

LABORATORY CORP OF AMERICA HOLDINGS

Form 10-K

February 24, 2012

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

☒ Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2011

or

☐ Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from _____ to _____

Commission file number - 1-11353

LABORATORY CORPORATION OF AMERICA HOLDINGS

(Exact name of registrant as specified in its charter)

Delaware

13-3757370

(State or other jurisdiction of incorporation or organization)

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

358 South Main Street,

Burlington, North Carolina

27215

(Address of principal executive offices)

(Zip Code)

(Registrant's telephone number, including area code) 336-229-1127

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

Title of each class

Common Stock, \$0.10 par value

Name of exchange on which registered

New York Stock Exchange

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

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

Indicate by check mark whether the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☒.

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐.

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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 (paragraph 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐.

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

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

Large accelerated filer ☒

Accelerated Filer ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☐

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

As of June 30, 2011, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$9.8 billion, based on the closing price on such date of the registrant's common stock on the New York Stock Exchange.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date: 97.2 million shares as of February 17, 2012.

DOCUMENTS INCORPORATED BY REFERENCE

List hereunder the following documents if incorporated by reference and the Part of the Form 10-K into which the document is incorporated:

Portions of the Registrant's Notice of Annual Meeting and Proxy Statement to be filed no later than 120 days following December 31, 2011 are incorporated by reference into Part III.

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PART I

Item 1. BUSINESS

Laboratory Corporation of America Holdings and its subsidiaries (the “Company”), headquartered in Burlington, North Carolina, is the second largest independent clinical laboratory company in the United States based on 2011 net revenues. Since the Company’s founding in 1971 as a Delaware corporation, it has grown into a national network of 54 primary laboratories and over 1,700 patient service centers (“PSCs”) along with a network of branches and STAT laboratories (which are laboratories that have the ability to perform certain routine tests quickly and report the results to the physician immediately). Through its national network of laboratories, the Company offers a broad range of clinical laboratory tests that are used by the medical profession in routine testing, patient diagnosis, and in the monitoring and treatment of disease. In addition, the Company has developed specialty testing operations, such as oncology testing, HIV genotyping and phenotyping, diagnostic genetics and clinical trials.

With over 31,000 employees worldwide, the Company processes tests on more than 450,000 patient specimens daily and provides clinical laboratory testing services to clients in all 50 states, the District of Columbia, Puerto Rico, Belgium, Japan, the United Kingdom, China, Singapore and three provinces in Canada. Its clients include physicians, hospitals, managed care organizations, governmental agencies, employers, pharmaceutical companies and other independent clinical laboratories that do not have the breadth of its testing capabilities. Several hundred of the Company’s tests are frequently used in general patient care by physicians to establish or support a diagnosis, to monitor treatment or to search for an otherwise undiagnosed condition. The most frequently-requested of these routine tests include blood chemistry analyses, urinalyses, blood cell counts, thyroid tests, Pap tests, HIV tests, microbiology cultures and procedures, and alcohol and other substance-abuse tests. The Company performs this core group of routine tests in its major laboratories using sophisticated and computerized instruments, with most results reported within 24 hours. In addition, the Company provides specialty testing services in the areas of allergy, clinical trials, diagnostic genetics, identity, forensics, infectious disease, oncology and occupational testing.

The Company’s Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports are made available free of charge through the Investor Relations section of the Company’s internet website at www.labcorp.com as soon as practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission. The matters discussed in this "Business" section should be read in conjunction with the Consolidated Financial Statements found under Item 8 of Part II of this annual report, which include additional financial information about the Company's total assets, revenue, measures of profit and loss, and other important financial information.

The Company is committed to providing the highest quality laboratory services to its clients in full compliance with all federal, state and local laws and regulations. The Company’s Code of Business Conduct and Ethics outlines ethics and compliance policies adopted by the Company to meet this commitment. These policies apply to all employees of the Company as well as the Company’s Board of Directors. The Code of Business Conduct and Ethics, as well as the Charters for the Audit, Compensation, Quality and Compliance, and Nominating and Corporate Governance Committees, and the Company’s Corporate Governance Guidelines, are posted on the Company’s website www.labcorp.com. The Company has established a Compliance Action hotline (1-800-801-1005), which provides a confidential and anonymous method to report a possible violation of a LabCorp compliance policy or procedure, or a federal or state law or regulation; a HIPAA Privacy hotline (1-877-234-4722), which provides a confidential and anonymous method to report a possible violation of a HIPAA privacy, security or billing policy or procedure; and an Accounting hotline (1-866-469-6893), which provides a confidential and anonymous method to report a possible violation of internal accounting controls or auditing matters.

The Clinical Laboratory Testing Industry and Competition

Laboratory tests and procedures are used generally by hospitals, physicians and other health care providers and commercial clients to assist in the diagnosis, evaluation, detection, therapy selection, monitoring and treatment of diseases and other medical conditions through the examination of substances in the blood, tissues and other specimens. Clinical laboratory testing is generally categorized as either clinical pathology testing, which is performed on body fluids including blood, or anatomical pathology testing, which is performed on histologic or cytologic samples (e.g., tissue and other samples, including human cells). Clinical and anatomical pathology procedures are frequently ordered as part of regular physician office visits and hospital admissions in connection with the diagnosis and treatment of illnesses. Certain of these tests and procedures are used in the diagnosis and management of a wide variety of medical conditions such as cancer, infectious disease, endocrine disorders, cardiac disorders and genetic disease.

The clinical laboratory industry consists primarily of three types of providers: hospital-based laboratories, physician-office laboratories and independent clinical laboratories, such as those owned by the Company. The Company believes that in 2010, the United States clinical laboratory testing industry generated revenues of approximately \$55 billion based on Washington G-2 reports

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and other industry publications. The Centers for Medicare and Medicaid Services ("CMS") of the Department of Health and Human Services ("HHS") has estimated that in 2010 there were approximately 5,400 independent clinical laboratories in the United States.

The clinical laboratory business is intensely competitive. There are presently two major national independent clinical laboratories: the Company and Quest Diagnostics Incorporated ("Quest"), which had approximately \$7.5 billion in revenues in 2011. In addition, the Company competes with many smaller independent clinical and anatomical laboratories as well as laboratories owned by hospitals and physicians. The Company believes that health care providers in selecting a laboratory often consider the following factors, among others:

- accuracy, timeliness and consistency in reporting test results;
- reputation of the laboratory in the medical community or field of specialty;
- contractual relationships with managed care companies;
- service capability and convenience offered by the laboratory;
- number and type of tests performed;
- connectivity solutions offered; and
- pricing of the laboratory's services.

The Company believes that consolidation will continue in the clinical laboratory testing business. In addition, the Company believes that it and the other large independent clinical laboratory testing companies will be able to increase their share of the overall clinical laboratory testing market due to a number of external factors including cost efficiencies afforded by large-scale automated testing, reimbursement reductions and managed health care entities that require cost efficient testing services and large service networks. In addition, legal restrictions on physician referrals and their ownership of laboratories as well as increased regulation of laboratories are expected to contribute to the continuing consolidation of the industry.

Effect of Market Changes on the Clinical Laboratory Business

Many market-based changes in the clinical laboratory business have occurred over the past several years, primarily as a result of the shift away from traditional, fee-for-service medicine to managed-cost health care. The growth of the managed care sector and consolidation of managed care companies present various challenges and opportunities to the Company and other independent clinical laboratories. During 2006, the Company signed a ten-year agreement with UnitedHealthcare to become its exclusive national laboratory. This agreement represented an industry first in terms of its length and exclusivity at a national level. In September of 2011, the Company extended this agreement for an additional two years through the end of 2018. The various managed care organizations ("MCOs") have different contracting philosophies. Some MCOs contract with a limited number of clinical laboratories and negotiate fees charged by such laboratories. Other MCOs allow any willing provider to be contracted at specified rates. The Company's ability to attract and retain managed care clients is critical given these evolving models. In addition, some MCOs have used capitated payment contracts in an attempt to fix the cost of laboratory testing services for their enrollees. Under a capitated payment contract, the clinical laboratory and the managed care organization agree to a per member, per month payment to pay for all authorized laboratory tests ordered during the month by the physician for the members, regardless of the number or cost of the tests actually performed. The Company makes significant efforts to ensure that its services are adequately compensated in its capitated arrangements, including in some instances provisions to reimburse esoteric tests (which are more sophisticated tests used to obtain information not provided by routine tests and generally involve a higher level of complexity and more substantial human involvement than routine tests) on a fee-for service basis, as an exclusion to the capitated payment. Capitated payment contracts shift the risks of increased test utilization to the clinical laboratory. For the year ended December 31, 2011, such capitated contracts accounted for approximately \$163.4 million, or 2.9%, of the Company's net sales.

In addition, Medicare (which principally services patients 65 and older), Medicaid (which principally services low-income patients) and insurers have increased their efforts to control the cost, utilization and delivery of health care services. Measures to regulate health care delivery in general and clinical laboratories in particular have resulted in reduced prices, added costs and decreased test utilization for the clinical laboratory industry by increasing complexity and adding new regulatory and administrative requirements. From time to time, Congress has also considered changes to the Medicare fee schedules, and the Company believes that pressure to reduce reimbursement for Medicare services will continue. In March 2010 comprehensive health care reform legislation, the Patient Protection and Affordable Care Act ("ACA"), was enacted, and among its provisions were reductions in the Medicare clinical laboratory fee schedule updates, one of which is a permanent reduction and the other to be applied in 2011 through 2015. On February 17, 2012, Congress passed legislation that will reduce payment rates under the Medicare clinical laboratory fee schedule by 2% effective January 1, 2013. This reduction will apply after adjustment of the fee schedule by the annual CPI update as reduced by the productivity adjustment (1.1-1.3%) and the 1.75% reduction under the ACA, and before the

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scheduled 2% sequestration reduction mandated by the Budget Control Act of 2011, which is also effective January 1, 2013. Similar pressure for reductions in the reimbursement rates of other third-party payers is likely to occur as well.

Despite the potential market changes discussed above, the Company believes that the volume of clinical laboratory testing will be positively influenced by several factors, including an expanded insured population under ACA, increased knowledge of the human genome leading to an enhanced appreciation of the value of gene-based diagnostic assays and the development of new therapeutics that have a “companion diagnostic” to help identify the sub-set of the population for whom it is effective or that may suffer adverse events.

The Company believes its enhanced esoteric menu and geographic footprint provide a strong platform for growth. Additional factors that may lead to future volume growth include an increase in the number and types of tests that are readily available (due to advances in technology and increased cost efficiencies) for testing and diagnosis of disease and the general aging of the population in the United States. The impact of these factors is expected to be partially offset by declines in volume as a result of increased controls over the utilization of laboratory services by Medicare and other third-party payers, particularly MCOs. In addition, movement by patients into consumer driven health plans may have an impact on the utilization of laboratory testing.

Company Strategy

The Company's strategic plan focuses on the disciplined execution of a five-pillar strategy to grow the business and increase shareholder value. These five strategic pillars are:

- Deploy capital first to acquisitions that enhance the Company's footprint and test menu, then to repurchase shares,
- Enhance IT capabilities to improve the physician and patient experience,
- Continue to improve efficiency to remain the most efficient and highest value provider of laboratory services,
- Continue scientific innovation to offer new tests at reasonable and appropriate pricing, and
- Participate in the development of alternative delivery models to improve patient outcomes and reduce the cost of care.

The Company believes that the successful execution of this five-pillar strategy will allow it to fulfill its core mission - to offer the highest quality laboratory testing and most compelling value to its customers.

Pillar One: Deploy capital first to acquisitions that enhance the Company's footprint and test menu, then to repurchase shares

The Company remains committed to growing its business through strategic acquisitions and licensing agreements. The Company has invested a total of \$1,531.2 million over the past three years in strategic business acquisitions. These acquisitions have helped strengthen the Company's geographic presence along with expanding capabilities in the specialty testing operations. The Company believes the acquisition market remains attractive with a number of opportunities to strengthen its scientific capabilities, grow esoteric testing capabilities and increase presence in key geographic areas.

The Company believes that its acquisition of Genzyme Genetics¹ in December of 2010, combined with its existing genomic capabilities, created one of the premier genetics and oncology businesses in the laboratory industry. The acquisition allowed the Company to offer significant customer benefits in areas such as prenatal genetic tests, which are performed during pregnancy to screen for birth defects. The acquisition also provided its customers with broad access to novel testing technologies such as the SMA molecular genetics assay and the entire Reveal family of SNP Microarrays. As market demand for prenatal genetics increases, the Company believes it is well positioned to provide the broadest range of offerings, including the services of approximately 150 genetic counselors. In oncology, the

Company's broad molecular oncology test menu and specialized sales force complemented the strong pathology expertise of Genzyme Genetics.

In 2011, the Company continued to deploy cash and return value to shareholders through share repurchase. During the year, the Company acquired approximately 7.4 million LabCorp shares for \$643.9 million. Since 2004, the Company has repurchased more than \$3.9 billion in shares at an average price of approximately \$65 per share.

1. Genzyme Genetics and its logo are trademarks of Genzyme Corporation and used by Esoterix Genetic Laboratories, LLC, a wholly-owned subsidiary of LabCorp, under license. Esoterix Genetic Laboratories and LabCorp are operated independently from Genzyme Corporation.

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Pillar Two: Enhance IT capabilities to improve the physician and patient experience

The Company introduced LabCorpBeacon order entry nationally in the third quarter, which enables customers to place electronic orders for essentially all of its brands and services. Combined with Beacon results delivery capability, customers can now place orders and receive results through a simple, customer-friendly portal. There has been significant growth in adoption of Beacon in 2011, making it the Company's fastest growing external software offering. With the addition of Apple and Android versions, Beacon capabilities are being introduced to the fast growing mobile device customer base.

Additionally, the Company completed development of the Beacon Patient Portal. This portal is a secure and easy-to-use online solution that enables patients to receive and share lab results, make lab appointments, pay bills, set up automatic alerts and notifications and manage health information for the entire family. The Company currently has active pilot participation and plans to launch nationwide during 2012.

The Company continues to improve its Electronic Medical Record ("EMR") connectivity with more than 500 current EMR connections. The Company is working closely with leading EMR partners to streamline connectivity and enhance lab workflow, ensuring that clients can take advantage of these solutions. Over 6,000 new client EMR interfaces were added during 2011 - a 71% increase over 2010.

For 2012, the Company will continue its efforts to enhance the physician and patient experience by enhancing Beacon, Patient Portal, EMR connectivity and mobile solutions. Key enhancements will include decision support, enhanced results reporting and services aimed at speeding up the lab ordering and resulting process.

Pillar Three: Continue to improve efficiency to remain the most efficient and highest value provider of laboratory services

The Company's emphasis on continually improving productivity extends throughout all phases of its operations - from specimen collection to processing and testing, result reporting and billing. LabCorp Touch™ accessioning provides leading-edge automation at the Company's patient service center ("PSC") locations. LabCorp Touch allows the Company to deploy personnel more productively, and it is now installed in more than 1,100 sites, representing approximately 75 percent of the Company's PSC volume.

The Company's automation initiatives, improvements to its logistics network, and enhancements to its supply chain operations have increased its per-employee throughput in core laboratories by 40 percent since 2007. The Company has also improved its call center operations by improving call response time while reducing the number of facilities by over 65%. Further, the Company's service metrics, customer satisfaction ratings, and turnaround times are at historically high levels.

The Company's expansion of the Powell Center for Esoteric Testing in Burlington, North Carolina leverages LEAN principles to conduct testing more efficiently and consolidate satellite locations. LEAN strategies have also proven effective in creating process improvements in the Company's billing and collection operations.

Pillar Four: Continue scientific innovation to offer new tests at reasonable and appropriate pricing

Innovative tests continue to be an important growth driver for the Company. In 2011, the Company introduced a total of 104 new assays, collaborating with leading companies and academic institutions to provide physicians and patients with the most scientifically advanced testing in the industry.

The Company is playing an important role in many aspects of this emerging model of care in which treatments and therapeutics are tailored to an individual, often based on his or her genetic signature (or that of a particular tumor/strain of virus). LabCorp was a leader in HIV genotyping, one of the first major advances in personalized medicine, which was used to test for resistance to specific drugs. The Company continues to build on this legacy through the development of new tests and/or resources such as the January 2011 release of the Virology Report on the Company's research web page, the acquisition of new and/or expanded capabilities such as the 2010 and 2009 acquisitions of Genzyme Genetics and Monogram Biosciences, Inc. ("Monogram"), respectively.

In 2011, the Company added to its industry-leading suite of companion diagnostic testing by being the first national lab to introduce assays that can help physicians appropriately prescribe the drugs Zelboraf™ and XALKORI® in the treatment of certain types of cancer. The FDA recently approved Zelboraf for use with patients with metastatic melanoma that carry the BRAF V600E gene mutation. The companion diagnostic test the Company provides is essential for identifying patients who have this mutation and may benefit from this therapy. Also in 2011, XALKORI received FDA approval for use in a subset of non-small cell lung

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cancer patients classified as ALK-positive. The Company's clinically validated companion diagnostic identifies these ALK-positive patients that should benefit from XALKORI.

In 2011, the Company launched a series of hepatitis C ("HCV") drug resistance assays developed to support the clinical evaluation of anti-viral agents and their effective use in the management of HCV infection. These tests add to the Company's industry leading suite of HCV testing.

Through its clinical trials division, the Company has taken a leadership role in working with pharmaceutical companies to develop companion diagnostics. The Company's capabilities in assay development, its access to a broad spectrum of testing platforms, and its experience with clinical trials has positioned LabCorp as a market leader. The Company continues to add capabilities to strengthen this companion diagnostics offering. The Company opened a new state-of-the-art biorepository for sample storage and retention in 2009. In 2011, the Company acquired Clearstone Central Laboratories, a global central laboratory specializing in drug development and pharmaceutical services. This acquisition provides the Company with access to Clearstone's global network of labs, including China, Europe, Singapore and Canada. The pharmaceutical industry is increasingly conducting work outside of North America and the Company is expanding its ability to perform work internationally.

Beyond clinical trials, there are also many examples where companion diagnostics have moved into the commercial setting and are helping improve care, such as: (1) assisting in determining the efficacy of a drug for an individual; (2) helping the physician select the correct dosage; and (3) reducing adverse events. The Company will continue to play an important role in both bringing new companion diagnostics to the market and making them commercially available once the drug has been approved.

Pillar Five: Participate in the development of alternative delivery models to improve patient outcomes and reduce the cost of care

With new health policy mandates and a need to control costs, the Company believes the healthcare system will continue to move away from traditional fee-for-service payment models. As the most efficient, highest value provider of laboratory services, the Company believes it is positioned to prosper in a market environment increasingly focused on the efficient delivery of quality services.

Laboratory Testing Operations and Services

The Company has a national network of primary testing laboratories, specialty testing laboratories, branches, PSCs and STAT laboratories. A branch is a central facility that collects specimens in a region for shipment to one of the Company's laboratories for testing. A branch is also frequently used as a base for sales and distribution staff. Generally, a PSC is a facility maintained by the Company to serve the patients of physicians in a medical professional building or other strategic location. The PSC collects the specimens for testing if requested by the physician. The specimens are collected from physicians offices and PSCs and sent, principally through the Company's in-house courier system (and, to a lesser extent, through independent couriers), to one of the Company's primary testing facilities for testing. Some of the Company's PSCs also function as STAT labs, which are laboratories that have the ability to perform certain routine tests quickly and report results to the physician immediately. Patient specimens are typically delivered to the Company accompanied by a test request form (electronic or hard copy). These forms, which are completed by the client or transcribed by a Company patient service technician from a client order, indicate the tests to be performed and provide the necessary billing information.

Each specimen and related request form is checked for completeness and then given a unique identification number. The unique identification number assigned to each specimen helps to ensure that the results are attributed to the

correct patient. The test request forms are sent to a data entry operator who ensures that a file is established for each patient and the necessary testing and billing information is entered. Once this information is entered into the software system, the tests are performed and the results are entered through an electronic data interchange interface or manually, depending upon the tests and the type of equipment involved. Most of the Company's automated testing equipment is connected to the Company's information systems. Most routine testing is completed by early the next morning and test results are in most cases electronically delivered to clients via LabCorp Beacon, smart printers, personal computer-based products or computer interfaces.

Testing Services

Routine Testing

The Company offers a broad range of clinical laboratory tests and procedures. Several hundred of these are frequently used in general patient care by physicians to establish or support a diagnosis, to monitor treatment or medication, or to search for an otherwise undiagnosed condition. The most frequently requested tests include blood chemistry analyses, urinalyses, blood cell

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counts, thyroid tests, Pap tests, microbiology cultures and procedures and alcohol and other substance-abuse tests. These routine procedures are most often used by physicians in their outpatient office practices. Physicians may elect to send such procedures to an independent laboratory or they may choose to establish their own laboratory to perform some of the tests.

The Company performs this core group of routine tests in each of its primary laboratories. This testing constitutes a majority of the tests performed by the Company. The Company generally performs and reports most routine procedures within 24 hours, utilizing a variety of sophisticated and computerized laboratory testing instruments.

Specialty Testing

While the information provided by many routine tests may be used by nearly all physicians, regardless of specialty, many other procedures are more specialized. One of the growth strategies of the Company is the continued expansion of its specialty testing operations, which involve certain types of unique testing capabilities and/or client requirements. In general, the specialty testing operations serve two market segments: (i) markets that are not typically served by the standard clinical testing laboratory; and (ii) markets that are served by the clinical testing laboratory and offer the possibility of adding related services (such as clinical trials or occupational drug testing) from the same supplier. The Company's research and development group continually seeks new and improved technologies for a variety of diagnostic and prognostic indications. For example, the Company's Center for Molecular Biology and Pathology ("CMBP") is a leader in molecular diagnostics, utilizing the polymerase chain reaction ("PCR") as well as other molecular technologies, which are often able to provide earlier, more reliable and detailed information about cancer, genetic diseases, HIV and other viral and bacterial diseases. The Company's subsidiary, National Genetics Institute, Inc. ("NGI"), is a leader in the development of PCR assays for detection of pathogens in biologic products, and its Viro-Med Laboratories, Inc. subsidiary offers molecular microbial testing using real time PCR platforms. DIANON Systems, Inc. is a leader in anatomic pathology testing and US LABS is a leader in anatomic pathology and oncology testing services. The Company's subsidiary, Esoterix, is a leading provider of specialty reference testing and Litholink is a nationally-recognized kidney stone analysis laboratory known for its extensive stone management program. The Company believes these technologies represent potential significant savings to the healthcare system either by increasing the detection of early stage (treatable) diseases or by more effectively managing chronic disease conditions. In August 2009, the Company acquired Monogram, an industry leader in HIV resistance testing, which has developed new technologies in oncology such as the accurate measurement of proteins involved in cancer development and/or progression. In December 2010, the Company acquired Genzyme Genetics, a leading provider of complex reproductive and oncology testing services and the preferred provider for such services to maternal fetal medicine specialists and obstetrician/gynecologists nationally. The Company now provides reproductive genetic testing services under the name Integrated Genetics, and oncology genetic testing services under the name Integrated Oncology. The Company's expansive menu of complex tests offered includes technologies that span the continuum of care, ranging from maternal serum screening and prenatal diagnostics to carrier screening and postnatal testing services. Integrated Genetics also has a broad network of board-certified geneticists and genetic counselors, offering infertility and prenatal genetic counseling expertise to physicians and patients.

The following are some of the specific areas of specialty testing provided by the Company.

Infectious Disease. The Company provides complete HIV testing services including viral load measurements, genotyping and phenotyping and host genetic factors (e.g., such as its HLAB5701 test) that are all important tools in managing and treating HIV infections. The addition of the Monogram resistance tests, PhenoSense, PhenoSenseGT and Trofile, complement the existing HIV GenoSure assay and provide an industry leading, comprehensive portfolio of HIV resistance testing services. The Company also provides extensive testing services for HCV infections including both viral load determinations and strain genotyping and host genetic factors (e.g., such as its IL-28B test) at

CMBP, NGI and ViroMed. The Company continues to develop other molecular assays for influenza viruses including H1N1. In January 2011, the Company published on its website a comprehensive virology report that detailed the results from hundreds of thousands of infectious disease tests performed every year. The report analyzes the vast amount of data gathered at the Company to inform clinicians, public health authorities and other laboratory scientists regarding viral frequencies, distributions, trends, genotypes and associations.

Endocrinology. The Company has emerged as a leading provider of advanced hormone/steroid testing including comprehensive services for the Endocrine specialist. The Company has expanded its menu in esoteric endocrine testing and has launched a companywide initiative to develop steroid testing utilizing Mass Spectrometry technology. Mass Spectrometry is quickly becoming the gold standard for detection of low levels of small molecule steroids including testosterone in women, children and Hypogonadal men. The Company additionally offers several endocrine related genetic tests that include CYP21 mutation for Congenital Adrenal Hyperplasia, SHOX gene for short stature, as well as the RET mutation for thyroid cancer.

Diagnostic Genetics. The Company offers cytogenetic, molecular cytogenetic, biochemical and molecular genetic tests. The biochemical genetics offerings include a variety of prenatal screening options including integrated and sequential prenatal assays for more sensitive assessment of Down syndrome risk. The Company has expanded its cytogenetics offerings through

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the use of whole genome SNP microarray technology, which provides enhanced detection of subtle chromosomal changes associated with the etiology of mental retardation, developmental delay and autism. The molecular genetics services have been expanded to include multiplex analyses of a variety of disorders and a focus on gene sequencing applications for both somatic and germ-line alterations. The addition of Genzyme Genetics in December 2010 provides the Company with the most comprehensive genetic test menu in the industry as well as a complement of approximately 150 genetic counselors to work with the Company's physician clients in optimizing patient outcomes.

Oncology Testing. The Company offers an extensive series of testing technologies that aid in diagnosing and monitoring certain cancers and predicting the outcome of certain treatments, including hematopathology, dermatopathology and uropathology. Applications for molecular diagnostics continue to increase in oncology for both the analysis of leukemia as well as the assessment of solid tumors. In cancers such as colon and lung cancer, assays such as K-ras, BRAF and EGFR mutation analysis are associated with appropriate therapy choices for a given patient.

Clinical Trials Testing. The Company regularly performs clinical laboratory testing for pharmaceutical and diagnostics companies conducting clinical research trials on new drugs or diagnostic assays. This testing often involves periodic testing of patients participating in the trial over several years. In 2011, the Company acquired Clearstone Central Laboratories, a global central laboratory specializing in drug development and pharmaceutical services. The Company has made a concerted effort in companion diagnostics to translate predictive biomarkers used in clinical trials into clinical practice.

Identity Testing. The Company provides forensic identity testing used in connection with criminal proceedings and parentage evaluation services which are used to assist in determining parentage for child support enforcement proceedings and determining genetic relationships for immigration purposes. Parentage testing involves the evaluation of immunological and genetic markers in specimens obtained from the child, the mother and the alleged father. The Company also provides testing services in reconstruction cases, which assist in determining parentage without the presence of the parent in question. In 2011, the Company acquired Orchid Cellmark, Inc. ("Orchid"), a leader in the forensic and paternity testing business for over 30 years.

Occupational Testing Services. The Company provides testing services for the detection of drug and alcohol abuse for private and government customers. These testing services are designed to produce forensic quality test results that satisfy the rigorous requirements for admissibility as evidence in legal proceedings. The Company also provides other analytical testing and a variety of management support services.

The specialized testing services noted above, as well as other complex procedures, are sent to designated facilities where the Company has concentrated the resources for performing these procedures so that quality and efficiency can be most effectively monitored. CMBP, NGI, ViroMed, Dianon, Integrated Oncology, Esoterix, Monogram and Integrated Genetics also specialize in new test development and related education and training.