LABORATORY CORP OF AMERICA HOLDINGS
Form 10-K
February 28, 2019
Index

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

[X] Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended December 31, 2018
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	Name of exchange on which registered
Common Stock, $0.10 par value	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 [X] No [ ].

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

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 [X] No [ ].

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes [X] No [ ].

1

Index

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 232.405) 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, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company”, and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer [X] Accelerated filer [ ]
Non-accelerated filer [ ] Smaller reporting company [ ]
Emerging growth company [ ]

If emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

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

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

As of June 30, 2018, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately $17.5 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: 98.6 million shares as of February 26, 2019.

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, 2018, are incorporated by reference into Part III.

Index

Index

		Page
	Part I	
Item 1.	Business	4
	Business Segments	7
	LabCorp Diagnostics Segment	7
	Covance Drug Development	15
	Customers	19
	Capital Allocation	20
	Seasonality	20
	Investments in Joint Venture Partnerships	20
	Sales, Marketing and Customer Service	21
	Information Systems	21
	Quality	21
	Intellectual Property Rights	23
	Employees	23
	Regulation and Reimbursement	23
	Compliance Program	30
	Information Security	30
Item 1A.	Risk Factors	31
Item 1B.	Unresolved Staff Comments	43
Item 2.	Properties	44
Item 3.	Legal Proceedings	45
Item 4.	Mine Safety Disclosures	49
	Part II	
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities	50
Item 6.	Selected Financial Data	51
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	53
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	69
Item 8.	Financial Statements and Supplementary Data	70
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	70
Item 9A.	Controls and Procedures	70
Item 9B.	Other Information	71
	Part III	
Item 10.	Directors, Executive Officers and Corporate Governance	71
Item 11.	Executive Compensation	76
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	76
Item 13.	Certain Relationships and Related Transactions, and Director Independence	76
Item 14.	Principal Accountant Fees and Services	76
	Part IV	
Item 15.	Exhibits and Financial Statement Schedules	77

Item 16. Form 10-K Summary 82

Index

PART I

Item 1. BUSINESS

Laboratory Corporation of America® Holdings (LabCorp® or the Company) is a leading global life sciences company that is deeply integrated in guiding patient care. The Company provides comprehensive clinical laboratory and end-to-end drug development services through LabCorp Diagnostics (LCD) and Covance Drug Development (CDD). LabCorp is positioned at the convergence of research and care delivery to enable more precise and individualized healthcare, bringing together world-class diagnostics and drug development capabilities. With nearly 61,000 employees worldwide, the Company's mission is to improve health and improve lives by delivering world-class diagnostics, accelerating the availability of innovative medicines to patients, and using technology to change the way care is delivered. LabCorp, an S&P 500 company, was named to FORTUNE magazine's 2019 List of World's Most Admired Companies, making the annual list for the second consecutive year.

The Company provides diagnostic, drug development and technology-enabled solutions for more than 120 million patient encounters per year. The Company typically processes tests on more than 2.5 million patient specimens per week and also supports clinical trial activity in approximately 100 countries through its industry-leading central laboratory, preclinical, and clinical development businesses, generating more safety and efficacy data to support drug approvals than any other company. CDD collaborated on 93% of the novel drugs approved by the U.S. Food and Drug Administration (FDA) in 2018, including 94% of the novel rare and orphan disease drugs and 94% of the novel oncology drugs. In addition, CDD has been involved in the development of all of the current top 50 drugs on the market as measured by sales revenue.

The Company, a Delaware corporation, is headquartered in Burlington, North Carolina, and was incorporated in 1971. Although portions of its business have an even longer history, the Company identifies its founding in 1969 and will celebrate its 50th anniversary in 2019. The Company has continually expanded and diversified its business offerings, technological expertise, geographic reach, revenue base, and financial growth opportunities through a combination of organic investments and disciplined acquisitions.

Combined, Global Capabilities

Today, the Company participates in drug development from discovery through commercialization; it is the go-to partner for the development, validation and commercialization of companion diagnostics, which are key drivers of personalized medicine; it offers a growing menu of nearly 5,000 high-quality, high-value clinical laboratory tests; and, increasingly, it provides guidance to consumers and care providers about how to integrate drugs and diagnostics into patient care.

The combination of LCD's and CDD's core capabilities enables the Company to create compelling advantages for clients. LCD's patient insights and CDD's global physician-investigator performance data create a powerful competitive advantage that presents significant long-term growth potential. As a result, LabCorp can win studies and recruit patients and investigators for trials more efficiently. The Company has proprietary data sets with more than 30 billion lab test results, reaching roughly 50% of the United States (U.S.) population and a significant database of experienced investigators and trial sites. The 2017 acquisition of Chiltern International Group, Inc. (Chiltern) further enhanced Covance's offerings as a major partner serving the top 20 biopharmaceutical segment and expanded the Company's current offering to include a dedicated focus on the high-growth emerging and mid-market biopharmaceutical segments.

The combined capabilities of the business have also contributed to the Company's position as a market leader in the development and commercialization of companion and complementary diagnostics. Companion diagnostics are tests that should be used before a patient can be treated with a specific therapeutic to help identify how or if the therapeutic will be effective or if it may cause adverse events. Complementary diagnostics are not required for determining who should receive the therapeutic, or how it should be used, but can give physicians valuable information about a patient's potential response to a specific therapeutic or class of therapeutics. The Company's dedicated companion diagnostics team collaborated with over 50 clients on more than 100 companion diagnostics projects in 2018. LCD and CDD have been involved in the development of drugs and their associated companion diagnostics for more than 20 years, and

together have supported more FDA-approved companion diagnostics than any other company.

The Company serves a broad range of customers, including managed care organizations (MCOs), biopharmaceutical and medical device companies, governmental agencies, physicians and other healthcare providers (e.g. physician assistants and nurse practitioners, generally referred to herein as physicians), hospitals and health systems, employers, patients and consumers, contract research organizations (CROs) and independent clinical laboratories. Through the tools the Company provides, customers can leverage the Company’s deep scientific and therapeutic experience, cutting-edge technology, and considerable real-world data and patient intelligence, LabCorp customers can understand and respond to evolving patient needs with precision. The breadth of the Company’s offerings has accelerated revenue and profit growth while generating strong returns for shareholders through share price appreciation. The Company's diversified service offerings also help to balance the impact of changes in the U.S. healthcare

Index

payment system, such as the reductions to the Medicare fee schedule under the Protecting Access to Medicare Act (PAMA), and associated reductions to other payers including Medicaid.

Positioning the Company for the Future

The Company believes that it can play a larger role in the rapidly evolving healthcare environment by continuing to focus on three key strategic initiatives to broaden its role: supporting customers' transition to value-based care, streamlining the drug development process, and creating a leading and differentiated consumer experience. In addition, the Company believes that continued consolidation in healthcare and the Company's strong relationships with hospitals and health systems will allow LabCorp to provide leading solutions to help improve patient outcomes and reduce healthcare costs as health systems increasingly become the focal point of coordinated patient care.

Value-Based Care

The healthcare system is in the midst of a complex and iterative transition to value-based care, with increased use of reimbursement models based on quality of care and on patient outcomes, and less reliance on traditional fee-for-services based payments. The Company is focused on improving efficiency in care delivery, reducing the overall cost of patient care, and using the Company's combination of diagnostic and drug development capabilities to accelerate progress towards more precise and individualized healthcare.

The Company is supporting customers transitioning to value-based care through its differentiated, comprehensive solutions including leading laboratory services, clinical decision support (CDS), robust data integration offerings, drug development solutions, and payer and provider collaborations. The Company is a critical player in enabling targeted, tailored, high-value care in part by helping physicians choose the right test to determine the right medication at the right dosage, and helping to deliver the next generation of lifesaving drugs, which increasingly rely on the individual patient's genetic makeup to determine appropriateness of use, dosing and co-treatment options. In 2018, LabCorp announced that effective January 1, 2019, it would be an in-network laboratory for Aetna, in addition to extending its existing in-network agreement with UnitedHealthcare. With these agreements, the Company is a contracted laboratory partner for all of the major national managed care plans, which reinforces the Company's differentiated value proposition to physicians and patients. In November 2018, the Company also extended its agreement with Horizon Blue Cross Blue Shield of New Jersey. The Company will continue to be the exclusive laboratory for Horizon Medicaid members. The Company will no longer be the exclusive capitated laboratory for Horizon HMO Members but will continue to be an in-network laboratory for all Horizon members, including HMO members.

Streamlining Drug Development

In today's healthcare landscape, there is a need to streamline the drug development process to bring new drugs to market faster. However, the number of compounds in the pipeline continues to grow and the development path is increasingly complex and costly. These trends have led to growing competition for investigators and patients in clinical studies. In this environment, demand from biopharmaceutical companies for data-driven study design and execution, scalable, innovative tools and processes, and access to relevant analytes, biomarkers and tests continues to rise.

CDD's unique end-to-end global capabilities provide biopharmaceutical and medical device companies with differentiated solutions to streamline development by allowing for more efficient study design, and faster and more targeted identification of eligible patients and investigators. The Company's investment in CDD's unmatched combination of capabilities, analytics and scale has strengthened its leadership advantage in areas such as companion diagnostics and real-world evidence insights. The Company's integration of new innovations in this space, such as using robotic software process automation, also enhances efficiency and quality. In addition, LCD's strategic relationships with hospitals and health systems create opportunities for those organizations to become research partners to participate in studies and clinical trials with CDD.

The unique combination of the Company's diagnostic and drug development operating models enables the Company to create differentiated and innovative solutions to streamline the drug development process. The Company expects to see increasing adoption of virtual clinical trials and mobile health technology by clinical trial sponsors. For example, the Company is applying its market access call-center capabilities to enroll and engage patients, its patient service centers (PSCs) to provide blood draws and biometric assessments in locations convenient to patients, and its central

laboratory services to perform the associated testing. These offerings, individually or in combination, can speed patient recruitment and site selection, improve trial design and data quality, and thereby decrease study duration, costs, and the patient burden of participating in clinical research.

The Growing Importance of the Consumer in Healthcare

Patients are increasingly interested in their health and wellness and and they are becoming more influential in their healthcare decision-making, instead of simply reacting to symptoms of disease. They have more responsibility for the costs of their care and technological advances are driving an expectation of convenient channels for accessing healthcare. This change requires healthcare providers to increasingly view patients as consumers. The Company is investing in new tools and technology to create a

Index

differentiated consumer experience through innovations to increase consumer engagement and new channels to enhance consumer convenience and access to LabCorp's high-quality lab services.

In 2018, the Company announced plans to significantly expand the LabCorp at Walgreens collaboration to at least 600 locations over the next four years, following positive feedback to the initial sites in four states. Consumers, healthcare providers, and managed care plans have expressed strong interest in this innovative partnership. LabCorp's and Walgreens complementary healthcare expertise underpins LabCorp at Walgreens, which is uniquely situated to deliver a wide range of personalized, integrated, consumer-facing services over time. Additional collaboration opportunities with Walgreens are focused on improving the consumer experience and using data integration to enhance product and service offerings.

The Company also launched Pixel by LabCorp℠, a consumer-initiated testing platform that features sample self-collection from the comfort of home and personalized online results. Consumers can now purchase test packages with home-based sample collection that offer screening for wellness, heart health, diabetes, and colorectal cancer. Additional test offerings and use cases are planned for the future. In 2019, the Company also plans to add a consumer-initiated, phlebotomy-based offering to the Pixel platform that will broaden consumer access to the most important and frequently requested tests. With this added service, consumers are empowered to order tests online and visit LabCorp PSCs for sample collection.

In 2018, the Company completed the rollout of several patient self-service tools to enhance the experience in its PSCs, including self-check-in, improved insurance card recognition technology using machine learning, enhanced mobile applications and upgraded online bill payment.

LCD's online LabCorp | Patient portal and mobile app offer convenient access to new and historical test results, information about tests, and an option to receive information about clinical trials. In an effort to further expand consumers' ability to easily access their health records from any location, the Company announced that it supports Health Records on iPhone®, a service that allows LabCorp patients to access their LabCorp laboratory test results along with other available medical data from multiple providers in the Apple® Health app.

The Company's multi-faceted consumer engagement strategy is advancing at a rapid pace, which further differentiates the Company's offerings from competitors and creates new opportunities for long-term profitable growth. The Company also continues to invest in and evaluate technologies that may enable additional methods for self-collection of specimens, and is exploring the potential use of wearable devices for diagnostics and in clinical trials.

The Company performs the DNA testing for 23andMe. The Company also continues to support telemedicine, and other new care delivery models, that empower and engage healthcare consumers.

Hospital and Health System Partnerships

The healthcare industry continues to consolidate with private medical practices joining larger medical groups or affiliating with health systems, and health systems merging and absorbing additional facilities. MCOs are increasingly taking on the roles of both payers and care providers, and in some markets, large health systems are creating their own MCO. These combined organizations can provide economies of scale and the capital to make substantially greater investments in technology, and in some cases they can exercise greater control over how and where patients access care.

The Company supports those goals through its unique combination of diagnostics and drug development. It offers highly efficient and integrated lab testing across multiple types of care settings. It can simplify information technology structures and interfaces to standardize lab testing and data across a disparate network of providers, facilities and systems. That data can also identify patients that may be eligible for clinical trials and physicians who may be able to serve as clinical trial investigators. The Company believes that its ability to offer these high-value integrated solutions is a differentiator in the marketplace.

For more than three decades, the Company has developed and maintained a broad range of collaborations with hospitals and health systems and the Company continues to develop those relationships. In 2018, the Company entered into or extended strategic relationships with multiple health systems across the country, including Appalachian Regional Healthcare, Mount Sinai Health System, and Baptist Healthcare System, Inc. based in Louisville, Kentucky, among others. These relationships are foundational in delivering high-quality, outcomes-driven, and cost-effective

care to patients. The Company will continue to invest in its team and capabilities to support this important strategic initiative.

The Company is uniquely positioned to capitalize on the opportunities of the rapidly changing healthcare system. The combination of its leading diagnostics and drug development businesses strengthens its value proposition to key stakeholders and differentiates the Company from its competitors.

Company Reporting

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 website

Index

at www.labcorp.com as soon as reasonably practicable after such material is electronically filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC). Additionally, the SEC maintains a website at http://www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers, including the Company, that file electronically with the SEC.

The matters discussed in this "Business" section should be read in conjunction with the Consolidated Financial Statements found in Item 8 of Part II of this report, which include additional financial information about the Company, such as financial information about geographic areas. This report includes forward-looking statements that involve risks or uncertainties. The Company's results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risk factors described in Item 1A of Part I of this report and elsewhere. For more information about forward-looking statements, see "Forward-Looking Statements" in Item 7.

Business Segments

The Company reports its business in two segments, LCD and CDD. In 2018, LCD and CDD contributed 62% and 38%, respectively, of revenues to the Company, and in 2017 contributed 67% and 33%, respectively. For further financial information about these segments, including information for each of the last three fiscal years regarding revenue, operating income and other important information, see Note 21 to the Consolidated Financial Statements.

LCD Segment

LCD is an independent clinical laboratory business. It offers a comprehensive menu of frequently requested and specialty testing through an integrated network of primary and specialty laboratories across the U.S. This network is supported by a sophisticated information technology system, with more than 65,000 electronic interfaces to deliver test results, nimble and efficient logistics, and local labs offering rapid response testing. The Company also provides patient access points, strategically and conveniently located throughout the U.S., including nearly 2,000 PSCs operated by the Company and more than 6,000 in-office phlebotomists who are located in customer offices and facilities. In addition to diagnostic testing, LCD also offers a range of other testing services, including paternity and occupational and wellness testing for employers. During 2018, the Company sold its Covance Food Solutions (CFS) business, which provided food testing and integrity services, as well as its domestic and international forensic analysis businesses. LCD offers an expansive test menu including a wide range of clinical, anatomic pathology, genetic and genomic tests, and regularly adds new tests and improves the methodology of existing tests to enhance patient care. In 2018, with the introduction of Pixel by LabCorp, the Company also began offering consumer-initiated wellness testing.

Through the dedicated effort of approximately 39,000 employees, LCD typically processes tests on more than 2.5 million patient specimens each week and has laboratory locations throughout the U.S. and other countries, including Canada.

Clinical Laboratory Testing Industry

It is estimated that although laboratory services account for less than 3.0% of total U.S. healthcare spending (and approximately 1.0% of Medicare expenditures), the results of those tests impact an estimated 70% of all decisions regarding a patient's care.

Laboratory tests and procedures are used generally to assist in the diagnosis, monitoring and treatment of diseases and medical conditions through the examination of substances in blood, tissues and other specimens. The results of such tests can help in the evaluation of health, the detection of conditions or pathogens and the selection of appropriate therapies. Clinical laboratory testing is generally categorized as either clinical pathology testing, which is performed on body fluids including blood, or anatomical pathology testing, in which a pathologist examines histologic (i.e., tissue) or cytologic samples (i.e., human cells). Clinical and anatomical pathology procedures are frequently ordered as part of regular healthcare office visits and hospital admissions in connection with patient care. 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 Company believes that in 2018, the U.S. clinical laboratory testing industry generated revenues of approximately $80.0 billion. The clinical laboratory industry consists primarily of three types of providers: hospital-based

laboratories, physician-office laboratories and independent clinical and anatomical pathology laboratories, such as those operated by LCD. The clinical laboratory business is intensely competitive. The Centers for Medicare and Medicaid Services (CMS) of the U.S. Department of Health and Human Services (HHS) has estimated that in 2018 there were approximately 9,000 hospital-based laboratories, approximately 122,000 physician-office laboratories and more than 6,000 independent clinical laboratories in the U.S. LCD competes with all of those laboratories.

LCD believes that the selection of a laboratory is primarily based on the following factors:

- Quality, timeliness and consistency in reporting test results;
- Reputation of the laboratory in the medical community or field of specialty;
- Contractual relationships with MCOs;
- Service capability and convenience;

Index

- Number and type of tests performed;
- Connectivity solutions offered; and
- Pricing of the laboratory's services.

LCD believes that it competes favorably in all of these areas.

LCD believes that consolidation in the clinical laboratory testing business will continue. In addition, LCD believes that it and 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 factors, including cost efficiencies afforded by large-scale automated testing, mergers and acquisitions of complementary businesses; changes in payment models to performance and value-based reimbursement to deliver better outcomes at lower cost, and large, integrated service networks. In addition, legal restrictions on physician referrals and physician ownership of laboratories, as well as ongoing regulation of laboratories, are expected to continue to contribute to the ongoing consolidation of the industry.

Although testing for healthcare purposes and customers who provide healthcare services represents the most significant portion of the clinical laboratory industry, clinical laboratories also perform testing for other purposes and customers, including employment and occupational testing, DNA testing to determine parentage and to assist in immigration eligibility determinations, environmental testing, wellness testing, toxicology testing, pain management testing, and medical drug monitoring.

LCD Testing Operations and Productivity

LCD has a network of PSCs offering specimen collection services, phlebotomists placed at a customer location, branches, rapid response (STAT) laboratories, primary testing laboratories and specialty testing laboratories. Many of LCD's laboratories hold ISO 15189 certification, providing customers with the assurance of quality that comes with this rigorous global standard.

Generally, a PSC is a facility maintained by LCD to serve patients. The PSC staff collects specimens for testing as requested by the physician. PSC staff also perform specimen preparation to produce laboratory-ready samples that can be tested upon receipt by the testing laboratory, expediting the delivery of test results. A significant portion of patient specimens are collected by the customer's staff at its office or facility, or in some cases, by an LCD phlebotomist who has been placed in the customer location for the specific purpose of collecting and processing specimens to be tested by LCD.

The Company has developed a comprehensive and nimble logistics system that efficiently brings specimens from the point of collection to the testing laboratory, incorporating specimen intake, tracking, and processing procedures that minimize errors and expedite the performance of testing and delivery of results. Specimens collected at PSCs and at customer locations are then picked up principally by LCD's in-house courier system (and to a lesser extent, through independent couriers) and delivered to a branch or directly to one of LCD's laboratories for testing. A branch is a central facility that collects specimens in a region for shipment to a regional or specialty laboratory for testing, and is also frequently used as a base for sales and distribution staff. STAT laboratories, which may be co-located with a branch or a PSC, perform critical testing for nearby customers, with results typically delivered within 2-3 hours of receipt of the specimen. Primary testing laboratories perform frequently requested testing on a large scale. Specialty testing laboratories perform one or more types of specialty and esoteric testing.

Each specimen and the associated test order is checked for completeness and given a unique identification number. The unique identification number assigned to each specimen associates the results to the appropriate patient. The testing, billing information and test results are entered into LCD's systems electronically or manually depending on physician, test type and equipment involved. Most of LCD's automated testing equipment is connected to its information systems. Most specimens are picked up from the customer's location by late afternoon or early evening and delivered to the testing laboratory by late evening on the day of collection or overnight. Test results are, in most cases, electronically delivered to the physician via electronic interfaces, the LabCorp Link™ (formerly LabCorp Beacon) platform, smart printers or personal computer-based products. The Company makes test results available directly to patients through its LabCorp | Patient mobile app and online tool, and by enabling access to test results through Health Records on iPhone.

LCD remains focused on improving quality and productivity while lowering costs throughout all phases of its operations, supported by LCD's technology, automation and facility rationalization initiatives. As part of an ongoing commitment to remain the most efficient and highest-value provider of laboratory services, LCD executed a comprehensive business process improvement initiative, referred to as LaunchPad, to reengineer its systems and processes to create a sustainable and more efficient business model, and to improve the experience of all stakeholders. The Company achieved its LaunchPad goals of delivering both short- and long-term savings, and implementing system and process improvements that are expected to yield continuing benefits for the foreseeable future. In late 2018, the Company announced that it had begun phase II of LaunchPad for LCD. The Company expects phase II of LCD’s LaunchPad initiative to deliver approximately $200.0 in net savings over the next three years, while incurring approximately $40.0 in one-time implementation costs. Approximately one-third of the total savings are expected to be realized each year.

Index

LCD Testing Services

LCD offers a growing menu of nearly 5,000 tests. Several hundred of those tests are 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 tests include blood chemistry analyses, urinalyses, blood cell counts, thyroid tests, Pap tests, hemoglobin A1C, prostate-specific antigen (PSA), tests for sexually-transmitted diseases [e.g. chlamydia, gonorrhea, trichomoniasis and human immunodeficiency virus (HIV)], hepatitis C (HCV), tests, vitamin D, microbiology cultures and procedures, and alcohol and other substance-abuse tests. LCD performs this core group of tests in its major laboratories using sophisticated instruments, with most results reported within 24 hours or less.

In addition, LCD provides a comprehensive range of specialty testing services in the areas of women's health, allergy, diagnostic genetics, cardiovascular disease, infectious disease, endocrinology, oncology, coagulation, pharmacogenetics, toxicology and medical drug monitoring.

LCD also performs a range of other testing services, including parentage and occupational testing and wellness testing for employers. In addition, until the sale of the CFS business, which was completed on August 1, 2018, LCD provided testing services to the food, beverage, nutraceutical, animal feed, chemical and agrochemical industries, which included nutritional analysis and equivalency, nutritional content fact labels, microbiological and chemical contaminant safety analysis, product development expertise, sensory testing, pesticide screening and stability testing. LCD also provided forensic services to assist in DNA analysis for investigations until the sale of its foreign and domestic forensic testing services businesses during the third and fourth quarters of 2018, respectively.

LCD’s Specialty Testing Group performs esoteric testing, cancer diagnostics and other complex procedures. The Specialty Testing Group offers advanced methods and access to scientific expertise and consultation in the following disciplines:

Anatomic Pathology/Oncology. LCD offers advanced comprehensive tumor tissue analysis, including immunohistochemistry, (IHC), cancer cytogenetics and fluorescence in situ hybridization (FISH), through its Dianon Pathology and Integrated Oncology specialty testing laboratories. Applications for molecular diagnostics continue to increase in oncology for leukemia analysis and solid tumor assessment. In cancers such as colon and lung cancer, assays that analyze genetic mutations can help guide appropriate therapy choices for a given patient. Through the combined expertise of LCD and CDD, the Company is a recognized leader in the development and introduction of companion and complementary diagnostics, which are becoming increasingly important in the treatment of cancer with new, targeted therapies for which only certain patients may be eligible, or which may provide greater or lesser benefits to certain patients, based on their individual genetic makeup.

Cardiovascular Disease. LCD’s cardiovascular menu includes cholesterol tests, expanded lipid profiles, a metabolic syndrome profile and tests for heart failure, thrombosis and stroke. LCD also offers complete testing for monitoring disease progression and therapy response, including its CDS portfolio to help guide treatment and monitoring decisions.

Coagulation. LCD offers an extensive menu of tests for hemostasis and thrombosis, including bleeding profiles and screening tests, factor analysis, thrombin generation markers, and thrombotic risk evaluation. LCD recently introduced new, internally developed methods to test for ADAMTS13 and serotonin release in the evaluation of heparin-induced thrombocytopenia, both of which are life-threatening blood clot disorders. The new methods offer clinically significant improvements to previously available tests. LCD also performs testing in support of clinical trials largely for therapies to treat hemophilia.

Diagnostic Genetics. LCD 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 and non-invasive prenatal testing (NIPT) for more sensitive and earlier assessment of risk for multiple fetal chromosomal aneuploidies, such as Down syndrome. LCD has expanded its cytogenetics offerings through the use of whole genome single-nucleotide polymorphism (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 include multiplex analyses of a variety of disorders, gene sequencing applications for both somatic and germ-line alterations and whole exome sequencing. Through Integrated Genetics,

LCD provides the most comprehensive genetic test menu in the industry, as well as an experienced team of genetic counselors and medical geneticists to provide patients and their physicians with analysis, assessment and interpretation of genetic test results to help optimize patient decisions and outcomes.

Endocrinology. LCD is a leading provider of advanced hormone/steroid testing, including comprehensive services for the endocrine specialist. LCD has expanded its menu in esoteric endocrine testing and has launched an initiative to develop steroid testing utilizing mass spectrometry technology. Mass spectrometry is used for detection of low levels of small molecule steroids, including testosterone in women, children and hypogonadal men. Additionally, LCD offers endocrine-related tests for genetic conditions including congenital adrenal hyperplasia, short stature, and thyroid cancer, along with providing extensive age- and gender-related reference intervals for those tests.

Index

Infectious Disease. LCD provides complete HIV testing services, including viral load measurements, genotyping and phenotyping, and host genetic factors that are important tools in managing and treating HIV infections. The addition of resistance tests, including PhenoSense®, PhenoSenseGT®, Trofile®, and GenoSure PRIme® complements the existing HIV GenoSure® assay and provides LCD with an industry-leading, comprehensive portfolio of HIV resistance testing services. LCD also provides extensive testing services for HCV infections, including both viral load determinations and strain genotyping and host genetic factors. LCD continues to develop molecular assays for infectious disease.

Women's Health. LCD offers a comprehensive menu of women's health testing. A key feature of this menu is the industry's leading suite of NIPT tests, including MaterniT® GENOME, a fully validated genome-wide NIPT test, reflecting the Company's deep prenatal genetics capabilities. Other LCD testing options for women's health include the NuSwab® portfolio, featuring high-quality, convenient single-swab tests for common infections of the genital tract; an innovative age-based test protocol for cervical cancer and sexually-transmitted disease screening; liquid-based Pap testing with image-guided cervical cytology for improved cervical cancer detection; and out-of-the-vial Pap testing with options for human papillomavirus (HPV). LCD also offers tests that utilize the latest technical innovations for the full range of reproductive care, including maternal serum screening, prenatal diagnostics, ethnicity carrier screening, testing for causes of infertility or miscarriage as well as postnatal testing services.

Pharmacogenetics. LCD provides access to the latest tests in the emerging field of pharmacogenetics. These tests can help physicians understand how a patient metabolizes certain drugs, allowing them to select the most appropriate therapies or adjust dosing.

Parentage and Donor Testing. LCD provides forensic testing used in connection with parentage evaluation services that 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 or putative father. LCD also provides testing services in reconstruction cases, which assist in determining parentage without the presence of the parent in question. Additionally, LCD provides human leukocyte antigen testing to match organ and tissue transplant recipients with compatible donors.

Occupational Testing Services. LCD provides testing services for the detection of drug and alcohol use for private and government customers. These testing services are designed to produce forensic quality test results that satisfy the rigorous requirements of regulated and non-regulated workplace drug testing programs. Additionally, LCD provides employee wellness screenings comprised of biometric measurements and diagnostic tests to assist in the detection of health risks including cardiovascular disease and diabetes. LCD also provides medical drug monitoring tests that detect common pain medications and illicit drugs to assist physicians with assessing the full scope of a patient’s drug use.

Medical Drug Monitoring Services. Medical drug monitoring is laboratory testing that monitors patients for the use of prescription pain medications or other controlled substances. These testing services are designed to provide physicians with information relevant to the treatment of patients who are prescribed controlled substances, including opioid pain medications, antianxiety medications, stimulants, and medications prescribed in medication-assisted treatment programs. This testing can help physicians identify patients who are not taking their prescribed doses, which could be an indication that the drugs are being diverted elsewhere, and also to identify patients who may be supplementing their prescribed medication with other, non-prescribed substances. LCD offers broad choice in medical drug monitoring test options. LCD testing may assist in identifying patients who may benefit from greater caution and increased monitoring or interventions when risk factors are identified.

Chronic Disease Programs. LCD uses a programmatic approach to the comprehensive evaluation and treatment of chronic diseases, including chronic kidney disease, cardiovascular disease, metabolic bone disease and diabetes, and it offers CDS reports to both physicians and patients. LCD believes these chronic disease programs represent potential significant savings to the healthcare system by facilitating more effective management of these chronic diseases.

Kidney Stone Prevention. LCD provides services to assist physicians and patients to prevent or minimize the formation of kidney stones, a painful and often debilitating condition that can also require expensive treatment if

kidney stones are formed. Through sophisticated algorithms created by the leading specialists in the field, LCD provides patient-specific treatment recommendations and other clinical and patient support for those who have a history of kidney stones or are identified as likely to develop kidney stones.

Development of New Tests

Advances in medicine continue to fundamentally change diagnostic testing. New tests are allowing clinical laboratories to provide unprecedented amounts of health-related information to physicians and patients. New molecular diagnostic tests that have been introduced over the past several years, including a gene-based test for HPV, HIV drug resistance assays, and molecular genetic testing for cystic fibrosis, have now become part of standard clinical practice. LCD continued its industry leadership in gene-based

Index

and esoteric testing in 2018. As science continues to advance, LCD expects new testing technologies to emerge and, therefore, intends to continue to invest in advanced testing capabilities so that it can remain on the forefront of diagnostic laboratory testing. The Company has added, and expects to continue to add, new testing technologies and capabilities through a combination of internal development initiatives, technology licensing and partnership transactions, and selected business acquisitions. Through its sales force, LCD rapidly introduces new testing technologies to customers. This differentiation is important in the retention and growth of business.

In 2018, LCD continued its emphasis on scientific innovation and leadership with the introduction of significant test menu and automation enhancements and by launching more than 70 new tests. LCD is focused on the expansion of existing programs in molecular diagnostics as well as the introduction of new assays and assay platforms through licensing partnerships, acquisitions and internal development. The Company's commitment to the scientific advancement in the development and assessment of new diagnostics and therapeutics is evidenced by producing nearly 600 peer-reviewed publications and presentations at scientific meetings, along with regular presentations in academic medical center grand rounds and seminars, in 2018.

Examples of new tests and services introduced in 2018 include:

Infectious Diseases. LCD now offers a series of BioFire® test panels, produced by bioMerieux, with application across four clinical areas: respiratory, blood culture, gastrointestinal, and meningitis/encephalitis. These panels identify more than a hundred pathogens, including viruses, bacteria, yeast, parasites, and antimicrobial resistance genes, with faster turnaround times to help physicians more quickly and precisely diagnose and begin treatment in often-critical cases.

Oncology. LCD continued its leadership in oncology by offering a significant number of new tests focused on the diagnosis and treatment of cancer. LCD was one of the first laboratories to join Thermo Fisher’s Next-Generation Sequencing Companion Dx Center of Excellence Program, offering enhanced participation in clinical trials and early access to novel testing platforms and assays. With the Omniseq Immune Report Card℠ test and the OmniSeq Comprehensive® panel, LCD became the exclusive laboratory to provide U.S. physicians with unique insights to help guide treatment decisions for cancer patients who may be appropriate candidates for immunotherapy and other targeted treatments. LCD extended its offering of proprietary NGS VistaSeq℠ Cancer panels. The VistaSeq tests screen for elevated risk of hereditary cancer, and the expanded offering includes tests for multiple additional types of cancer.

Women's Health. LCD maintained its leading position in women's health testing, including a robust menu of NIPT testing options, ranging from screening for the common autosomal trisomies, to detection of select microdeletions, to a genome-wide assessment of large copy number variants. These offerings provide the most comprehensive menu of noninvasive fetal aneuploidy screening. LCD began to offer ReproSURE™, a blood test designed to provide information about ovarian reserve, which is an indication of a woman's reproductive potential to help physicians and patients in selecting the most appropriate fertility treatment to increase chances of becoming pregnant.

Medical Drug Monitoring and Toxicology. LCD’s existing expertise in medical drug monitoring and toxicology, through MedTox Laboratories and LabCorp Occupational Testing Services, was enhanced through the acquisition of Pathology Associates Medical Laboratory (PAML). The combination will allow LCD to provide expanded access and capacity for medical drug monitoring and toxicology services.

LCD continues its collaborations with university, hospital and academic institutions, such as Boston University, Columbia University, Duke University, Johns Hopkins University, The Mount Sinai Hospital, the University of Tennessee and Yale University, to license and commercialize new diagnostic tests.

LCD Technology-Enabled Solutions

LCD’s technology-enabled solutions include an innovative and proprietary suite of applications to enable patients, healthcare providers, health systems, accountable care organizations (ACOs), and insurers with convenient and secure access to LCD’s data and services. These industry-leading solutions are designed to improve health and improve lives by providing a better laboratory experience for physicians and patients, and ultimately improving the delivery of care.

LCD's centralized and proprietary LabCorp | Link™, which focuses on physicians and health systems, is a suite of capabilities that enhance the customer experience and provide an end-to-end lab solution. These assets and functionalities include:

- A physician portal optimized for web and mobile devices;
- Express electronic ordering for essentially all of LCD's brands and services;
- Integrated results viewing and enhanced reports;
- Lab analytics that provide one-click trending of patient, test and population data;
- Clinical Decision Support tools at the point of testing and resulting;
- AccuDraw, which provides graphical, step-by-step guidance to help improve accuracy, workflow and turnaround time in the collection and processing of specimens at the point of collection;

Index

- Services-oriented architecture with rules-based engines, content aggregation and seamless integration with practice workflow; and
- An installable mobile app available through the Apple and Google app stores which enables healthcare providers to receive alerts that test results are available, view test results, and access test information and contact information for LCD experts from their own mobile device at any time or location.

LCD's centralized and proprietary LabCorp | Patient is a suite of web and mobile applications that enhances the patient's experience. These assets and functionalities include:

- A patient web application optimized for use on desktop computers and mobile devices;
- An installable mobile app published in the Apple Store and Google app stores;
- Biometric ID login support;
- Integrated results viewing and patient education materials;
- Online appointment scheduling;
- Electronic invoice presentment and payment;
- An online patient cost estimator for select genetic tests; and
- An option to receive information about clinical trials.

LCD also fully deployed two new patient self-service products in 2018 across all PSCs nationwide.

- LabCorp | PreCheck™ is a mobile-optimized web application that allows patients to easily schedule a PSC visit in advance and to complete all demographic and insurance entry and verification in advance, to streamline the check-in process when they arrive for service. PreCheck also features a mobile check-in to indicate arrival in the waiting room without having to wait in line for an Express tablet.
- LabCorp | Express™ uses tablets in custom enclosures and proprietary software located in PSC waiting rooms to enable patients with or without an appointment to check into the PSC. If they do not already have an appointment, they can find the next available one at that or a nearby PSC. Express is optimized to capture and confirm demographic and insurance information through barcode scanning and OCR technologies, eliminating typing on the screen. During 2018, payment processing was also added to Express, enabling card payments of overdue or current balances.

These solutions are now fully deployed across the nationwide PSC network and are designed to expedite the intake process and improve patient flow at the PSC. Both also provide options to receive testing and appointment notifications via email or text message. These apps have demonstrably increased patient and staff satisfaction. In addition, the notifications may help increase test compliance, and the patient data collected will help accelerate enrollment in LabCorp | Patient and further increase the growing population of patients who may receive information about clinical study opportunities with CDD.

LCD's centralized and proprietary LabCorp | Payer™ enables healthcare insurers and ACOs to obtain test results and quality data through a self-service web application. Results and quality data are increasingly important as the healthcare system focuses on new payment models and the need to deliver better patient outcomes and reduce cost. Over time, this new portal will be expanded to deliver a wide variety of data and analytic value.

During 2018, LCD delivered more than 6.0 million enhanced CDS reports for chronic health conditions, including kidney disease, cardiovascular disease, metabolic bone disease and diabetes. LCD's proprietary CDS reports integrate patient-specific diagnostic information and evidence-based healthcare content to help physicians and patients better manage health. In addition, these decision-support programs promote physician adherence to evidence-based treatment guidelines.

LCD continues to develop new population health analytics programs that provide healthcare business intelligence tools to health systems, physician practices, and ACOs. These tools are intended to assist customers in their compliance and reporting requirements with respect to efficient management of their productivity, quality and patient outcome metrics.

Billing for Laboratory Services

Billing for laboratory services is a complicated process involving many payers such as MCOs, Medicare, Medicaid, physicians and physician groups, hospitals, patients and employer groups, all of which have different billing requirements. In addition, billing arrangements with third-party administrators may further complicate the billing

process. Most testing services are billed to a party other than the physician or other authorized person who ordered the test. A growing portion of revenue is derived from patients in the form of deductibles, coinsurance, copayments, and charges for non-covered tests.

LCD utilizes a centralized billing system in the collection of approximately 92.4% of its domestic revenue (87.6% of consolidated LCD revenue). This system generates bills to LCD customers based on payer type. Client payers (which includes physicians, hospitals, health systems, ACOs, employers and other entities) are typically billed monthly, whereas patient, Medicare, Medicaid, and MCO bills are typically generated daily. Accounts receivable are then monitored by billing personnel and follow-up activities are conducted as necessary.

Index

Revenue is adjusted for price concessions related to negotiated discounts and the anticipated impact of adjustments, denials (Medicare, Medicaid and MCOs), and account write-offs (collection risk). Anticipated write-offs are recorded as an adjustment to revenue and at an amount considered necessary to record the segment's revenue at its net realizable value.

The majority of LCD's collection risk is related to accounts receivable from both insured and uninsured patients who are unwilling or unable to pay. In 2018, LCD continued its focus on process, technology innovation and account management initiatives to reduce the negative impact of patient accounts receivable write-offs. In 2017, the Company implemented system enhancements to provide patients with an estimate of their out-of-pocket costs when presenting at a LabCorp PSC.

Non-credit-related issues that slow the billing process, such as missing or incorrect billing information on test requisitions also contribute to a reduction in sales. LCD vigorously attempts to obtain any missing information or rectify any incorrect billing information received from the ordering physician. However, LCD typically performs the requested tests and returns the test results regardless of whether billing information is correct or complete. LCD believes that this experience is similar to that of its primary competitors. LCD continues to focus on process initiatives aimed at reducing the impact of these non-credit-related issues. This is accomplished through ongoing identification of root-cause issues, deploying technology-enabled solutions, training provided to internal and external resources involved in the patient data capture process, and an emphasis on the use of electronic test ordering. Specific to technology-enabled solutions, in 2016 LCD deployed insurance eligibility verification and address validation at the time of service in all PSCs. In 2018, the Company developed a self-serve platform for physicians to resolve claim issues related to diagnosis denials.

For the Company's operations in Ontario, Canada, the Ontario Ministry of Health and Long-Term Care (Ministry) determines who can establish a licensed community medical laboratory and caps the amount that each of these licensed laboratories can bill the government-sponsored healthcare plan. The Ontario government-sponsored healthcare plan covers the cost of clinical laboratory testing performed by the licensed laboratories. The provincial government discounts the annual testing volumes based on certain utilization discounts and establishes an annual maximum it will pay for all community laboratory tests. The agreed-upon reimbursement rates are subject to Ministry review at the end of each year and can be adjusted at the government's discretion based upon the actual volume and mix of testing services performed by the licensed healthcare providers in the province during the year. In 2018, the amount of the Company's capitated revenue derived from the Ontario government-sponsored healthcare plan was CAD $188.1 million.

Effect of U.S. Market Changes on the Clinical Laboratory Business

The delivery of, and reimbursement for, healthcare continues to change in the U.S., impacting all stakeholders, including the clinical laboratory business. Medicare (which principally serves patients who are 65 and older), Medicaid (which principally serves low-income patients) and insurers have increased their efforts to control the cost, utilization and delivery of healthcare services. Measures to regulate healthcare 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 imposing new, increasingly complex regulatory and administrative requirements. The government also has continued to adjust the Medicare and Medicaid fee schedules at the national and local level, and LCD believes that pressure to reduce government reimbursement will continue.

Fees for most laboratory services reimbursed by Medicare are established in the Clinical Laboratory Fee Schedule (CLFS) and fees for other testing reimbursed by Medicare, primarily related to pathology, are covered by the Physician Fee Schedule (PFS). During 2018, approximately 12.9% of LCD’s revenue was reimbursed under the CLFS (12.6% in 2017), and approximately 0.7% was reimbursed under the PFS (0.7% in 2017). Over the past several years, LCD has experienced governmental reimbursement reductions as a direct result of the Patient Protection and Affordable Care Act (ACA), the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), and the Achieving a Better Life Experience Act of 2014 (ABLE Act). Payer policy changes have further impacted the reimbursement for LCD. PAMA, which became law on April 1, 2014, and went into effect on January 1, 2018, resulted in a net reduction in reimbursement revenue of approximately $70.0 million in 2018 from all payers affected

by the CLFS. Unless further implementation of PAMA is delayed or changed, an additional reduction of approximately $115.0 million is expected for 2019, from all payers affected by the CLFS. These laws include provisions designed to control healthcare expenses reimbursed by government programs through a combination of reductions to fee schedules, incentives to physicians to participate in alternative payment models such as risk-sharing, and new methods to establish and adjust fees.

In 2018, LCD realized a net reduction of approximately $1.7 million in PFS revenue, driven by reductions in reimbursement for flow cytometry procedures. In 2019, LCD anticipates it will realize an additional net reduction of approximately $2.1 million in PFS revenue attributable to continued reductions in reimbursement for flow cytometry procedures.

Beginning in 2018, under PAMA, CMS set the CLFS using the weighted median of reported private payer prices paid to certain laboratories that receive a majority of their Medicare revenue from the CLFS and PFS and that bill Medicare under their own National Provider Identifier (NPI). On June 23, 2016, CMS issued a final rule to implement PAMA that required applicable laboratories, including LCD, to begin reporting their test-specific private payer payment amounts to CMS during the first quarter of 2017. CMS exercised enforcement discretion to permit reporting for an additional 60 days, through May 30, 2017. CMS used

Index

that private market data to calculate weighted median prices for each test (based on applicable current procedural technology (CPT) codes) to represent the new CLFS rates beginning in 2018, subject to certain phase-in limits. For 2018-2020, a test price cannot be reduced by more than 10.0% per year; for 2021-2023, a test price cannot be reduced by more than 15.0% per year. The process of data reporting and repricing will be repeated every three years for Clinical Diagnostic Laboratory Tests (CDLTs). The second data reporting period for CDLTs will occur during the first quarter of 2020, and new CLFS rates for CDLTs will be established based on that data beginning in 2021, subject to the previously described phase-in limits for 2021-2023. The third data reporting period for CDLTs will occur during the first quarter of 2023, and new CLFS rates for CDLTs will be established based on that data beginning in 2024. CLFS rates for 2024 and subsequent periods will not be subject to phase-in limits. CLFS rates for Advanced Diagnostic Laboratory Tests (ADLTs) will be updated annually.

CMS published its initial proposed CLFS rates under PAMA for 2018-2020 on September 22, 2017. Following a public comment period, CMS made adjustments and published final CLFS rates for 2018-2020 on November 17, 2017, with additional adjustments published on December 1, 2017.

The final rates published by CMS were based on data reported by only 1% of all laboratories paid by Medicare in 2015, and only 1% of the reported data was from hospital laboratories. Consequently, the American Clinical Laboratory Association (ACLA) filed a federal civil action against HHS for declaratory and injunctive relief on December 11, 2017, arguing that CMS violated the PAMA statute by excluding most of the laboratory market from reporting data on which the rates were based, resulting in rates that do not fairly reflect the private market as the clear language of PAMA requires. On September 21, 2018, the U.S. District Court for the District of Columbia dismissed the action for lack of subject matter jurisdiction, and in December 2018, ACLA filed an appeal.

On November 1, 2018, CMS released its final rule for the 2019 PFS, which included two revisions to the regulatory definition of “applicable laboratory” under PAMA. First, CMS indicated that hospital outreach labs that bill Medicare Part B using bill type 14X will now qualify as applicable laboratories even if they do not bill Medicare Part B using their own NPI, provided they meet other applicable requirements. Second, CMS removed Medicare Advantage (Medicare Part C) revenue from the denominator of the “majority of Medicare revenues” ratio for identifying applicable laboratories.

A November 2018 report issued by the U.S. Government Accountability Office (GAO) questioned the methodology used by CMS for the new payment rates under PAMA and suggested that implementation of PAMA could lead to significant increases in Medicare expenditures. In January 2019, the U.S. Senate Finance Committee sent a letter to HHS about the GAO report and inquired about the potential cost to taxpayers. ACLA has stated that the GAO’s report reflects inaccurate assumptions and a misunderstanding of standard industry practice for laboratory billing.

ACLA continues to work with Congress and with CMS on potential legislative and regulatory reform of PAMA, which if adopted could reduce the negative impact of PAMA as currently implemented by CMS. The Company supports the ongoing efforts to prevent or lessen the negative impact of the changes to the CLFS pursuant to PAMA, and the full impact of those efforts, and what the long-term effect will be on the CLFS rates is not yet known.

On November 4, 2016, CMS noted in a final rule implementing MACRA that it intended to apply Merit-Based Incentive Payment System (MIPS) requirements to pathologists practicing in independent laboratories, including LCD. Under this requirement, LCD pathologists would have been required to begin reporting certain quality metrics in 2017 for LCD to avoid negative PFS payment adjustments or to qualify for positive PFS payment adjustments beginning in 2019. ACLA met with CMS on March 9, 2017, regarding implementation of this requirement, which was not proposed in the MACRA proposed rule. CMS clarified that it would not apply MIPS requirements to pathologists practicing in independent laboratories.

Further healthcare reform could occur in 2019, including changes to the ACA and Medicare reform, as well as administrative requirements that may continue to affect coverage, reimbursement, and utilization of laboratory services in ways that are currently unpredictable.

In addition, market-based changes have affected and will continue to affect the clinical laboratory business. Reimbursement from commercial payers for diagnostic testing has shifted and will continue to shift away from traditional, fee-for-service models to alternatives, including value-based, bundled pay-for-performance, and other

risk-sharing payment models. The growth of the managed care sector and consolidation of MCOs present various challenges and opportunities to LCD and other clinical laboratories.

In May 2018, the Company signed an extension of its long-term agreement with UnitedHealthcare, however, effective January 1, 2019, the Company will no longer be UnitedHealthcare's exclusive national laboratory in the U.S. The Company also signed an agreement with Aetna in May 2018, under which it became a preferred national laboratory for Aetna, effective January 1, 2019; the Company had previously been in-network for a limited number of Aetna members. In November 2018, the Company also extended its agreement with Horizon Blue Cross Blue Shield of New Jersey. The Company will continue to be the exclusive laboratory for Horizon Medicaid members. The Company will no longer be the exclusive capitated laboratory for Horizon HMO Members but will continue to be an in-network laboratory for all Horizon members, including HMO members. These agreements

Index

reflect a trend by MCOs away from laboratory exclusivity, and toward their opening their networks to additional laboratory providers in order to give their members increased choice.

The Company also serves many other MCOs. These organizations have different contracting philosophies, which are influenced by the design of their products. Some MCOs contract with a limited number of clinical laboratories and engage in direct negotiation of rates. Other MCOs adopt broader networks with generally uniform fee structures for participating clinical laboratories. In some cases, those fee structures are specific to independent clinical laboratories, while the fees paid to hospital-based and physician-office laboratories may be different, and are typically higher. MCOs may also offer Managed Medicare or Managed Medicaid plans. In addition, some MCOs use capitation rates to fix the cost of laboratory testing services for their enrollees. Under a capitated reimbursement arrangement, the clinical laboratory receives a per-member, per-month payment for an agreed upon menu of laboratory tests provided to MCO members during the month, regardless of the number of tests performed. For the year ended December 31, 2018, capitated contracts with MCOs accounted for approximately $279.3 million, or 4.0%, of LCD's revenues. LCD's ability to attract and retain MCO customers has become even more important as the impact of various healthcare reform initiatives continues, including expanded health insurance exchanges and ACOs.

In addition to reductions in test reimbursement, the Company also anticipates potential declines in test volumes as a result of increased controls over the utilization of laboratory services by Medicare, Medicaid, and other third-party payers, particularly MCOs. MCOs are implementing, directly or through third parties, various types of laboratory benefit management programs, which may include lab networks, utilization management tools (such as prior authorization and/or prior notification), and claims edits, which impact coverage and reimbursement of clinical laboratory tests. Some of these programs address clinical laboratory testing broadly, while others are focused on molecular and genetic testing. In addition, continued movement by patients into consumer-driven health plans may have an impact on the utilization of laboratory testing.

Despite the overall negative market changes regarding reimbursement discussed above, LCD believes that the volume of clinical laboratory testing is positively influenced by several factors, including the expansion of Medicaid, managed care, and private insurance exchanges. In addition, LCD believes that increased knowledge of the human genome and continued innovation in laboratory medicine will continue to foster greater appreciation of the value of gene-based diagnostic assays. 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 the diagnosis of disease, and the general aging of the U.S. population. As previously discussed, LCD also believes that it and 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 market factors, primarily related to a continued drive to improve outcomes and reduce costs across the healthcare system. LCD believes that its enhanced and growing esoteric menu of tests, leading position with companion diagnostics, broad geographic footprint, and operating efficiency provide a strong platform for growth.

CDD Segment

CDD provides end-to-end drug development, medical device and diagnostic development solutions from early-stage research to clinical development and commercial market access. Its customers comprise biopharmaceutical, medical device and diagnostic companies across the world. With more than 21,000 employees worldwide and a global network of operations, CDD offers deep expertise in early development and clinical trials in each main therapeutic category. Through its industry-leading central laboratory business, it supports clinical trial activity in approximately 100 countries, generating more safety and efficacy data to support drug approvals than any other company. CDD collaborated on more than 93% of the novel drugs approved by the FDA in 2018, including more than 94% of the novel rare and orphan disease drugs and 94% of the novel oncology drugs. In addition, CDD has been involved in the development of all current top 50 drugs on the market as measured by 2017 U.S. sales revenue.

Drug Development Industry

Drug development services companies like CDD are also referred to as CROs and typically derive substantially all of their revenue from research and development (R&D), as well as marketing expenditures of the biopharmaceutical industry. Outsourcing of R&D services by biopharmaceutical companies to CROs has increased in the past, and is

expected to continue increasing in the future. Increasing pressures to improve return on investment, to increase spending on R&D, to stay abreast of scientific advances and to comply with stringent government regulations have all contributed to this outsourcing to CROs. A CRO provides biopharmaceutical companies flexibility in aligning resources to demand. The investment and amount of time required to develop new products are significant and have been increasing. These trends create opportunities for CDD and other CROs that can help make the development process more efficient.

The drug development industry has many participants ranging from hundreds of small providers to a limited number of large CROs with global capabilities. CDD competes against these small and large CROs, as well as in-house departments of biopharmaceutical, medical device and diagnostic companies, and to a lesser extent, selected universities and teaching hospitals.

CDD believes that customers selecting a CRO often consider the following factors, among others:

Index

•Reputation for quality, efficient, timely performance and regulatory compliance;
•Expertise and experience in operations;
•Application of technology and innovation;
•Specific therapeutic and scientific expertise;
•Market access services;
•Ability to recruit patients;
•Scope of service offerings;
•Strengths in various geographic markets;
•Price;
•Quality of facilities;
•Ability to acquire, process, analyze and report data in a rapid and accurate manner;
•Quality of relationships including investigator and patient;
•Ability to manage large-scale clinical trials both domestically and internationally, including the recruitment of appropriate and sufficient clinical-trial subjects; and
•Size and scale.

CDD believes that it competes favorably in all of these areas.

Preclinical Services

CDD’s preclinical service offerings include research models, lead optimization, analytical services, safety assessment, and chemistry manufacturing and control (CMC) services for drug and device development. CDD offers solution-based approaches by leveraging highly experienced program development directors and project managers to help guide strategic decisions and manage development in an integrated, streamlined manner across CDD's nine analytical laboratories and preclinical laboratories in the U.S., the United Kingdom (U.K.), Germany and China. CDD's historical innovations in the preclinical area include technologies such as Covance MarketPlace and StudyTracker®. Covance MarketPlace is a private, secure web portal providing potential investors or partners access to information about new drugs in development. StudyTracker is an internet-based customer access product, allowing customers of toxicology, bioanalytical, metabolism, and reproductive and developmental toxicology services to review study schedules and data on a near real-time basis.

Research Models. CDD is an American Association for Accreditation of Laboratory Animal Care (AAALAC) International accredited provider of purpose-bred research models globally. Due to regulation by the FDA and other foreign regulatory bodies, safety and efficacy testing on research models is required as part of the drug development process prior to testing in humans. CDD has a strong commitment to animal welfare, and has instituted progressive enrichment practices and rigorous health testing standards that exceed industry standards to protect the health of CDD's models. CDD is also committed to seeking out alternatives to, or the reduction of, the use of research models when possible. CDD's research models include standard lines as well as disease state and genetically altered models to accommodate customers’ needs. CDD offers purpose-bred-specific, pathogen-free rabbits, canines, nonhuman primates, and other species, as well as blood and tissue products and surgical/technical services, including telemetry. The purpose-bred research animals are sold to biopharmaceutical companies, university research centers and CROs.

Lead Optimization. Lead optimization services are non-regulated experiments designed to connect early discovery activities to regulated pre-clinical studies. These services include toxicology, in vivo pharmacology with model development and integrated safety and efficacy capabilities, nonclinical imaging, nonclinical pathology services, pharmacokinetic/toxicokinetic (PK/TK) analysis reporting and immunology services.

Analytical Services. Bioanalytical testing services help determine the appropriate dose and frequency of drug administration from late discovery evaluation through Phase III clinical testing on a full-scale, globally integrated basis. CDD’s analytical services offering includes liquid chromatography-mass spectroscopy immunoanalytical solutions and specialty support, translational biomarker solutions, discovery bioanalysis, vaccine analysis, PK/TK analysis and reporting, and organic synthesis. In addition, CDD offers a growing menu of validated, nonproprietary assays for hundreds of compounds, eliminating method development and validation time, and reducing program cost. CDD has dedicated lab facilities across three continents providing in vitro drug metabolism, in vivo radiolabeled

absorption, distribution, metabolism and excretion studies; metabolite identification/profiling and nonclinical PK screening; and radiosynthesis services. CDD also provides pharmaceutical chemistry services that determine the metabolic profile and bioavailability of drug candidates.

Safety Assessment. Safety assessment services include general, genetic, and immunotoxicology services; nonclinical pathology services; safety pharmacology services; preclinical medical device services; and developmental and reproductive toxicology (DART) studies. CDD’s drug development services employ state-of-the-art technology and an integrated program for both large and small molecules with facilities across three continents. CDD's nonclinical pathology group comprises certified veterinary pathologists who provide critical insights and recommendations to help customers navigate the drug development process. CDD’s safety pharmacology services utilize the Value Added Safety Pharmacology & Toxicology approach to

Index

economically assess pharmacology endpoints during toxicology studies to minimize safety issues during the clinical phases. DART services help customers assess the birth defect risk for potential drug candidates.

Biopharm CMC Manufacturing Solutions. CDD's CMC solutions offer packages supporting FDA Investigational New Drug Application and New Drug Application/Biologics License Application submissions, as well as programs to help CDD's customers meet acceptance criteria for the release of drug products for both biologics and small molecules. CDD's CMC solutions provide well-coordinated capabilities and expertise operating within a global quality system framework to deliver robust, cost-effective solutions. Capabilities include safety, identity, strength, quality and purity assessments for biologics.

Early Phase Development Solutions. Early Phase Development Solutions (EPDS) offers customers access to a focused, multidisciplinary team of experts that crafts integrated solutions to rapidly identify and develop lead drug candidates and reduce development challenges. EPDS provides customers with seamless integration of the complete array of CDD nonclinical and early clinical services, with a focus on scientific integrity and human subject safety. EPDS also offers an innovative parallel study approach for shorter proof-of-concept studies. This approach can increase clinical return on investment through the application of medical, scientific and therapeutic expertise, along with patient stratification strategies.

Central Laboratory Services

CDD provides central laboratory and specialty testing services to biopharmaceutical customers through its global network of central laboratories in the U.S., Switzerland, Singapore and China, as well as its strategic agreement for central laboratory services testing in Japan with BML, Inc., a leading Japanese laboratory testing company.

CDD’s capabilities provide customers the flexibility to conduct studies on a global basis. Because CDD uses standardized laboratory equipment, methods, reagents and calibrators for studies, data can be combined with clinical trials in different regions to produce global trial reference ranges. Combinable data eliminates the cumbersome process of harmonizing results generated using different methods in different laboratories on different equipment. CDD also offers external-facing tools such as LabLink+ and Xcellerate® Investigator Portal, which are internet-based customer programs that allow customers to review and query clinical trial lab data on a near real-time basis, that provide an opportunity for enhanced collaboration between the investigator sites, CROs and sponsors.

CDD operates the world’s largest automated clinical trial sample collection kit production line, located in Indianapolis, Indiana. This facility provides kits and supplies to investigator sites around the world, promoting global consistency in sample collection. Extensive automation in the kit production process enables kits to be produced with 5.5 sigma precision, while maintaining the scalability needed to meet increasing global demand. CDD's biorepository facility in Greenfield, Indiana, is dedicated to long-term storage of clinical trial specimens. CDD has additional sample storage facilities in Indianapolis, Indiana; Geneva, Switzerland; Singapore; and Shanghai, China, as well as a state-of-the-art distribution center in Mechelen, Belgium. These actively monitored facilities are able to store a wide range of specimens, including plasma, serum, whole blood, DNA and tissue.

CDD has six ISO 15189-certified laboratories that provide customers with the assurance that comes with this rigorous global standard. In addition to utilizing the broad scientific expertise of the LCD Specialty Testing Group, CDD has implemented a novel model for external lab selection and management that provides rigor and reduces internal resource drain for trial sponsors. The extended laboratory management solutions team focuses on managing all aspects of referral laboratory services, including vendor negotiations, governance, quality management, data services and contract services.

CDD, in conjunction with LCD’s expertise in a wide range of specialty and esoteric testing disciplines, offers a scientifically rich and diverse menu of specialty testing capabilities, spanning the clinical development continuum. These include applied genomics, next-generation sequencing, anatomic and molecular pathology, flow cytometry, clinical immunoassays as well as preclinical and exploratory biomarker development. The combination of CDD and LCD differentiated capabilities and unparalleled experience in companion and complementary diagnostic services support the parallel development of a new medicine and its associated diagnostic assay. The Company's dedicated companion diagnostics team collaborated with over 50 clients on more than 100 companion diagnostic projects in 2018. CDD can support the development of in-vitro diagnostic, companion diagnostics and laboratory-developed tests

(LDTs). By combining CDD's strength in central laboratory and early-stage clinical development with LCD's strength in test commercialization, the Company is well positioned to offer comprehensive, end-to-end support for companion diagnostic development.

Clinical Development and Commercialization Services

CDD offers a comprehensive range of clinical development and commercialization services, including the full service management of Phase I through IV clinical studies, along with a wide offering of functional service provider (FSP) solutions. CDD has extensive experience in all major therapeutic areas, and provides the following core services either on an individual or aggregated basis to meet its customers' needs: study design and modeling; patient recruitment; coordination of study activities; trial logistics; monitoring of study site performance; clinical data management and biostatistical analysis; pharmacovigilance/safety assessments; and medical writing and regulatory services. CDD also has a dedicated group with extensive experience in

Index

the conduct of trials for medical devices, to provide services for the expanding market in medical devices, including mobile health (mHealth) devices.

CDD has extensive experience in designing and managing global clinical trials and regional clinical trial activities in North America, Europe, Latin America and the Asia-Pacific region. These trials may be conducted separately or simultaneously as part of a multinational or global development plan. CDD can manage every aspect of a clinical trial, from clinical development plans and protocol design to new drug applications and other supporting services.

CDD provides clinical pharmacology services at its four clinics in the U.S. and Europe, including first-in-human trials, and early clinical trial subject proof-of-concept studies of new biopharmaceuticals.

CDD offers a range of commercialization solutions, including life cycle management and post-approval studies, which are typically conducted after a drug has successfully undergone clinical efficacy and safety testing and the New Drug Application/Biologics License Application has been submitted to and approved by the FDA and/or comparable applications are submitted to and approved by other regulatory bodies. CDD also offers market access solutions, including reimbursement consulting and hotlines, patient assistance programs, health economic and outcomes research services, observational studies, real-world evidence and analytics services, and value communication services. Biopharmaceutical companies purchase these services to serve patients in need of therapy and to help optimize their return on R&D investments.

CDD Technology-Enabled Solutions

CDD’s technology-enabled solutions are designed to improve the drug development process, by providing its biopharmaceutical customers with greater access to key insights and improved trial management. These proprietary software as a service (SaaS) solutions include the award-winning Xcellerate informatics platform, the PharmAcuity suite of software applications, and CDD's endpoint trial management solution. In addition to these solutions, CDD offers its biopharmaceutical customers unique laboratory specimen management solutions from its Global Specimen Solutions (GSS) service platform as well as an efficient, global interactive study randomization technology, to optimize study management and reduce trial-supply costs. Covance MarketPlace securely connects developers with interested companies for licensing opportunities and to accelerate strategic discussions.

Xcellerate integrates and operates with multiple sources of data to deliver unique and timely information throughout the course of customer studies. Xcellerate helps to reduce the cost, time, complexity and risk associated with clinical trials. These solutions leverage a highly innovative data integration and visualization technology that provides timely, secure, integrated and contextualized access to all clinical trial data to enable proactive risk management and informed decision making. Key Xcellerate modules include Trial Design, Clinical Trial Management, Clinical Data Hub, Monitoring, Data Management and Insights:

- Xcellerate Trial Design enables customers to map available patient populations and identify optimal sites and investigators by drawing on the world’s largest proprietary clinical trial knowledge base.
- Xcellerate Clinical Trial Management provides the foundational operating systems to enable frictionless execution of clinical trials.
- Xcellerate Clinical Data Hub integrates clinical trial data from any source and makes it accessible to study teams in a timely, secure and contextualized manner to support a broad range of monitoring, analytic, and reporting needs.
- Xcellerate Data Management enables data managers to enhance data quality and completeness, and accelerates database locking by identifying missing, erroneous or inconsistent data as well as managing queries holistically.
- Xcellerate Monitoring enables customers to improve data quality, clinical trial subject safety and protocol compliance in the execution of clinical trials by proactively identifying and mitigating risks at the study site and clinical trial subject level.
- Xcellerate Insights enables effective operational oversight by providing interactive, up-to-date views of a broad range of operational metrics and key performance indicators at the study and portfolio levels through a secure collaboration portal, producing insights that enable its users to make decisions about study management and patient impacts.

PharmAcuity is a cloud-based suite of software applications that helps biopharmaceutical companies fine-tune their clinical trial strategy, planning, and design months before a trial begins. The performance data available via

PharmAcuity is derived from past trials and public data sources covering more than 130 countries, reflecting the worldwide nature of clinical trials. Key PharmAcuity modules include Metrics and Benchmarking, and Trial Forecasting:

- PharmAcuity Metrics and Benchmarking enables clients to assess the performance of historical trials relative to current targets, as well as set accurate and feasible targets for a variety of future trial milestones. Utilizing the rest of the biopharmaceutical industry’s performance data as a benchmark, this module allows the client to evaluate clinical trial performance against the industry, leading to more efficient trial, enrollment, and country planning.
- PharmAcuity Trial Forecasting empowers clients to forecast their own clinical trial performance and build different forecasting scenarios across multiple dimensions, all based on proprietary inputs and historical, contextual industry performances.

Covance MarketPlace enables biopharmaceutical companies to showcase therapeutic assets to interested parties for licensing opportunities during the early phases of drug development. With unprecedented access to the Company's exclusive network of

Index

drug developers and through its private, secure web portal, companies can share non-confidential information about their assets to attract potential investors or partners. Interested parties can find asset listings via targeted asset alerts and easy-to-use search functions. The platform provides users with direct, secure communication with asset owners, accelerating strategic discussions. It is one more way the Company helps transform drug development programs, delivered by the only global drug development partner with the expertise spanning preclinical, clinical and commercial phases.

GSS provides a suite of innovative software applications for lifecycle specimen management. GSS' GlobalCODE® application provides unified data from a single-interface that allows for tracking of specimens from collection through destruction, as well as cross-protocol analytics and management of samples according to informed consent-allowable usage. The GSS SnapTRACK® application provides for capture of information upon sample collection, and pushes sample-related information into GlobalCODE in near real-time. The GSS LabCODE® platform provides an innovative and client-configurable cloud-based Laboratory Information Management System (LIMS) to biopharmaceutical companies, enabling rapid data integration across numerous in-house laboratories.

CDD’s endpoint trial management solutions offer interactive response technology (IRT) to provide visibility across a client’s clinical development portfolio, enabling optimization of study management and reduced trial supply costs while helping to bring novel therapies to market faster. Key endpoint modules include:

- endpoint’s proprietary PULSE® platform comprises pre-validated, configurable study components that enable rapid development and quicker modification to a client’s existing IRT system. PULSE can help to streamline complex trial randomization methods, improve drug supply management, and simplify site, study, and subject management. The fully digital, mobile-ready system allows access to patient data and outcomes in real time.
- endpoint’s DRIVE platform provides visibility into supplies management for an entire clinical development portfolio. It provides automated supply functionality to help minimize costs, reduce waste, and manage regulatory compliance across multiple trial sites.

CDD’s other proprietary technology assets include an investigator database and analytic methodologies that are used to design and manage site selection and clinical trial subject enrollment. Covance MarketPlace provides a private, secure web portal to potential investors or partners, enabling access to information about new drugs in development. Together, CDD's technology-enabled solutions improve the transparency, quality and speed of clinical trials, resulting in reduced costs and increased market potential for biopharmaceutical customers.

Customers

The Company provides its services to a broad range of customers. The primary customer groups serviced by the Company include:

MCOs. The Company serves many MCOs, each of which operate on a national, regional or local basis. Fees for clinical laboratory testing services rendered for physicians may be billed to a patient’s third-party payer, such as an MCO, with reimbursement typically based on a negotiated, fee-for-service basis, and in some circumstances reimbursement is based on a capitated arrangement.

Biopharmaceutical Companies. The Company serves hundreds of biopharmaceutical companies, ranging from the world’s largest biopharmaceutical companies to emerging to mid-market organizations. Contracts with these institutions generally take the form of fee-for-service or fixed-price arrangements.

Physicians and Other Healthcare Providers. Physicians who require clinical laboratory testing for their patients are a primary source of requests for LCD's testing services. Physicians may practice individually, or as part of small or large physician groups, including those operated as part of a broader health system. Fees for clinical laboratory testing services rendered for physicians are billed either to the physician, the physician group, the patient or the patient’s third-party payer, such as an MCO, Medicare or Medicaid. Billings are typically on a fee-for-service basis. If the billings are to the physician, they are based on a customer-specific fee schedule and are subject to negotiation. Otherwise, the patient or third-party payer is billed at the Company's patient fee schedule, subject to third-party payer contract terms and negotiation by physicians on behalf of their patients. Patient sales are recorded at the Company’s patient fee schedule, net of any discounts negotiated with physicians on behalf of their patients, or made available through charity care or an uninsured or underinsured patient program. Revenues received from Medicare and

Medicaid billings are based on government-set fee schedules and reimbursement rules.

Hospitals and Health Systems. The Company provides hospitals and health systems with services ranging from core and specialty testing to supply chain and technical support services, and the opportunity to be a research partner for participation in studies and clinical trials with CDD. Individual hospitals generally maintain on-site laboratories to perform immediately needed testing for patients receiving care. However, they also refer less time-sensitive procedures, less frequently needed procedures and highly specialized procedures to outside facilities, including independent clinical laboratories such as the

Index

Company and laboratories operated by larger hospitals or health systems. In some cases, a hospital's on-site laboratory may be operated or managed by an outside contractor or independent laboratory, including the Company. The Company typically charges hospitals for any such tests on a fee-for-service basis that is derived from the Company's client fee schedule. Fees for laboratory management services are typically billed monthly at contractual rates.

Other Customers. The Company serves a broad range of other customers, including, but not limited to, governmental agencies, employers, patients and consumers, CROs, academic institutions and independent clinical laboratories. Until the sale of the CFS business in the third quarter of 2018, the Company also served food and nutritional companies. These customers typically pay on a negotiated fee-for-service basis or based on a set fee schedule.

Capital Allocation

The Company believes it has a strong track record of deploying capital to investments that enhance the Company's business and return capital to shareholders.

From 2014, the Company has invested net cash of approximately $6.4 billion and equity of $1.8 billion in strategic business acquisitions. These acquisitions have significantly expanded the Company's service offerings, expanded its customer and revenue mix, as well as strengthened and broadened the scope of its geographic presence. The Company continues to evaluate acquisition opportunities that leverage the Company's core competencies, complement existing scientific and technological capabilities, increase the Company's presence in key geographic, therapeutic and strategic areas, and meet or exceed the Company's financial criteria.

From 2014, the Company repurchased approximately $1.4 billion in shares at an average price of approximately $137.04 per share. During 2018, the Company purchased 4.2 million shares of its common stock at a total cost of $700.0 million. At the end of 2018, the Company had outstanding authorization from the board of directors to purchase an additional $443.5 million of Company common stock. On February 6, 2019, the board of directors replaced the Company's existing share repurchase plan with a new plan authorizing repurchase of up to $1.25 billion of the Company's shares. The repurchase authorization has no expiration date.

During 2018, the Company repaid $400.0 million of its Senior Notes and $295.0 million of its term loans. In addition, the Company borrowed and repaid $467.2 million of debt through its revolving credit facility within 2018. The Company will continue to evaluate all opportunities for strategic deployment of capital in light of market conditions.

From 2014, capital expenditures other than acquisitions have been $1.4 billion, representing approximately 3.1% of the Company's total net revenues during the same period. The Company expects such capital expenditures in 2019 to be approximately 4.0% of net revenues, primarily in connection with projects to support growth in the Company's core businesses, facility expansion and updates, ongoing projects related to LaunchPad within the LCD business, LaunchPad's expansion within the CDD business, phase II of LCD's LaunchPad and further acquisition integration initiatives.

Seasonality and External Factors

The Company experiences seasonality in both segments of its business. For example, testing volume generally declines during the year-end holiday period and other major holidays and can also decline due to inclement weather or natural disasters. Declines in testing volume reduce net revenues, operating margins and cash flows. Operations are also impacted by changes in the global economy, exchange rate fluctuations, political and regulatory changes, the progress of ongoing studies and the startup of new studies, as well as the level of expenditures made by the biopharmaceutical industry in R&D. The results of both segments are impacted by exchange rate fluctuations. Approximately 22.1% of the Company's net revenues are billed in currencies other than the U.S. dollar, with the Swiss franc, British pound, Canadian dollar and the euro representing the largest components of its currency exposure. The inclusion of Chiltern for a full twelve months in 2018 increased the Company's percentage of revenues billed in currencies other than the U.S. dollar. Given the seasonality and changing economic factors impacting the business, comparison of the results for successive quarters may not accurately reflect trends or results for the full year.

Investments in Joint Venture Partnerships

The Company holds investments in joint venture partnerships, with two located in Alberta, Canada, one located in Florence, South Carolina and several that were acquired through the Company's acquisition of PAML. These businesses are primarily represented by partnership agreements between the Company and other independent

diagnostic laboratory investors. Under these agreements, all partners share in the profits and losses of the businesses in proportion to their respective ownership percentages. All partners are actively involved in the major business decisions made by each joint venture. The Company does not consolidate the results of these joint ventures.

The first Canadian partnership is a leader in occupational testing across Canada similar to LCD's U.S. occupational testing services. The second Canadian partnership has a license to conduct diagnostic testing services in the province of Alberta.

Index

Substantially all of its revenue is received as reimbursement from the Alberta government's healthcare programs (AHS). In August 2016, AHS and the Canadian partnership reached an agreement to extend the contract for five additional years through March 2022, with the intent to have the services provided pursuant to the contract transferred to AHS at the end of the five-year period. In consideration of AHS acquiring the assets and assuming liabilities in accordance with the parties' agreement, AHS will pay CAD 50.0 million to the partnership when the transfer is effective, subject to a working capital adjustment.

As a result of the acquisition of PAML, the Company acquired PAML's ownership interests in six joint ventures. During 2017 and 2018, the Company further acquired the ownership interests of the other members of four of the six joint ventures, and divested interest in one of the six joint ventures to the other member. The Company and the other members of the sixth joint venture made the decision to dissolve the sixth joint venture to be effective in 2019.

Sales, Marketing and Customer Service

LCD offers its diagnostic services through a sales force focused on serving the specific needs of customers in different market segments. These market segments generally include primary care, women's health, specialty medicine (e.g., infectious disease, endocrinology, gastroenterology and rheumatology), oncology, ACOs, and hospitals and health systems. LCD's general sales force is also supported by a team of clinical specialists that focuses on selling esoteric testing and meeting the unique needs of the specialty medicine markets.

CDD's global sales activities are conducted by sales personnel in North America, Europe and the Asia-Pacific region. The sales force provides customer coverage across the biopharmaceutical industry for services including lead optimization, preclinical safety assessment, analytical services, clinical trials, central laboratories, biomarkers and companion diagnostics, market access and technology solutions. Customer segments called upon include global and regional biopharmaceutical companies, other CROs and academic institutions.

The sales force is responsible for both new sales and for customer retention and relationship building and is compensated through a combination of salaries, commissions and bonuses at levels commensurate with each individual's qualifications, performance and responsibilities.

Information Systems

The Company is committed to developing and commercializing technology-enabled solutions to support its operations and provide better care. LCD and CDD each operate standard platforms for their core business services, and the Company operates standard platforms for its financial and reporting systems. These standard systems provide consistency within workflows and information as well as a high level of system availability, security, and stability. LCD's and CDD's primary laboratory systems, including standardized support for molecular diagnostics, digital pathology and enhanced specialty laboratory solutions. The Company's centralized information systems are responsible for tremendous operational efficiencies, enabling the Company to achieve consistent, structured, and standardized operating results and superior patient care.

In addition, LCD and CDD each offer proprietary and industry-leading information systems, which are discussed in more detail in the sections dedicated to each of those segments.

Quality

LCD and CDD have comprehensive quality systems and processes that the Company believes are appropriate for their respective businesses. This includes licensing, credentialing, training and competency of professional and technical staff, and internal auditing. In addition to the Company's own quality programs, the Company's laboratories, facilities and processes are subject to on-site regulatory agency inspections and accreditation evaluations, and surveys, as applicable, by local or national government agencies; external proficiency testing programs; and inspections and audits by customers.

Virtually all facets of the Company's services are subject to quality programs and procedures, including accuracy and reproducibility of tests; turnaround time; customer service; data integrity; patient satisfaction; and billing. The Company's quality program includes measures that compare current performance against desired performance goals to monitor critical aspects of service to its customers and patients.

The Company has procedures for monitoring its internal performance, as well as that of its vendors, suppliers and other key stakeholders. In addition, various groups and departments within the Company provide oversight to monitor

and control vendor products and performance, and play an essential role in the Company’s approach to quality through improvements in processes and automation. These groups include LCD's National Office of Quality, CDD’s Global Regulatory Compliance and Quality Assurance Unit, the Company's supply chain management department, CDD's clinical trial services global vendor management department, CDD's central laboratory services expanded laboratory management services department, and project management staff supporting LCD and CDD.

Index

Customer Interaction. Continual improvement in the customers' experience with the Company is essential. Use of technology and workflow improvements are helping to improve the patient experience by: reducing patient wait times at PSCs through advance appointment scheduling and patient check-in through LabCorp | PreCheck; expediting the patient registration process at the PSC through LabCorp | Express; enhancing the specimen collection process through LabCorp Touch and AccuDraw; and allowing patients to access their test results, obtain educational materials, schedule appointments and pay bills directly through LabCorp | Patient. LabCorp | Payer provides healthcare organizations with a centralized location to access test results and quality data. CDD processes permit faster clinical trial study start-up and subject enrollment along with timely delivery of established deliverables to enhance and improve customer interaction.

Specimen Management. The Company's standardized logistics and specimen tracking technologies allow the timely transportation, monitoring, and storage of specimens. The Company is continually working to maintain and improve its ability to timely collect, transport and track specimens from collection points to all Company or designated external locations. In December 2017, CDD acquired GSS, which has expertise in streamlined global specimen tracking, as well as tracking for informed consent, and live data analytics that deliver actionable insights from specimens across development programs. CDD had previously entered into a strategic alliance with GSS in October 2016.

Quality Control. The Company regularly performs quality control testing. This may include in-process and post-process quality control checks; use of applicable control materials and reference standards, peer reviews, and data review meetings; programmed data edit checks to detect variances and unusual data patterns; dual programming; and mock runs.

LCD Internal Proficiency Testing. LCD has an extensive internal proficiency testing program to assess LCD's analytical and post-analytical phases of laboratory testing, accuracy, precision of its testing protocols, and technologist/technician performance. This program supplements the external proficiency programs required by the laboratory accrediting agencies.

Accreditation. The Company participates in numerous externally administered quality surveillance programs, including the College of American Pathologists (CAP) program. CAP is an independent non-governmental organization of board-certified pathologists that offers an accreditation program to which laboratories voluntarily subscribe. CAP has been granted deemed status authority by CMS to inspect clinical laboratories to determine adherence to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements. The CAP program involves both on-site inspections of the laboratory and participation in a CAP accepted proficiency testing program for all categories in which the laboratory is accredited. A laboratory's receipt of accreditation by CAP satisfies the CMS requirement for CLIA certification. LCD's major diagnostic laboratories, CDD's major central laboratory facilities, and CDD's Phase I clinical research unit in Dallas, Texas, are accredited by CAP.

The Company has multiple labs that have received ISO 15189 accreditation. ISO 15189 is an international standard that recognizes the quality and technical competence of medical laboratories. The list below reflects the Company's labs that have achieved this accreditation and the year in which it was achieved:

LCD

- Regional Testing Facility, Raritan, New Jersey - January 2017
- Regional Testing Facility, Knoxville, Tennessee - November 2016
- Regional Testing Facility, San Antonio, Texas - July 2016
- Colorado Coagulation, Denver, Colorado - January 2016
- Dynacare, Laval, Québec - March 2015
- Regional Testing Facility, Dublin, Ohio - March 2015
- Endocrine Sciences, Calabasas, California - January 2015
- Regional Testing Facility, Dallas, Texas - April 2014
- Regional Testing Facility, Denver, Colorado - March 2014
- Integrated Genetics, Santa Fe, New Mexico - October 2013
- Integrated Genetics, Westborough, Massachusetts - September 2013

- Dynacare, Montreal, Québec - June 2013
- Regional Testing Facility, Phoenix, Arizona - April 2013
- Regional Testing Facility, Birmingham, Alabama - February 2013
- Integrated Oncology, Brentwood, Tennessee - February 2012
- ViroMed, Burlington, North Carolina - January 2012
- Center for Molecular Biology and Pathology (CMBP), Research Triangle Park, North Carolina - February 2011
- Regional Testing Facility, Tampa, Florida - January 2010
- Integrated Oncology, Phoenix, Arizona - September 2009

CDD

- Covance Central Laboratory Services Inc., Los Angeles, California - August 2018
- Covance Central Laboratory Services Inc., Indianapolis, Indiana - August 2015

Index

- BML Covance Central Laboratory, Tokyo, Japan - March 2015 (Operated for CDD pursuant to a strategic agreement with BML, Inc.)
- Covance Pharmaceutical Research and Development (Shanghai) Co. Ltd., Shanghai, China - March 2015
- Covance (Asia) Pte. Ltd., Singapore - June 2014
- Covance Central Laboratory Services SARL, Geneva, Switzerland - October 2013

Intellectual Property Rights

The Company relies on a combination of patents, trademarks, copyrights, trade secrets, and nondisclosure and non-competition agreements to establish and protect its proprietary technology. The Company has filed and obtained numerous patents in the U.S. and abroad, and regularly files patent applications, when appropriate, to establish and protect its proprietary technology. Occasionally, the Company also licenses U.S. and non-U.S. patents, patent applications, technology, trade secrets, know-how, copyrights or trademarks owned by others. The Company believes, however, that no single patent, technology, trademark, intellectual property asset or license is material to its business as a whole.

Patents covering the Company's technologies are subject to challenges. Issued patents may be successfully challenged, invalidated, circumvented, or declared unenforceable so that patent rights would not create an effective competitive barrier.