INVERNESS MEDICAL INNOVATIONS INC
Form 10-K/A
March 04, 2010

Table of Contents

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

FORM 10-K/A
(Amendment No. 1)

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

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2009
or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number 000-16789

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of February 24, 2010, the registrant had 83,874,282 shares of common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive proxy statement to be filed in connection with the registrant s annual meeting of shareholders currently scheduled to be held on June 30, 2010 are incorporated by reference into Part III of this Form 10-K.

INVERNESS MEDICAL INNOVATIONS, INC.

FORM 10-K
For The Fiscal Year Ended December 31, 2009

Table of Contents

EXPLANATORY NOTE

We are filing this Amendment No. 1 to our Annual Report on Form 10-K for the year ended December 31, 2009 which was filed with the U.S. Securities and Exchange Commission on March 1, 2010 (the Original Report) in order to provide additional signatures, which were inadvertently omitted from the Original Report.

We have made no other significant changes to the Original Report, although we have corrected certain historical interest rates provided within Note 6(a) to the consolidated financial statements filed as part of the Original Report and refiled Exhibit 21.1 to the Original Report. In order to preserve the nature and character of the disclosures set forth in the Original Report, this report speaks as of the date of the filing of the Original Report, March 1, 2010, and we have not updated the disclosures in this report to speak as of a later date.

Table of Contents

PART I

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Readers can identify these statements by forward-looking words such as may, could, should, would, intend, will, expect, anticipate, believe, estimate, continue or similar words. Readers should carefully review statements that contain these words because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other forward-looking information. We caution investors that all such forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from any projected results or expectations that we discuss in this report. You should therefore carefully review the risk factors and uncertainties discussed in Item 1A entitled Risk Factors, which begins on page 14 of this report, as well as those factors identified from time to time in our periodic filings with the Securities and Exchange Commission. We undertake no obligation to update any forward-looking statements.

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

ITEM 1. BUSINESS

GENERAL

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

Inverness Medical Innovations, Inc., a Delaware corporation, was formed to acquire the women s health and professional diagnostics businesses of its predecessor, Inverness Medical Technology, Inc., through a split-off and merger transaction, which occurred in November 2001. Our common stock is listed on the New York Stock Exchange under the symbol IMA. We have grown our businesses through strategic acquisitions, tactical use of our superior intellectual property portfolio and through organic growth.

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

Segments

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

Statements which are included elsewhere in this report.

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

Table of Contents

Products and Services

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

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

Our current professional diagnostic products test for over 100 disease states and conditions and include point-of-care and laboratory tests in the following areas:

Cardiology. Cardiovascular disease encompasses a spectrum of conditions and illnesses, including high blood pressure, high cholesterol, metabolic syndrome, coronary artery disease, heart attack, heart failure and stroke. It is estimated that 80 million Americans alone have one or more types of cardiovascular disease. The worldwide cardiology diagnostic market, including the markets for heart failure diagnostics, coronary artery disease risk assessment, coagulation testing and acute coronary syndrome, exceeds $1.5 billion. Our Triage, Cholestech LDX and INRatio products, all acquired through acquisitions in 2007, have established us as a leader in this market. The Triage system consists of a portable fluorometer that interprets consumable test devices for cardiovascular conditions, as well as the detection of certain drugs of abuse. The Triage cardiovascular tests include the following:

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

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

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

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

evaluation of patients suspected of having disseminated intravascular coagulation and thromboembolic events, including pulmonary embolism and deep vein thrombosis, and the risk stratification of patients with acute coronary syndromes. This panel combines troponin I, CK-MB, myoglobin, BNP and d-dimer to provide rapid, accurate results in whole blood and plasma.

Table of Contents

Triage D-Dimer Test. An immunoassay for use as an aid in the assessment and evaluation of patients suspected of having disseminated intravascular coagulation or thromboembolic events, including pulmonary embolism and deep vein thrombosis.

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

The INRatio System is an easy-to-use, hand-held blood coagulation monitoring system for use by patients and healthcare professionals in the management of warfarin, a commonly prescribed medication used to prevent blood clots. The INRatio System measures PT/INR, which is the patient s blood clotting time reported pursuant to an internationally normalized ratio, to help ensure that patients with risk of blood clot formation are maintained within the therapeutic range with the proper dosage of oral anticoagulant therapy. The INRatio System is 510(k) cleared by the FDA for use by healthcare professionals, as well as for patient self-testing, and is also CE marked in Europe. The INRatio System is targeted to both the professional, or point-of-care market, as well as the patient self-testing market. Recently we introduced the INRatio2 System, which targets the patient self-testing market and offers enhanced ease of use. Patient self-testing has gained significant momentum since March 2008 when Centers for Medicare & Medicaid Services expanded coverage of home INR monitoring to include chronic atrial fibrillation and venous thromboembolism patients on warfarin.

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

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

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

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

Osteomark brands.

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

Table of Contents

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

In addition to point-of-care products, we also offer a line of indirect fluorescent antibody, or IFA, assays for over 20 viral, bacterial and autoimmune diseases, a full line of serology diagnostic products covering a broad range of disease categories and over 70 enzyme-linked immunosorbent assays (ELISA) tests for a wide variety of infectious and autoimmune diseases, as well as a full line of automated instrumentation for processing ELISA assays. We are the exclusive U.S. distributor of the AtheNA Multi-Lyte® Test System, a multiplexed, fluorescent bead-based system designed to simultaneously perform multiple assays from a single sample using just one well. It offers a simple and streamlined alternative to IFA and ELISA testing, providing improved clinical sensitivity and comparable clinical specificity in a labor-saving, automation-friendly format. Our IFA, serology and ELISA products, which generally serve the clinical diagnostics laboratory markets, are generally marketed under our Wampole brand.

Demand for certain infectious disease tests, primarily Influenza A/B, or flu, is significantly affected by the seasonal nature of the cold and flu season. As a result, we typically experience higher sales of our flu tests in the first and fourth quarters. Sales of our flu products also vary from year to year based in large part on the severity, length and timing of the onset of the cold and flu season. While we believe that the severity, length and timing of the onset of the cold and flu season will continue to impact sales of certain of our infectious disease products, there can be no assurance that our future sales of these products will necessarily follow historical patterns.

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

Our Clearview FOB and Ultra FOB rapid tests aid in the early detection of colorectal cancer, the third most common type of cancer in men and the second most common in women.

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

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

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

Table of Contents

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

Our rapid drugs of abuse tests are sold primarily under the brands Triage, iScreen, Concateno and SureStep. The TOX Drug Screen panel sold for use with our Triage system detects the presence of any illicit or prescription drugs listed above at the point-of-care in approximately 15 minutes. It is widely used in hospital and clinical testing as a laboratory instrument to aid in the detection of drug abuse. Our Drug Detection System, or DDS, is an enhanced, on-site saliva drug detection system which displays results for the presence of up to six different drugs in under five minutes and two drugs in under 90 seconds.

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

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

Our expert-designed health management programs:

- embrace the entire lifespan, from pre-cradle to end-of-life, and targeted health states, from wellness to prevention to total health management of the individual for those having various chronic illnesses.
- target high-cost chronic conditions with programs designed to improve outcomes and reduce expenditures.
- provide health coaches who engage and motivate participants during teachable moments.
- help participants improve their health by supporting their individual health goals.
- bring greater clarity to healthcare with empowering technologies that lead to better outcomes.
- offer the expertise of 1,850 healthcare professionals who share a passion for patient and customer care.

Our key health management programs are:

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

to comply with their treatment plan.

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

Table of Contents

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

Consumer Diagnostics. On May 17, 2007, we and affiliates of The Procter & Gamble Company, or P&G, commenced a 50/50 joint venture for the development, manufacturing, marketing and sale of existing and to-be-developed consumer diagnostic products, outside the cardiology, diabetes and oral care fields. As part of this arrangement, we transferred essentially all of the assets of our consumer diagnostics business, other than our manufacturing and core intellectual property assets, to the joint venture, and P&G acquired its interest in the joint venture. Accordingly, substantially all of the consumer diagnostics business conducted by us prior to the joint venture, including all of our products targeting the worldwide over-the-counter pregnancy and fertility/ovulation test market, are now sold by the joint venture, which is an unconsolidated entity operating primarily under the name SPD Swiss Precision Diagnostics GmbH, or SPD.

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

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

Methods of Distribution and Customers

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

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

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

Table of Contents

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

Manufacturing

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

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

Research and Development

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

Global Operations

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

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

Competition

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

Table of Contents

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

Our competitors in the ELISA diagnostics market include the large diagnostics companies named above, which manufacture state-of-the-art automated immunoassay systems and a wide array of diagnostic products designed for processing on those systems. Other competitors in this market, DiaSorin and Diamedx, in particular, are smaller companies who compete based on quality and service. In the United States and Canada, we focus on matching the instrumentation and product testing requirements of our customers by offering a wide selection of diagnostic products and test equipment.

The markets for our serology and our IFA and microbiology products are mature and competition is based primarily on price and customer service. Our main competitors in serology and microbiology testing include Remel and Biokit. Our main competitors in IFA testing are Bio-Rad Laboratories, INOVA Diagnostics, Immuno Concepts, The Binding Site, Trinity Biotech, Meridian Biosciences and DiaSorin. However, products in these categories also compete to a large extent against rapid membrane and ELISA products, which are often easier to perform and read and can be more precise.

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

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

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

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

Table of Contents

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

Consumer Diagnostics. Our First Check tests compete against over-the-counter diagnostic tests sold primarily by Phamatech, Inc., but also by other smaller competitors. Essentially, all of our remaining consumer diagnostic product sales are to SPD, our joint venture. These products are sold by SPD in retail markets where competition is intense and based primarily on brand recognition and price. Our revenues, as well as our share of the profits from the sale of these products by SPD, are dependent upon SPD s ability to effectively compete in these markets.

Patents and Proprietary Technology; Trademarks

We have built a strong intellectual property portfolio consisting of an increasing number of patents, patent applications and licensed patents which protect our vision of the technologies, products and services of the future. Our intellectual property portfolio consists of patents that we own and, in some cases, licenses to patents or other proprietary rights of third parties which may be limited in terms of field of use, transferability or may require royalty payments.

The medical products industry, including the diagnostic testing industry, historically has been characterized by extensive litigation regarding patents, licenses and other intellectual property rights. As the fact of our pending litigation with Healthways, Inc. and Robert Bosch North America Corp. and with Health Hero Network Inc. suggests, litigation relating to intellectual property rights is also a risk in the health management industry. For more information regarding these pending matters see Item 3 entitled Legal Proceedings beginning on page 31.

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

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

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

afford us. For more information regarding the risks associated with our reliance on intellectual property rights see the risk factors discussed in Item 1A entitled Risk Factors on pages 14 through 30 of this report.

Table of Contents

Government Regulation

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

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

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

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

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

Employees

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

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

Table of Contents

ITEM 1A. RISK FACTORS

The risks described below may materially impact your investment in our company or may in the future, and, in some cases already do, materially affect us and our business, financial condition and results of operations. You should carefully consider these factors with respect to your investment in our securities. This section includes or refers to certain forward-looking statements; you should read the explanation of the qualifications and limitations on such forward-looking statements beginning on pages 3 and 36 of this report.

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

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

Our business has substantial indebtedness, which could, among other things, make it more difficult for us to satisfy our debt obligations, require us to use a large portion of our cash flow from operations to repay and service our debt or otherwise create liquidity problems, limit our flexibility to adjust to market conditions, place us at a competitive disadvantage and expose us to interest rate fluctuations.

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

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

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

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

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

which we operate;

impair our ability to obtain additional financing;

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

Table of Contents

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

We expect to obtain the money to pay our expenses and to pay the principal and interest on our indebtedness from cash flow from our operations and potentially from other debt or equity offerings. Accordingly, our ability to meet our obligations depends on our future performance, which will be affected by financial, business, economic and other factors. We will not be able to control many of these factors, such as economic conditions in the markets in which we operate and pressure from competitors. We cannot be certain that our cash flow will be sufficient to allow us to pay principal and interest on our debt and meet our other obligations. If our cash flow and capital resources prove inadequate, we could face substantial liquidity problems and might be required to dispose of material assets or operations, restructure or refinance our debt, seek additional equity capital or borrow more money. We cannot guarantee that we will be able to do so on acceptable terms. In addition, the terms of existing or future debt agreements may restrict us from adopting any of these alternatives.

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

The agreements governing our indebtedness, including the credit agreements governing our secured credit facilities and the indentures governing our senior notes, our senior subordinated notes and our senior subordinated convertible notes, subject us to various restrictions on our ability to engage in certain activities, including, among other things, our ability to:

incur additional debt;

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

acquire other businesses;

make investments;

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

prepay indebtedness;

enter into transactions with affiliates;

raise additional capital;

make capital or finance lease expenditures;

dispose of or encumber assets; and

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

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

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

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

Table of Contents

facilities, including the interest rates, financial and restrictive covenants and security requirements of the secured credit facilities, on terms that may be significantly less favorable to us.

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

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

coordinating geographically separate organizations.

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

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

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

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

the inability to complete the acquisition or investment;

disruption of our ongoing businesses and diversion of management attention;

difficulties in integrating the acquired entities, products or technologies;

difficulties in operating the acquired business profitably;

difficulties in transitioning key customer, distributor and supplier relationships;

difficulties in evaluating, integrating and retaining key management;

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

unanticipated costs.

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

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

use of significant amounts of cash;

the incurrence of debt;

the assumption of significant liabilities, including litigation;

unfavorable financing terms;

large one-time expenses; and

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

Table of Contents

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

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

- we may not be able to agree on terms and conditions which we believe are reasonable;
- we may be out bid by another party or parties;
- we may not be able to finance the purchase price;
- we may not have enough available stock to use as consideration;
- a competitor may come to an agreement to acquire a targeted business before we are able to; or
- antitrust or other laws or regulations may prohibit the acquisition or prevent us from completing the acquisition or investment in a manner which we believe would benefit us.

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

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

- difficulties in integrating our corporate culture and business objectives with that of P&G into the joint venture;
- diversion of our management s time and attention from other business concerns;
- difficulties in retaining key employees who are necessary to manage the joint venture; or
- difficulties in working with an entity based in Switzerland and thus remote or inconvenient to our Waltham, Massachusetts headquarters.

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

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

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

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

of such a transaction.

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

In connection with the accounting for our acquisitions we have recorded, or will record, a significant amount of goodwill and other intangible assets. Under current accounting guidelines, we must assess, at least annually and potentially more frequently, whether the value of goodwill and other intangible assets has been impaired. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings, which could materially adversely affect our reported results of operations in future periods.

Table of Contents

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

Many of our manufacturing processes are complex and involve sensitive scientific processes, including unique and often proprietary antibodies which cannot be replicated or acquired through alternative sources without undue delay or expense. In addition, our manufacturing processes often require complex and specialized equipment which can be expensive to repair or replace with required lead times of up to a year. Also, our private label consumer diagnostics business relies on operational efficiency to mass produce products at low margins per unit. We also rely on numerous third parties to supply production materials and, in some cases, there may not be alternative sources immediately available.

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

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

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

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

- any of the products or services under development will prove to be effective in clinical trials;
- any products or services under development will not infringe on intellectual property rights of others;
- we will be able to obtain, in a timely manner or at all, regulatory approval to market any of our products or services that are in development or contemplated;
- the products and services we develop can be manufactured or provided at acceptable cost and with appropriate quality; or
- these products and services, if and when approved, can be successfully marketed.

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

Table of Contents

If the results of clinical studies required to gain regulatory approval to sell our products are not available when expected, or do not demonstrate the anticipated safety and effectiveness of those potential products, we may not be able to sell future products and our sales could be adversely affected.

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

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

If we are unable to obtain required clearances or approvals for the commercialization of our products in the United States, we may not be able to sell future products and our sales could be adversely affected.

Our future performance depends on, among other matters, our estimates as to when and at what cost we will receive regulatory approval for new products. Regulatory approval can be a lengthy, expensive and uncertain process, making the timing, cost and ability to obtain approvals difficult to predict. In addition, regulatory processes are subject to change, and new or changed regulations can result in increased costs and unanticipated delays.

In the United States, clearance or approval to commercially distribute new medical devices is received from the FDA through clearance of a Premarket Notification, or 510(k), or through approval of a Premarket Approval, or PMA. To receive 510(k) clearance, a new product must be substantially equivalent to a medical device first marketed in interstate commerce prior to May 1976. The FDA may determine that a new product is not substantially equivalent to a device first marketed in interstate commerce prior to May 1976 or that additional information is needed before a substantial equivalence determination can be made. A not substantially equivalent determination, or a request for additional information, could prevent or delay the market introduction of new products that fall into this category. The 510(k) clearance and PMA review processes can be expensive, uncertain and lengthy. It generally takes from three to five months from submission to obtain 510(k) clearance, and from six to eighteen months from submission to obtain a PMA approval; however, it may take longer, and 510(k) clearance or PMA approval may never be obtained.

Modifications or enhancements that could significantly affect safety or effectiveness, or constitute a major change in the intended use of the device, require new 510(k) or PMA submissions. We have made modifications to some of our products since receipt of initial 510(k) clearance or PMA. With respect to several of these modifications, we filed new 510(k)s describing the modifications and received FDA 510(k) clearance. We have made other modifications to some of our products that we believe do not require the submission of new 510(k)s or PMAs. The FDA may not agree with any of our determinations not to submit a new 510(k) or PMA for any of these modifications made to our products. If the FDA requires us to submit a new 510(k) or PMA for any device modification, we may be prohibited from marketing the modified products until the new submission is cleared by the FDA.

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

Table of Contents

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

In addition to regulatory requirements in the United States, we are subject to the regulatory approval requirements for each foreign country to which we export our products. In the European Union, regulatory compliance requires affixing the CE mark to product labeling. Although our products are currently eligible for CE marking through self-certification, this process can be lengthy and expensive. In Canada, as another example, our products require approval by Health Canada prior to commercialization, along with International Standards Organization, or ISO, 13485/CMDCAS certification. It generally takes from three to six months from submission to obtain a Canadian Device License. Any changes in foreign approval requirements and processes may cause us to incur additional costs or lengthen review times of our products. We may not be able to obtain foreign regulatory approvals on a timely basis, if at all, and any failure to do so may cause us to incur additional costs or prevent us from marketing our products in foreign countries, which may have a material adverse effect on our business, financial condition and results of operations.

Failure to comply with ongoing regulations applicable to our businesses may result in significant costs or, in certain circumstances, the suspension or withdrawal of previously obtained clearances or approvals.

Our businesses are extensively regulated by the FDA and other federal, state and foreign regulatory agencies. These regulations impact many aspects of our operations, including manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping. For example, our manufacturing facilities and those of our suppliers and distributors are, or can be, subject to periodic regulatory inspections. The FDA and foreign regulatory agencies may require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any product approvals that could restrict the commercial applications of those products. In addition, the subsequent discovery of previously unknown problems with a product may result in restrictions on the product, including withdrawal of the product from the market. We are also subject to routine inspection by the FDA and certain state agencies for compliance with the Quality System Regulation and Medical Device Reporting requirements in the United States and other applicable regulations worldwide, including but not limited to ISO requirements. CLIA extended federal oversight to many clinical laboratories, including certain of our drug testing laboratories in the United States, by requiring that they be certified to meet quality assurance, quality control and personnel standards. Laboratories also must undergo proficiency testing and are subject to inspections. Certain of our drug testing laboratories perform drug testing on employees of federal government contractors and certain other entities and are therefore regulated by SAMHSA, which has established detailed performance and quality standards that laboratories must meet to be approved to perform drug testing on employees of federal government contractors and certain other entities. Certain portions of our health management business are subject to unique licensing or permit requirements. For example, we may be required to obtain certification to participate in governmental payment programs, such as state Medicaid programs, we may need an operating license in some states, and some states have established Certificate of Need programs regulating the expansion of healthcare operations. In addition, we believe certain of our health management services are educational in nature, do not constitute the practice of medicine or provision of healthcare, and thus do not require that we maintain federal or state licenses to provide such services. However, it is possible that federal or state laws regarding the provision of virtual or telephonic medicine could be revised or interpreted to include our services, or that other laws may be enacted which require licensure or otherwise relate to our health management services. In such event, we may incur significant costs to comply with such laws and regulations. In addition, we are subject to numerous federal, state and local laws relating to such matters as privacy, healthcare kickbacks and false claims, safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with these laws and regulations. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products or injunctions against our distribution, termination of our service agreements by our customers, disgorgement of money, operating

restrictions and criminal prosecution.

Table of Contents

New federal or state laws may be enacted, or regulatory agencies may impose new or enhanced standards, that would increase our costs, as well as expose us to risks associated with non-compliance. In addition, the federal government recently enacted the Genetic Information Non-discrimination Act of 2008, or GINA, and we may incur additional costs in assisting our customers with their efforts to comply with GINA while continuing to offer certain of our services.

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

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

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

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

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

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

Table of Contents

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

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

- our ability to differentiate our health management services from those of our competitors;
- the extent and timing of the acceptance of our services as a replacement for, or supplement to, traditional managed care offerings;
- the effectiveness of our sales and marketing and engagement efforts with customers and their health plan participants;
- our ability to sell and implement new and additional services beneficial to health plans and employers and their respective participants or employees;
- our ability to achieve, measure and effectively communicate cost savings for health plans and employers through the use of our services; and
- our ability to retain health plan and employee accounts as competition increases and as health plan customers may choose to provide health management services themselves.

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

Increasing health insurance premiums and co-pays may cause individuals to forgo health insurance and avoid medical attention, either of which may reduce demand for our products and services.

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

Demands of non-governmental payers may adversely affect our growth in revenues.

Our ability to negotiate favorable contracts with non-governmental payers, including managed care plans, significantly affects the revenues and operating results of our health management business. These non-governmental payers increasingly are demanding discounted fee structures, and the trend toward consolidation among non-governmental payers tends to increase their bargaining power over fee structures. Reductions in price increases or the amounts received from managed care, commercial insurance or other payers could have a material, adverse effect on the financial position and results of operations of our health management business.

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

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

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

Table of Contents

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

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

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

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

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

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

The medical products industry is rapidly evolving, and developments are expected to continue at a rapid pace. Competition in this industry, which includes both our professional diagnostics and consumer diagnostics businesses, is intense and expected to increase as new products and technologies become available and new competitors enter the market. Our competitors in the United States and abroad are numerous and include, among others, diagnostic testing and medical products companies, universities and other research institutions.

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

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

Table of Contents

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

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

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

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

We are involved in various legal proceedings arising out of our businesses, including those matters discussed in Item 3 entitled Legal Proceedings beginning on page 31. Because of the nature of our business, we may be subject at any particular time to commercial disputes, product liability claims, negligence claims or various other lawsuits arising in the ordinary course of our business, including infringement, employment or investor matters, and we expect that this will continue to be the case in the future. Such lawsuits generally seek damages, sometimes in substantial amounts, for commercial or personal injuries allegedly suffered and can include claims for punitive or other special damages. An adverse ruling or rulings in one or more such lawsuits could, individually or in the aggregate, have a material adverse effect on our sales, operations or financial performance. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties. These suits can be expensive and result in counterclaims challenging the validity of our patents and other rights. We cannot assure you that these lawsuits or any future lawsuits relating to our business will not have a material adverse effect on us.

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

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

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

pending patent applications we have filed, or to which we have exclusive rights, may not result in issued patents or may take longer than we expect to result in issued patents;

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

our inability to develop additional proprietary technologies that are patentable;

patents licensed or issued to us or our customers may not provide a competitive advantage;

other parties may challenge patents or patent applications licensed or issued to us or our customers;

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

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

all patents have a limited life, meaning at some point valuable patents will expire and we may lose the competitive advantage which they provide.

In addition to patents, we rely on a combination of trade secrets, non-disclosure agreements and other contractual provisions and technical measures to protect our intellectual property rights. Nevertheless, these

Table of Contents

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

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

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

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

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

assert claims of infringement;

enforce our patents;

protect our trade secrets or know-how; or

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

Table of Contents

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

Our Series B Preferred Stock is convertible into common stock in certain circumstances. If the conditions to conversion were satisfied, then subject to adjustment, each of the approximately 2.0 million shares of Series B Preferred Stock outstanding as of December 31, 2009 could convert into 5.7703 shares of our common stock, or approximately 11.4 million shares of our common stock. Upon certain extraordinary transactions, depending on the market price of our common stock at that time, the conversion rate could increase such that significantly more shares of common stock could be issued. Our $150.0 million principal amount of senior subordinated convertible notes is convertible into shares of our common stock at a conversion price of approximately $43.98 per share, or approximately 3.4 million shares. Sales of a substantial number of shares of our common stock in the public market could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. We cannot predict the effect that future sales of our common stock or other equity-related securities would have on the market price of our common stock. The price of our common stock could be affected by possible sales of our common stock by holders of our Series B Preferred Stock or our senior subordinated convertible notes and by other hedging or arbitrage trading activity that may develop involving our common stock.

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

The current outstanding shares of our Series B Preferred Stock have an aggregate stated liquidation preference of approximately $793.7 million. Dividends accrue on the shares of Series B Preferred Stock at a rate of 3% per annum, and we have the option to pay these dividends in shares of common stock or additional shares of Series B Preferred Stock and in either case must satisfy the dividend obligation by issuing the requisite number of shares based upon market prices. Upon a liquidation of our company, the holders of shares of Series B Preferred Stock shall be entitled to receive a liquidation payment prior to the payment of any amount with respect to the shares of our common stock. The amount of this preferential liquidation payment is the aggregate stated liquidation preference, plus any accrued but unpaid dividends. Because of the substantial liquidation preference to which the holders of the Series B Preferred Stock shall be entitled, the amount available to be distributed to the holders of our common stock upon a liquidation of our company could be substantially limited or reduced to zero.

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

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

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

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

following:

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

Table of Contents

provision may have the effect of keeping the current members of our board of directors in control for a longer period of time than stockholders may desire;

our certificate of incorporation authorizes our board of directors to issue shares of preferred stock without stockholder approval and to establish the preferences and rights of any preferred stock issued, which would allow the board to issue one or more classes or series of preferred stock that could discourage or delay a tender offer or change in control;

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

A "business combination" is defined to include mergers, asset sales and other transactions resulting in financial benefit to a stockholder. In general, an "interested stockholder" is a person who, together with affiliates and associates, owns 15% or more of a corporation's voting stock or within three years did own 15% or more of a corporation's voting stock.

The above-described provisions of the Delaware General Corporations Law may limit certain transactions with interested stockholders.

Description of Warrants

We may issue warrants to purchase shares of common stock. We may issue warrants independently or together with the shares of common stock offered, and the warrants may be attached to or separate from these securities. We may issue warrants in such amounts or in as many distinct series as we wish. The warrants will be issued under warrant agreements to be entered into between us and a warrant agent as detailed in the prospectus supplement relating to the warrants being offered.

Specific Terms of the Warrants

The applicable prospectus supplement will describe the following terms, where applicable, of the warrants in respect of which this prospectus is being delivered:

- the title of the warrants;
- the aggregate number of the warrants;
- the price or prices at which the warrants will be issued;
- the designation, amount, and terms of the shares of common stock purchasable upon exercise of the warrants;
- if applicable, the date on and after which the warrants and the shares of common stock purchasable upon exercise of the warrants will be separately transferable;
- the price or prices at which the shares of common stock purchasable upon exercise of the warrants may be purchased;
- the date on which the right to exercise the warrants shall commence and the date on which the right shall expire;
- the minimum or maximum amount of the warrants which may be exercised at any one time;
- information with respect to book-entry procedures, if any;
- in the case of warrants to purchase our shares of common stock, any provisions for adjustment of the number or amount of shares of our shares of common stock receivable upon exercise of the warrants or the exercise price of the warrants; and
- any other material terms of the warrants, including terms, procedures, and limitations relating to the redemption, exchange and exercise of the warrants.

Exercise of Warrants

Each warrant will entitle the holder of the warrant to purchase the shares of common stock at the exercise price as shall be set forth in or be determinable as set forth in, the prospectus supplement relating to the warrants. Warrants may be exercised at any time up to the close of business on the expiration date set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Upon receipt of payment and the warrant certificate properly completed and duly executed at the office indicated in the prospectus supplement, we will, as soon as practicable, forward the securities purchased upon such exercise. If less than all of the warrants represented by a warrant certificate are exercised, a new warrant certificate will be issued for the remaining warrants.

Prior to the exercise of any warrants, holders of the warrants will not have any of the rights of holders of the securities purchasable upon exercise, including the right to vote or to receive any payments of dividends on the preferred or shares of common stock purchasable upon exercise.

Certificates for warrants to purchase securities will be exchangeable for new warrant certificates of different denominations.

Description of Units

The following description, together with the additional information we may include in any applicable prospectus supplement, summarizes the material terms and provisions of the units that we may offer under this prospectus. While the terms we have summarized below will apply generally to any units that we may offer under this prospectus, we will describe the particular terms of any series of units in more detail in the applicable prospectus supplement. The terms of any units offered under a prospectus supplement may differ from the terms described below.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from a current report on Form 8-K that we file with the SEC, the form of unit agreement that describes the terms of the series of units we are offering, and any supplemental agreements, before the issuance of the related series of units. The following summaries of material terms and provisions of the units are subject to, and qualified in their entirety by reference to, all the provisions of the unit agreement and any supplemental agreements applicable to a particular series of units. We urge you to read the applicable prospectus supplements related to the particular series of units that we sell under this prospectus, as well as the complete unit agreement and any supplemental agreements that contain the terms of the units.

General

We may issue units comprised of one or more shares of common stock and warrants in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit, and the components of the units may separate upon issuance. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued, if any, may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

We will describe in the applicable prospectus supplement the terms of the series of units, including:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any provisions of the governing unit agreement that differ from those described below; and
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units.

The provisions described in this section, as well as those described under “Description of Shares of common stock” and “Description of Warrants” will apply to each unit and to any shares of common stock or warrants included in each unit, respectively.

Issuance in Series

We may issue units in such amounts and in such numerous distinct series as we determine.

Enforceability of Rights by Holders of Units

Each unit agent will act solely as our agent under the applicable unit agreement and will not assume any obligation or relationship of agency or trust with any holder of any unit. A single bank or trust company may act as unit agent for more than one series of units. A unit agent will have no duty or responsibility in case of any default by us under the applicable unit agreement or unit, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a unit may, without the consent of the related unit agent or the holder of any other unit, enforce by appropriate legal action its rights as holder under any security included in the unit.

Title

We, the unit agent and any of their agents may treat the registered holder of any unit certificate as an absolute owner of the units evidenced by that certificate for any purpose and as the person entitled to exercise the rights attaching to the units so requested, despite any notice to the contrary.

22

PLAN OF DISTRIBUTION

We may sell the securities offered under this prospectus:

- through underwriters;
- through dealers;
- through agents; or
- directly to purchasers.

Each prospectus supplement relating to an offering of securities will state the terms of the offering, including:

- the names of any underwriters, dealers, or agents;
- the public offering or purchase price of the offered securities and the net proceeds that we will receive from the sale;
- any underwriting discounts and commissions or other items constituting underwriters' compensation;
- any discounts, commissions, or fees allowed or paid to dealers or agents; and
- any securities exchange or market on which the offered securities may be listed.

With respect to any offering under this prospectus, the aggregate of all underwriting discounts, commissions and other compensation and any discounts, commissions or fees allowed or paid to dealers or agent shall not exceed 15% of the gross proceeds of such offering.

Distribution Through Underwriters

We may offer and sell securities from time to time to one or more underwriters who would purchase the securities as principal for resale to the public, either on a firm commitment or best efforts basis. If we sell securities to underwriters, we will execute an underwriting agreement with the underwriters at the time of the sale and will name them in the applicable prospectus supplement. In connection with these sales, the underwriters may be deemed to have received compensation from us in the form of underwriting discounts and commissions. The underwriters also may receive commissions from purchasers of securities for whom they may act as agent. Unless we specify otherwise in the applicable prospectus supplement, the underwriters will not be obligated to purchase the securities unless the conditions set forth in the underwriting agreement are satisfied, and if the underwriters purchase any of the securities, they will be required to purchase all of the offered securities. The underwriters may acquire the securities for their own account and may resell the securities from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or varying prices determined at the time of sale. The underwriters may sell the offered securities to or through dealers, and those dealers may receive discounts, concessions, or commissions from the underwriters as well as from the purchasers for whom they may act as agent. Any initial public offering price and any discounts or concessions allowed or reallowed or paid to dealers may be changed from time to time.

Distribution Through Dealers

We may offer and sell securities from time to time to one or more dealers who would purchase the securities as principal. The dealers then may resell the offered securities to the public at fixed or varying prices to be determined

by those dealers at the time of resale. We will set forth the names of the dealers and the terms of the transaction in the applicable prospectus supplement.

Distribution Through Agents

We may offer and sell securities on a continuous basis or otherwise through agents that become parties to an underwriting or distribution agreement. We will name any agent involved in the offer and sale and describe any commissions payable by us in the applicable prospectus supplement. Unless we specify otherwise in the applicable prospectus supplement, the agent will be acting on a best efforts basis during the appointment period.

Direct Sales

We may sell directly to, and solicit offers from, institutional investors or others who may be deemed to be underwriters, as defined in the Securities Act of 1933 for any resale of the securities. We will describe the terms of any sales of this kind in the applicable prospectus supplement.

General Information

Underwriters, dealers, or agents participating in an offering of securities may be deemed to be underwriters, and any discounts and commissions received by them and any profit realized by them on resale of the offered securities for whom they act as agent, may be deemed to be underwriting discounts and commissions under the Securities Act of 1933.

We may sell securities at a fixed price or prices, which may be changed, at market prices prevailing at the time of sale, at prices relating to the prevailing market prices or at negotiated prices. The distribution of the securities may be effected from time to time in one or more transactions, by means of one or more of the following transactions, which may include:

- block trades;
- at-the-market offerings;
- negotiated transactions;
- put or call option transactions relating to the securities;
- under delayed delivery contracts or other contractual commitments;
- a combination of such methods of sale; and
- any other method permitted pursuant to applicable law.

Only underwriters named in the prospectus supplement are underwriters of the securities offered by the prospectus supplement.

In connection with an underwritten offering of securities, the underwriters may engage in over-allotment, stabilizing transactions, and syndicate covering transactions in accordance with Regulation M under the Exchange Act. Over-allotment involves sales in excess of the offering size, which creates a short position for the underwriters. The underwriters may enter bids for, and purchase, securities in the open market in order to stabilize the price of the securities. Syndicate covering transactions involve purchases of the securities in the open market after the distribution has been completed in order to cover short positions. In addition, the underwriting syndicate may reclaim selling concessions allowed to an underwriter or a dealer for distributing the securities in the offering if the syndicate

repurchases previously distributed securities in transactions to cover syndicate short positions, in stabilization transactions, or otherwise. These activities may cause the price of the securities to be higher than it would otherwise be. Those activities, if commenced, may be discontinued at any time.

Ordinarily, each issue of securities will be a new issue, and there will be no established trading market for any security other than our shares of common stock prior to its original issue date. We may choose not to list any particular series of securities on a securities exchange or quotation system. Any underwriters to whom or agents through whom the offered securities are sold for offering and sale may make a market in the offered securities. However, any underwriters or agents that make a market will not be obligated to do so and may stop doing so at any time without notice. We cannot assure you that there will be a liquid trading market for the offered securities.

Under agreements entered into with us, underwriters and agents may be entitled to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, or to contribution for payments the underwriters or agents may be required to make.

Although we expect that delivery of securities generally will be made against payment on or about the third business day following the date of any contract for sale, we may specify a longer settlement cycle in the applicable prospectus supplement. Under Rule 15c6-1 of the Exchange Act, trades in the secondary market generally are required to settle in three business days, unless the parties to a trade expressly agree otherwise. Accordingly, if we have specified a longer settlement cycle in the applicable prospectus supplement for an offering of securities, purchasers who wish to trade those securities on the date of the contract for sale, or on one or more of the next succeeding business days as we will specify in the applicable prospectus supplement, will be required, by virtue of the fact that those securities will settle in more than T+3, to specify an alternative settlement cycle at the time of the trade to prevent a failed settlement and should consult their own advisors in connection with that election.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

As permitted by SEC rules, this prospectus does not contain all of the information that prospective investors can find in the registration statement of which it is a part or the exhibits to the registration statement. The SEC permits us to incorporate by reference, into this prospectus, information filed separately with the SEC.

This prospectus incorporates by reference the documents set forth below that we previously have filed with the SEC pursuant to the Securities Exchange Act of 1934 (File no. 001-12497). These documents contain important information about us and our financial condition.

(1) The Registrant's Annual Report on Form 10-K for the year ended December 31, 2011, filed with the SEC on March 30, 2012, as amended by Amendment No. 1 on April 30, 2012;*

(2) The Registrant's Quarterly Reports on Form 10-Q filed with the SEC on May 11, 2012 and August 10, 2012;*

(3) The Registrant's Current Reports on Form 8-K filed with the SEC on January 11, 2012, January 19, 2012, February 23, 2012, April 5, 2012, April 24, 2012, May 7, 2012, May 14, 2012, June 21, 2012, July 10, 2012, August 13, 2012, August 22, 2012 and September 13, 2012 (excluding any information that is furnished pursuant to Item 2.02 or 7.01 and related Exhibits);* and

(4) The description of the Common Shares of the Registrant contained in its Amendment No. 4 on Form 10/A filed with the SEC on July 9, 2012.*

* File No. 001-12497.

All documents filed by us pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act after the date of this registration statement, and prior to the filing of a post-effective amendment which indicates that all securities offered hereby have been sold or which de-registers all securities then remaining unsold, shall be deemed to be incorporated by reference in this registration statement and to be a part hereof from the date of filing of such documents. Any statement contained in a document incorporated by reference herein shall be deemed to be modified or superseded for purposes of this registration statement to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

Upon written or oral request, we will provide without charge to each person to whom a copy of this prospectus is delivered, including any beneficial owner, a copy of the information that has been or may be incorporated by reference in this prospectus. Direct any request for copies to Stephen Huang, Chief Financial Officer, at our corporate headquarters, located at 204 Edison Way, Reno, NV 89502, telephone number (775) 858-3750.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, information statements and other information with the SEC. You may read and copy any reports, statements or other information that we file at the SEC's public reference rooms at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of this information by mail from the Public Reference Section of the SEC, 100 F Street, N.E., Washington, DC 20549 at prescribed rates. Please call the SEC at 1 (800) SEC-0330 for further information on the public reference rooms. The SEC also maintains a web site at http://www.sec.gov, at which reports, proxy and information statements and other information regarding our company are available.

LEGAL MATTERS

Certain legal matters are being passed upon for us by Parr Brown Gee & Loveless, PC, of Salt Lake City, Utah. Additional legal matters may be passed on for us, or any underwriters, dealers or agents, by counsel that we will name in the applicable prospectus supplement.

EXPERTS

The consolidated financial statements as of December 31, 2011, and for the year then ended incorporated in this Prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2011 have been so incorporated in reliance on the report of Crowe Horwath LLP, independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

The consolidated financial statements as of December 31, 2010 and for each of the two years in the period ended December 31, 2010 incorporated in this Prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2011 have been audited by Perry-Smith, LLP, an independent registered public accounting firm, as stated in their report incorporated herein by reference and have been so incorporated in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the registrant, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act of 1933 and is therefore unenforceable.

PART II. INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The registrant will bear all expenses of this offering. The estimated expenses, other than underwriting or broker-dealer fees, discounts, and commissions, in connection with the offering are as follows:

	Amount
SEC registration fee	$5,730
Accounting fees and expenses*	10,000
Legal fees and expenses*	20,000
Printing expenses*	5,000
Blue sky fees and expenses*	5,000
Transfer agent fees and expenses*	1,000
Miscellaneous expenses*	3,320
Total	$50,000

*Estimated

Item 15. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation by reason of the fact that he is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees)), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit or proceeding if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful.

Section 145 further provides that a corporation similarly may indemnify any such person serving in any such capacity who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that he is or was a director, officer, employee or agent of the corporation or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorney's fees) actually and reasonably incurred in connection with the defense or settlement of such action or suit if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation. Notwithstanding the foregoing, no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Delaware Court of Chancery or such other court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Delaware Court of Chancery or such other court shall deem proper.

Our bylaws authorize the indemnification of officers and directors of the corporation consistent with Section 145 of the Delaware General Corporation Law. In addition, we have entered into, or will enter into, indemnification agreements with its directors in connection with the domestication providing the directors contractual rights to indemnification, and expense advance and reimbursement, to the fullest extent permitted under the Delaware General Corporation Law.

Other Indemnification Information

Indemnification may be granted pursuant to any other agreement, bylaw, or vote of shareholders or directors. In addition to the foregoing, the Registrant maintains insurance through a commercial carrier against certain liabilities which may be incurred by its directors and officers. The foregoing description is necessarily general and does not describe all details regarding the indemnification of officers, directors or controlling persons of the Registrant.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions or otherwise, the Registrant has been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The rights of indemnification described above are not exclusive of any other rights of indemnification to which the persons indemnified may be entitled under any bylaw, agreement, vote of stockholders or directors or otherwise.

Item 16. List of Exhibits.

1.1	Form of underwriting agreement*
3.1	Certificate of incorporation (1)
3.3	Bylaws (1)
4.1	Instruments defining the rights of securities*
4.2	Form of Warrant*
4.3	Specimen Stock Certificate (1)
4.4	Revised Amended and Restated Shareholder Rights Plan dated May 31, 2012 with Registrar and Transfer Company (2)
4.5	Form of Unit Agreement*
5.1	Opinion of Parr Brown Gee & Loveless, PC
23.1	Consent of Parr Brown Gee & Loveless, PC (including in Exhibit 5)
23.2	Consent of Crowe Horwath LLP
23.3	Consent of Perry-Smith LLP
24.1	Power of attorney (including on signature page of this registration statement)

*	To be filed by amendment or incorporated by reference prior to the offering of securities if applicable.
(1)	Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on Mary 15, 2012, File No. 001-12497.
(2)	Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on July 9, 2012, File No. 001-12497.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission (the "Commission") pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (i), (ii) and (iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by a Registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Securities Exchange Act"), that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(a) each prospectus filed by a Registrant pursuant to Rule 424(b)(3) shall be deemed to be part of this registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(b) each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of this registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however , that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of a Registrant under the Securities Act to any purchaser in the initial distribution of the securities, in a primary offering of securities of an undersigned Registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned Registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(a) any preliminary prospectus or prospectus of an undersigned Registrant relating to the offering required to be filed pursuant to Rule 424;

(b) any free writing prospectus relating to the offering prepared by or on behalf of a Registrant or used or referred to by an undersigned Registrant;

(c) the portion of any other free writing prospectus relating to the offering containing material information about an undersigned Registrant or its securities provided by or on behalf of an undersigned Registrant; and

(d) any other communication that is an offer in the offering made by an undersigned Registrant to the purchaser.

(6) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the Company’s annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered herein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(7) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, and controlling persons of a Registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by a Registrant for expenses the incurred or paid by a director, officer, or controlling person in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement on Form S-3 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Reno, State of Nevada on October 29, 2012.

ALTAIR NANOTECHNOLOGIES INC.

By: /s/ Alex Lee
Alex Lee,
Chief Executive Officer

ADDITIONAL SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated. Each person whose signature to this Registration Statement appears below hereby constitutes and appoints Alex Lee and Stephen Huang, and each of them, as his true and lawful attorney-in-fact and agent, with full power of substitution, to sign on his behalf individually and in the capacity stated below and to perform any acts necessary to be done in order to file all amendments and post-effective amendments to this Registration Statement, and any and all instruments or documents filed as part of or in connection with this Registration Statement or the amendments thereto and each of the undersigned does hereby ratify and confirm all that said attorney-in-fact and agent, or his substitutes, shall do or cause to be done by virtue hereof.

Signature	Title	Date
/s/ Alexander Lee Alexander Lee	Chief Executive Officer and Director (Principal Executive Officer and authorized representative of the Registrant in the United States)	October 29, 2012
/s/ Stephen B. Huang Stephen B. Huang	Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	October 29, 2012
/s/ Yincang Wei Yincang Wei	Chairman of the Board	October 29, 2012
/s/ Guohua Sun Guohua Sun	Director	October 29, 2012
/s/ Liming Zou Liming Zou	Director and President	October 29, 2012
/s/ Jun Liu Jun Liu	Director	October 29, 2012
/s/ Frank Zhao Frank Zhao	Director	October 29, 2012
/s/ Hong Guo Hong Guo	Director	October 29, 2012

EXHIBIT INDEX

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