

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)**

**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**

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

**For the transition period from            to**

**Commission file number 000-16789**

**INVERNESS MEDICAL INNOVATIONS, INC.**  
**(Exact Name of Registrant as Specified in Its Charter)**

**Delaware**

**(State or other jurisdiction of incorporation or  
organization)**

**04-3565120**

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

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

**(Address of principal executive offices)**

**02453**

**(Zip Code)**

**(781) 647-3900**

**(Registrant's telephone number, including area code)**

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

**Title of Each Class**

**Name of Each Exchange on Which Registered**

Common Stock, \$0.001 per share par value

New York Stock Exchange

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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  No

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

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

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

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

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

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

The aggregate market value of the voting common stock held by non-affiliates of the registrant based on the closing price of the registrant's stock on the 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](http://www.invmed.com) and we make available through this site, free of charge, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and Amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the Securities and Exchange Commission, or the SEC. These reports may be accessed through our website's investor information page. We also make our code of ethics and certain other governance documents and policies available through this site.

**Segments**

Our major reportable operating segments are professional diagnostics, health management, 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 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<sup>®</sup> 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 health 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 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 collectibility 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 significantly affects the revenues and operating results of our health management business. The business' future success will depend, in part, on its ability to retain and renew its managed care contracts and 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*