

Employers use clinical tests for drugs-of-abuse to determine an individual's employability and his or her "fitness for duty." Companies with high turnover and safety conscious environments provide the highest volumes of testing. Factors such as the general economy and job market can impact the utilization of clinical testing. We seek to grow our employer volumes through offering new and innovative programs to help companies with their goal in maintaining a safe and productive workplace. One of these innovations is our Blueprint for Wellness program where we provide wellness screenings to employers and their employees.

## GENERAL

**Sales and Marketing.** Our sales force is organized to focus on customer groups and service types. The majority of representatives focus on marketing clinical laboratory testing, anatomic pathology and related services to physicians, including physician specialists. Supporting our physician sales teams are genomics and esoteric testing specialists, who are specially trained and focused on educating our clients on new and more complex tests. In addition, we have a health plan sales organization that focuses on regional and national insurance and healthcare organizations. We also have a hospital sales organization that focuses on meeting the unique clinical testing needs of hospitals and promotes the specialized capabilities of our Nichols Institute esoteric testing laboratories and our Focus Diagnostics infectious and immunologic disease testing laboratory. A smaller portion of our sales force focuses on selling substance-of-abuse and wellness testing to employers. We also have a sales force that focuses on selling risk assessment testing services to life insurance companies. In addition, we have a sales organization that focuses on selling diagnostic products to hospitals, commercial clinical laboratories, physician office laboratories, blood banks and clinics. We also have a sales force that focuses on our clinical trials services to drug developers. We focus our sales efforts on obtaining and retaining profitable accounts. We have an active customer management process to evaluate the growth potential and profitability of all accounts.

**Information Technology.** Information systems are used extensively in virtually all aspects of our business, including clinical laboratory testing, test reporting, billing, customer service, logistics and management of medical data. We endeavor to establish systems that create value and efficiencies for our patients and customers. The successful delivery of our services depends, in part, on the continued and uninterrupted performance of our information technology systems.

We have made substantial investments in our healthcare information technology systems, and believe that they help differentiate us. Innovations in our healthcare information technology have the potential to improve patient care, promote efficiency and reduce expense. Both at the federal and state levels, there are public and private efforts to bring together healthcare providers, information technology vendors and other stakeholders to facilitate the creation of standards for the exchange and use of electronic healthcare data, including standard clinical code sets. If certain healthcare data and information technology standards were adopted, we could be required to make substantial investments in our systems to comply with such standards or systems.

Our systems may be vulnerable to damage from a variety of causes, including telecommunications or network failures, human acts and natural disasters. Moreover, despite the security measures we have implemented, our systems may be subject to physical or electronic break-in attempts, computer viruses and similar disruptive problems. We also have taken precautionary measures to prevent unanticipated problems that could affect our systems. Nonetheless, system failures, such as those that interrupt our ability to process test orders, deliver test results or perform tests in a timely manner, could adversely affect our reputation and result in a loss of customers and net revenues.

Some of our historic growth has come through acquisitions and we continue to use non-standardized billing, laboratory or other core information systems. We have standardized some of our systems and are implementing standard laboratory information and billing systems across our operations, including those from our most recent acquisitions. We expect implementation will take several more years to complete, and will result in significantly more centralized systems, improve operating efficiency, provide management with more timely and comprehensive information and enhance control over our operational environment. Failure to properly implement the new systems could materially adversely affect our business. During system conversions of this magnitude, workflow is re-engineered to take advantage of best practices and enhanced system capabilities, which may cause temporary disruptions in service.

**Quality Assurance.** In our clinical testing business, our goal is to continually improve the processes for collection, storage and transportation of patient specimens, as well as the precision and accuracy of analysis and result reporting. Our quality assurance efforts focus on positive patient identification of specimens and reports, proficiency testing, process audits, statistical process control and personnel training for all of our laboratories and patient service centers. We continue to implement our Six Sigma and standardization initiatives to help achieve our goal of becoming recognized as the undisputed quality leader in the healthcare services industry. In 1998, our

Nichols Institute esoteric testing laboratory in California was the first clinical laboratory in North America to achieve International Organization for Standardization, or ISO, 9001 certification. Several other of our laboratories also are ISO certified. These certifications are international standards for quality management systems.

We have extensive internal proficiency testing, quality control and audits for our clinical laboratory operations. Quality control samples are processed in parallel with the analysis of patient specimens. The results of tests on quality control samples are monitored to identify trends, biases or imprecision in our analytical processes. We also perform internal process audits as part of our comprehensive quality assurance program.

We have external proficiency testing and accreditation for our clinical laboratory operations. All of our laboratories participate in various external quality surveillance programs. They include, but are not limited to, proficiency testing programs administered by the College of American Pathologists (“CAP”), as well as some state agencies. CAP is an independent, non-governmental organization of board-certified pathologists approved by the Centers for Medicare and Medicaid Services (“CMS”) to inspect clinical laboratories to determine compliance with the standards required by the Clinical Laboratory Improvement Amendments of 1988. CAP offers an accreditation program to which laboratories may voluntarily subscribe. All of our major regional and esoteric laboratories and most of our rapid response laboratories are accredited by CAP. Accreditation includes on-site inspections and participation in the CAP (or equivalent) proficiency testing program. Also, all of our cytotechnologists and pathologists participate in an individual proficiency testing program.

Our diagnostic products businesses maintain extensive quality assurance programs focused on compliance with applicable regulatory requirements in the United States, Europe and Australia. Focus Diagnostics, Enterix and HemoCue maintain sites certified in accordance with, or audited to, ISO 13485.

**Intellectual Property Rights.** We own significant intellectual property, including patents, patent applications, technology, trade secrets, know-how, copyrights and trademarks in the United States and other countries. Our Company also is licensed under U.S. and non-U.S. patents, patent applications, technology, trade secrets, know-how, copyrights and trademarks owned by others. In the aggregate, these intellectual property assets and licenses are of material importance to our business. We believe, however, that no single patent, technology, trademark, intellectual property asset or license is material to our business as a whole.

Our approach is to manage our intellectual property assets to safeguard them and to maximize their value to our enterprise. We generally actively defend our intellectual property assets and pursue protection on our products, processes and other intellectual property where possible.

Our success in remaining a leading innovator in the diagnostic testing industry by continuing to introduce new tests, technology and services will depend, in part, on our ability to license new and improved technologies on favorable terms. Other companies or individuals, including our competitors, may obtain patents or other property rights on tests or processes that we may be performing, particularly in such emerging areas as gene-based testing and other specialty testing, that could prevent, limit or interfere with our ability to develop, perform or sell our tests or operate our business. As a result, we may be involved in intellectual property litigation and we may be found to infringe on the proprietary rights of others, which could force us to do one or more of the following:

- cease developing, performing or selling products or services that incorporate the challenged intellectual property;
- obtain and pay for licenses from the holder of the infringed intellectual property right;
- redesign or reengineer our tests;
- change our business processes; or
- pay substantial damages, court costs and attorneys’ fees, including potentially increased damages for any infringement held to be willful.

**Competition.** While there has been significant consolidation in the clinical testing industry in recent years, our industry remains fragmented and highly competitive. We primarily compete with three types of clinical testing providers: hospital-affiliated laboratories, other commercial clinical laboratories and physician-office laboratories. Our largest independent clinical laboratory competitor is Laboratory Corporation of America Holdings, Inc. In addition, we compete with many smaller regional and local commercial clinical laboratories, specialized esoteric laboratories and laboratories owned by physicians and hospitals. In anatomic pathology, additional competitors include anatomic pathology practices, including those in academic institutions. In addition, there has been a trend among specialty physician practices to bring pathologists into those practices.

We believe that healthcare providers consider a number of factors when selecting a testing provider, including:

- service capability and quality;
- accuracy, timeliness and consistency in reporting test results;
- pricing;
- patient insurance coverage;
- number and type of tests performed by the provider;
- number, convenience and geographic coverage of patient service centers;
- reputation in the medical community;
- healthcare information technology solutions;
- qualifications; and
- ability to develop new and useful tests.

We believe that we are an effective competitor in each of these areas. We also believe that the differentiation we are creating through our focus on a superior patient experience, Six Sigma quality, unparalleled access and distribution, the most comprehensive test menu and innovative test and information technology offerings provide us with a competitive advantage and enables us to compete on more than price alone.

We believe that large commercial clinical laboratories may be able to increase their share of the overall clinical testing market due to their large service networks and lower cost structures. These advantages should enable larger clinical laboratories to more effectively serve large customers and members of large healthcare plans. In addition, we believe that consolidation in the clinical testing industry will continue. However, a significant portion of clinical testing is likely to continue to be performed by hospitals, which generally have affiliations with community physicians that refer testing to us. As a result of these affiliations, we compete against hospital-affiliated laboratories primarily on the basis of service capability and quality as well as other non-pricing factors. Our failure to provide service superior to hospital-affiliated laboratories and other laboratories could have a material adverse effect on our net revenues and profitability. In addition, recent market activity, including actions by payers to exclude large national clinical laboratories from contracts, may enhance the relative competitive position of regional laboratories.

The diagnostic testing industry is faced with changing technology and new product introductions. Advances in technology may lead to the development of more cost-effective tests that can be performed outside of a commercial clinical laboratory such as (1) point-of-care tests that can be performed by physicians in their offices; (2) complex tests that can be performed by hospitals in their own laboratories; and (3) home testing that can be carried out without requiring the services of clinical laboratories. Development of such technology and its use by our customers and patients would reduce the demand for our laboratory testing services and negatively impact our net revenues. However, as a result of our point-of-care test strategy, we believe that we are well positioned to service this market for physicians and hospitals. We also believe that our overall point-of-care test strategy will strengthen our relationship with our customers by enabling us to offer more solutions that improve their effectiveness and the care of their patients by enabling faster diagnosis and treatment.

The diagnostic product market is highly competitive. We have many competitors, some of which have much more extensive experience in this market and some of which have greater resources than our Company. We compete in this area by attempting to find and exploit unique differentiated products, including products that take advantage of our healthcare information technology solutions. There is no guarantee that we will be able to compete successfully in this market.

**Employees.** At December 31, 2007, we employed approximately 43,500 people. This total excludes employees of the joint ventures where we do not have a majority interest. We have no collective bargaining agreements with any unions covering any employees in the United States, and we believe that our overall relations with our employees are good.

## **BILLING AND REIMBURSEMENT**

**Billing.** We generally bill for clinical testing services on a fee-for-service basis under one of two fee schedules. These fees are generally subject to negotiation with or discounted to non-governmental payers. The fee schedules are: