4 million in 2007.

Gross Profit from Services Revenue by Business Segment. Gross profit from services revenue was $228.4 million and $11.4 million in 2008 and 2007, respectively, and represents gross profit related to services revenue associated with our newly-formed health management business segment, which includes our recent

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acquisitions of QAS, Alere Medical, ParadigmHealth and Matria, our professional drugs of abuse testing and screening businesses, and our long-term services agreement related to our consumer diagnostics joint venture formed with P&G in May 2007. Gross profit from services revenue by segment for 2008 and 2007 is as follows (in thousands):

	2008	2007
Professional diagnostics	$ 14,380	$
Health management	211,627	8,903
Consumer diagnostics	2,357	2,482
Gross profit from services revenue	$ 228,364	$ 11,385

Professional Diagnostics

Gross profit from services revenue for our professional diagnostics business segment was $14.4 million in 2008 and represents gross profit related to the services provided by our professional drugs of abuse testing and screening business, Redwood, which was acquired in December 2007.

As a percentage of our professional diagnostics services revenue, gross margin for 2008 was 49%.

Health Management

Gross profit from services revenue for our newly-formed health management business segment was $211.6 million and $8.9 million in 2008 and 2007, respectively, and represents gross profit related to the services provided by our health management businesses, primarily Alere Medical, ParadigmHealth, QAS and Matria.

As a percentage of our health management services revenue, gross margin for 2008 and 2007 was 57% and 63%, respectively.

Consumer Diagnostics

Gross profit from services revenue for our consumer diagnostics business segment was $2.4 million and $2.5 million in 2008 and 2007, respectively, and represents gross profit from services revenue related to our long-term services agreements with the joint venture, pursuant to which we provide certain operational support services to the joint venture. We presently do not allocate any cost of goods sold to the services revenue related to this long-term service agreement. All costs for this segment are recorded in the gross profit from net product sales.

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 venture with P&G. Additionally, our funding relationship with ITI 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 8% for 2007.

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Purchase of In-Process Research and Development (IPR&D). In connection with two of our acquisitions since 2007, we have 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 current 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 $218.5 million, or 130%, to $386.3 million in 2008, from $167.8 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, 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 23% for 2008, from 20% for 2007.

General and Administrative Expense. General and administrative expense increased by $140.2 million, or 89%, to $298.6 million in 2008, from $158.4 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 $14.6 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

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Biosite. Partially offsetting the increases was the favorable impact from the formation of our 50/50 joint venture with P&G. Amortization expense of $18.4 million and $0.3 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 18% for 2008, from 19% 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	$ 6,718	$ 11,486	$ (4,768)
Foreign exchange gains (losses), net	(897)	(1,609)	712
Other	(8,033)	(1,103)	(6,930)
Other income (expense), net	$ (2,212)	$ 8,774	$ (10,986)

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 $15.7 million, to a $16.7 million benefit in 2008, from a $1.0 million benefit in 2007. The effective tax rate in 2008 was 43%, compared to 0.4% 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 provision 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. 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.

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 15 of our

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consolidated financial statements included elsewhere in this Annual Report on Form 10-K for the calculation of net loss per common share.

Year Ended December 31, 2007 Compared to Year Ended December 31, 2006

During 2007 and 2008, we entered the growing health management market with our acquisitions of QAS, Alere Medical, ParadigmHealth and more recently Matria. As a result of these acquisitions, we formed our health management reporting unit in 2008. For presentation and comparative purposes certain amounts for prior periods have been reclassified to conform to the current period classification.

Net Product Sales. Net product sales increased by $248.8 million, or 45%, to $800.9 million in 2007, from $552.1 million in 2006. Excluding the favorable impact of currency translation, net product sales in 2007 grew by approximately $237.8 million, or 43%, over 2006. Of the currency adjusted increase, revenue increased primarily as a result of our acquisitions of: (i) First Check, in January 2007, which contributed revenue of $12.9 million, (ii) Instant, in March 2007, which contributed revenue of $22.8 million, (iii) Biosite, in June 2007, which contributed revenue of $167.8 million, (iv) Cholestech, in September 2007, which contributed revenue of $24.1 million, (v) Bio-Stat Healthcare Group, or Bio-Stat, in October 2007, which contributed revenue of $8.1 million, (vi) HemoSense, in November 2007, which contributed revenue of $3.5 million and (vii) various less significant acquisitions, which contributed an aggregate of $19.4 million of such increase. Partially offsetting the increased revenue as a result of acquisitions was the decrease in revenue associated with the formation of our 50/50 joint venture with P&G on May 17, 2007 in which 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 transaction 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. We recorded $76.1 million of net product sales in 2007 (through the date the joint venture was formed), as compared to $171.6 million of net product sales in 2006. During 2007, we recorded $65.0 million of manufacturing revenue associated with our manufacturing agreement with the joint venture, whereby we manufacture and sell consumer diagnostics to the joint venture. Organic growth, particularly from our professional infectious disease and drugs of abuse products, also contributed to the growth, as well as higher license and royalty revenue.

Net Product Sales by Business Segment. Net product sales by business segment for 2007 and 2006 are as follows (in thousands):

	2007	2006	% Increase (decrease)
Professional diagnostics	$ 565,265	$ 298,472	89%
Health management	9,210		%
Consumer diagnostics	153,616	171,607	(11)%
Vitamins and nutritional supplements	72,824	82,051	(11)%
Net product sales	$ 800,915	$ 552,130	45%

Professional Diagnostics

The increase in net product sales from our professional diagnostics business segment was $266.8 million, or 88%, comparing 2007 to 2006. Revenue increased primarily as a result of our acquisitions of: (i) Instant, in March 2007,

which contributed revenue of $22.8 million, (ii) Biosite, in June 2007, which contributed revenue of $167.8 million, (iii) Cholestech, in September 2007, which contributed revenue of $24.1 million, (iv) Bio-Stat, in October 2007, which contributed revenue of $8.1 million, (v) HemoSense, in November 2007, which contributed revenue of $3.5 million and (vi) various less significant acquisitions, which contributed an aggregate of $17.2 million of such increase. Organic growth, particularly from our professional infectious disease and drugs of abuse products, also contributed to the growth.

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Health Management

Effective January 1, 2008, we formed our health management business segment which includes the activities of our recent acquisitions of QAS, which was acquired in June 2007; Alere Medical, which was acquired in November 2007; and ParadigmHealth, which was acquired in December 2007. Net product sales associated with our recently acquired health management businesses was $9.2 million during 2007.

Consumer Diagnostics

The decrease in net product sales from our consumer diagnostics business segment was $18.0 million, or 11%, comparing 2007 to 2006. The decrease was primarily driven by the formation of our 50/50 joint venture with P&G on May 17, 2007 in which 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 transaction 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 of our consumer diagnostics for 2007 included $65.0 million 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 $12.9 million of net product sales from our First Check consumer drugs of abuse product line which was acquired in January 2007.

Vitamins and Nutritional Supplements

Our vitamins and nutritional supplements net product sales decreased by $9.2 million, or 11%, comparing 2007 to 2006. The decrease was driven primarily by our private label business.

Services Revenue. Services revenue of $16.6 million in 2007 represents revenue related to our health management businesses, Alere Medical, ParadigmHealth and QAS, all of which were acquired during 2007.

Net Product Sales and Services Revenue by Geographic Location. Net product sales and services revenue by geographic location for 2007 and 2006 are as follows (in thousands):

	2007	2006	% Increase (decrease)
United States	$ 511,941	$ 323,046	58%
Europe	196,379	134,528	46%
Other	109,241	94,556	16%
Net product sales and services revenue	$ 817,561	$ 552,130	48%

Net product sales and services revenue of $511.9 million and $323.0 million generated in the United States were approximately 63% and 59%, respectively, of total net product sales and services revenue for the year ended December 31, 2007 and 2006, 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 $4.7 million, or 27%, to $22.0 million in 2007, from $17.3 million in 2006. The increase primarily relates to $3.9 million of royalty revenue contributed by Biosite, which was acquired in June 2007. Additionally, incremental royalty revenue was derived from new royalty agreements entered into during 2007, 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 $164.5 million, or 72%, to $393.7 million in 2007, from $229.2 million in 2006. Gross profit during 2007 benefited from higher than average margins earned on revenue from our recently acquired businesses and from the favorable impact of our low cost manufacturing

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facilities in China. Included in cost of net revenue in 2007 were restructuring charges totaling $2.0 million associated with our joint venture related restructuring plans, a charge of $8.2 million associated with the write-up of inventory acquired to fair value in connection with our acquisitions of Biosite, Cholestech and HemoSense, and $0.6 million of stock-based compensation expense. Additionally, gross profit in 2007 was unfavorably impacted by the formation of our 50/50 joint venture with P&G. Included in cost of net revenue during 2006 was a restructuring charge of $9.5 million related to the closure of our ABI operation in San Diego, California, along with the write-off of fixed assets at other facilities impacted by our 2006 restructuring plans and the closure of CDIL, our manufacturing facility in Galway, Ireland. Cost of net revenue during 2006 also included a $0.4 million charge for stock-based compensation expense. Cost of net revenue included amortization expense of $24.0 million and $11.2 million in 2007 and 2006, respectively.

Overall gross margin was 47% in 2007, compared to 40% in 2006.

Gross Profit from Net Product Sales by Business Segment. Gross profit from net product sales represents total gross profit less gross profit associated with services revenue and license and royalty revenue. Gross profit from net product sales increased by $152.2 million to $369.5 million in 2007, from $217.3 million in 2006. Gross profit from net product sales by business segment for 2007 and 2006 is as follows (in thousands):

	2007	2006	% Increase (decrease)
Professional diagnostics	$ 306,710	$ 129,636	137%
Health management	3,076		%
Consumer diagnostics	52,760	82,658	(36)%
Vitamins and nutritional supplements	6,966	5,037	38%
Gross profit from net product sales	$ 369,512	$ 217,331	70%

Professional Diagnostics

Gross profit from our professional diagnostics net product sales increased by $177.1 million, or 137%, comparing 2007 to 2006, 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 an $8.2 million charge associated with the write-up of inventory acquired to fair value in connection with our acquisitions of Biosite, Cholestech and HemoSense, $0.5 million in restructuring charges and $0.3 million of stock-based compensation expense. Reducing gross profit for 2006 was a $7.2 million restructuring charge associated with management s decision to close our ABI operations in San Diego, California.

As a percentage of our professional diagnostics net product sales, gross profit from our professional diagnostics business was 54% in 2007, compared to 43% in 2006.

Health Management

Effective January 1, 2008, we formed our health management business segment which includes the activities of our recent acquisitions of QAS, which was acquired in June 2007; Alere Medical, which was acquired in November 2007; and ParadigmHealth, which was acquired in December 2007. Net product sales associated with our recently-acquired health management businesses was $3.1 million during 2007.

As a percentage of our health management net product sales, gross margin for 2007 was 33%.

Consumer Diagnostics

Gross profit from our consumer diagnostics net product sales decreased $29.9 million, or 36%, comparing 2007 to 2006. 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 revenue from acquired businesses, primarily our First Check acquisition, as discussed above; the 5% mark-up on products

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sold under our manufacturing agreement with the joint venture, a restructuring charge of $1.5 million associated with the decision to close facilities and the formation of our joint venture with P&G and $0.3 million of stock-based compensation expense. Gross profit for 2006 was adversely impacted by restructuring charges totaling $2.2 million related to the closure of our CDIL manufacturing facility and $0.4 million of stock-based compensation expense.

As a percentage of our consumer diagnostics net product sales, gross profit from our consumer diagnostics business was 34% for 2007, compared to 48% in 2006.

Vitamins and Nutritional Supplements

Gross profit from our vitamins and nutritional supplements net product sales increased $1.9 million, or 38%, comparing 2007 to 2006. The increase is primarily the result of improved customer mix, improved factory utilization and our cost reduction initiatives in our private label manufacturing business.

As a percentage of our vitamins and nutritional supplements net product sales, gross profit from our vitamins and nutritional supplements business was 10% in 2007, compared to 6% in 2006.

Gross Profit from Services Revenue. Gross profit from services revenue was $11.4 million in 2007, and represents gross profit related to services revenue associated with our newly-formed health management business segment, which includes our recent acquisitions of QAS, Alere Medical, ParadigmHealth and Matria, our professional drugs of abuse testing and screening businesses, and our long-term services agreement related to our consumer diagnostics joint venture formed with P&G in May 2007.

Research and Development Expense. Research and development expense increased by $20.8 million, or 43%, to $69.5 million in 2007, from $48.7 million in 2006. Research and development expense in 2007 and 2006 is reported net of co-development funding of $18.5 million and $16.6 million, respectively, arising from the co-development funding arrangement that we entered into with ITI in February 2005. The year over year increase in research and development expense is primarily the result of increased spending related to our cardiology research programs, $21.5 million of spending related to our 2007 acquisitions, partially offset by the transition of our consumer-related research and development efforts into our 50/50 joint venture with P&G in the second quarter of 2007. Also included in research and development expense is $2.2 million of stock-based compensation expense, representing an increase of approximately $0.8 million from 2006. Restructuring charges associated with the formation of our 50/50 joint venture and our 2007 restructuring plan to integrate our newly-acquired businesses totaling $2.5 million were included in research and development expense during 2007. Amortization expense of $2.9 million and $3.3 million was included in research and development expense for 2007 and 2006, respectively.

Research and development expense as a percentage of net product revenue decreased to 9% for 2007, from 10% for 2006.

Purchase of In-Process Research and Development (IPR&D). In connection with three of our acquisitions since 2006, we have 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 current 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. If products based on our

acquired IPR&D programs and technology platforms do not become commercially viable, our results of operations

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could be materially adversely affected. The following table sets forth IPR&D projects for companies and certain assets we have acquired since 2006 (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
Clondiag/2006	$ 24,000	$ 1,800	CHF (Congestive Heart Failure)	37%	2008-2009	
		2,500	ACS (Acute Coronary Syndrome)	37%	2009-2010	
		660	HIV (Human Immuno-deficiency Virus)	37%	2008-2009	
		$ 4,960				$ 9,500

(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 $73.3 million, or 78%, to $167.8 million in 2007, from $94.4 million in 2006. The increase in sales and marketing expense is primarily the result of approximately $56.1 million of additional spending related to newly-acquired businesses, primarily Biosite, Instant, Cholestech and the various less significant acquisitions. Also included in sales and marketing expense is $1.7 million

of stock-based compensation expense, representing an increase of approximately $1.0 million from 2006. Partially offsetting the increases was the favorable impact of the formation of our 50/50 joint venture with P&G. Amortization expense of $36.9 million and $6.8 million was included in sales and marketing expense for 2007 and 2006, respectively.

Sales and marketing expense as a percentage of net product sales and services revenue increased to 21% for 2007, from 17% for 2006.

General and Administrative Expense. General and administrative expense increased by $87.2 million, or 122%, to $158.4 million in 2007, from $71.2 million in 2006. The increase in general and administrative expense is primarily the result of approximately $26.9 million of additional spending related to newly-acquired businesses, primarily Biosite, Instant, Cholestech and the various less significant acquisitions. Also included in general and administrative expense is $53.0 million of stock-based compensation expense, representing an increase of approximately $50.0 million from 2006. The $53.0 million stock-based compensation expense includes a one-time charge of $45.2 million associated with the stock option acceleration and conversion in connection with the acquisition of Biosite. Partially offsetting the increases was the favorable impact of the formation of our 50/50 joint venture with P&G. Amortization expense of $0.3 million and $0.4 million was included in general and administrative expense for 2007 and 2006, respectively.

General and administrative expense as a percentage of net product sales and services revenue increased to 19% for 2007, from 13% for 2006.

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Interest Expense. Interest expense in 2007 includes interest charges, amortization of deferred financing costs, prepayment premiums and the amortization of non-cash discounts associated with our debt issuances. Interest expense for 2006 includes interest charges, the write-off and amortization of deferred financing costs and the amortization of non-cash discounts associated with our debt issuances in 2004. Interest expense increased by $56.4 million, or 212%, to $83.0 million in 2007, from $26.6 million in 2006. Interest expense increased in 2007 as a result of higher debt balances than in the prior period. Additionally, in 2007 we recorded a 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. In 2006, we recorded a charge of $1.3 million related to prepayment penalties and the write-off of debt origination costs resulting from the early repayment of our $20.0 million, 10% subordinated promissory notes on September 8, 2006.

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):

	2007	2006	Change
Interest income	$ 11,486	$ 1,693	$ 9,793
Foreign exchange gains (losses), net	(1,609)	2,643	(4,252)
Other	(1,103)	4,412	(5,515)
Other income (expense), net	$ 8,774	$ 8,748	$ 26

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.

Other income (expense), net, for 2006 includes a foreign exchange gain of $4.3 million associated with the closure of our Galway, Ireland manufacturing operation and $4.7 million in other income, related to the portion of our settlement with Vedalab S.A., or Vedalab relating to periods prior to 2006.

(Benefit) Provision for Income Taxes. (Benefit) provision for income taxes decreased by $6.7 million, to a $1.0 million benefit in 2007, from a $5.7 million provision in 2006. The effective tax rate in 2007 was 0.4%, compared to (52)% in 2006. The decrease in the provision for income taxes from 2006 to 2007 is primarily related to the recognition of the benefit of current year losses in the U.S. and the United Kingdom.

The primary components of the 2007 provision for income taxes relates to the recognition of benefit on U.S. and U.K. losses, state income taxes, and taxes on foreign income. We recognized the benefit of U.S. 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. We released approximately $83.0 million of valuation allowance for these U.S. deferred tax assets, which was released to goodwill. Thereafter, we recognized a benefit for the current year U.S. losses. The primary components of the 2006 provision for income taxes are related to the recognition of U.S. deferred tax liabilities for temporary differences between the book and tax bases of goodwill and certain intangible assets with indefinite lives and to taxes on foreign income.

Net Loss. We incurred a net loss of $244.8 million in 2007, while we incurred a net loss of $16.8 million in 2006. Net loss per common share available to common stockholders was $4.75 per basic and diluted common share in 2007, as

compared to net loss of $0.49 per basic and diluted common share in 2006. The net loss in 2007 and 2006 resulted from the various factors as discussed above. See Note 15 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

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improve our operating margins and grow our business through new product introductions 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, because of the unprecedented nature and severity of the ongoing financial crisis in the capital and credit markets, 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. 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.

As of December 31, 2008, in addition to other indebtedness, we had approximately $1.1 billion in aggregate principal amount of indebtedness outstanding under our First Lien Credit Agreement, $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 facilities), and $150.0 million in indebtedness under our outstanding 3% senior subordinated convertible notes, or the senior subordinated convertible notes. Included in the secured credit facilities is a revolving line-of-credit of $150.0 million, of which $142.0 million was outstanding as of December 31, 2008.

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 is a term loan in the amount of $250.0 million. Interest on this term loan, 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

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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, 2008, interest expense, including amortization of deferred financing costs, under the secured credit facilities was $85.2 million. As of December 31, 2008, accrued interest related to the secured credit facilities amounted to $3.4 million. As of December 31, 2008, we were in compliance with all debt covenants related to the above debt, which consisted principally of maximum consolidated leverage and minimum interest coverage requirements.

Interest expense related to our senior subordinated convertible notes for the year ended December 31, 2008, including amortization of deferred financing costs, was $5.0 million. As of December 31, 2008, accrued interest related to the senior subordinated convertible notes amounted to $0.6 million.

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%. These interest rate swap contracts were entered into to convert $350.0 million of the $1.2 billion variable rate term loan under the secured 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 fixed rate of 1.195%. These interest rate swap contracts were entered into to convert $500.0 million of the $1.2 billion variable rate term loan under the secured credit facility into fixed rate debt.

As of December 31, 2008, we had 1.9 million shares of our Series B preferred stock issued and outstanding. 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.

Summary of Changes in Cash Position

As of December 31, 2008, we had cash and cash equivalents of $141.3 million, a $273.4 million decrease from December 31, 2007. Our primary sources of cash during the year ended December 31, 2008 included $147.8 million generated by our operating activities, $20.7 million from common stock issues under employee stock option and stock purchase plans, $137.2 million from borrowing under of existing credit facilities, and a decrease of $139.2 million in restricted cash. Investing activities during the year ended December 31, 2008 used a total of $713.3 million of cash, net of cash acquired, primarily related to our acquisition activities and capital expenditures. Our financing activities, aside from the decrease in restricted cash, proceeds from borrowings under our secured credit facilities and cash received from common stock issues under employee stock option and stock purchase plans, used $15.1 million of cash related to repayments under our secured credit facilities and capital lease obligations. Fluctuations in foreign currencies negatively impacted our cash balance by $5.7 million during the year ended December 31, 2008.

Operating Cash Flows

Net cash provided by operating activities during the year ended December 31, 2008 was $147.8 million, which resulted from $287.0 million of non-cash items, offset by our net loss of $21.8 million and $117.4 million of cash used

to meet net working capital requirements during the period. The $287.0 million of non-cash items included $267.9 million related to depreciation and amortization, $24.2 million related to the impairment of assets, $26.4 million related to non-cash stock-based compensation expense and $5.9 million related to the amortization of deferred financing costs, partially offset by a $41.8 million decrease related to the recognition of a tax benefit for current year losses and a $1.1 million decrease related to equity investments in unconsolidated entities.

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Investing Cash Flows

Our investing activities during the year ended December 31, 2008 utilized $713.3 million of cash, including $649.9 million used for acquisitions and transaction-related costs, net of cash acquired, $65.0 million of capital expenditures, net of proceeds from sale of equipment, partially offset by a $1.6 million decrease in investments and other assets, which included an $11.2 million return of cash from our 50/50 joint venture with P&G.

The acquisitions of Matria, BBI and Panbio during 2008 accounted for approximately $576.5 million of the $649.9 million of cash used for acquisitions.

Financing Cash Flows

Net cash provided by financing activities during the year ended December 31, 2008 was $297.8 million. During 2007, in connection with our acquisition of BBI, a restricted cash balance was created in the amount of approximately $140.5 million. Subsequent to the acquisition of BBI in February 2008, this cash balance became unrestricted and available for future financing-related activities. Additionally, financing activities provided $20.7 million from issuance of common stock under employee stock option and stock purchase plans, as well as $137.2 million from borrowings under existing credit facilities.

As of December 31, 2008, we had an aggregate of $1.0 million in outstanding capital lease obligations which are payable through 2013.

Income Taxes

As of December 31, 2008, we had approximately $256.6 million of domestic NOL carryforwards and $15.9 million of foreign NOL carryforwards, respectively, which either expire on various dates through 2027 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, 2008 included approximately $199.2 million of pre-acquisition losses at Matria, Alere Medical, Paradigm Health, Biosite, Cholestech, Diamics, Inc., or Diamics, HemoSense, IMN, Ischemia and Ostex. Prior to adoption of Statement of Financial Accounting Standards (SFAS) No. 141-R, *Business Combinations*, these 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 SFAS No. 141-R the reduction of a valuation allowance is generally recorded to reduce our income tax expense. Also included in our domestic NOL carryforwards at December 31, 2008 is approximately $17.5 million resulting from the exercise of employee stock options, the tax benefit of which, when recognized, will be accounted for as a credit to additional paid-in capital rather than a reduction of income tax.

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 NOL s 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, 2008.

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Contractual Obligations

The following table summarizes our principal contractual obligations as of December 31, 2008 and the effects such obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

		Payments Due by Period			
Contractual Obligations	**Total**	**2009**	**2010-2011**	**2012-2013**	**Thereafter**
Long-term debt obligations(1)	$ 1,519,615	$ 19,058	$ 26,530	$ 20,027	$ 1,454,000
Capital lease obligations(2)	973	495	446	32	
Operating lease obligations(3)	94,382	25,377	34,539	20,996	13,470
Long-term and other liabilities(4)	3,403	469	938	938	1,058
Minimum royalty obligations	220	220			
Acquisition-related obligations(5)	6,473	5,428	1,045		
Purchase obligations capital expenditure	17,492	17,492			
Purchase obligations other(6)	69,763	68,996	767		
Interest on debt(7)	33,177	4,500	9,000	9,000	10,677
Total	$ 1,745,498	$ 142,035	$ 73,265	$ 50,993	$ 1,479,205

(1) 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 are $0.2 million in technology license payment obligations and $3.4 million in pension obligations. Our liability associated with Financial Accounting Standards Board (FASB) Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement 109*, has not been included in the table above, as we estimate payments annually.

(5) Amounts represent obligations associated with our acquisitions which are discussed in more detail below.

(6) Other purchase obligations relate to inventory purchases and other operating expense commitments.

(7) Amounts are based on $150.0 million senior subordinated notes. Amounts exclude interest on all other debt due to variable interest rates. See Note 6 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

We have contingent consideration contractual terms related to our acquisitions of Alere Medical, Ameditech, Binax, Inc., or Binax, Bio-Stat, CLONDIAG chip technologies GmbH, or Clondiag, Diamics, First Check, Gabmed GmbH, or Gabmed, Global Diagnostics CC, or Global , Matritech, Promesan S.r.l., or Promesan, Spectral Diagnostics Private Limited and its affiliate Source Diagnostics (India) Private Limited, or Spectral/Source, Vision Biotech Pty Ltd, or Vision and our most recently acquired healthcare business. With the exception of Alere Medical, the contingent considerations will be accounted for as increases in the aggregate purchase prices if and when the contingencies occur.

With respect to Alere Medical, the terms of the acquisition agreement provided for contingent consideration payable to each Alere Medical stockholder who owned shares of our common stock or retained the option to purchase shares of our common stock on the six-month anniversary of the closing of the acquisition. The contingent consideration, payable in cash or stock at our election, was equal to the number of such shares of our common stock or options to purchase our common stock held on the six-month anniversary multiplied by the amount that $58.31 exceeded the greater of the average price of our common stock for the ten business days preceding the six-month anniversary date, or 75% of $58.31. Accordingly, based on the price of our common stock for the ten business days preceding the six-month anniversary of the closing of the

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acquisition, we issued approximately 0.1 million shares of our common stock on May 30, 2008 to the Alere Medical stockholders based on the remaining outstanding shares at that time. Payment of this contingent consideration did not impact the purchase price for this acquisition.

With respect to Ameditech, the terms of the acquisition agreement require us to pay an earn-out upon successfully meeting certain revenue targets for the one-year period ending on the first anniversary of the acquisition date and the one-year period ending on the second anniversary of the acquisition date. The maximum amount of incremental consideration payable is $4.0 million.

With respect to Binax, the terms of the acquisition agreement provide for $11.0 million of contingent cash consideration payable to the Binax shareholders upon the successful completion of certain new product developments during the five years following the acquisition. As of December 31, 2008, the remaining contingent consideration to be earned is approximately $7.3 million.

With respect to Bio-Stat, the terms of the acquisition provided for contingent consideration payable in the form of loan notes to the Bio-Stat shareholders, if certain EBITDA (earnings before interest, taxes, depreciation and amortization) milestones were met for 2007. The EBITDA milestones were met in 2007 and loan notes totaling £3.4 million ($6.2 million) were issued during the third quarter of 2008. As of December 31, 2008, the loan notes remain outstanding with an approximate value of $4.9 million.

With respect to Clondiag, the terms of the acquisition agreement provided for $8.9 million of contingent consideration, consisting of approximately 0.2 million shares of our common stock and approximately $3.0 million of cash or stock in the event that four specified products were developed on Clondiag s platform technology during the three years following the acquisition date. Successful completion of the second milestone occurred during the first quarter of 2008 for which we made a payment for $0.9 million and issued 56,080 shares of our common stock during the first quarter of 2008. Successful completion of the third and fourth milestones occurred during the third quarter of 2008 for which we made payment for $1.6 million and issued 0.1 million shares of our common stock during the fourth quarter of 2008. No further milestones exist.

With respect to Diamics, the terms of the acquisition agreement provide for contingent consideration payable upon the successful completion of certain milestones, including development of business plans and marketable products. As of December 31, 2008, the remaining contingent consideration to be earned is approximately $2.3 million.

With respect to First Check, the terms of the acquisition agreement required us to pay an earn-out to First Check equal to the incremental revenue growth of the acquired products for 2007 and for the first nine months of 2008, as compared to the immediately preceding comparable periods. The 2007 milestone, totaling $2.2 million, was met and accrued as of December 31, 2007 and was paid during the first quarter of 2008. The 2008 milestone, totaling $0.3 million, was met and accrued during the third quarter of 2008 and was paid in the fourth quarter of 2008. No further milestones exist.

With respect to Gabmed, the terms of the acquisition agreement provide for contingent consideration totaling up to 750,000 payable in up to five annual amounts beginning in 2007, upon successfully meeting certain revenue and EBIT (earnings before interest and taxes) milestones in each of the respective annual periods. The 2007 milestone, totaling 0.1 million ($0.2 million), was met and accrued as of June 30, 2008 and was paid during the third quarter of 2008.

With respect to Global, the terms of the acquisition agreement provided for contingent consideration payable upon successfully meeting certain revenue targets in 2008. As of December 31, 2008, the 2008 revenue targets were met resulting in accrued contingent consideration totaling $0.2 million. No further milestones exist.

With respect to Matritech, the terms of the acquisition agreement required us to pay an earn-out to the former Matritech shareholders upon successfully meeting certain revenue targets in 2008. As of December 31, 2008, the milestones were not achieved. No further milestones exits.

With respect to Promesan, the terms of the acquisition agreement provide for contingent consideration payable upon successfully meeting certain annual revenue targets. Total contingent consideration of up to

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0.6 million is payable in three equal annual amounts of 0.2 million beginning in 2007 and ending in 2009. The 2007 milestone, totaling 0.2 million ($0.3 million), was met and accrued as of December 31, 2007 and was paid during the first quarter of 2008. The 2008 milestone, totaling 0.2 million ($0.3 million), was met and accrued as of December 31, 2008.

With respect to Spectral/Source, the terms of the acquisition agreement required us to pay an earn-out equal to two times the consolidated revenue of Spectral/Source less $4.0 million, if the consolidated profits before tax of Spectral/Source was at least $0.9 million on the one year anniversary (milestone period) following the acquisition date. If consolidated profits before tax of Spectral/Source for the milestone period were less than $0.9 million, then the amount of the payment would be equal to seven times Spectral/Source s consolidated profits before tax less $4.0 million. The contingent consideration was payable 60% in cash and 40% in stock. The revenue and profit milestones were met and accrued during the fourth quarter of 2008 for which we made payment for $1.6 million and issued 53,372 shares of our common stock during the fourth quarter of 2008. No further milestones exist.

With respect to Vision, the terms of the acquisition agreement provide for incremental consideration payable to the former Vision shareholders. The maximum amount of incremental consideration payable is approximately $3.2 million, of which $1.0 million is guaranteed and accrued as of December 31, 2008. The remaining contingent consideration is payable upon the completion of certain milestones and successfully maintaining certain production levels and product costs during each of the two years following the acquisition date. As of December 31, 2008, no milestones have been met.

With respect to our most recently acquired healthcare business, the terms of the acquisition agreement provide for contingent consideration payable upon successfully meeting certain revenue and EBITDA targets for the twelve months ending June 30, 2009 and December 31, 2010, respectively. We accrued a liability in the amount of $3.8 million to avoid recognition of negative goodwill, as a result of not recognizing additional purchase price consideration that is contingent on future events. As of December 31, 2008, the $3.8 million liability remains accrued.

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, 2008 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.

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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.

In connection with the acquisition of the Determine business in June 2005 from Abbott Laboratories, we entered into a transition services agreement with Abbott, whereby Abbott would continue to distribute the acquired products until both parties agreed the transition was completed. During the transition period, we recognized revenue on sales of the products when title transferred from Abbott to third party customers.

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 $48.0 million, $48.9 million and $52.8 million, or 4%, 6% and 10%, respectively, of net product sales in 2008, 2007 and 2006, respectively, which have been recorded against product sales to derive our net product 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 $280.6 million and $163.4 million, net of allowances for doubtful accounts of $12.8 million and $12.2 million, as of December 31, 2008 and December 31, 2007, 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

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we have met the performance criteria. If we do not meet the performance targets at the end of the contractual period we are obligated under the contract to refund some or all of the at risk fees. Our deferred revenue balance was $22.0 million and $5.3 million, as of December 31, 2008 and December 31, 2007, 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 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 $199.1 million and $148.2 million, net of a provision for excess and obsolete inventory of $10.8 million and $8.1 million, as of December 31, 2008 and 2007, 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, 2008, the balances of property, plant and equipment, goodwill and other intangible assets, net of accumulated depreciation and amortization, were $284.5 million, $3.0 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, SFAS No. 142, *Goodwill and Other Intangible Assets*, requires that impairment reviews be performed 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

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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, 2008, using 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, 2008, which could lead to significant impairment charges of goodwill in the future. As of December 31, 2008, we have goodwill balances related to our professional diagnostics, health management and consumer diagnostics reporting units, which amounted to $1.7 billion, $1.3 billion and $52.7 million, respectively.

Despite current economic conditions and the fluctuation in our common stock price during the fourth quarter of 2008, we determined that, based on our 2008 financial performance, our unchanged expectations of future financial performance and the improvement in our common stock price subsequent to year end, a triggering event that would warrant further impairment testing had not occurred and therefore no updated testing was performed and no goodwill impairment was recorded during 2008. Should economic conditions deteriorate further or remain depressed for a prolonged period of time, estimates of future cash flows for each reporting unit may be insufficient to support carrying value and the goodwill assigned to it, requiring us to test for impairment. Impairment charges, if any, may be material to our results of operations and financial position.

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 under SFAS No. 142. Although we believe that the carrying value of our long-lived tangible and intangible assets was realizable as of December 31, 2008, future events could cause us to conclude otherwise.

Stock-Based Compensation

We account for stock-based compensation in accordance with SFAS No. 123-R, *Share-Based Payment*. Under the fair value recognition provisions of this statement, share-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the vesting period. Determining the fair value of share-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. SFAS No. 123-R requires forfeitures to be 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 in the application of SFAS No. 123-R, the compensation expense that we record in future periods may differ significantly from what we have recorded in the current period.

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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 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 $12.7 million as of December 31, 2008 due to uncertainties related to the future benefits, if any, from our deferred tax assets related primarily to our foreign businesses and certain U.S. net operating losses and tax credits. Included in this valuation allowance is $3.7 million for deferred tax assets of acquired companies, the future benefits of which will be generally applied to reduce our income tax expense as required SFAS No. 141-R, *Business Combinations.* This is a reduction of $6.2 million from the valuation allowance of $18.9 million as of December 31, 2007, and resulted in additional goodwill. The decrease is primarily related to the recognition of foreign NOL s. 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.

On January 1, 2007 we adopted Financial Accounting Standards Board (FASB) Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement 109*. In accordance with FIN 48, 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.

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Recent Accounting Pronouncements

Recently Issued Standards

In June 2008, the FASB ratified Emerging Issue Task Force (EITF) Issue No. 07-05, *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity s Own Stock*, which addresses the accounting for certain instruments as derivatives under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. Under this new pronouncement, specific guidance is provided regarding requirements for an entity to consider embedded features as indexed to the entity s own stock. This Issue is effective for fiscal years beginning after December 15, 2008. We are currently in the process of evaluating the impact of adopting this pronouncement.

In May 2008, the FASB issued FASB Staff Position (FSP) APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled In Cash upon Conversion (Including Partial Cash Settlement)*. FSP APB 14-1 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. FSP APB 14-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years. This FSP should be applied retrospectively for all periods presented. We are currently in the process of evaluating the impact of adopting this pronouncement.

In April 2008, the FASB issued FSP 142-3, *Determination of the Useful Life of Intangible Assets*. FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets. FSP 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008, as well as interim periods within those fiscal years. We are currently in the process of evaluating the impact of adopting this pronouncement.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities an Amendment of FASB Statement No. 133*. This statement 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, how the provisions of SFAS No. 133 have been applied and the impact that hedges have on an entity s financial position, financial performance and cash flows. This statement is effective for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. We are currently in the process of evaluating the impact of adopting this pronouncement.

In December 2007, the FASB ratified the consensus reached by the EITF in EITF Issue No. 07-01, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*. The EITF 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. Revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF Issue No. 99-19, Reporting Revenue Gross as a Principal versus Net as an Agent, and other accounting literature. Payments to or from collaborators would be evaluated and presented based on the nature of the arrangement and its terms, the nature of the entity s business, and whether those payments are within the scope of other accounting literature. 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 EITF Issue No. 07-01 applies to the entire collaborative agreement. This Issue is effective for fiscal years beginning after December 15, 2008, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. We are

currently in the process of evaluating the impact of adopting this pronouncement.

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In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an Amendment of Accounting Research Bulletin (ARB) No. 51*. This statement amends ARB No. 51 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 statement also establishes standards for presentation and disclosure of the non-controlling results on the consolidated income statement. SFAS No. 160 is effective for fiscal years beginning on or after December 15, 2008. We are currently in the process of evaluating the impact of adopting this pronouncement.

In December 2007, the FASB issued SFAS No. 141-R, *Business Combinations*. This statement replaces SFAS No. 141, but retains the fundamental requirements in SFAS No. 141 that the acquisition method of accounting be used for all business combinations. This statement requires an acquirer to recognize and measure the identifiable assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at their fair values as of the acquisition date. The statement requires acquisition costs and any restructuring costs associated with the business combination to be recognized separately from the fair value of the business combination. SFAS No. 141-R establishes requirements for recognizing and measuring goodwill acquired in the business combination or a gain from a bargain purchase as well as disclosure requirements designed to enable users to better interpret the results of the business combination. SFAS No. 141-R is effective for fiscal years beginning on or after December 15, 2008. Given our history of acquisition activity, we anticipate the adoption of SFAS No. 141-R to have a significant impact on our consolidated financial statements. Early adoption of this statement is not permitted. As of December 31, 2008 there were $3.8 million in capitalized acquisition costs classified in other non-current assets. The capitalized costs will be written off in January 2009 when this statement becomes effective.

Recently Adopted Standards

Effective October 2008, we adopted FSP 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*. FSP 157-3 clarifies the application of SFAS No. 157 in an inactive market. It demonstrated how the fair value of a financial asset is determined when the market for that financial asset is inactive. The adoption of these provisions did not have a material impact on our consolidated financial statements.

Effective January 1, 2008, we adopted EITF Issue No. 07-03, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*. EITF 07-03 concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. The effect of applying this EITF is prospective for new contracts entered into on or after the date of adoption. The adoption of this EITF did not have a material impact on our consolidated financial statements.

Effective January 1, 2008, we adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB No. 115*. This Statement provides companies with an option to measure, at specified election dates, many financial instruments and certain other items at fair value that are not currently measured at fair value. The standard also establishes presentation and disclosure requirements designed to facilitate comparison between entities that choose different measurement attributes for similar types of assets and liabilities. If the fair value option is elected, the effect of the first remeasurement to fair value is reported as a cumulative effect adjustment to the opening balance of retained earnings. The statement is to be applied prospectively upon adoption. The adoption of these provisions did not have a material impact on our consolidated financial statements.

Effective January 1, 2008, we adopted SFAS No. 157, *Fair Value Measurements,* for all financial instruments and non-financial instruments accounted for at fair value on a recurring basis. SFAS No. 157 establishes a framework for

measuring fair value in generally accepted accounting principles, and expands

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disclosures about fair value measurements. The standard applies whenever other standards require, (or permit), assets or liabilities to be measured at fair value. The standard does not expand the use of fair value in any new circumstances. The FASB has provided a one-year deferral for the implementation for other non-financial assets and liabilities. The adoption of these provisions did not have a material impact on our consolidated financial statements. For further information about the adoption of the required provisions of SFAS No. 157 see Note 7.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Interest Rate Risk

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

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, 2008, our short-term investments approximated market value.

At December 31, 2008, we had a term loan in the amount of $960.8 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, 2008, under our First Lien Credit Agreement. Interest on the term loan, 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, 2008, we also had a term loan in the amount of $250.0 million under our Second Lien Credit Agreement. Interest on this term loan, 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 have a maturity date of September 28, 2010. These interest rate swap

contracts will pay us variable interest at the three-month LIBOR rate, and we will pay the counterparties a fixed rate of 4.85%. These interest rate swap contracts were entered into to convert $350.0 million of the $1.2 billion variable rate term loan under the senior credit facility into fixed rate debt.

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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 fixed rate of 1.195%. These interest rate swap contracts were entered into to convert $500.0 million of the $1.2 billion variable rate term loan under 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 outstanding borrowings as of December 31, 2008 over the next twelve months is quantified and summarized as follows (in thousands):

	Interest Expense Increase
Interest rates increase by 100 basis points	$ 5,028
Interest rates increase by 200 basis points	$ 10,055

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 2008, the net impact of foreign currency changes on transactions was a loss of $0.9 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 European and Chinese 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 49.6% in 2008. If the U.S. dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during 2008, our gross margin on total net product sales would have been 49.7%, 49.9% and 50.1%, 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 loss would have been impacted by approximately the following amounts (in thousands):

	Approximate Decrease in Net Revenue	Approximate Increase in Net Loss
If, during 2008, the U.S. dollar was stronger by:		
1%	$ 3,909	$ 229
5%	$ 19,545	$ 1,143
10%	$ 39,089	$ 2,287

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.

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The following table presents selected quarterly financial data for each of the quarters in the years ended December 31, 2008 and 2007, (in thousands, except per share data):

	2008			
	First Quarter(2)	Second Quarter(3)	Third Quarter(4)	Fourth Quarter(5)
Net revenue	$ 372,233	$ 401,127	$ 438,800	$ 459,266
Gross profit	$ 180,390	$ 206,102	$ 228,148	$ 245,919
Net (loss) income	$ (4,174)	$ (30,348)	$ (3,659)	$ 16,413
Net (loss) income per common share basic and diluted(1)	$ (0.05)	$ (0.43)	$ (0.12)	$ 0.14

	2007			
	First Quarter(6)	Second Quarter(7)	Third Quarter(8)	Fourth Quarter(9)
Net revenue	$ 158,979	$ 154,965	$ 237,636	$ 287,960
Gross profit	$ 78,338	$ 66,340	$ 110,298	$ 138,751
Net income (loss)	$ 6,305	$ (54,674)	$ (180,612)	$ (15,772)
Net income (loss) per common share basic and diluted(1)	$ 0.14	$ (1.17)	$ (3.74)	$ (0.24)

(1) Net (loss) income available to common stockholders and basic and diluted net (loss) income per common share are computed as consistent with the annual per share calculations described in Notes 2(n) and 15 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(2) Included in net loss for the first quarter of 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 Limited 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.

(3) 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.

(4) 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.

(5) 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.

(6) Included in net income for the first quarter of 2007 is $0.6 million related to the restructuring charge associated with the closure of our ABI operation, a $0.2 million charge to write-off deferred financing costs related to the

payment of outstanding debt, and $1.6 million of non-cash stock-based compensation expense.

(7) Included in net loss for the second quarter of 2007 is $0.4 million related to restructuring charges associated with the decision to close facilities and the formation of our joint venture with P&G, a $1.2 million write-off related to an inventory write-up recorded in connection with the Biosite acquisition, a charge of $15.4 million associated with the write-off of debt origination costs and a prepayment premium paid upon early extinguishment of related debt, a $1.9 million foreign currency gain realized on the settlement of intercompany notes, and $47.3 million of non-cash stock-based compensation expense.

(8) Included in net loss for the third quarter of 2007 is $0.5 million related to restructuring charges associated with the decision to close facilities and the formation of our joint venture with P&G, a $6.3 million write-off related to inventory write-ups recorded in connection with the Biosite and Cholestech acquisitions, a

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write-off of $169.0 million associated with the value of purchased IPR&D incurred in connection with the Biosite acquisition, and $3.3 million in non-cash stock-based compensation expense.

(9) Included in net loss for the fourth quarter of 2007 is $5.2 million related to restructuring charges associated with the decision to close facilities and formation of our joint venture with P&G, a $0.8 million write-off related to inventory write-ups recorded in connection with the Cholestech and HemoSense acquisitions, a write-off of $4.8 million associated with the value of purchased IPR&D incurred in connection with the Diamics acquisition, a $3.9 million unrealized foreign currency loss associated with a cash escrow established in connection with the acquisition of BBI, and $5.3 million in 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 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.

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Management assessed the effectiveness of our company s internal control over financial reporting as of December 31, 2008. 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, 2008.

In conducting management s evaluation of the effectiveness of our company s internal control over financial reporting, management excluded all 2008 acquisitions except for Matria. The contribution from these acquisitions represented approximately 2% and 4% of total assets and net revenue, respectively, as of and for the year ended December 31, 2008. 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 68.

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 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited Inverness Medical Innovations, Inc. and Subsidiaries (the Company) internal control over financial reporting as of December 31, 2008, 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 2008 acquisitions, except for Matria, which are all included in the consolidated balance sheet of the Company as of December 31, 2008, and the related consolidated statements of operations, stockholders equity and comprehensive loss, and cash flows for the year then ended. The acquired entities which were excluded constituted 2% and 4% of total assets and net revenue, respectively, as of and for the year ended December 31, 2008. 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 2008. 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 above acquisitions.

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In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, 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 as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders equity and comprehensive loss, and cash flows for each of the three years in the period ended December 31, 2008 and our report dated February 27, 2009 expressed an unqualified opinion thereon.

/s/ BDO Seidman, LLP

Boston, Massachusetts
February 27, 2009

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information regarding directors, executive officers and corporate governance included in our definitive Proxy Statement to be filed pursuant to Regulation 14A in connection with our 2009 Annual Meeting of Shareholders (the Proxy Statement) is incorporated herein by reference.

On or about January 5, 2009, in connection with the transfer of our common stock from AMEX to the NYSE, we filed with the NYSE the Annual CEO Certification regarding our compliance with the NYSE s corporate governance listing standards as required by Section 303A-12(a) of the NYSE Listed Company Manual. In addition, we have filed as exhibits to this Annual Report on Form 10-K, the applicable certifications of our Chief Executive Officer and our Chief Financial Officer required under Section 302 of the Sarbanes-Oxley Act of 2002, regarding the quality of our public disclosures.

ITEM 11. EXECUTIVE COMPENSATION

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

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

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

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

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

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

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

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) 1. Financial Statements.

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

2. Financial Statement Schedules.

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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 Reorganization dated as of June 4, 2007, among Inverness Medical Innovations, Inc., Iris Merger Sub, Inc. and Cholestech Corporation (incorporated by reference to Exhibit 2.1 to the Company s Current Report on Form 8-K, event date June 4, 2007, filed on June 4, 2007)
2.3	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)
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company s Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
3.2	First Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.4 to Company s Annual Report on Form 10-K, as amended, for the year ended December 31, 2007)
3.3	Second Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.3 to Company s Quarterly Report on Form 10-Q for the period ended June 30, 2008)
3.4	Certificate of Designation, Preferences and Rights of Series A Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 99.2 to the Company s Current Report on Form 8-K dated December 20, 2001)
3.5	Certificate of Designations of Series B Convertible Perpetual Preferred Stock of the Company (incorporated by reference to Exhibit 3.1 to the Company s Current Report on Form 8-K, event date, May 9, 2008, filed on May 14, 2008)
3.6	Certificate of Elimination of Series A Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3.2 to the Company s Current Report on Form 8-K, event date, May 9, 2008, filed on May 14, 2008)
3.7	Certificate of Correction to the First Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.5 to the Company s Annual Report on Form 10-K, as amended, for the year ended December 30, 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)
+10.1	Distribution Agreement between Biosite and Fisher Scientific Company L.L.C. effective January 1, 2006 (incorporated by reference to Exhibit 10.18 to Annual Report of Biosite Incorporated on Form 10-K, filed March 12, 2007)

*10.2	Amendment No. 1 to Distribution Agreement between Biosite and Fisher Scientific Company L.L.C., effective January 1, 2006
*10.3	Amendment No. 2 to Distribution Agreement between Biosite and Fisher Scientific Company L.L.C., effective June 30, 2008
*10.4	Amendment No. 2B to Distribution Agreement between Biosite and Fisher Scientific Company L.L.C., effective July 8, 2008

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*10.5	Amendment No. 3 to Distribution Agreement between Biosite and Fisher Scientific Company L.L.C., effective July 11, 2008
+10.6	Semi-exclusive BNP Diagnostic License Agreement Between Biosite Diagnostics Incorporated and Scios, Inc. effective December 30, 1996 (incorporated by reference to Exhibit 10.19 to Annual Report of Biosite Incorporated on Form 10-K, filed March 12, 2007)
+10.7	First Amendment to Semi-exclusive BNP Diagnostic License Agreement between Biosite Incorporated and Scios, Inc. effective August 1, 1997 (incorporated by reference to Exhibit 10.20 to Annual Report of Biosite Incorporated on Form 10-K, filed March 12, 2007)
+10.8	Amendment #2 To Semi-exclusive BNP Diagnostic License Agreement Biosite Incorporated and Scios, Inc. effective August 30, 2002 (incorporated by reference to Exhibit 10.21 to Annual Report of Biosite Incorporated on Form 10-K, filed March 12, 2007)
+10.9	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)
+10.10	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)
10.11	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)
10.12	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)
10.13	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)
10.14	Agreement, dated December 1, 1986, between Bernard Levere, Zelda Levere, Pioneer Pharmaceuticals, Inc. and Essex Chemical Corp. and Unconditional Guarantee by Essex Chemical Corp. (incorporated by reference to Exhibit 10.33 to the Company s Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
10.15	Option to Assume and Extend Lease, dated as of February , 1995, between Bernard Levere, Zelda Levere and International Vitamin Corporation (incorporated by reference to Exhibit 10.34 to the Company s Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
10.16	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)
10.17	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)
10.18	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)
10.19	Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company s Registration Statement on Form S-4, as amended (File No. 333-67392))

10.20 Amendment No. 1 to Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 4.4 to the Company s Registration Statement on Form S-8 (File No. 333-90530)

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10.21	Amendment No. 2 to Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 4.6 to Company s Registration Statement on Form S-8, as amended (File No. 333-106996))
10.22	Amendment No. 3 to Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.3 to Company s Quarterly Report on Form 10-Q, for the period ended June 30, 2005)
10.23	Amendment No. 4 to Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.41 to the Company s Annual Report on Form 10-K, as amended, for the year ended December 30, 2006)
10.24	Amendment No. 5 to Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.42 to the Company s Annual Report on Form 10-K, as amended, for the year ended December 30, 2006)
10.25	Amendment No. 6 to Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.40 to the Company s Annual Report on Form 10-K, as amended, for the year ended December 30, 2007)
10.26	Amendment No. 7 to Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.41 to the Company s Annual Report on Form 10-K, as amended, for the year ended December 30, 2007)
10.27	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)
10.28	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)
10.29	Form of Incentive Stock Option Agreement for Senior Executives under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.6 to Company s Quarterly Report on Form 10-Q for the period ended June 30, 2005) (relating to grants made prior to August 29, 2008)
*10.30	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (relating to grants made on or after August 29, 2008)
*10.31	Form of Non-Qualified Stock Option Agreement for U.S. Executives under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (relating to grants made on or after August 29, 2008)
*10.32	Form of Non-Qualified Stock Option Agreement for Non-U.S. Executives under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (relating to grants made on or after August 29, 2008)
*10.33	Form of Incentive Stock Option Agreement for Executives under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (relating to grants made on or after August 29, 2008)
*10.34	Inverness Medical Innovations, Inc. HM Revenue and Customs Share Option Plan (2007) (relating to grants made on or after August 29, 2008)
*10.35	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)
10.36	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)

10.37 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 30, 2007)

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10.38	Inverness Medical Innovations, Inc. 2001 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.2 to the Company s Registration Statement on Form S-4, as amended (File No. 333-67392))
10.39	Inverness Medical Innovations, Inc. 2001 Employee Stock Purchase Plan First Amendment (incorporated by reference to Exhibit 10.9 to the Company s Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
10.40	Inverness Medical Innovations, Inc. 2001 Employee Stock Purchase Plan Second Amendment (incorporated by reference to Exhibit 10.6 to the Company s Annual Report on Form 10-K, as amended, for the year ended December 30, 2006)
10.41	Inverness Medical Innovations, Inc. 2001 Employee Stock Purchase Plan Third Amendment (incorporated by reference to Exhibit 10.1 to Company s Quarterly Report on Form 10-Q for the period ended June 30, 2008)
10.42	Underwriting Agreement dated January 25, 2007 (incorporated by reference to Exhibit 1.1 to the Company s Current Report on Form 8-K, dated January 26, 2007)
10.43	Underwriting Agreement dated November 14, 2007 (incorporated by reference to Exhibit 1.1 to the Company s Current Report on Form 8-K, dated November 16, 2007)
10.44	$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)
10.45	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)
10.46	$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)
10.47	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)
10.48	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)
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 30, 2006)
*21.1	List of Subsidiaries of the Company as of February 25, 2009
*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.

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

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SIGNATURES

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

INVERNESS MEDICAL INNOVATIONS, INC.

Date: February 27, 2009

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.

Signature	Title	Date
/s/ Ron Zwanziger Ron Zwanziger	Chief Executive Officer, President and Director (Principal Executive Officer)	February 27, 2009
/s/ David Teitel David Teitel	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 27, 2009
/s/ Carol R. Goldberg Carol R. Goldberg	Director	February 27, 2009
/s/ Robert P. Khederian Robert P. Khederian	Director	February 27, 2009
/s/ John F. Levy John F. Levy	Director	February 27, 2009
/s/ Jerry McAleer Jerry McAleer	Director	February 27, 2009
/s/ John A. Quelch John A. Quelch	Director	February 27, 2009
/s/ David Scott	Director	February 27, 2009

David Scott		
/s/ Peter Townsend	Director	February 27, 2009
Peter Townsend		
/s/ James Roosevelt, Jr.	Director	February 27, 2009
James Roosevelt, Jr.		

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INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Inverness Medical Innovations, Inc. and Subsidiaries (the Company) as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders equity and comprehensive loss, and cash flows for each of the three years in the period ended December 31, 2008. 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, 2008 and 2007, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2008, in conformity with accounting principles generally accepted in the United States of America.

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, 2008, 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 27, 2009, expressed an unqualified opinion thereon.

/s/ BDO Seidman, LLP

Boston, Massachusetts
February 27, 2009

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INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	2008	2007	2006
Net product sales	$ 1,240,138	$ 800,915	$ 552,130
Services revenue	405,462	16,646	
Net product sales and services revenue	1,645,600	817,561	552,130
License and royalty revenue	25,826	21,979	17,324
Net revenue	1,671,426	839,540	569,454
Cost of net product sales	624,654	431,403	334,799
Cost of services revenue	177,098	5,261	
Cost of license and royalty revenue	9,115	9,149	5,432
Cost of net revenue	810,867	445,813	340,231
Gross profit	860,559	393,727	229,223
Operating expenses:			
Research and development	111,828	69,547	48,706
Purchase of in-process research and development		173,825	4,960
Sales and marketing	386,284	167,770	94,445
General and administrative	298,595	158,438	71,243
Loss on dispositions, net			3,498
Operating income (loss)	63,852	(175,853)	6,371
Interest expense, including amortization of original issue discounts and write-off of deferred financing costs	(101,144)	(83,025)	(26,570)
Other (expense) income, net	(2,212)	8,774	8,748
Loss before (benefit) provision for income taxes	(39,504)	(250,104)	(11,451)
(Benefit) provision for income taxes	(16,686)	(979)	5,727
Equity earnings of unconsolidated entities, net of tax	1,050	4,372	336
Net loss	(21,768)	(244,753)	(16,842)
Preferred stock dividends	(13,989)		
Net loss available to common stockholders	$ (35,757)	$ (244,753)	$ (16.842)
Net loss per common share basic and diluted	$ (0.46)	$ (4.75)	$ (0.49)
Weighted average shares basic and diluted	77,778	51,510	34,109

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

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INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands, except par value amounts)

	December 31, 2008	2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 141,324	$ 414,732
Restricted cash	2,748	141,869
Marketable securities	1,763	2,551
Accounts receivable, net of allowances of $12,835 and $12,167 at December 31, 2008 and 2007, respectively	280,608	163,380
Inventories, net	199,131	148,231
Deferred tax assets	104,311	18,170
Income tax receivable	6,406	5,256
Receivable from joint venture, net	12,018	
Prepaid expenses and other current assets	74,234	58,785
Total current assets	822,543	952,974
Property, plant and equipment, net	284,483	267,880
Goodwill	3,046,083	2,148,850
Other intangible assets with indefinite lives	42,984	43,097
Core technology and patents, net	459,307	432,583
Other intangible assets, net	1,169,330	869,644
Deferred financing costs, net, and other non-current assets	46,884	51,747
Investments in unconsolidated entities	68,832	77,753
Marketable securities	591	20,432
Deferred tax assets	14,323	15,799
Total assets	$ 5,955,360	$ 4,880,759
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 19,058	$ 20,320
Current portion of capital lease obligations	451	776
Accounts payable	112,704	72,061
Accrued expenses and other current liabilities	233,132	174,935
Payable to joint venture, net		10,816
Total current liabilities	365,345	278,908
Long-term liabilities:		
Long-term debt, net of current portion	1,500,557	1,366,395
Capital lease obligations, net of current portion	468	358

Deferred tax liabilities	462,787	326,128
Deferred gain on joint venture	287,030	293,078
Other long-term liabilities	60,335	29,225
Total long-term liabilities	2,311,177	2,015,184
Commitments and contingencies (Notes 8, 9 and 11)		
Stockholders equity:		
Series B preferred stock, $0.001 par value (liquidation preference, $751,479) Authorized: 2,300 shares Issued and outstanding: 1,879 shares	671,501	
Common stock, $0.001 par value Authorized: 150,000 shares Issued and outstanding: 78,431 shares at December 31, 2008 and 76,789 shares at December 31, 2007	78	77
Additional paid-in capital	3,029,694	2,937,143
Accumulated deficit	(393,590)	(371,822)
Accumulated other comprehensive (loss) income	(28,845)	21,269
Total stockholders equity	3,278,838	2,586,667
Total liabilities and stockholders equity	$ 5,955,360	$ 4,880,759

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

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INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE LOSS

(in thousands, except par value amounts)

	Preferred Stock $0.001 Par Value	Common Stock $0.001 Par Value						
	Number of Shares	Number of Shares	Additional Paid-in Capital	Notes Receivable From Stockholders	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders Equity	Total Comprehensive Loss
BALANCE, DECEMBER 31, 2005	$	27,497	$ 27	$ 515,147	$ (14,691)	$ (110,227)	$ 7,052	$ 397,308	
Issuance of common stock in connection with acquisitions and equity offering, net of issuance costs of $9,617		10,893	11	295,488				295,499	
Exercise of common stock options and warrants and shares issued under employee stock purchase plan		825	1	10,330				10,331	
Stock-based compensation related to grants of common stock options				5,455				5,455	
Stock option income tax benefits				567				567	
Repayment of notes receivable from stockholder options					14,691			14,691	
Effect of adoption of SFAS No. 158							(3,738)	(3,738)	
Changes in cumulative							10,823	10,823	$ 10,823

translation adjustment								
Unrealized gain on available-for-sale securities						44	44	44
Net loss					(16,842)		(16,842)	(16,842)
Total comprehensive loss								$ (5,975)
BALANCE, DECEMBER 31, 2006	$ 39,215	$ 39	$ 826,987	$	$ (127,069)	$ 14,181	$ 714,138	

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

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INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE LOSS
(Continued)
(in thousands, except par value amounts)

	Preferred Stock $0.001		Common Stock $0.001						
	Number of Shares	Par Value	Number of Shares	Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders Equity	Total Comprehensive Loss
BALANCE, DECEMBER 31, 2006		$	39,215	$ 39	$ 826,987	$ (127,069)	$ 14,181	$ 714,138	
Issuance of common stock in connection with acquisitions and equity offerings, net of issuance costs of $44,204			35,204	35	1,859,985			1,860,020	
Exercise of common stock options and warrants and shares issued under employee stock purchase plan									