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LABORATORY INDUSTRY REPORT™

Vol. 13, Iss. 20, October 23, 2013

HIGHLIGHTS

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Quest CEO: Company's Helm Not Responding As Quickly as Hoped

Quest Diagnostics is the nation's largest laboratory operator by a wide margin. It is also quite profitable. But when and whether it will extract itself from a cycle of flat revenues and earnings remains to be seen.

For the third quarter, Quest reported net income of $413.9 million on revenues of $1.8 billion. That compares to net income of $171.6 million on revenues of $1.82 billion for the third quarter of 2012.

However, Quest netted $300 million after taxes for the sale of its royalty rights to the cancer drug Ibrutinib to Royalty Pharma for $485 million. It also sold off its Enterix colon cancer screening line of business to an Australian firm for an undisclosed sum. The cash from those deals factored into the bottom line.

Meanwhile, Quest's revenues were nearly 3 percent below what had been the consensus of Wall Street analysts, while net income was 15 percent below estimates.

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LabCorp CEO Demurs During Earnings Call, Is Blunt at Lab Institute

Running a multibillion-dollar company often requires different tones to get specific results, and LabCorp Chief Executive Officer Dave King demonstrated extraordinary range in modulating them earlier this month.

The restrained King delivered LabCorp's third-quarter earnings report to analysts on Oct. 18. His company's performance topped its rival Quest Diagnostics but reflected the struggles the laboratory sector is facing these days trying to grow.

Net income for LabCorp in the third quarter was $148.3 million on revenues of $1.46 billion, compared to net income of $148 million on revenues of $1.42 billion. Although both were marginal improvements, for the first nine months of 2013, net income was $448.7 million on revenues of $4.37 billion, compared to net income of $462.9 million on revenues of $4.27 billion for the first nine months of 2012.

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■ **Quest CEO: Company's Helm Not Responding,** *from page 1*

The numbers prompted Quest to revise its guidance downward. The company now forecasts revenues to be 3.5 percent below 2012—compared to the prior 1 percent to 2 percent projected dip. Its earnings per share for the year are expected to be between $3.85 and $3.95, down from the prior guidance of $4.35 to $4.50 per share. Cash flow projections were cut to $850 million, down from the prior projection of $1 billion.

A high-ranking Quest executive remarked at G2 Intelligence's Lab Institute earlier this month that while the cost-cutting program initiated by Chief Executive Officer Steve Rusckowski has been effective, the forecasts of when its impact would take hold was overly optimistic.

During an earnings call, Rusckowski noted that the numbers during the early part of the third quarter had met expectations but then softened. Testing volumes for the quarter were down about 2 percent compared to the third quarter of 2012. Revenue per requisition was down about 3.3 percent, attributed primarily to payment cuts from both Medicare and commercial payers, as well as continued denials for some molecular tests.

"Clearly, our third-quarter performance was disappointing," he told analysts. "We recognized that we have missed expectations this year and revised our guidance more than once. We understand it is extremely important to achieve expectations, and we are focused on improving our predictability."

Quest attempted to soften its missed number by previewing its third quarter on Oct. 10, a week before it announced earnings. Its stock dropped more than 6 percent in response, and another 1.5 percent after earnings were released. It has not rebounded.

"Quest's third quarter miss is disappointing, although not entirely surprising," said Deutsche Bank analyst Darren Lerrich. He cited the company's "somewhat aggressive" forecast for a recovery of volumes in the second half of 2013 and a weak utilization environment.

Quest's aggregate performance for the first nine months of 2013 has been reflective of its third quarter. Net income has been $1.2 billion on revenues of $5.4 billion. That compares to net income of $935.8 billion on revenues of $5.6 billion for the first nine months of 2012. However, revenues from continuing operations were down 3.9 percent, while adjusted income from continuing operations was down 14.8 percent.

Growing Through Acquisitions

With volumes and revenues in decline, Quest is attempting to grow through acquisitions focused specifically on laboratory operations. On Oct. 7, it purchased ConVerge Diagnostic Services LLC from the strategic investor firm Water Street Healthcare Partners for an undisclosed sum. It's the fourth deal for lab services Quest has consummated this year. The prior transactions included the acquisition of Dignity Health's lab outreach business, the acquisition of the University of Massachusetts' health system's outreach business, and the toxicology business of Concentra Health.

Analysts expect ConVerge, which operates a lab in Peabody, Mass., to eventually be folded into the huge regional facility Quest is building in Marlborough, Mass., 40 miles to the east, part of its plan to consolidate the UMass operations.

Rusckowski said the three deals outside of the ConVerge transaction have helped to propel revenue by a modest amount, about 2 percent so far this year.

"We are encouraged by [Quest's] acquisition activity this year, however we remain neutral given sluggish organic volume growth and reimbursement headwinds," Piper Jaffray analysts Kevin Ellich and Bradley Maiers observed in a recent report.

However, Rusckowski did note that the company's extensive and ambitious reorganization—which included the consolidation of divisions and the elimination of 600 management-level jobs—has been completed. He projected it will save Quest $600 million by 2014 and $1 billion in the years beyond.

"Restoring growth is a gradual process and it takes time," he said.

Takeway: It is taking longer than expected to get Quest Diagnostics back onto a path of continuing growth. G2

Ongoing Reimbursement Cuts Have United Laboratory Sector

If the reimbursement cuts from the Medicare and Medicaid programs have done anything positive for the laboratory sector, it is to unite them against further reductions.

That was the consensus of officials from the American Clinical Laboratory Association (ACLA), the College of American Pathologists (CAP), and the Mayo Clinic. They discussed the issue during G2 Intelligence's annual Lab Institute in Arlington, Va., earlier this month.

The feeling among the speakers was that the Clinical Laboratory Fee Schedule is antiquated, with many tests being paid at rates lower than when the schedule was originally introduced in 1984.

"We're getting about 17 percent less today than we were 19 or 20 years ago," said Alan Mertz, president of ACLA. He believes the Centers for Medicare and Medicaid Services (CMS) is more focused on cutting spending than providing care, a view shared by Jennifer Nord Mallard, Mayo's director of federal government relations. "It's completely dysfunctional," she said.

John Scott, a vice president in the advocacy division of CAP, also believes the polarized Congress has allowed CMS to operate without the optimum amount of oversight. "It's moving very aggressively."

As a result, CAP, ACLA, and other lab advocates have to respond in kind, flooding the agency with comments regarding proposed rate changes, according to Scott. He added that such continued persistent advocacy will be the key to staving off further cuts in the future.

Takeaway: Continued cuts in reimbursement have united the laboratory sector in the hopes that future reductions can be resisted. G2

Hospital Systems Use Variety of Methods to Control Test Utilization

Although many students are taught to the test, it is the experience of Johns Hopkins University physician and professor Larry Feldman, M.D., that medical residents learn from the test instead.

And while residents gain knowledge from ordering large volumes of assays, Johns Hopkins's bottom line loses traction in the process.

"Residents send tests all of the time. And it was driving people crazy," Feldman said during a workshop at G2 Intelligence's annual Lab Institute on how providers reduce utilization while optimizing costs and outcomes. The institute was held in Arlington, Va., Oct. 16-18.

Examples of lab utilization management programs were cited from Johns Hopkins and two other renown providers: the Mayo Clinic and the University of Michigan Health System.

"Residents send tests all of the time. And it was driving people crazy."
—Larry Feldman, M.D., Johns Hopkins University

Feldman said the goal of Johns Hopkins was to have its residents be "Oslerian" in the way they diagnosed a patient, in reference to medical scholar William Osler's teachings. But the organization also wanted them to be "parsimonious" in test ordering and usage.

That's a tall order for the health care industry. Feldman noted that clinicians are always itching to use the latest technologies to diagnose and treat patients, leading to unwarranted usage, uncoordinated care, and other examples of waste. And most doctors have "no clue" how much their overutilization costs, he observed.

Feldman cited one study from Australian researchers who concluded that nearly 68 percent of all lab tests ordered in hospital settings—about two per patient per day—did not contribute to patient care.

"Does this happen at Johns Hopkins? Absolutely!" he exclaimed. Baked-in institutional policies—such as washboards reminding clinicians to run CMP, CBC, and ionized calcium tests as a matter of routine—contribute to this issue.

Even the system's electronic medical records (EMRs) can help pile on, with a "repeat" button readily available to order duplicative tests on a daily basis, or glitches that make it difficult to retrieve previous results, prompting retesting.

A culture of test permissiveness also leads to what Jeffrey Warren, M.D., director of the division of clinical pathology at the UM Health system, termed "bizarre" requests. Among them was an order for a complete mitochondrial DNA sequencing, apparently in the search for a new form of mitochondrial myopathy.

Jim Hernandez, M.D., chair of Mayo Clinic Arizona's division of laboratory medicine, called this approach to testing "carpet bombing" and dryly illustrated it with a B-52 dropping dozens of pieces of ordnance.

At Mayo, Hernandez said the blanket fashion in which tests are being performed tended to actually harm the health of its patients, as unnecessary bleed time tests could lead to iatrogenic anemia. "We are literally phlebotomizing patients," he said.

A New Culture

How did Johns Hopkins instill a culture of assay parsimony in its residents—and how did Mayo and Michigan similarly cut test volumes?

By giving some or all of the clinicians a clue on costs.

Johns Hopkins developed a pilot program wherein the Medicare allowable fee for performing a specific test popped up on the EMR system at the point of order, giving clinicians an idea of how much they actually cost. Mayo began educating its medical staff on test overuse. And UM Health created a testing "formulary" that simply barred clinicians from ordering tests not normally considered medically necessary unless there was a valid reason for doing so.

"We are literally phlebotomizing patients."
—Jim Hernandez, M.D., chair, division of laboratory medicine, Mayo Clinic Arizona

For the UM formulary, which was created in 2008, the use of tests must be evidence-based, with a committee poring over efficacy and utilization data. A similar evidence-based approach was adopted by Mayo, although it does not have a formulary per se.

Although Warren noted that most lab tests normally performed have been kept in the formulary, some assays have been dropped, including 57 send-out tests and 11 in-house tests. A myelin-based protein test that cost $61 to perform was dropped after it was determined no more than 60 such assays were being performed systemwide, the majority for outpatient neurology patients. Another, a proprietary celiac disease panel, was dropped altogether. Multiple myeloma fluorescence in situ hybridization tests are limited to one per patient. Circulating tumor cell tests may only be ordered by oncologists.

At Mayo, Hernandez estimated that about 30 percent of the tests it performs could be pared back without impacting patient care. He noted that the system was performing 112.3 lab tests per patient discharge during the first quarter of 2013. That's down from 126 per discharge last year but is similar to the 2011 rate of 112.7. He noted that Massachusetts General Hospital was able to cut tests per discharge from 81 in 2002 to 60 in 2007, meaning Mayo has the equivalent of "a high golf score."

A Mayo team comprised of pathologists, scientists, nurses, finance experts, and administrators examines literature on best practices and outcomes to determine which tests may be unnecessary. Heavy users of specific tests receive "report cards" drawing attention to their ordering practices. Overutilization "alerts" are also inserted into Mayo's EMR system to remind clinicians of the last time that specific test was ordered.

Among the system's two most overutilized tests: NT-proBNP, which determines some probability for heart attacks or other cardiac events, and magnesium testing. Literature suggested that NT-proBNP had efficacy on patients with congestive heart failure but not on patients who had no cardiac symptoms at all. Mayo's EMR system is currently tracking repeat orders of the test. And less than 5 percent of magnesium testing orders demonstrated any clinical value at all, even though inpatients were undergoing more than five such assays during an average stay. One patient was tested for magnesium levels 228 times during a single hospital stay.

At Johns Hopkins, Feldman noted that the national "Choosing Wisely" initiative to reduce unnecessary testing and procedures has been helpful in communicating to residents the need to curtail unnecessary testing.

Altogether, 35 of Johns Hopkins's most frequently ordered tests and 35 of the most expensive tests (ordered at least 50 times in the past year) had their costs pop up when ordered up by a clinician.

"If there's debate, we tend to err on the side of liberalism . . . in making changes"
—Jeffrey Warren, M.D., director, division of clinical pathology, University of Michigan Health

As a result of putting those prices in front of the doctors, Johns Hopkins reduced tests per patient day from about 3.7 to 3.4 among the group exposed to costs (the testing rate went up in the control group, which did not see the testing costs). It helped save $433,000 during the first six months of the implementation of the program, according to Feldman.

Communication Is Key

Communication with clinicians is key in reducing test utilization. UM always notifies medical staff in advance if a test is being evaluated. It also performs follow-up assessments six months after a decision has been made. An appeals process is also in place if there are objections to a decision, although it is rarely used.

"We've done a good job of prospective communication," Warren said. He added that the mission of the formulary committee is to improve quality and utilization, not cut costs, and that its tone is along those lines.

"If there's debate, we tend to err on the side of liberalism . . . in making changes," he said.

Although progress in these campaigns has been incremental, that it is occurring at more than one health care system was encouraging to Feldman.

"If it's being picked up by Hopkins—which has a tendency not to change—it is being picked up in other places as well," he said.

Takeaway: Hospitals and hospital systems are slowly but steadily focusing on the overutilization of laboratory tests. G2

■ **LabCorp CEO Demurs During Earnings Call**, *from page 1*

In a call with analysts, King admitted LabCorp was having difficulty collecting payments on some molecular tests because pricing had still not yet been firmly established but politely declined to provide specifics. He also declined to provide any forecasts about sales for the BRCA test the company will start offering later this year and details about new agreements involving its BeaconHealth platform in Florida.

It was a much blunter King who addressed the audience at G2 Intelligence's Lab Institute two days prior. The institute was held Oct. 16-18 in Arlington, Va.

King said the sector needs to be more aggressive in its messaging that it is being hurt by payment cuts and lower utilization due to higher out-of-pocket costs for patients. He also is concerned that regulators believe LabCorp and Quest comprise much of the lab sector, thereby overlooking the concerns of the other 1,500 to 2,000 smaller operators.

"The community labs and the service provided by community labs to our health care system are fundamental. They're vital," King said.

CMS Proposal 'Mind-Boggling'

One particular issue is a proposal by the Centers for Medicare and Medicaid Services (CMS) to cap payment for some laboratory tests provided by independent labs at rates paid under Medicare's Outpatient Prospective Payment System. While officials with CMS wants payment rates to be the same at every site of service, independent laboratories get hurt because they don't have the flexibility hospitals have in laying off costs to other departments—it's a standalone expense for them.

"You can't take allocated costs and direct costs and compare them," King said.

Although King noted that members of Congress have supported labs on this position, getting CMS officials to adopt the same stance is a separate challenge. He observed that some officials with the agency have expressed puzzlement about the value labs provide, a position he labeled "mind-boggling."

King also noted that labs are often reimbursed at a fraction of the National Limitation Amount in some states and much higher rates in others, making for revenue imbalances.

"We ought to be able to have an open and transparent dialogue with CMS about how labs are paid. The problem is . . . what we have is a black box," King said. As a result, labs may get paid for one thing one year and not get paid for it the next year.

"There is a lack of consistency [from both CMS] and the carriers. The Uniform Coverage Policies are all out of uniform, because they are all over the place." King suggested pushing for negotiated rulemaking around the fee schedules so both sides can have equal input.

Regarding the new molecular code prices, King said he was greatly concerned no price was determined for cystic fibrosis testing, likely because it's not used much by Medicare patients. However, he believes it could lead to coverage denials by commercial payers. King believes the matter of molecular test coverage may eventually have to be litigated.

Takeaway: National labs do not comprise the entire laboratory landscape, and the sector must be more assertive in voicing its concerns to lawmakers and regulators. G2

INDUSTRY BUZZ

New Liver Cancer Test Being Developed With Eye Toward U.S. Market

Researchers at Georgia Regents University (Augusta, Ga.) have developed a new molecular-based assay for the early detection of liver cancer and are working with the North American branch of multinational firm Biogenex to possibly distribute it in the United States.

The test researchers developed stains mir-21, a form of microRNA that appears in liver cancer cells and can survive the chemicals used to prepare slides. In a small retrospective study involving 20 patients, the test was able to correctly diagnose liver cancer in each case. A new study has been expanded to include more than 200 patients.

"There is no definitive test for early diagnosis of liver cancer," said Ravindra Kolhe, M.D., a pathologist and medical director of Georgia Esoteric Labs, Georgia Regents' commercial development branch. "Our test adds a level of comfort for making the diagnosis."

Liver cancer kills about 22,000 Americans every year, while another 30,000 new cases are diagnosed annually, primarily in men. The five-year survival rate from even the most contained form of the disease is about 28 percent, and it drops precipitously should tumors spread beyond the liver.

Among the reasons for the low survival rate is that most patients are asymptomatic until the disease is in an advanced stage, making it too late to perform a liver transplant, partially excise the existing organ, or expose it to heat or cryogenic treatments.

Even those patients at a high risk for the disease because of a history of hepatitis cannot be easily tested because cancer cells are not readily visible until they are far along in development. Hepatitis also often leads to cirrhosis, a scarring of the liver that makes slide interpretations more complicated and provides even more cover for the development of cancer cells.

Georgia Esoteric worked with BioGenex to develop the test. Kolhe noted that a deal to distribute the assay should it receive regulatory approval "will evolve in later meetings."

Kolhe noted that such an assay would likely be priced in the $250 to $400 range, including pathologist interpretation.

Takeaway: Liver cancer must be diagnosed sooner to boost survival rates, and the laboratory sector is responding by developing a new test to identify the cancer earlier.

References

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202-637-9466

BioGenex
510-824-1400

College of American Pathologists
847-832-7000

Georgia Regents University
706-721-0211

Johns Hopkins Medicine
410-955-5000

LabCorp
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Mayo Clinic Arizona
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Quest Diagnostics
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LIR 10/13b

October 23, 2013

 Laboratory Industry Report (ISSN 1060-5118) is published by G2 Intelligence, 24 Railroad Street, Keene, NH 03431-3744 USA. Tel: 800-531-1026. Fax: +1-603-357-8111. Web site: www.G2Intelligence.com.

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