

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

FORM 8-K

CURRENT REPORT

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

June 7, 2019

(Date of earliest event reported)

**LABORATORY CORPORATION OF
AMERICA HOLDINGS**

(Exact Name of Registrant as Specified in its Charter)

Delaware

1-11353

13-3757370

(State or other jurisdiction of Incorporation)

(Commission File Number)

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

358 South Main Street,

Burlington, North Carolina

(Address of principal executive offices)

27215

(Zip Code)

336-229-1127

(Registrant's telephone number including area
code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure

LabCorp® (NYSE: LH), a leading global life sciences company that is deeply integrated in guiding patient care, today announced a new companion diagnostic called *therascreen*® PIK3CA PCR mutation analysis, which is now available through LabCorp and its Integrated Oncology specialty laboratory.

The test, developed by QIAGEN (NYSE: QGEN, Frankfurt Stock Exchange: QIA), a world leader in Sample to Insight solutions for molecular testing, identifies whether a patient has the specific gene mutation that is a prerequisite for treatment with Piqray® (aplelisib), a new therapy from Novartis for the treatment of postmenopausal women and all men with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-), PIK3CA-mutated, advanced or metastatic breast cancer, as detected by an FDA-approved test following progression on or after an endocrine-based regimen. Piqray, in combination with fulvestrant, and *therascreen* PIK3CA PCR mutation analysis assay received approval from the U.S. Food and Drug Administration (FDA) on May 24, 2019. LabCorp is able to make the test available quickly after FDA approval through its participation in QIAGEN's Day-One Lab Readiness program, under which LabCorp began test validation and development of operating protocols while the test was under regulatory review and is therefore able to make the test available to patients just two weeks after approval.

Exhibit Index [Exhibit 99.1](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

LABORATORY CORPORATION OF AMERICA HOLDINGS

Registrant

By:

/s/ SANDRA VAN DER VAART

Sandra van der Vaart

Global General Counsel and Corporate Secretary

June 7, 2019

FOR IMMEDIATE RELEASE

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LABCORP AND QIAGEN ANNOUNCE NEW THERASCREEN PIK3CA MUTATION ANALYSIS COMPANION DIAGNOSTIC FOR METASTATIC BREAST CANCER

New Therapy Specifically for Patients with PIK3CA Mutation in
HR+/HER2- Advanced Breast Cancer

BURLINGTON, N.C., June 7, 2019 - LabCorp® (NYSE: LH), a leading global life sciences company that is deeply integrated in guiding patient care, today announced a new companion diagnostic called *therascreen*® PIK3CA PCR mutation analysis, which is now available through LabCorp and its Integrated Oncology specialty laboratory.

The test, developed by QIAGEN (NYSE: QGEN, Frankfurt Stock Exchange: QIA), a world leader in Sample to Insight solutions for molecular testing, identifies whether a patient has the specific gene mutation that is a prerequisite for treatment with Piqray® (aplelisib), a new therapy from Novartis for the treatment of postmenopausal women and all men with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-), PIK3CA-mutated, advanced or metastatic breast cancer, as detected by an FDA-approved test following progression on or after an endocrine-based regimen. Piqray, in combination with fulvestrant, and *therascreen* PIK3CA PCR mutation analysis assay received approval from the U.S. Food and Drug Administration (FDA) on May 24, 2019. LabCorp is able to make the test available quickly after FDA approval through its participation in QIAGEN's Day-One Lab Readiness program, under which LabCorp began test validation and development of operating protocols while the test was under regulatory review and is therefore able to make the test available to patients just two weeks after approval.

"Piqray (aplelisib), from Novartis, is the first and only therapy for HR+/HER2- advanced breast cancer with a PIK3CA mutation," said Marcia Eisenberg, PhD, chief scientific officer, LabCorp Diagnostics. "Through our collaboration with QIAGEN and participation in their Day-One Lab Readiness Program, LabCorp is able to quickly make new companion diagnostics available to help identify patients who are eligible for the most innovative treatments, individualized to their disease. Enabling patients to gain access to new treatments faster, furthering LabCorp's mission to improve health and improve lives."

The American Cancer Society estimates that in 2019, there will be 268,600 new cases of breast cancer and approximately 70% will be HR+/HER2-. For patients with HR+/HER2-advanced breast cancer, approximately 40% have the PIK3CA mutation, which is associated with tumor growth, resistance to endocrine treatment and a poor overall prognosis.

The availability of this new companion diagnostic demonstrates LabCorp's continued leadership in companion diagnostics and precision medicine, with the industry's leading portfolio of tests that identify personalized characteristics for each patient, and help guide more specific treatment choices. For more than 20 years, long before they joined forces, LabCorp Diagnostics and Covance Drug Development have been involved in the development, commercialization and launch of companion and complementary diagnostics, and together they have supported more FDA-approved companion diagnostics than any other company. Since 2018, the Company has collaborated with more than 75 clients on over 150 projects targeted at the development of new companion diagnostics.

LabCorp joined QIAGEN's Day-One Lab Readiness program in early 2019. In addition to the *therascreen* PIK3CA PCR mutation analysis assay announced today, LabCorp also recently launched the *therascreen* FGFR mutation assay by RGQ RT-PCR for bladder cancer through the Day-One program. Multiple other assays, including novel companion diagnostics for lung, colorectal, bladder and other cancers, and eventually pan-tumor disease areas, are currently in LabCorp's Day-One Lab Readiness pipeline.

"The promise of precision medicine is delivering the right drug to the right patient at the right time, and it can be an absolute game-changer for cancer patients," said Dr. Dot Adcock, chief medical officer, LabCorp Diagnostics. "LabCorp's close relationships with numerous hospitals, health systems, cancer clinics and oncologists across the U.S. enables us to provide genetic testing for an increasing number of patients, helping them to more quickly access the targeted therapy that is right for them. We're seeing

extraordinary breakthroughs in precision medicine in oncology patients, and it's exciting to be a part of these advances in patient care.”

For more information about LabCorp's leadership role in precision medicine, visit <https://www.labcorp.com/about-us/labcorp-thought-leadership/>.

Piqray® is a registered trademark of Novartis AG.

therascreen® is a registered trademark of QIAGEN N.V.

About LabCorp

LabCorp (NYSE: LH), an S&P 500 company, is a leading global life sciences company that is deeply integrated in guiding patient care, providing comprehensive clinical laboratory and end-to-end drug development services. With a mission to improve health and improve lives, LabCorp delivers world-class diagnostic solutions, brings innovative medicines to patients faster, and uses technology to improve the delivery of care. LabCorp reported revenue of more than \$11 billion in 2018. To learn more about LabCorp, visit www.LabCorp.com, and to learn more about Covance Drug Development, visit www.Covance.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements, including but not limited to statements with respect to clinical laboratory testing, the impact of various factors on operating and financial results, and the opportunities for future growth. Each of the forward-looking statements is subject to change based on various important factors, many of which are beyond the Company's control, including without limitation, competitive actions and other unforeseen changes and general uncertainties in the marketplace, changes in government regulations, including healthcare reform, customer purchasing decisions, including changes in payer regulations or policies, other adverse actions of governmental and third-party payers, the Company's satisfaction of regulatory and other requirements, patient safety issues, changes in testing guidelines or recommendations, adverse results in material litigation matters, failure to maintain or develop customer relationships, our ability to develop or acquire new products and adapt to technological changes, failure in information technology, systems or data security, and employee relations. These factors, in some cases, have affected and in the future (together with other factors) could affect the Company's ability to implement the Company's business strategy and actual results could differ materially from those suggested by these forward-looking statements. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements. The Company has no obligation to provide any updates to these forward-looking statements even if its expectations change. All forward-looking statements are expressly qualified in their entirety by this cautionary statement. Further information on potential factors, risks and uncertainties that could affect operating and financial results is included in the Company's most recent Annual Report on Form 10-K and subsequent Forms 10-Q, including in each case under the heading RISK FACTORS, and in the Company's other filings with the SEC.

About QIAGEN

QIAGEN N.V., a Netherlands-based holding company, is the leading global provider of Sample to Insight solutions that enable customers to gain valuable molecular insights from samples containing the building blocks of life. Our sample technologies isolate and process DNA, RNA and proteins from blood, tissue and other materials. Assay technologies make these biomolecules visible and ready for analysis. Bioinformatics software and knowledge bases interpret data to report relevant, actionable insights. Automation solutions tie these together in seamless and cost-effective workflows. QIAGEN provides solutions to more than 500,000 customers around the world in Molecular Diagnostics (human healthcare) and Life Sciences (academia, pharma R&D and industrial applications, primarily forensics). As of March 31, 2019, QIAGEN employed approximately 5,100 people in over 35 locations worldwide. Further information can be found at www.qiagen.com.

QIAGEN Forward-Looking Statement

Certain statements contained in this press release may be considered forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, and Section 21E of the U.S. Securities Exchange Act of 1934, as amended. To the extent that any of the statements contained herein relating to QIAGEN's products, collaborations markets, strategy or operating results, including without limitation its expected adjusted net sales and adjusted diluted earnings results, are forward-looking, such statements are based on current expectations and assumptions that involve a number of uncertainties and risks. Such uncertainties and risks include, but are not limited to, risks associated with management of growth and international operations (including the effects of currency fluctuations, regulatory processes and dependence on logistics), variability of operating results and allocations between customer classes, the commercial development of markets for our products to customers in academia, pharma, applied testing and molecular diagnostics; changing relationships with customers, suppliers and strategic partners; competition; rapid or unexpected changes in technologies; fluctuations in demand for QIAGEN's products (including fluctuations due to general economic conditions, the level and timing of customers' funding, budgets and other factors); our ability to obtain regulatory approval of our products; difficulties in successfully adapting QIAGEN's products to integrated solutions and producing

such products; the ability of QIAGEN to identify and develop new products and to differentiate and protect our products from competitors' products; market acceptance of QIAGEN's new products and the integration of acquired technologies and businesses. For further information, please refer to the discussions in reports that QIAGEN has filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC).

QIAGEN

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