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LABORATORY INDUSTRY REPORT™

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HIGHLIGHTS

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Upcoming G2 Events

Lab Institute

October 14-16, 2015

Hyatt Regency Washington DC on Capitol Hill

www.labinstitute.com

LabCorp Reports Strong 4Q Earnings, Makes Bullish 2015 Forecast

Much like its rival Quest Diagnostics, national player LabCorp has gotten its mojo back. After a couple of years of tepid to flat growth, the North Carolina-based LabCorp reported strong growth in the fourth quarter ending Dec. 31.

LabCorp reported net income for the quarter of $120 million on revenue of $1.5 billion. Although its profit was down slightly from the $126.7 million it reported for the fourth quarter of 2013, revenue was up 5.3 percent from $1.4 billion. The company had taken $13 million in special charges during the quarter, much of that related to its recent acquisition of drug testing firm Covance for $5.7 billion. That deal closed last month.

LabCorp's earnings per share came in at $1.65, a couple of pennies above the consensus of analysts.

"We are pleased with our fourth quarter operating performance, highlighted by solid organic growth and adjusted operating margin improvement," said LabCorp Chief Executive Officer Dave King in a press release. "We are excited about the opportunity in 2015."

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23andMe Obtains FDA Approval for Direct-to-Consumer Test

The California-based genetic testing firm 23andMe has taken another step toward remaking itself as a laboratory company, obtaining one of the first federal approvals for a direct-to-consumer genetic test.

23andMe announced last week it has obtained approval from the U.S. Food and Drug Administration to market a test aimed at identifying carriers of Bloom Syndrome, a rare genetic condition.

The announcement was a departure from the company's prior history with the FDA, which had intervened over its marketing of genetic sequencing data directly to consumers.

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23andMe Obtains FDA Approval for Direct-to-Consumer Test, *from page 1*

In late 2013, the agency had ordered the company to stop offering interpretations of its genetic tests, a move 23andMe initially resisted but with which it eventually complied, all but stopping its business model in its tracks. As an alternative, it offered only general ancestral information to those customers willing to remit their DNA swabs and $99.

But the company began remaking itself last year, garnering a seven-figure grant from the National Institutes for Health to analyze genetic data more in depth. Earlier this year it also published research indicating a genetic link to motion sickness. And last June, it submitted the Bloom Syndrome assay to the FDA for marketing approval.

The FDA granted the request last week. The approval was granted after the agency classified the test as de novo, a fast-track process that means the test was considered low to medium risk and there are no other equivalents on the market. The FDA also said it would classify future genetic carrier screening tests as low to medium risk, meaning most would be exempt from a pre-market review.

"This is a major milestone for our company and for consumers who want direct access to genetic testing," said Anne Wojcicki, 23andMe's CEO and co-founder, in the company's press release announcing the approval. "We have more work to do, but we remain committed to pursuing a regulatory path for additional tests and bringing the health reports back to the US market. This important first step would not have been possible without the hard work and guidance of the FDA."

Bloom Syndrome is a rare genetic disorder characterized by having short stature, sensitivity to sunlight, and a higher risk for contracting multiple forms of cancer early in life. It is diagnosed in one in about 50,000 people, primarily those of Eastern European Jewish heritage. If both parents carry the gene for Bloom Syndrome, their child has a 25 percent chance of being born with the disorder.

23andMe's test is able to determine if a subject is a carrier of Bloom Syndrome with a straightforward saliva test. The company ran more than 3,000 validation assays prior to receiving FDA approval. The test was 100 percent accurate when compared against the standard testing method of using human tissue.

"This regulatory process helped establish the parameters for consumer genetics. We are pleased with the agency's decision and its affirmation that consumers can understand and benefit from direct access to genetic information," said Kathy Hibbs, 23andMe's chief regulatory and legal officer, in the company's announcement.

Despite the victory and the fact that 23andMe now has an assay it can market directly to consumers, the test will not be released anytime in the immediate future. The company said in a statement that it will not market the test "until it completes the regulatory process for additional test reports and can offer a more comprehensive product offering."

Takeaway: 23andMe has taken the first steps of remaking its relationship with the Food and Drug Administration..

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Corgenix Gets FDA Clearance for Emergency Use of Its Ebola Test

The U.S. Food and Drug Administration (FDA) has granted emergency use authorization to Denver-based Corgenix for its rapid point-of-care assay for detecting Ebola.

"The FDA and World Health Organization have been working closely with us throughout this process to get this new test in the hands of those battling on the front lines of the Ebola outbreak as quickly as possible."

— Douglass Simpson, CEO, Corgenix

The FDA's ruling permits Corgenix's ReEBOV assay under those circumstances when use of a rapid Ebola test would be more appropriate than use of the currently authorized Ebola molecular test. That test may require a turnaround time of up to two days. The Corgenix test can confirm a diagnosis in 15 to 25 minutes.

Late last year, Corgenix received $818,000 in grants from the Bill and Melinda Gates Foundation and the Paul G. Allen Family Foundation to help develop the assay for general clinical use.

"The FDA and World Health Organization have been working closely with us throughout this process to get this new test in the hands of those battling on the front lines of the Ebola outbreak as quickly as possible," said Corgenix Chief Executive Officer Douglass Simpson in a press release. "Completing this product development in less than a year demonstrates how governmental agencies, regulatory bodies, industry, non-profits and others can work together to find solutions to catastrophic events such as the Ebola virus outbreak. This collaboration has enabled us to quickly deliver this critically important point-of-care test and potential breakthrough in the fight against Ebola in the current outbreak in West Africa."

Although the Corgenix assay can be used in emergency situations, under the FDA rules it cannot be used for general screening such as at airports. The World Health Organization recently approved the test for field use outside of the United States.

The first ever cases of Ebola in the United States were confirmed in the latter part of last year, initially linked to a Liberian national who traveled to Texas after already being infected in Africa. He died from the disease, and two health care workers who treated that patient were infected but later recovered. A New York physician who performed relief work in West Africa was also diagnosed with the disease after returning to the U.S. but recovered.

There have been no cases in the U.S. this year, but large public health agencies such as the California Department of Public Health announced suspected cases of Ebola as recently as the end of January.

And despite the handful of cases confirmed in the U.S., the Centers for Disease Control and Prevention performed close surveillance of more than 450 individuals who were in contact with those who contracted Ebola, suggesting that a rapid diagnostic test could have a market in the U.S. even if the number of confirmed cases within its borders are limited.

Corgenix's stock, which trades over-the-counter, dropped about 4 percent on the day of the announcement, to around 27 cents per share.

Takeaway: Federal regulators have lent a helping hand in developing a rapid confirmation diagnostic for the Ebola virus. G2

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Inside The Lab Industry

In Public Comments, Lab Lobbies Want FDA to Back Off on LDT Regs

The primary lobbying groups for the laboratory sector have submitted their comments to the U.S. Food and Drug Administration (FDA) regarding its proposal to regulate lab-developed tests, or LDTs.

The consensus is that major changes need to be made by the FDA to the proposed regulations—or even have the agency withdraw them completely—before the sector will consider them acceptable.

"The clinical laboratory industry emphatically maintains that the FDA lacks the statutory authority to regulate laboratory developed testing services and likens its attempt to define a lab test as a medical device to trying to fit a round peg into a square hole."

— Alan Mertz, ACLA President

The FDA issued the draft regulations last year out of concern that the complexity of some LDTs may wind up placing patients in danger if improperly used or interpreted. It proposed classifying tests in three different risk designations and requiring labs to obtain premarket approval for the riskiest assays. The new regulations would be phased in over the better part of a decade.

The lobbies expressed significant concern in their comments that many of their constituents would not be able to commit the resources to get their tests to pass FDA regulatory muster. As a result, they fear that the hundreds, if not thousands, of LDTs that are created every year could diminish in both volume and clinical value.

"If the guidance is finalized as written, (the) FDA would require laboratories, as medical device manufacturers, to submit applications for pre-market review for thousands of laboratory-developed testing services," the Association for Molecular Pathology said in a statement. "AMP members will likely be unable to continue offering these tests; therefore, FDA will have in effect significantly diminished or eliminated patient and physician access to these services."

FDA's Legal Authority Challenged

The American Clinical Laboratory Association went so far as to raise specific legal issues regarding the FDA's ability to regulate LDTs at all.

"The clinical laboratory industry emphatically maintains that the FDA lacks the statutory authority to regulate laboratory developed testing services and likens its attempt to define a lab test as a medical device to trying to fit a round peg into a square hole," said ACLA President Alan Mertz in a press release regarding the Association's submitted comments. "FDA's attempted expansion of its authority is inconsistent with the statutory text and would raise serious constitutional questions that Congress itself sought to avoid when crafting the current regulatory framework for LDTs."

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The ACLA has been the most aggressive of the lobbying groups in challenging the FDA. It has gone so far as to retain two of the nation's leading federal appellate attorneys, Laurence H. Tribe and Paul Clement, strongly suggesting it would litigate the matter in the federal courts.

Most of the comments submitted suggest that the current CLIA regulations will suffice for regulating LDTs. Along with its comments, the College of American Pathologists submitted a 41-page graph demonstrating where the FDA's proposed regulations "crosswalk" with CLIA's. The CAP asked the agency to refrain from requiring each LDT to have a unique device identifier; remove the requirement that a change of specimen type in a test results in an LDT; and relax its guidelines for assessing the patient risk stemming from an LDT.

Currently, the FDA proposes that it use its existing classification system for medical devices, which the CAP objected to. "The existing FDA medical classifications categories will subject many well-established and validated LDTs to higher-level regulatory requirements. These well-established LDTs already represent the standard of care with required proficiency testing and professional guidelines written for recommended performance and interpretation."

The CAP suggested that "LDTs should be classified based on patient risk, the laboratory's claims for the test, and the potential for harm to patients in instances of an incorrect or misinterpreted test."

The CAP also wants the FDA to include multi-hospital health care systems under the definition of a single laboratory. "The laboratories in many of these systems continue to operate collectively as a single laboratory when developing an LDT. We believe the FDA's definition would arbitrarily restrict these laboratories that have the same safeguards and controls as single laboratories from developing vital tests," wrote the CAP in its comments, which were authored by President Gene Herbek, M.D.

"Without these changes, the CAP believes the guidance would stifle medical innovation and cause significant hardship for laboratories and patients," Herbek said. "The College's comments to the FDA seek to address oversight of these tests in an inclusive, systematic way that is best for our patients."

More Legal Brief Than Commentary

The ACLA's comments were in the form of a nearly philosophical critique that reads like a legal brief, questioning whether the right exists at all for the FDA to regulate LDTs. Its conclusion: Not.

"FDA has authority to regulate only manufacturers of commercially distributed medical 'devices,' including devices that perform standardized clinical tests (so-

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called 'test kits'). But laboratory-developed testing services are processes and methodologies that are qualitatively and categorically different from the tangible goods that FDA may regulate as 'devices,'" the ACLA claimed. "Statutory text, basic principles of interpretation, and common sense leave no doubt that laboratory-developed testing services are not medical 'devices.'"

The dense yet pointed 17-page document went on to question whether LDTs are placed into interstate commerce (no); whether the FDA not regulating LDTs for decades prior suggested that the tests were breaking federal laws (no); whether CLIA eclipsed the FDA's regulatory authority (yes); whether FDA had the authority to establish regulations through "guidance documents" as opposed to the more onerous process of rulemaking and gathering comments (no); whether the FDA had considered the economic impact of the regulations (no).

"In summary, FDA must withdraw the draft 'guidances' in their entirety," concluded the comments, which were under Mertz's signature but no doubt contained many of Tribe and Clement's fingerprints.

The AMP requested more clarity from the agency as to how it plans to classify LDTs by risk. It also objected to classifying the use of companion diagnostic tests into the higher risk categories and restricting the "off-label" use of tests—assigning them to assay issues for which they were not originally designed. Physicians are able to prescribe drugs for off-label uses with few restrictions.

Like the CAP, the AMP also wants the proposed restrictions on multi-hospital system labs relaxed. And it also wants the FDA to restrict reporting of any adverse patient events connected to tests restricted to those where premarket approval has already been obtained.

The laboratory sector has gained some allies in some unusual places. The Boston Globe recommended against the new regulations in a January editorial, saying it was "far from reassuring" that the FDA is involved. The newspaper warned that the proposed regulations are "overkill" and would stifle innovation in prenatal testing. The Boston area is home to a significant swath of biotechnology companies, including a number of labs that offer esoteric molecular testing.

"Advocates for the labs recommend a wiser course: making a few changes to CLIA regulations that would address the questions raised by the FDA. Non-invasive prenatal screening has a valid place in the physician's toolkit—so long as the results are properly understood," the Globe concluded.

The FDA is expected to issue final regulations sometime later this year.

Takeaway: The laboratory sector is pushing back hard against the regulation of laboratory-developed tests.

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LabCorp Reports Strong 4Q Earnings, Makes Bullish 2015 Forecast, *from page 1*

For calendar 2014, LabCorp reported net income of $512.6 million on revenue of $6.01 billion. That compares to 2013 net income of $575.4 million on revenue of $5.8 billion. Cash on hand ballooned from $404 million at the end of 2013 to $580 million at the end of last year.

Test volume was up 6.4 percent during the quarter, of which 5.3 percent was organic and not tied to acquisitions of other laboratories.

Yet despite LabCorp's strong numbers, the sector remains under financial pressure, as indicated by the company reporting a 1.1 percent drop in revenue per test requisition.

Company officials said they expect annual revenue to grow 40 to 44 percent during calendar 2015, including business from Covance, and will gain about $100 million in efficiencies after the company is fully integrated. That would put LabCorp on track to report 2015 revenue of about $8.5 billion. Earnings per share are projected to grow 8 percent to 13 percent.

Of particular note was the introduction of an efficiency initiative known as "Project Launchpad." It is projected to save $150 million over the next three years.

"Project LaunchPad savings will favorably impact both gross profit and SG&A through improved customer to cash processes, bad debt reduction, outsourcing, procurement savings, and labor efficiency," Chief Financial Officer Glenn A. Eisenberg said during a call with analysts to discuss earnings. Few other details on the initiative were available. King noted on the same call that "LaunchPad is not a short-term cost-cutting measure. It is a long-term structural change in how we deliver our services."

Aside from the announcement of the initiative, LabCorp also disclosed the inevitable post-Covance restructuring changes. The company will operate in two divisions, LabCorp Diagnostics and Covance Drug Development. LabCorp's former chief operating officer, Jay Boyle, has been appointed as CEO of the LabCorp Diagnostics division. Former Covance CEO Joe Herring has been named as CEO of the Covance Drug Development division.

Both will report to King.

Stock analyst firm Zacks is fairly bullish on LabCorp moving forward, citing its strong quarterly numbers. "We are also optimistic about the solid revenue and earnings outlook for 2015, which indicate improving industry trends as along with expected positive synergy from the Covance integration," the company said in a recent report.

LabCorp's stock rose nearly 4 percent on Feb. 20, the day it announced its earnings. The company's shares are up more than 20 percent since last October.

Takeaway: LabCorp is moving swiftly toward becoming the largest national laboratory in the U.S.

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INDUSTRY BUZZ

Children's Hospital Los Angeles Invests $50 Million in Genomic Initiative

One of the nation's largest acute care pediatric hospitals has committed an eight-figure sum to expand its personalized medicine initiative.

The study of more than 100 urologists, published in the most recent edition of the Journal of Kidney Cancer, suggested a majority would use a test distributed by Rosetta Genomics to determine the difference between a benign renal oncocytoma and a renal cell carcinoma, a cancerous malignancy. Children's Hospital Los Angeles will spend $50 million over the next five years in order to make health care delivery for children more personalized and effective. The hospital's expanded Center for Personalized Medicine will also be integrated into its department of pathology and laboratory medicine.

"In the near future, a newborn's genome will be sequenced at birth (or even before), permitting clinicians to plan a lifetime of personalized, preventive health care that focuses on preventing, rather than reacting to, illness," said Alexander R. Judkins, M.D., the executive director of CHLA's Center for Personalized Medicine and head of the hospital's pathology and laboratory medicine departments, in a statement. "When we look at our peers using personalized medicine for children, the area where CHLA will be investing its efforts is in taking research outcomes and innovations and translating them into improvements in bedside care—an area where we already excel. This is where the real impact for children will be."

The center will focus initially on pediatric cancers, as well as inherited and infectious diseases. It recently developed a test that identifies all changes related to the RB1 gene, which is linked to retinoblastoma, a rare form of eye cancer that is diagnosed in about 200 to 300 children a year nationwide. The hospital treats about 20 percent of all retinoblastoma patients in the U.S.

"This is just one example of bench-to-bedside translational research involving pediatric cancer genomics already underway at CHLA," Judkins said. "Our expansion will provide us with the opportunity to study genomic features of all new and recurrent cancers treated at CHLA."

Officials said the hospital will eventually expand its genomic research to seek genetic links to epilepsy, autism, neurocognitive disorders, congenital heart disease, and cleft palates. In addition to the sum being spent by the hospital, it will also launch a philanthropic campaign to raise an additional $50 million to finance the translation of research data into new modes of health care delivery.

Takeaway: Children's Hospital Los Angeles believes genomic laboratory advances are where its future lies. G2

References

23andMe
650-938-6300

American Clinical Laboratory Association
202-637-9466

Association of Molecular Pathology
301-634-7939

Children's Hospital Los Angeles
323-660-2450

College of American Pathologists
847-832-7000

CorGenix
303-457-4345

Food and Drug Administration
888-463-6332

LabCorp
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Quest Diagnostics
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