Your Independent Source for Business & Financial News

LABORATORY INDUSTRY REPORT®

Vol. 13, Iss. 15, August 12, 2013

HIGHLIGHTS

www.G2Intelligence.com

Second-Quarter Earnings Less Than Stellar for Quest, LabCorp

The first-half whistle has blown for the laboratory sector in 2013, and Quest Diagnostics and LabCorp are still tackling softness in testing volumes and reimbursement.

Analysts are mildly optimistic about how those plans will unfurl over the coming months and years. And while companies are enjoying strong cash flow and sit on large money reserves, they are taking their lumps on the bottom line and, for Quest, in revenue as well.

Quest, the larger of the two nationals, reported net income of $165 million on revenue of $1.8 billion for the quarter, both figures down from the net income of $177.7 million on revenue of $1.9 billion for the second quarter of 2012.

"We saw a continued revenue softness in the second quarter due to lower health care utilization, which impacted many health care providers, as well as reductions in our reimbursement," Quest Chief Executive Officer Steve Rusckowski said in a July 18 call to discuss earnings.

According to Rusckowski, overall test volume was down 1.5 percent compared to a year ago, a marginal improvement over the 2 percent decline in volume that occurred during the first quarter of 2013.

Continued on page 2

Cigna Mandates Some Genetic Counseling, But Compulsory Referrals Still Rare

Insurance giant Cigna Corp. will soon require genetic counseling before covering some laboratory tests to determine the likelihood of an inherited medical condition—a shift in policy slow to take hold among payers, officials said.

Starting in mid-September, Cigna will require enrollees who want to undergo testing for certain genetic disorders to undergo counseling first. The conditions include breast and colorectal cancer, as well as Long QT disorder, a genetic condition that can lead to an erratic heart rhythm and sometimes sudden death. The insurer believes as many as one-fourth of the tests it currently provides for these conditions may not be medically necessary.

Cigna has retained the genetic counseling firm InformedDNA to perform the counseling. The Florida-based company will ask Cigna

Continued on page 7

■ Second-Quarter Earnings Less Than Stellar, *from page 1*

LabCorp fared a little better: Its revenue was up 3 percent, to $1.47 billion for the quarter compared to $1.42 billion for the second quarter of 2012. But net income was down to $152.3 million, compared to $153.8 million for the year-ago quarter, a drop of 1 percent. Although test volumes were up 5 percent, that was undercut by declines in Medicare reimbursements that reduced revenue per requisition by 1.8 percent (Quest took an even larger hit on revenue per requisition, which was down 3.7 percent for the quarter).

"We were absorbing approximately $55 million in payment reductions in 2013 due to Medicare fee schedule reductions, from sequestration, the 88305 reduction, and other reductions," LabCorp CEO Dave King said during the earnings call. He added that his company was concerned by proposed changes to the clinical laboratory fee schedule (CLFS), which has already been reduced 8 percent since 2010.

King also expressed disappointment in the delays in properly pricing the molecular test codes placed on the CLFS. "It is our expectation that we will receive appropriate payment for our services and that these unprecedented nonpayment policies will be reversed, which would result in upside to our guidance," he said. Altogether, pending payments for molecular tests total about 4 percent of revenues, officials said.

Yet LabCorp is far from impoverished: The company bought back $362 million in stock during the second quarter, compared to $113.9 million during the first quarter of 2013. King also said progress had been made in cutting the ratio of LabCorp's debt to pretax earnings, beefing up the company's IT systems, and in improving efficiency at its lab near its Burlington, N.C., headquarters. Its 240,000 square-foot Phoenix lab will go online this fall, resulting in the consolidation of four smaller regional labs.

"We were absorbing approximately $55 million in payment reductions in 2013 due to Medicare fee schedule reductions, from sequestration, the 88305 reduction, and other reductions."
—Dave King, Chief Executive Officer, LabCorp

Rusckowski believes that the implementation of the Affordable Care Act will be an upside for the company but that its rollout will be stretched out. "It's now seemingly likely that the expected entry of the uninsured people into the health care systems will ramp up more slowly than initially anticipated," he said, adding that only half the states are expected to participate in Medicaid expansion, and that the state exchanges are ramping up more slowly than expected.

In the meantime, Rusckowski reported that Quest is on schedule for its plans to deliver $600 million in cost reductions by the end of the next year—it has already delivered $250 million more in savings this year than in 2012. The company has also reorganized its sales force and has inked key contracts with payers offering diagnostic services through the health insurance exchanges.

Additionally, Quest sold its rights to the royalties of the drug ibrutinib to Royalty Pharma for $485 million—a transaction the company believes will net $300 million after taxes.

Both LabCorp and Quest also reported strong growth in workplace drug testing assays.

Analysts Cautious

Analysts are taking a wait-and-see attitude with the companies. They were particularly concerned by Quest's decision to revise its 2013 guidance downward. The company projects that revenues will decline 1 percent to 2 percent compared to 2012. It also narrowed its range for earnings per share.

"While Quest is doing an admirable job of monetizing non-core assets, we believe the current fundamental environment remains challenging due to slower underlying volume trends and reimbursement pressure," said Bradley D. Maiers and Kevin K. Ellich, research analysts with Piper Jaffrey. Although they praised Quest's cost-cutting and noted that its long-term strategies are gaining traction, it maintained a neutral rating on its stock due to "weaker volume trends and pricing pressure."

Maiers and Ellich also noted that while LabCorp's organic volume growth of 1.4 percent beat estimates, the decline in revenues per requisition was worse than expected.

"We believe the Medicare reimbursement environment will remain challenging given recent cuts, uncertainty around the proposed physician fee schedule cuts, and the longer-term potential cuts to clinical lab fee schedule, which keeps us on the sidelines." They maintained neutral ratings on LabCorp and Quest's stock.

Takeaway: Quest Diagnostics and LabCorp are still confronting soft test volumes and flat growth, but they are endeavoring to strengthen their fiscal position and reverse the trend. G2

GAO Delves Into Pathology Self-Referrals, Concludes Such Practices Drive Up Utilization

The Government Accountability Office (GAO) has expressed alarm about the rising number of self-referred tests from pathologists participating in the Medicare program and has recommended safeguards to curb the practice.

The report was generally well-received from the pathology and lab communities, which agree that self-referrals drive up utilization whether or not the care provided is medically necessary.

According to the GAO, the volume of self-referred anatomic pathology (AP) services more than doubled between 2004 and 2010, from 5.6 million to 7.8 million, with self-referrals particularly high among providers that switched to self-referrals sometime during that period.

The GAO estimated that in 2010, providers engaged in self-referrals made 910,000 more referrals than if their volumes per biopsy were similar to those of their nonreferring counterparts.

"Physician self-referral is a national problem," said College of American Pathologists President-elect Gene Herbek, M.D. "It contributes to widespread abuses, increased medical costs, and overutilization."

Herbek recommended that AP be removed from the in-office ancillary services (IOAS) exception, but he did not support GAO's recommendation that the Centers for Medicare and Medicaid Services construct a payment mechanism to discourage self-referrals. New legislation introduced in Congress would remove AP services from the IOAS.

The American Clinical Laboratory Association also concurred with CAP regarding eliminating the IOAS exception without targeting all laboratories.

Takeaway: Self-referrals in anatomic pathology drive up utilization rates, but groups representing pathologists and laboratories would like a more targeted response than that recommended by the GAO. G2

Lung Cancer Initiative With Mandatory Molecular Testing Could Boost Lab Volumes

A new program spearheaded by a charitable foundation aims to use molecular testing to fundamentally alter how care is provided to lung cancer patients.

The 360 Community Hospital program could be seen as a potential boon for labs that perform the handful of molecular tests associated with lung cancer treatments.

"It will have an ultimate end effect on the volume of tests these labs perform," said Danielle Hicks, director of patient services and programs for the Bonnie J. Addario Lung Cancer Foundation, the San Carlos, Calif.-based philanthropy behind the initiative.

Lab executives are a little less sanguine about the business promise of the 360 program. "On the face of it, this would increase volumes," said Stephanie Astrow, vice president of research and development for Response Genetics, a Los Angeles laboratory that assists a Bonnie Addario affiliate on lung cancer research. But Astrow could not provide any guidance on what that number might be.

> ***"There's a fractionation of medical care—you might see an oncologist . . . then see a radiologist, and a pathologist has to do an analysis—there really is no pathway."***
>
> ***—Steve Young, President, Addario Lung Cancer Medical Institute***

Instead, lab executives see the initiative as more of a bootstrap to pull closer to the value-over-volume proposition they believe is required for the sector to thrive in the long term. Meanwhile, some pathologists are concerned it could dilute the quality of cancer care and drive up costs.

Whatever the doubts, the 360 program is in the midst of a national rollout after a successful pilot program at El Camino Hospital in Mountain View, Calif. Addario officials envision smaller nonteaching hospitals using molecular testing as a matter of course in a couple of years. Currently, many use it sporadically, if at all.

Addario officials noted that the 360 program is intended to address the biggest shortfall in lung cancer care at community hospitals—that many patients often wait weeks before receiving accurate diagnoses about their conditions, leading to delays in care and sometimes inappropriate treatment. Patients with the KRAS biomarker, for example, are poor candidates for chemotherapy—something that would not be known without molecular testing.

Such issues are apparently commonplace despite the fact that the large majority of lung cancer patients are diagnosed at stage 3 and higher, making swift and precise treatment crucial.

"There is no one person or party driving the care decisions. It becomes a serial process," said Steve Young, president of the Addario Lung Cancer Medical Institute, the foundation's research affiliate. "There's a fractionation of medical care—you might see an oncologist . . . then see a radiologist, and a pathologist has to do an analysis—there really is no pathway."

Young added that some doctors may be reluctant to perform a biopsy because of the risk of a lung collapse, and others may not perform molecular testing at all. "There's a lot of pessimism regarding lung cancer," he said, noting that five-year survival rates barely top 15 percent.

Amy Cunniffe, a senior vice president with Caris Life Sciences, a Texas-based lab that works closely with Addario on its initiatives, echoed Young's concern. "You want to start with the most effective therapy possible, as soon as possible, and get the most effective shot on goal to beat the cancer," she said.

Molecular testing itself remains a hit-or-miss proposition for lung cancer patients. According to Young, only about 15 percent to 20 percent of patients test positive for biomarkers that suggest drugs such as Tarciva and Crizotinib would be effective in their treatments. But it's a start, he added.

"At least you are looking where you can see. Molecular testing at least will steer you to a beam of light, at least you have a chance for the subset of patients with biomarkers," Young said.

The El Camino Data

Every single non-small-cell lung cancer patient at El Camino received molecular testing in the pilot—about 100 patients in all. They underwent a panel of 10 different assays. And despite operating a brand new, technically advanced facility in one of the wealthiest communities in California, El Camino's lung cancer patients had received molecular testing only 20 percent of the time prior to the pilot.

The preliminary results are telling: Diagnosis-to-treatment time was slashed to 10 days from 45 days—a reduction of 77 percent. And nearly two-thirds of the patients underwent a tumor board review—something that rarely happens at a community hospital.

Molecular Tests in the 360 Community Hospital Lung Cancer Panel

- Ros1
- EFGR
- ALK
- KRAS
- ERCC1
- RRM1
- C-MET
- TS Expression
- PIK 3CA
- T790

Source: Bonnie J. Addario Lung Cancer Foundation

As a result, the 360 Community Hospital program is being rolled out to three other community hospitals in the Southeast and East: Lehigh Clinic in Boston, the Northside Hospital system in Atlanta, and the Lynn Cancer Institute in Boca Raton, Fla. Under the

program, the hospitals can pick their own outsourcing labs for testing, but the entire 10-test panel has to be performed.

Northside, which is also participating in a lung cancer tissue collection program overseen by the Addario Lung Cancer Medical Institute, has been performing two molecular tests since 2008 for its lung cancer patients: EGFR and ALK. Both are outsourced to local labs.

Jewel Chang, M.D., a Northside pathologist, noted that the patients are tested for ROS1 if they are negative for the first two tests. It's the kind of stepped assays that lead to care delays—something that is resolved by undergoing all the panels at once, according to Addario officials.

"From a medical insurer perspective, I would not do testing without the physician saying the patient is a candidate for chemotherapy."
—Robert Boorstein, M.D., Director, ClasGroup

But despite the push for broader molecular testing, some pathologists are concerned that community hospitals are involved in treatment of lung cancer patients at all.

"I have a bias in this area—I think all patients should get treated at cancer [specialty] hospitals," said Bruce A. Friedman, M.D., an emeritus professor of pathology at the University of Michigan and president of the Pathologist Education Consortium.

Hicks noted that 225,000 Americans are diagnosed with lung cancer every year, meaning there simply is not enough capacity at specialty hospitals to treat even a large fraction of them.

Robert Boorstein, M.D., a pathologist and director at the ClasGroup Co. near New York City, is concerned that such a large panel of tests could lead to unnecessary utilization. "Remember, this is just for [non-small cell], which is 30 percent of lung cancer. There is potential for creep into squamous," he said. "From a medical insurer perspective, I would not do testing without the physician saying the patient is a candidate for chemotherapy."

Cost is a concern for the 360 initiative—the panel of tests runs about $2,700 to $3,500. And while Hicks noted that most insurers cover EGFR and KRAS tests, others may balk at paying for them all.

Response Genetics has agreed to pick up the cost of testing for any patient involved in the 360 initiative if they don't have insurance. But the labs also seem to agree that the best thing they can do is come up with a BRCA equivalent for lung cancer.

"We need to develop a reliable risk-based test," Cunniffe said.

Takeaway: Speeding lung cancer care may boost molecular testing volumes, but without a more definitive diagnostic test, could also increase unnecessary utilization.

■ **Cigna Mandates Some Genetic Counseling**, *from page 1*

enrollees to submit to an online questionnaire, as well as an approximately one-hour interview with one of its 40 counselors prior to making a recommendation, according to David Nixon, InformedDNA's chief executive officer. The counseling ranges in price from $100 to $300, depending on its complexity. By contrast, a BRCA test can run $3,000 or more.

Nixon estimates that about one-third of Cigna enrollees who receive counseling will eventually undergo lab testing. He was unable to say whether the counseling will drive down the number of tests performed for Cigna's enrollees.

According to Nixon, other large insurers such as UnitedHealth and Aetna also provide genetic counseling, which was confirmed by officials with America's Health Insurance Plans (AHIP), a trade group representing health carriers. But the primary difference is that Cigna is making such testing mandatory. "With the other carriers, it's [just] strongly recommended," said Nixon, whose company also works with those two other plans.

Susan Pisano, a spokesperson with AHIP, noted that the Affordable Care Act requires insurers to cover BRCA testing for women considered at high risk for developing breast cancer—typically when other close relatives in one's family contract the disease. While Pisano observed that the practice of insurers using genetic counseling is growing, they are doing so to sort out whether they should pay for tests that have high levels of false positives, or for which there is no treatment protocol should the patient test positive for developing a specific disease or disorder.

Takeaway: Genetic counseling is becoming more widespread among health plans, but mandatory counseling is still rare. G2

Ambry Claims Myriad Violating Antitrust Laws

Ambry Genetics has struck back against Myriad Genetics, claiming the Utah-based lab's efforts to keep a grip on the process to test for the genetic risk of breast cancer represents a violation of U.S. antitrust law.

The California-based Ambry filed a counterclaim on Aug. 5 in U.S. District Court in Utah.

The case stems from a June U.S. Supreme Court ruling that Myriad did not hold a patent on nonmodified genes. Within days of the ruling, Ambry and several other labs said they would market BRCA tests.

Myriad sued Ambry last month, claiming patent infringement. At the same time, it widened its financial assistance program for patients.

"Myriad continues . . . using sharp and overreaching practices to wrongfully monopolize the diagnostic testing of human BRCA1 and BRCA2 genes in the United States and to attempt to injure any competitor who dares to challenge Myriad's monopoly, including Ambry," read a portion of the counterclaim.

"Being sued for patent infringement a month after the Supreme Court ruled 9-0 unanimously against Myriad is just wrong," said Ambry Chief Executive Officer Charles Dunlop.

Takeaway: Despite a unanimous U.S. Supreme Court decision, litigation over BRCA testing is likely to continue for years. G2

INDUSTRY BUZZ

Evogen, MRIGlobal to Collaborate on Test Development

Two Midwest companies that focus on laboratory testing equipment and medical research have joined forces to develop laboratory tests.

Kansas City, Mo.-based MRIGlobal has come to terms with Lenexa, Kan.-based Evogen for a five-year agreement on the development of several products, including assays in the disease detection and molecular arenas.

"Evogen and MRIGlobal see opportunities to collaborate on delivering new and innovative solutions that can help physicians make earlier and more accurate diagnoses," said Thomas M. Sack, MRIGlobal's interim chief executive officer.

Officials with both companies declined to disclose specific areas of testing they plan to focus on, citing potential issues with competitors. "MRIGlobal is working on several multiplex assays for infectious diseases," said Rich St.Clair, Evogen's vice president of commercialization. St.Clair added that the first of the tests would be available for distribution by the end of 2013. No details on how it would be distributed were available.

The agreement appears to move both firms into new fields. Evogen distributes a variety of laboratory support products, particularly for the collection of polymerase chain reaction (PCR) for use in molecular diagnostics, but it does not market any lab tests. In February, Evogen entered into a distribution deal with California-based Focus Diagnostics regarding HyBeacons, a proprietary PCR probe technology it had developed in-house.

MRIGlobal, which operates a CLIA-certified laboratory in Florida, primarily performs research for corporate and government clients, with an emphasis on national security and military projects. It has expertise in therapeutics, vaccines, pharmaceutical product development, and microbial forensics.

Evogen was spun off from MRIGlobal more than a decade ago, but the two firms have worked on various collaborations in the years since, officials said.

St.Clair noted that developing tests appeared to be the next logical step in the business relationship.

Takeaway: Two firms are entering into a joint agreement to propel themselves into the development and distribution of laboratory tests.

References

Ambry Genetics
949-900-5500

Bonnie J. Addario Lung Cancer Foundation
650-598-2857

Cigna
800-997-1654

ClasGroup Co.
917-312-3786

Evogen Inc.
913-948-5640

MRIGlobal
816-753-7600

Myriad Genetics
801-584-3600

Quest Diagnostics
800-222-0446

Response Genetics
323-224-3900

Note our change of address and phone numbers effective immediately.
To subscribe or renew *LIR*, call now +1-603-357-8101, 800-531-1026
(AAB and NILA members qualify for a special discount, Offer code: LIRNI1)

Online: www.G2Intelligence.com/LIR
Email: customerservice@G2Intelligence.com
Mail to: G2 Intelligence
24 Railroad Street
Keene, NH 03431-3744 USA
Fax: +1-603-357-8111

Multi-User/Multi-Location Pricing?
Please email jping@G2Intelligence.com or call 603-357-8160.

LIR 8/13a

Kimberly Scott, Managing Editor, kscott@G2Intelligence.com; Ron Shinkman, Editor; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, President and Publisher
Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at +1-603-357-8101.