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# LABORATORY

# INDUSTRY REPORT™

Vol. 14, Iss. 21, November 6, 2014



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## Upcoming G2 Events

### Lab Sales and Marketing: A New Playbook for the Changing Market

Dec. 15-16, 2014  
Westin Kierland Resort & Spa  
Scottsdale, Ariz.  
[www.G2Labsales.com](http://www.G2Labsales.com)

### Lab Revolution

March 11-14, 2015  
Loews Portofino Bay Hotel  
Universal Orlando®  
[www.LabRevolution.com](http://www.LabRevolution.com)

## LabCorp Acquires Covance in \$5.6 Billion Transaction

**L**abCorp has thrown its hat into the pharmaceutical testing arena in a huge way: It is acquiring biopharma contract testing giant Covance in the biggest transaction ever in the laboratory sector.

LabCorp came to terms earlier this week to purchase the Princeton, N.J.-based Covance for \$5.6 billion, not including assumption of debt. Covance shareholders will receive \$75.76 and slightly more than one-quarter of a LabCorp share for each share of their stock and will ultimately own about 15.5 percent of the merged company. At the equivalent of \$105.12 per share, the terms are at a 32 percent premium above Covance's stock price before the deal was announced. LabCorp is financing the transaction with a combination of cash on hand and financing from BofA Merrill Lynch and Wells Fargo Bank.

The deal, which is expected to close in the first quarter of next year, comes as more laboratories are devoting their resources to providing

*Continued on page 7*

## Metamark Introduces Assay That Determines Aggressiveness of Prostate Cancer

**M**assachusetts-based Metamark Genetics has released a new molecular-based prostate cancer test that can better pinpoint the overall aggressiveness of the disease.

The test, known as the ProMark, is designed for use in prostate cancer patients with Gleason scores in the 3+3 and 3+4 range. Those scores are among the most common for patients diagnosed with prostate cancer. Such a score makes it difficult to determine whether the cancer will stay mostly contained in the prostate or will spread to outlying areas. Of the 233,000 or so new cases diagnosed in the United States every year, more than 200,000 have primary Gleason scores in the three range.

The five-year survival rate for localized prostate cancer cases is nearly 100 percent, according to data from the National Cancer Institute. In many cases, the cancer can just be regularly monitored without any specific surgical interventions. However, aggressive forms of prostate cancer are entirely different: Survival rates drop below 30 percent once the cancer has spread to other parts of the body.

*Continued on page 2*

### ■ METAMARK INTRODUCES ASSAY THAT DETERMINES AGGRESSIVENESS, *from page 1*

The ProMark test, which retails for \$3,800, focuses on levels of protein biomarkers from regions of prostate tissue where the biomarkers have been altered as a result of tumor formation. The tissue can be obtained from a preliminary needle biopsy, and data can be obtained before the patient and their oncologist make any major treatment decisions, company officials said. Metamark is processing the test at its laboratory in Cambridge, Mass.

“The ProMark test may provide the health care community with additional information to assist distinguishing indolent from aggressive prostate cancer, thus better informing decisions on an appropriate course of treatment or surveillance,” said Neal D. Shore, M.D., medical director of the Carolina Urologic Research Center in Myrtle Beach, S.C.

According to Metamark spokesperson Theresa Dolge, the company estimates that based on clinical validation data, “widespread use of ProMark in the U.S. could help 50,000 to 60,000 patients avoid unnecessary treatment or overtreatment, such as prostatectomies, and allow them to be more confident in pursuing active surveillance as a treatment option. This would result in considerable savings to the health care system based on avoidable treatment costs, as well as reduced morbidities and treatment complications.”

Metamark officials said the company would work closely with payers to obtain reimbursement coverage in the near future. It also plans to offer a financial assistance program to patients to manage their out-of-pocket costs for the test, Dolge said.

*Takeaway: Metamark is attempting to diversify the options available for prostate cancer patients with its new test, potentially avoiding overtreatment and other cost drivers.* 

## Andraka, Dexter, and Myers Win Lab Institute Awards

**J**ack Andraka, a 17-year-old who invented a new rapid and inexpensive test for diagnosing pancreatic cancer, is the first recipient of G2 Intelligence’s Lab Innovation Award, designed to recognize innovation in the field of medical diagnostics.

The award, sponsored by Halfpenny Technologies Inc., was presented by Jack Redding, senior vice president, sales and marketing, for Halfpenny, during the 32nd annual Lab Institute, held Oct. 15-17, 2014, in Washington, D.C.



David Dexter (l) receives award from Scott Liff (r)

Andraka, of Crownsville, Md., worked with a professor from Johns Hopkins University to develop a new dipstick-type test for pancreatic cancer using a novel paper sensor, similar to that of the test strip used in diabetes. The test is more than 90 percent accurate in detecting the presence of mesothelin, a protein that can indicate the presence of pancreatic cancer. The test is also effective for detecting ovarian and lung cancer, due to the same biomarker they have in common.

**David Dexter**, president and chief executive officer of Sonora Quest Laboratories LLC, a joint venture between Quest Diagnostics and Banner Health, is the 2014 recipient of the G2 Intelligence Laboratory Public Service National Leadership Award.



# Inside The Lab Industry



## Quest, LabCorp Post Improved Volumes, Revenue for Third Quarter

Could the third quarter be the charm for the big national labs? Both Quest Diagnostics and LabCorp reported solid earnings for the quarter ending Sept. 30, indicating they were back on track toward actual volume growth. Although overall profits were down, the numbers come after a long procession of quarterly reports where revenue and test volumes had been all but stagnant.

The New Jersey-based Quest reported a 6.5 percent uptick in revenues, which reached \$1.9 billion for the quarter. That compares to \$1.8 billion for the third quarter of 2013. Officials say a rise in the number of insured patients played a significant role.

“Regarding the Affordable Care Act, while it’s still early, we continued to see modest shifts from uninsured patient volumes in the third quarter to government and other payers,” said Quest Chief Executive Officer Steve Rusckowski in a conference call with analysts to discuss the earnings numbers. “Regarding the market dynamics, we saw additional signs of improvement in health care utilization during the quarter. . . . We delivered a second solid quarter of top-line growth as we continue to build momentum.”

*“Regarding the Affordable Care Act, while it’s still early, we continued to see modest shifts from uninsured patient volumes in the third quarter to government and other payers.”*

*—Steve Rusckowski,  
Chief Executive Officer,  
Quest Diagnostics*

In addition to the improved quarterly numbers, Quest also bumped up its year-end forecast. It now projects that revenue will grow 3.5 percent for the year, up from the previous estimate of 2.5 percent to 3.5 percent for the year.

According to Chief Financial Officer Mark Guinan, Quest’s test volume was up 7.8 percent compared to the year-ago quarter, with recent acquisitions adding about 8 percent to the total.

“Last quarter, I shared that we had made prudent decisions regarding pricing and in some cases decided to walk away from existing business,” Guinan told analysts. “Excluding the impact on revenue from these decisions, our underlying volumes were favorable to the prior year by approximately 1.5 percent.” Guinan later added that prescription drug monitoring “continues to be an area of strength. Hepatitis C continues to be an area of strength. Obviously, we have launched our BRCA offering, which is growing.”

Quest also introduced earlier this week an enhanced BRCA offering known as BRCAvantge Plus to evaluate breast cancer risk in patients. The assay screens for mutations in the BRCA1 and BRCA2 genes and five additional genes: TP53, PTEN, CDH1, STK11, and PALB2. Quest officials said those additional genes account for between 3 percent and 4.5 percent of genetically inherited breast cancers.

## INSIDE THE LAB INDUSTRY

Net income for the quarter did take a hit. It was \$139 million for the quarter, down 67 percent from the year-ago period. However, the company had reported a \$300 million gain last year from the sale of the royalty rights for Ibrutinib. It also took a \$24 million write-off associated with restructuring and integration costs and another \$25 million write-off associated with the sale of the Enterix cancer screening test kit division.

For the first nine months of 2014, Quest reported net income of \$392 million on revenues of \$5.6 billion. That compares to \$732 million on revenues of \$5.4 billion for the first three quarters of 2013.

### Earnings Data for Quest Diagnostics and LabCorp

Company	2014 3Q Net Income	2013 3Q Net Income	2014 3Q Revenue	2013 3Q Revenue	Nine Months 2014 Revenue	Nine Months 2014 Net Income	Nine Months 2013 Net Income	2014 3Q Test Volume Growth
Quest Diagnostics	\$129.0 M	\$405.0 M	\$1.9 B	\$1.8 B	\$5.6 B	\$392.0 M	\$732.0 M	7.80%
LabCorp	\$137.2 M	\$148.7 M	\$1.6 B	\$1.5 B	\$4.5 B	\$392.7 M	\$447.5 M	6.90%

Source: Company Reports

Meanwhile, North Carolina-based LabCorp reported a similar surge of growth. Revenues for the quarter reached \$1.6 billion, up 6.1 percent from the \$1.46 billion reported in the third quarter of 2013. Net income was down about 8 percent, to \$137.2 million from \$143.8 million, although operating income stood at \$253 million, about 2 percent higher than in the third quarter of last year.

Glenn A. Eisenberg, LabCorp's chief financial officer, said that test volumes were up 6.9 percent from the year-ago quarter, with most of the growth being organic.

"We are pleased that strong volume growth generated an increase in the company's sales, which in turn generated improved adjusted operating income during the quarter," said LabCorp Chief Executive Officer Dave King.

King and Rusckowski's assessments tend to echo those of the investor community. Amanda Murphy and J.P. McKim of William Blair & Co. in Chicago observed in a recent report that "dynamics in the lab industry look more promising in 2015 than they have in a few years, particularly given the likelihood of more muted reimbursement pressure. While we do not expect multiple expansion from these levels, we see upside to earnings estimates relative to consensus."

LabCorp did report that revenue per requisition was down 0.7 percent, although a large chunk of that was due to foreign currency fluctuations.

## INSIDE THE LAB INDUSTRY

For the first nine months of the year, revenue stood at \$4.5 billion, up 2.9 percent from the first nine months of 2013. Total test volume has been up 5 percent, with most of that growth being organic. Revenue per test requisition is down 2 percent, although the drop is only 1.6 percent when currency fluctuations are factored out. Those numbers suggest that the third quarter was particularly strong for LabCorp, despite the dip in net income. The company projected that revenue growth for the entire year would stand at 3 percent compared to 2013. It said it would provide its 2015 guidance in February.

Murphy and McKim noted that “both labs’ commentary was more optimistic for the future, in our view, as reimbursement appears to have stabilized with no major contracts up for renewal in 2015. Volume growth has been stronger than anticipated and accelerated throughout the year; while it is difficult to know for sure, this outperformance has been attributed to the Affordable Care Act. . . . [F]rom a fundamental perspective, the ability to drive [pretax earnings] expansion in 2015 seems more attainable than it has been in the past.”

***“We continue to have concerns around the longer term effects of large cost cutting initiatives on organic volume growth at Quest and thus prefer LabCorp, which has continued to outperform on volume growth.”***

***—J.P. McKim and Amanda Murphy,  
analysts,  
William Blair & Co.***

The pair also praised the two labs for their focus on offering more complex—and therefore higher-priced—tests focusing on exome sequencing, somatic tumor panels, and women’s health. King noted that LabCorp’s recently launched Enlighten Health division would focus largely on self-paying patients, meaning its tests menu would not likely come under any serious reimbursement pressure.

The investor service Seeking Alpha also noted that LabCorp’s \$85 million purchase of LipoScience received regulatory approval on Oct. 22 and that it expects “LipoScience’s flagship test LipoProfile to be accretive to LabCorp’s revenues by several hundred million dollars per year since LabCorp’s nationwide footprint should facilitate acceptance of the test by major insurers.”

Murphy and McKim had mixed thoughts on which of the labs would fare better moving forward. They noted that Quest’s aggressive cost-cutting—some \$700 million since it was instituted in 2011 and \$200 million more than originally planned—may take a toll on the company’s ability to enter into an aggressive growth mode.

“We continue to have concerns around the longer term effects of large cost cutting initiatives on organic volume growth at Quest and thus prefer LabCorp, which has continued to outperform on volume growth,” they wrote.

***Takeaway: After many quarters of stagnant growth to shrinkage, the larger laboratories may have begun the journey back toward sustained growth.*** 

### ■ **LABCORP ACQUIRES COVANCE IN \$5.6 BILLION TRANSACTION**, *from page 1*

genomic profiling and other test services to the pharmaceutical sector in their quest to develop more sophisticated drugs.

As a result, LabCorp will have a huge stake in pharmaceutical development testing moving forward. That niche will account for 29 percent of the company's revenues, up from virtually negligible numbers prior to the transaction being consummated. It will be the second-largest source of revenue within the company behind managed care contracts, which will comprise about 32 percent of revenues. LabCorp also expects the deal to add to the bottom line almost immediately and realize \$100 million in savings over the next three years.

The deal will also make LabCorp the largest diagnostic company within the United States, with pro forma revenue of \$8.4 billion, based on the two firms' performance between Sept. 30, 2013, and this year.

"This transaction provides LabCorp with immediate scale and a comprehensive market-leading platform in the \$141 billion biopharmaceutical research and development market, while at the same time achieving the new sources of revenue, broader payer mix, and greater international presence we have long pursued," said Dave King, LabCorp's chief executive officer.

"Clearly LabCorp was going for a big splash by acquiring one of the clear contract research organization market leaders," said Michael Cherny, a managing director with Evercore CSI in New York. He labeled the deal as an "all-in strategic transaction" for LabCorp.

The merged company will be led by King, who will continue to serve as both CEO and chairman of the board. Covance CEO and Chairman Joe Herring will lead the Covance division inside LabCorp and report to King. LabCorp will continue to be headquartered in Wilmington, N.C., while the Covance division will keep its current New Jersey headquarters. Covance will also continue to operate as a brand separate from the LabCorp label.

"We are thrilled to join forces with another industry leader through a transaction that delivers to our shareholders substantial immediate cash value along with a meaningful stake in a combined company with exciting growth opportunities," Herring said. "Covance generates more safety and efficacy data for the approval of innovative medicines than any other company in the world, and LabCorp has longitudinal diagnostic data from more than 75 million patients."

While Cherny upped pro forma 2015 earnings by about 1.7 percent, Evercore kept its hold rating on LabCorp stock, noting that Covance has had volatility issues with its late-stage testing business and that the cost opportunity to engineer the deal may have been too high. LabCorp shares dropped nearly 9 percent after the transaction was announced.

*Takeaway: With a single mammoth deal, LabCorp not only has dived head-first into the pharmaceutical development realm but has leapfrogged Quest Diagnostics to become the nation's largest laboratory firm.* 

# INDUSTRY BUZZ

## LabCorp Develops Test That Will Guide HIV Anti-Retroviral Drug Treatments

**T**hirty years ago, HIV infection led to AIDS and an inevitable death sentence. In the last 15 years, the virus has become a manageable chronic condition. Now one of the biggest challenges facing the health care system is fine-tuning the medications of those infected patients whose levels of HIV are so immunosuppressed as to be undetectable.

HIV-infected patients often suffer side effects from their drug regimens such as anemia, nausea, and skin rashes. But adjusting their drugs without information on their actual viral load creates the risk of the HIV becoming resurgent and perhaps resistant to future treatments.

There are about 1.3 million Americans who are infected with HIV. And while the infection rate has dropped by a third over the past decade, there are still 40,000 new cases of HIV being diagnosed in the United States every year, according to data from the Centers for Disease Control and Prevention.

LabCorp has decided to address that dilemma by offering a new molecular test that provides clinicians with options about managing drugs even when they can't detect HIV in their patients. The test was developed by the company's Monogram Sciences affiliate.

Known as the GenoSure Archive, the assay uses next-generation sequencing in combination with amplifying any cell-associated HIV pathogens. It can then be analyzed and matched for genetic mutations that signal potential drug resistance for all the major medicines used to keep HIV in check. Monogram has about 150,000 such profiles on file for matching purposes.

"The launch of GenoSure Archive addresses an emerging need of today's HIV patients and their care providers, who are increasingly faced with choices to maintain or adjust anti-retroviral drug regimens when the patient has low or undetectable plasma virus," said Christos Petropoulos, Monogram's vice president of research and development. "This test helps ensure that HIV/AIDS remains a chronic, manageable disease rather than a terminal illness."

LabCorp did not release pricing for the test or projected volumes.

*Takeaway: The melding of laboratory assays and pharmaceutical suitability takes a new turn with the development of the GenoSure Archive test.* 

### References

Banner Health 602-747-4000	LabCorp 336-584-5171	Quest Diagnostics 800-222-0446
Covance 888-268-2623	McKesson 415-983-8300	Sonora Quest 602-685-5000
Evercore CSI 212-857-3100	Metamark 617-583-1400	William Blair & Co. 312-236-1600

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