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A DIVISION OF PLAIN LANGUAGE MEDIA

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LABORATORY INDUSTRY REPORT™

Vol. 15, Iss. 20, November 5, 2015

HIGHLIGHTS

LabCorp Reports Strong Third Quarter; Quest Less So

The two major national laboratories continue to wring higher profits out of their operations, even as organic revenue growth remained modest.

Both LabCorp and Quest Diagnostics fattened their bottom lines during the quarter ending Sept. 30. The Burlington, N.C.-based LabCorp reported net income of $153.1 million on revenue of $2.27 billion, while the Madison, N.J.-based Quest reported net income of $354 million on revenue of $1.88 billion.

LabCorp's acquisition of pharma giant Covance contributed $647 million in revenue for the quarter. Factoring that out, its revenues of $1.62 billion were up about 4.8 percent from the third quarter of 2014, when its pre-Covance revenue was $1.55 billion. Covance's revenue grew by 2.6 percent year-over-year.

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NeoGenomics Purchases GE Healthcare Affiliate Clarient for $275 Million

Florida-based NeoGenomics has made a move to bolster its cancer diagnostic offerings, purchasing Clarient, Inc. for $275 million in cash and stock.

Clarient and its affiliate Clarient Diagnostic Services, with operations in both California and Texas, comprise a portion of GE Healthcare's life sciences business and has about 410 employees. It reported 2014 revenue of $127 million and pre-tax earnings of $13 million.

Clarient performs a variety of molecular tests, but it focuses primarily on oncology assays, particularly companion diagnostics that gauge how a patient would react to drugs that treat lung cancer or lymphoma, among others.

"Our vision is to become America's premier cancer testing laboratory, and this acquisition is a major step forward in achieving that vision," said NeoGenomics Chief Executive Officer Douglas VanOort in a statement. "We have always respected Clarient's outstanding ca-

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NeoGenomics Purchases GE Healthcare Affiliate Clarient for $275 Million, *from page 1*

pabilities, and are very pleased to be able to combine them with our own outstanding service offering. Hospital, physician, and pathology clients will benefit from our ability to offer the 'best of the best' products and services available from each company."

VanOort projected growth synergies of $4 million to $6 million for NeoGenomics as a result of the acquisition next year. The deal is subject to regulatory review but is expected to close by the fourth quarter of this year.

The terms of the deal are fairly generous for GE Healthcare. It includes not only 15 million shares of NeoGenomics' common stock, but another $110 million in preferred stock, which may be redeemed for common stock at $7.50 per share after three years if NeoGenomics stock hits certain pricing targets, and automatically converts after 10 years.

The acquisition was a tonic for NeoGenomics' stock, which jumped by 25 percent, to more than $7 a share, after the announcement was made on Oct. 21.

A conversion would give GE Healthcare nearly another 15 million shares of common stock. That could potentially give GE a nearly 50 percent ownership in NeoGenomics—assuming the company did not issue another share of stock prior to the conversion period. It would represent a roughly one-third stake should NeoGenomics issue new shares to cover the conversion at a later date but did not issue any other stock.

VanOort said in addition to the deal, NeoGenomics would continue to collaborate with GE Healthcare on future precision genomics initiatives.

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"We view this as a good deal with a number of areas to drive synergies. The combination provides robust East and West Coast presences, a low-cost testing position in all testing paradigms, a combined clinical trials business of $25 million, and GE as a significant long-term investor," wrote Amanda Murphy, an analyst with William Blair & Co., in a report.

In addition to the acquisition, NeoGenomics also reported modest growth for the third quarter ending Sept. 30, as well as a narrowing of losses. It reported a loss of $125,000 on revenue of $25.1 million for the quarter, compared to a loss of $291,000 on revenue of $23.2 million for the third quarter of 2014. For the first nine months of the year, NeoGenomics reported a loss of $1.06 million on revenue of $72.5 million, compared to net income of $85,000 on revenue of $62.1 million for the first nine months of 2014.

Takeaway: NeoGenomics pushes its nascent growth with the help of a significant acquisition. G2

Millennium Health Settles Federal Charges; Bankruptcy Filing Likely

Millennium Health will pay $256 million to settle federal allegations of performing medically unnecessary tests that were ginned up in part through physician kickbacks, and appears headed for bankruptcy protection in the coming weeks.

The settlement is among the largest ever involving a laboratory, topping a $241 million settlement paid by Quest Diagnostics four years ago to settle Medicaid bid fixing allegations in California.

"We will not tolerate practices such as the ordering of excessive, non-patient specific tests and the provision of inducements to physicians that lead to unnecessary costs being imposed upon our nation's health care programs."

— Benjamin C. Mizer, Deputy Attorney General

According to the U.S. Justice Department, Millennium had overbilled the Medicaid, Medicare and other federal programs for unnecessary urine and genetic testing, encouraged in part by furnishing physicians with "custom profiles" for their patients, which the agency contended was actually standing orders for tests without assessing each patient's medical needs. Excessive testing was also encouraged by furnishing doctors with free point of care urine drug test cups, which were understood to be returned to Millennium for testing. The Justice Department said that practice violated both the Stark Law and Anti-Kickback Statute. The alleged conduct took place between 2008 and earlier this year.

"The Department of Justice is committed to ensuring that laboratory tests, including drug and genetic tests, are ordered based on each patient's medical needs and not just to increase physician and laboratory profits," said deputy attorney general Benjamin C. Mizer, head of Justice's civil division, in a statement. "We will not tolerate practices such as the ordering of excessive, non-patient specific tests and the provision of inducements to physicians that lead to unnecessary costs being imposed upon our nation's health care programs."

Under the terms of the settlement, Millennium will pay $227 million to resolve claims of overbilling; $10 million to settle allegations of false claims to federal health care programs; and $19.2 million to the Centers for Medicare & Medicaid Services to resolve administration actions that had been brought by that agency. Millennium has also entered into a five-year corporate integrity agreement with the Department of Health and Human Services Office of the Inspector General. It will include significant changes to its board of directors, said HHS Inspector General Daniel Levinson.

"While Millennium may debate some of the merits of the DOJ's allegations, we respect the government's role in health care oversight and enforcement. At the end of the day, it was time to bring closure to an investigation that began nearly four years ago," said Millennium Chief Executive Officer Brock Hardaway in a statement. "Millennium Health is currently a very different organization than we were in the past. We fully embrace our obligation to both commercial and publicly funded health plans to provide value to the health care system overall and ensure that doctors who order our testing solutions adequately demonstrate that those solutions are clinically necessary, and aligned with the latest available clinical guidelines."

Millennium said it would pay the settlement in part through a restructuring of its debt, which is currently about $1.8 billion. The company said in a statement this would be achieved through "an out-of-court basis or through a prepackaged chapter 11 proceeding that primarily affects the claims of lenders and equity holders." Several news reports have indicated that Millennium's creditors would gain control of the company. The restructuring is expected to be completed before the end of the year.

Takeaway: Millennium Health will use a massive debt restructuring or bankruptcy reorganization in order to turn a new page. G2

Inside The Lab Industry

Theranos: Is a Soft Landing Possible?

After soaring high into the stratosphere, tech darling Theranos—just weeks ago the putative future of the lab sector—is making what is perhaps an inevitable fall back to Earth. Whether its reentry will be fiery or controlled remains to be seen.

Based in the heart of California's Silicon Valley, Theranos and its founder, 31-year-old Elizabeth Holmes, have promised to transform the delivery of laboratory services by obtaining minute amounts of blood without performing traditional needlestick draws and performing tests at prices 50 percent below Medicare rates—far below what the rest of the sector charges for its services. And the company had lobbied successfully in Arizona to allow direct-to-consumer testing—a campaign that no doubt would have been expanded to other statehouses as Theranos had continued to grow.

With a 50 percent share in the company, Holmes went in relatively short time from a college dropout to a stylish, Silicon Valley billionaire, and one of the few health care executives to ever be profiled in the *New Yorker* magazine.

Holmes dropped out of Stanford University at the age of 19 to devote her time to the company. She has a politically connected father, Christian Holmes—the first-ever chief financial officer for the Environmental Protection Agency—and she landed choice appointments to her board of directors, including former secretaries of state Henry Kissinger and George Schultz. That no doubt helped to raise $400 million from outside investors and earn Theranos a $9 billion valuation—on par with Quest Diagnostics and LabCorp—even as it had only begun to offer its testing services in a handful of Walgreens pharmacies in Arizona and California.

With a 50 percent share in the company, Holmes went in relatively short time from a college dropout to a stylish, Silicon Valley billionaire, and one of the few health care executives to ever be profiled in the *New Yorker* magazine.

But Theranos has had its share of skeptics, particularly given the firm's already legendary reputation for secrecy, even though few of its products and services have been brought to market. Its vulnerability began to show last month, as the *Wall Street Journal* reported in a series of articles that Theranos' testing platform was only being used for a handful of assays, results from those tests were suspect, and most of Theranos' tests were being performed on more conventional platforms, requiring much larger specimens of blood than the minute amount originally promised.

The reportage came just days after Theranos had embarked on a campaign to raise an additional $200 million, and it propelled Elizabeth Holmes onto the offensive, with Theranos posting often bluntly combative statements on its website saying the *Journal*'s reportage was dead wrong—yet not demanding any corrections.

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"We provide blood tests faster, requiring far less blood and patient discomfort, than for any test previously available—or available today from any other laboratory," the company said in one of its postings on its corporate website.

> *"[W]e have been more skeptical than anything about this business and the opportunity to disrupt the market, particularly based on the fairly limited amount of knowledge we had on this company, and based on [the* Wall Street Journal*'s reporting], our skepticism becomes even higher."*
>
> — Michael Cherny, Analyst, Evercore ISI

Meanwhile, Theranos' image became earthbound overnight. Walgreens, which originally planned to install Theranos draw centers throughout the country, said it was revisiting its pact and putting on hold any further expansions of its draw centers at its retail sites.

The U.S. Food and Drug Administration also released documents last month indicating its own inspectors had concluded that Theranos' nanotubes used for collecting blood samples represented an unapproved medical device that was being transported across state lines as part of its intended function, in violation of federal regulations. The FDA also said that Theranos was not conducting required quality control inspections and reviews.

The issues with the FDA were essentially of Theranos' own making—Holmes had pledged to put the company's assays through the FDA's approval process, rather than the less stringent CLIA guidelines. But to date, the FDA has only approved one of the tests on Theranos' menu of more than 200.

As for the FDA reports that were made public, the company stated that "none of these observations were specific to Theranos' analytical devices, software, or chemistries, or the manufacturing infrastructure for Theranos' analytical devices or chemistries. All observations from this inspection pertained to quality systems associated with the use of one of our Nanotainer tubes under the CLIA lab quality framework instead of the FDA quality framework."

Michael Cherny, an analyst with Evercore ISI, observed in a note to investors that "we have been more skeptical than anything about this business and the opportunity to disrupt the market, particularly based on the fairly limited amount of knowledge we had on this company, and based on [the *Wall Street Journal*'s reporting], our skepticism becomes even higher." Cherny noted that even if Theranos was a truly revolutionary company, its risk to LabCorp and Quest Diagnostics would be over a very long term.

After Oct. 28, Theranos quietly disclosed that it had undertaken a makeover of its governance. Its board was shrunk from 12 directors to five, with Kissinger and Schultz—both of whom are in their 90s—among those departing. David Boies, a powerhouse lawyer who previously served as Theranos' legal advisor, joined the

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board. The new board also issued a statement of support for Holmes and the rest of the management team.

Not long after that, Holmes issued another statement saying that Theranos would become more transparent, and would release data validating its Edison testing platform and its performance.

The Cleveland Clinic, which entered into a strategic alliance with Theranos earlier this year, said late last week it would undertake validation testing of its own.

"I think that we need to have that verification done externally by a third party and we'd like to do that," Cleveland Clinic CEO Toby Cosgrove, M.D., told CNBC.

"Their technology has never to this point been verified ... they have a lot of explaining to do."

— Dennis Weissman, Consultant

As Theranos endeavors to remake itself as a more tightly focused company with greater transparency, some observers say it has its work cut out for itself.

"This has the potential to be one of the biggest scams we have ever seen," said Dennis Weissman, a Washington, D.C.-based laboratory industry consultant and one of the original founders of *G2 Intelligence*. But Weissman quickly added that Theranos could still turn things around by providing specific evidence that its testing platforms and protocols work as advertised.

Indeed, such evidence would be key to Theranos turning its fortunes around, according to Erik Deutsch, a longtime Los Angeles-based communications consultant who provides crisis PR to a variety of health care companies.

"If there is data, they should present it or publicize it. It will go a long way toward allaying those concerns," said Deutsch. He added that the data "needs to be critically examined and peer-reviewed. In the absence of data, PR can't help."

In the meantime, he suggested that Holmes' conduct with the media has been making the controversy worse. Deutsch recommended that a credible clinician such as a high-profile physician with a sound reputation would probably better serve the company as a spokesperson.

But clear data would serve Theranos even better.

"PR is not about concealing secrets. But at the moment, they don't seem to be in a position to publicize anything positive," Deutsch said.

Weissman was a little blunter. "Their technology has never to this point been verified ... they have a lot of explaining to do," he said.

Takeaway: Theranos is in a precarious position in its short history, with the lab being pressed to validate its testing data and become more transparent. G2

LabCorp Reports Strong Third Quarter; Quest Less So, *from page 1*

"After a bit of a choppy start to the year, LabCorp delivered a very strong 3Q, particularly against the backdrop of what has become an increasingly choppy healthcare services operating environment," said Evercore CSI Analyst Michael Cherny in a report.

"We delivered significant and measurable progress on the strategic priorities underlying the acquisition of Covance, positioning the Company well for long-term future profitable growth."

— Dave King, CEO, LabCorp

In a call with analysts, LabCorp Chief Financial Officer Glenn Eisenberg forecast total revenue growth for 2015 of 41 percent. That included 4.5 to 5.5 percent growth during this calendar year for the non-Covance operations, up from prior guidance of 3.5 to 5.5 percent "primarily due to continued strong organic growth." The diagnostics division experienced overall growth of 2.9 percent for the quarter and 2.3 percent in terms of organic growth.

Earnings per share guidance for the year was narrowed from $7.80 to $7.95, compared to prior guidance of $7.75 to $8.

For the first nine months of 2015, LabCorp reported net income of $323.5 million on revenue of $6.38 billion. That compares to net income of $392.7 million on revenue of $4.5 billion for the first nine months of last year.

"We delivered significant and measurable progress on the strategic priorities underlying the acquisition of Covance, positioning the Company well for long-term future profitable growth," said LabCorp Chief Executive Officer Dave King.

Quest was a slightly different story: Its revenue was down slightly from the $1.9 billion reported for the third quarter of 2014, and missed analyst consensus of $1.89 billion. The company said, on an equivalent basis, revenue actually grew by 0.9 percent, factoring in its clinical trials joint venture with Quintiles. But on a generally accepted accounting basis, revenue dropped 1.3 percent. Quest's net income for the third quarter of this year was more than double the $139 million reported for the third quarter of 2014.

That growth in net income is expected to provide some headwinds for the fourth quarter in terms of higher provisions for income taxes, said Quest CFO Mark J. Guinan.

Regarding guidance for all of 2015, Guinan said revenue would be just under $7.5 billion, with earnings per share of $4.75 to $4.80, flat to slightly lower than before.

Quest CEO Steve Rusckowski projected the company would see earnings growth of 8 percent to 10 percent over the next three years.

Amanda Murphy, an analyst with William Blair & Co., wrote in a report that "Quest's underlying business has improved relative to historical trends although organic growth in the underlying lab business has remained relatively flat. The company's cost-cutting initiative as well as easing reimbursement pressures has continued to drive leverage." As a result, she projects a relatively modest growth in its stock price for the coming months.

Takeaway: Quest Diagnostics and LabCorp continue to find ways to improve their bottom lines, even as there is little room to grow outside of acquisitions. G2

INDUSTRY BUZZ

Sequenom and University of Colorado Collaborate on Liquid Biopsy Test for Melanoma

Sequenom, the San Diego-based molecular testing company, has entered into a pact with the University of Colorado School of Medicine to develop a liquid biopsy test to better monitor the treatments of melanoma patients and their potential to relapse.

Most early stage melanomas are dealt with through the removal of the afflicted tissue—it usually has to be excised entirely as part of the treatment process. A liquid biopsy would provide more options regarding monitoring how the disease is reacting to treatment.

Sequenom has developed a research-only liquid biopsy. The University of Colorado will test the assay to determine whether circulating tumor DNA in melanoma patients can be used to monitor their clinical progress.

"I believe that the ability to match patients to new treatment options and to monitor their response with a simple blood test will yield significant clinical benefit," said William Robinson, M.D., an oncology professor at the University of Colorado, in a statement. "We anticipate that the collaboration with Sequenom will allow us to closely monitor treatment response and the emergence of resistance mutations over time and make changes or adjustments in treatment much earlier than can be done currently."

Financial terms of the collaboration were not disclosed.

Melanoma is the only deadly form of skin cancer. It is highly treatable in its early stages, but a patient's long-term survival rates drop quickly after the intermediate stages of the disease. About 74,000 adults are diagnosed with the disease in the U.S. every year, and about 10,000 Americans die annually, two-thirds of whom are men.

"Liquid biopsy has many potential applications for a variety of cancers," Daniel Grosu, M.D., Sequenom's chief medical officer, said in a statement. "This is our first collaborative study focusing on melanoma, which expands the range of cancers and clinical care settings that we are exploring with this novel technology. We are uniquely positioned to leverage our strong expertise in testing circulating cell-free DNA to move liquid biopsy from a research concept to routine clinical practice in oncology."

Takeaway: Sequenom continues to delve deeper into liquid biopsies with a clinical development pact. G2

References

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 Laboratory Industry Report (ISSN 1060-5118) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320. Phone: 1-888-729-2315. Fax: 1-855-649-1623. Web site: www.G2Intelligence.com.

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