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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

Molecular, Traditional Labs On Different Earnings Paths

As year-end earnings continue to flow in from the national and large regional laboratories, it is becoming increasingly clear the numbers look best from the molecular level.

The national and large regional labs that focus on molecular testing are posting strong earnings and revenue growth. Meanwhile, those labs engaging in the older line reference work and routine testing are struggling to move the needle.

After LabCorp and Quest Diagnostics recently reported numbers that were essentially flat, Sonic Healthcare USA discussed its own troubles.

Sonic, the U.S. subsidiary of the Australian testing giant, reported revenue of $367 million in Australian dollars for the first six months of its

Continued on page 2

McKesson, AMA Reach Agreement On Z-Code Mapping

McKesson and the American Medical Association (AMA) have entered into a pact intended to provide greater coding clarity to the thousands of molecular assays available to the health care profession.

Under the licensing agreement announced late last month, McKesson's Z-Code identifiers will be grouped and indexed to AMA's corresponding Current Procedural Terminology (CPT) code set.

Both McKesson and the AMA say the licensing agreement is intended to clear some of the confusion on how to classify the crush of molecular tests. More than 3,000 currently exist, and their popularity is rapidly growing. The parties had been in negotiations for a licensing pact for a year prior to its announcement.

"Greater clarity will bring health care stakeholders one step closer to the collaboration needed to assess these tests and make the most informed test selection, coverage, and payment decisions, resulting

Continued on page 7

■ **Molecular, Traditional Labs on Different Earnings Paths,** *from page 1*

fiscal year, ending Dec. 31 (essentially the same as U.S. currency). That compares to $378 million during the first six months of 2011, a numerical drop of 3 percent, and a total drop of 2.1 percent when currency fluctuations are factored in.

"Organic revenue growth in the USA was impacted by Superstorm Sandy and the weak economic environment, and was consistent with the organic growth rate of Sonic's major competitors in the USA market," said the company's earnings report. A Sonic USA spokesperson declined to provide specifics or comment.

For Sonic's companywide operations, revenues were up 5.6 percent, while earnings were up 8.8 percent. The company did not break out what portion of net income was attributable to U.S. operations.

Altogether, Sonic USA accounts for about 21 percent of the company's total revenues.

Company officials said its 2013 earnings would be on the lower end of guidance, attributable in part to the recent 52 percent Medicare payment cut in the technical component of CPT 88305.

BioReference Reports Continued Growth

"We have seen continued growth and expansion of our business, especially in the areas of women's health and genetics."
—Marc D. Grodman, M.D., CEO, BioReference

The numbers reported by Elmwood Park, N.J.-based BioReference Laboratories were strikingly different. It reported net income for its first fiscal quarter of 2013 of $8.7 million, compared to $7.4 million during the year-ago quarter, up 19 percent. Revenues were up 16 percent, to $161.3 million. The numbers moved solidly upward even though BioReference officials said Superstorm Sandy took a $2.5 million bite from revenues and $1.6 million from net income.

"We have seen continued growth and expansion of our business, especially in the areas of women's health and genetics," said Marc D. Grodman, M.D., BioReference's chief executive officer. "Since growth in these areas has historically brought attached routine business, we continued to see positive results in all of our lines of business." He added that recent reimbursement cuts from both Medicare and from some commercial payers would have minimal impacts moving forward.

Overall, BioReference's share of revenues from esoteric testing climbed to 62 percent for the quarter, compared to 59 percent in the first quarter of fiscal 2012.

Molecular Diagnostics Driving Growth

Redwood City, Calif.-based Genomic Health reported a dip in earnings, but otherwise robust revenue growth. Net income for the fourth quarter, ending December 2012, was $2 million, down 25 percent from the $2.6 million in the fourth quarter of 2011.

Revenue for the quarter was $60 million, up 11.2 percent from $53.2 million in the fourth quarter of 2011.

For calendar 2012, net income was $8.2 million, compared to $7.8 million for 2011. Revenue was $235.2 million, compared with $206.1 million for 2011, a bump of 14 percent.

For 2013, Genomic Health projected its revenues would range between $258 million and $266 million, an increase of at least 10 percent. Chief Executive Officer Kim Popovits said the launch of its new molecular prostate cancer test is expected to help drive the sales growth.

Fort Myers, Fla.-based Neogenomics, which focuses on oncology-centered genetic testing, reported similar forward momentum. Although its net loss for the quarter was $113,000, its revenue grew 16 percent, reaching $14.9 million. For the year, it reported net income of $65,000, down from $152,000 in calendar 2011, but revenue was $59.9 million, up 38 percent. Test volume grew by 50 percent during the year.

For 2013, revenue is projected to increase between 13 percent and 20 percent, despite the recent cuts to Medicare reimbursement.

Myriad Optimistic on Guidance

On March 1, Salt Lake City-based Myriad Genetics said it expected both 2013 revenue and earnings to be on the high end of its guidance, between $575 million and $585 million. That's despite the fact that Noridian Administrative Services LLC announced pricing for Myriad's BRACAnalysis 16 percent below current Medicare rates and 8 percent below private payer rates. Its Colaris test was priced at 3 percent below current Medicare rates and 14 percent below current commercial rates.

According to analysts with equity research firm William Blair (Chicago), Noridian's pricing rates were a bit below expectations though not as draconian as some had feared. Investors were expecting a roughly 10 percent reduction (closer to $2,900 for BRACAnalysis versus $2,795).

"The bigger concern is that Medicare pricing pervades to the commercial segment," write analysts Amanda Murphy and Sylvia Chao. "Private payers currently pay on average 8 percent below Medicare rates for BRCA testing. Based on our initial discussions with industry reps, feedback is mixed as to what commercial payers may do. While Medicare rates are typically used as a benchmark for reimbursement in the lab space and it seems lab payment contracts are increasingly tied to Medicare rates (versus a percentage of list or usual and customary charges), Myriad is in a unique position in that it is the sole provider of the test . . . and has already negotiated payments at specified rates."

Finding the Value Equation in a Tough Environment

Opinions on the industry's near future appeared as sharply etched at last month's G2 Intelligence's Volume to Value conference as measurements on a beaker. And few people present in Fort Lauderdale, Fla., Feb. 25-27 considered their laboratory glass half full.

Instead, the overarching theme of the two-plus days of sessions was that if the nonmolecular portion of the industry is to experience healthy growth anytime soon, it must remake itself as a powerfully intuitive adjunct to health care delivery's decisionmakers rather than an assembly line churning out results to any hospital, doctor, or patient in possession of a wallet.

The equation that spelled out the sector's relative lack of leverage was regularly repeated during the conference like a dark mantra: Although laboratory results influence approximately 70 percent of health care diagnosis and treatment, they comprise just 3 percent of overall health care expenditures—suggesting the labs' vulnerability to cuts that would seem minor to the overall health care delivery equation would devastate the lab sector. Many of the presentations focused on reworking that equation so the beakers would at least seem half full.

The Laboratory's Role in ACOs

The discussion of how labs can fully integrate themselves into accountable care organizations—the Patient Protection and Affordable Care Act (PPACA)-driven collaborations between hospitals and doctors to cut costs while improving patient outcomes—predominated the conference.

"Laboratories have to be contributing collaborators so they can show their value to the system," said John T. Daly, M.D., chief medical officer of the Commission on Laboratory Accreditation (COLA). The issue is how specifically to accomplish this. Daly noted that pathologists have been at the forefront of providing predictive personalized medicine, and this is the key role they can play in an ACO environment.

"It is imperative that pathologists show their value by providing to clinicians interpretative data on those complex tests to give clinicians a pathway they can go on [when] treating their patient," he said. That includes developing computerized physician order entry (CPOE) prompts for physicians as well as test-ordering algorithms—essentially, when and how clinicians should be ordering tests, as opposed to ordering them wholesale.

> ***"Laboratories have to be contributing collaborators so they can show their value to the system."***
> ***—John T. Daly, M.D., CMO, Commission on Laboratory Accreditation***

"They need to be able to tell health systems what makes the most sense at a given location for a given population of patients," Daly said. COLA has developed certifications and seals of excellence for laboratories wishing to participate in ACOs, Daly noted. Not only should the testing process be streamlined, there should be measurable results for the care that is derived, he stressed.

"Patients often don't get the care they need, and if we're going to have an impact in an ACO, we have to find a way to make it go better," said Conrad Schuerch, M.D., chairman of the department of laboratory medicine at Geisinger Health System in Pennsylvania, which operates its own ACO.

In an ideal ACO environment, Schuerch observed that "if the lab is doing its job well, the patient will be doing well."

Schuerch presented the ACO challenge for labs as being contained within opposing triangles. The points on the first triangle represent quality, cost, and service. It is contained within a triangle posing the challenges of data integration and management, utilization management, and clinical effectiveness.

According to Schuerch, laboratories should not only meet the objectives within the triangles but also help improve clinical efficiency throughout the continuum of care while making the overall experience of interfacing with a lab more seamless. That means more convenient methods of providing phlebotomy services, easier means to place orders, and quicker turnarounds.

Along those lines, Geisinger's labs are devoted to delivering blood gas reports on emergency room patients within 15 minutes, hospital stat tests within an hour, and ongoing testing for costly hospital-acquired infections such as MRSA and C. difficile.

Patient-Centric Care

In addition to working with providers, labs should also be able to help cater to the needs of specific patients, experts at the conferences agreed.

Unfortunately, this may be in conflict with the need to streamline services and cut costs in order to satisfy providers, according to Paul Epner, a consultant who recently founded the organization Society to Improve Diagnosis in Medicine. Instead, the result has been what Epner said was the creation of an "increasingly factorylike experience" that focuses solely on inputs and outputs. That ultimately pulls the patient out of the equation even though they are ultimately the ones who will determine the value of such tests.

"Our product is being underutilized, and that leads to an undervaluing of us."
—Paul Epner, Director, Society to Improve Diagnosis in Medicine

One of the biggest problems for patients? The failure to follow up on test results, according to Epner. He cited the case of Rory Staunton, a 12-year-old who died at NYU Langone Medical Center from community-acquired sepsis because clinicians there did not closely examine his blood tests after an emergency room visit a day prior to his admission.

"The opportunity to save this boy's life was waiting there, and the health care system didn't respond," Epner said, adding that despite Staunton's death being extensively reported in the *New York Times*, the failure to follow up on medical test results was satirized just a few months later in the *New Yorker* magazine.

"Our product is being underutilized, and that leads to an undervaluing of us," Epner said. This was borne out in a survey of 1,200 physicians and

their responses when they faced uncertainties in test ordering. Asking a laboratory professional for advice was the course they took the least often.

Meanwhile, in a survey of more than 300 closed medical malpractice cases, nearly half could be traced back to some issue in the laboratory: Either tests that were ordered were not performed, the tests were performed incorrectly, the result were incorrectly interpreted, or the results were not transmitted to the patient.

Like Schuerch, Epner suggested a CPOE interface with the laboratories but also greater use of reflective and reflex testing. The former would create protocols for the sequential addition of tests based on prior results. The latter would empower lab physicians' discretion to order additional tests based on their interpretations. He also recommended data mining—a retrospective look at results in order to improve and refine protocols. In an example, he noted that Kaiser Permanente's Southern California division has used lab data from its electronic medical records to create follow-up protocols for patients suspected of but not diagnosed with prostate cancer and chronic kidney disease, as well as more effective medication monitoring.

Meeting the Value Equation

Parsing all these changes and managing the lab sector effectively enough to change the industry from a volume to value proposition will be a major challenge, said L. Eleanor J. Herriman, M.D., managing director for G2 Intelligence's advisory services. Nevertheless, the role for laboratories is pretty clear: Hospitals and health care systems are facing "serious threats" in the coming years in terms of both the PPACA and planned cuts in reimbursement.

"CEOs need to get 20 to 40 percent of costs out of the system. . . . [T]here is no way to do this with the traditional levers" of cutting costs and waste, she said. Instead, it will represent a redefinition of care delivery.

How can labs assist with the redefinition? According to Herriman, it will include focusing on some of the collateral conditions in the hospital setting that are major cost drivers for care. That means providing such services as rapid molecular testing that would assist with such care as the targeted delivery of antibiotics for pressure ulcers and urinary tract infections; decision support for detecting and treating hyponatremia; locating biomarkers for victims of acute renal failure, strokes, and pneumonia; and providing support for diabetes care to avoid infections.

But Herriman provided no illusions that such a transition for labs would be rapid or easy. She observed as part of a later discussion panel that pathologists and pathology groups—and by extension their laboratories—are far more likely to enjoy success in an ACO or a value-oriented care setting if they had been interacting with clinicians prior to its formation.

"They had been going to the meetings with the physicians, they had been . . . interacting with the physicians outside of their lab," she said. "You do have to get out of the lab."

■ McKesson, AMA Reach Agreement on Z-Code Mapping, *from page 1*

in better business for providers and payers and better care for patients," said McKesson Health Solutions President Emad Rizk, M.D.

In a 2011 white paper, McKesson advocated for greater clarity in classifying genetic tests, noting for example that patients who take drugs on a long-term basis might benefit from specific molecular procedures to determine if they are properly metabolizing them.

The pact with the AMA is expected to provide much greater visibility and viability to the McKesson Diagnostics Exchange, which the Newtown, Mass.-based company launched in 2011 for molecular laboratories to submit information about their specific tests for cataloging.

"The added capabilities will complement the AMA's ongoing development and maintenance of a CPT code set for molecular diagnostic services and provide a valuable tool for physicians, hospitals, payers, and the diagnostics industry that will help organize vital information about [molecular diagnostic] tests," said James L. Madara, M.D., the AMA's chief executive officer.

There are currently 114 molecular CPT codes. McKesson spokesperson Sandra Cummings said that the joint effort is expected to cause that number to grow significantly.

"The AMA will be actively recruiting laboratories and other important stakeholders to participate in the mapping process," Cummings said.

Imperfect Art

However, assigning CPT codes to the Z-Codes is expected to be an imperfect art at best. In a joint statement, the parties noted that "not all Z-Code Identifiers will immediately map to a CPT code, and, in many cases, multiple Z-Code identifiers will map to a single CPT code." Cummings ruled out any chance that this might create a new form of molecular code stacking. The Centers for Medicare and Medicaid Services late last year eliminated that practice for Medicare billing using the existing molecular codes.

Cummings declined to disclose any terms of the deal, but trade associations such as the AMA typically charge outside parties to partake of services they provide.

The Chicago-based AMA said it would offer the mapping service to its membership and other parties in early 2014 and that it will be licensed like its other CPT-related products.

Cummings also said McKesson did not plan to commercialize any of the information it is gathering from laboratories on its molecular tests.

"McKesson supports the collection of the data within the diagnostics exchange but it does not assert any ownership or control over the data," she said, adding that no proprietary data gathered from labs would be used in any way without their consent. G2

INDUSTRY BUZZ

Asian Laboratory Receives CAP 15189 Certification

The College of American Pathologists (CAP) has accredited an Asian laboratory, its second such certification overseas, but the organization appears to be on the fence regarding any expansion of its growing 15189 accreditation program outside of the United States.

The accreditation was given to the Indian pharmaceutical giant Quintiles' central laboratory in Mumbai, India, and was announced in January. CAP had previously certified a Quintiles facility in Edinburgh, Scotland, in the United Kingdom.

CAP's 15189 certification program guarantees a laboratory undergoing it complies with the International Standard of Organizations' measurements for quality in processes and error avoidance in medical laboratories. It takes about three years to obtain a certification. The process includes an on-site assessment, including interviews with management, a report of nonconformities, and a couple of years of surveillance prior to the issuance of an accreditation.

"The accreditation focuses on the continuum of care directly connected with improved patient safety and risk reduction," said Anil Raghavan, managing director of Quintiles' India division.

Since it launched the certification process in 2008, CAP has certified 20 laboratories, which includes a mix of laboratories operated by national players such as LabCorp and Quest Diagnostics, as well as several hospital-operated facilities. As opposed to medical testing, Quintiles uses its laboratory facilities for testing associated with its pharmaceutical products.

Based on data supplied by CAP, the number of certified labs is expected to grow swiftly in the coming years. CAP spokesperson Joe Schramm said that 40 laboratories both in the United States and overseas are currently in the middle of the certification process.

Although Schramm said that there are no plans to make its certification program one with global scope, CAP Chief Executive Officer Charles Roussel noted in a brief interview at the recent G2 Intelligence Pathology Summit, held in Fort Lauderdale, Fla., Feb. 28-March 1, that the demand for accreditation from overseas labs indicates some promise for the program outside of the United States.

However, Roussel added that CAP's certification program could be in conflict with accreditations from other bodies, such as the one in Australia.

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