G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

Your Independent Source for Business & Financial News

# LABORATORY INDUSTRY REPORT™

Vol. 15, Iss. 4, February 19, 2015

## HIGHLIGHTS



www.G2Intelligence.com



## Quest's Latest Earnings Report Suggests Growth Is Gaining Momentum

Quest Diagnostics seems to have snapped out of it. The New Jersey-based laboratory giant posted a significant gain in both net income and revenue for the fourth quarter of 2014 and forecasts modest growth for 2015—the third consecutive quarter of gains.

For the quarter ending Dec. 31, Quest reported net income of $200 million, or $1.08 per share, on revenue of $1.9 billion. That compares to the fourth quarter of 2013, when Quest's net income was $151 million on revenue of $1.8 billion. That represents increases of 32 percent and 7.2 percent, respectively, for the latest quarter.

The fourth quarter numbers beat the expectations of several analysts, which had forecast earnings of about $1.05 a share and revenue in the range of $1.84 billion.

*Continued on page 7*

## After Adverse Legal Ruling, Myriad Quickly Settles BRCA Litigation

Myriad Genetics, which had been aggressively pursuing litigation related to molecular tests for breast and ovarian cancer risk, has pulled back after losing three sequencing patents in federal court late last year.

The U.S. Appeals Court for the Federal Circuit ruled on Dec. 17 that three patents Myriad had held for forms of BRCA testing should not have been granted.

As a result, the Salt Lake City-based Myriad has settled suits in recent weeks with two other laboratories in Southern California it had sued over their offering of testing of the BRCA gene or its variants. It settled a suit with San Diego-based Pathway Genomics on Jan. 23 and another case with Aliso Viejo-based Ambry Genetics on Feb. 2.

Although the exact terms of the settlements were not released, all of the sides agreed to dismiss their claims and counterclaims with prejudice, meaning the litigation cannot be reinstated at a later time.

*Continued on page 2*

### After Adverse Legal Ruling, Myriad Quickly Settles BRCA Litigation, *from page 1*

"We are very pleased to close this chapter and continue our focus on providing innovative cancer risk testing to patients around the world," said Pathway Genomics Chief Executive Officer Jim Plante in a statement.

Myriad, which is a spinoff business from the University of Utah, had held a virtual monopoly on BRCA testing through an assay marketed as BRAC*Analysis* until the U.S. Supreme Court ruled in 2013 that a single gene was essentially simple human tissue and therefore could not be patentable. That opened the door to other laboratories to begin to offer forms of BRCA testing, with many offered at price points well below Myriad's, which charged more than $3,000 for such a test.

Myriad had sued Ambry and Pathway, claiming the techniques they used to perform their assays were similar to a gene sequencing technique it had already patented.

As part of the litigation, Ambry had won a lower court ruling that the technique itself wasn't patentable, a decision upheld when Myriad appealed.

In its opinion, the appeals court had decided that the sequencing techniques did not create genetic material considerably different than what appears in nature, meaning that it could not be patented.

The rise of competitors in the BRCA space has stopped Myriad's growth and hit its bottom line. For the second fiscal 2015 quarter ending Dec. 31, the company reported net income of $24 million on revenue of $184.4 million. For the second quarter of fiscal 2014, its net income was $50.4 million on revenue of $196.2 million. For the first six months of fiscal 2015, its net income was $40 million on revenue of $343.7 million. For the first half of fiscal 2014, its net income was $62.1 million on revenue of $406.5 million.

Myriad has developed a variety of other assays that assess oncologic risks, including prostate, colorectal, pancreatic and lung cancers. It noted in its most recent filing with the Securities and Exchange Commission that sales of its recently introduced myRisk cancer panel have been brisk. The assay tests 25 genes for a patient's risk of developing eight types of cancer. Myriad said myRisk testing now represents "more than 50 percent of all hereditary cancer samples received." That has prompted the company to hire more staff and purchase more equipment to process those tests.

***Takeaway: Myriad Genetics appears to be turning a new page in the BRCA saga, and likely will spend less time on litigation in the future.***

## Palmetto Institutes New LCD Regarding Biopsy Stains

After a contentious process regarding the staining practices and clinical freedoms that should be granted pathologists, the Medicare fiscal intermediary Palmetto GBA has apparently initiated new local coverage determination guidelines.

Palmetto submitted the guidelines to the Centers for Medicare & Medicaid Services on Jan. 29. They appear mostly unchanged from draft guidelines it had proposed last year, with few revisions. The guidelines had drawn fire from the College of American Pathologists, which had asked in December that they be

withdrawn completely, suggesting that the medical literature on which they were based was inconsistent.

Palmetto had decided to scrutinize the issue last year, after some pathologists were billing for as many as a dozen stains for a single gastric case, with Medicare paying anywhere from $12.12 to $97.67 for each stain. Its new LCD also includes guidelines for breast, lung, gynecologic, kidney, skin, and soft tissue samples.

The LCD is altered little from Palmetto's original draft. Some leeway had been granted for pre-ordering ancillary stains for liver, kidney and some muscle biopsies, and if a patient has immunity issues that could lead to severe medical problems if the biopsy analysis is delayed. And analysis of Ki-67 for breast tissue biopsies will no longer be covered.

"The CAP continues to vigorously oppose the LCD because the purported supporting evidence is weak and appears to be comprised of citations selected to confirm a predetermined position," said George F. Kwass, M.D., chair of CAP's council on government and professional affairs. "Further, the LCD encroaches on pathologists' medical judgment by undercutting the core values of pathologists as physicians, consequently limiting beneficiary access to care, and fails to take into account patient populations that vary from practice to practice. The CAP will continue to advocate that the LCD be withdrawn."

***Takeaway: Palmetto GBA is moving forward with new immunohistochemical staining guidelines.*** G2

## Claritas Raises $15 Million in Funding

Claritas Genomics, the Massachusetts-based molecular lab that focuses on pediatric diagnostics, has received $15 million in second round funding to expand its operations.

The capital infusion came from Boston Children's Hospital, Cerner Corporation, and Cincinnati Children's Hospital Medical Center, all of which had contributed to Claritas's initial funding. Claritas was spun off from Boston Children's two years ago.

Claritas launched its first proprietary tests last fall. They focus on diagnosing genetically-based neurological and kidney diseases in children.

"Our work together has the potential to transform children's healthcare, as 40 percent of pediatric disorders are understood to have a clear genetic basis today," said Claritas CEO Patrice Milos. A new investor in this round is WuXi NextCODE Genomics. The company was formed as the result of the acquisition last month of NextCODE Genomics by Chinese company WuXi PharmaTech. NextCODE has operations in the United States and Iceland.

"Claritas is positioned to play a central role in advancing the use of sequence-based testing to improve the diagnosis of rare diseases," said Hannes Smarason, chief operating officer of WuXi NextCODE Genomics. "We are proud to contribute to that effort with our technology and as part of a group of industry-leading stakeholders."

***Takeaway: Claritas Genomics is poised to engage in a major expansion.*** G2

# Inside The Lab Industry

## Speeding Up of Value-Based Payments Could Be Clarion Call for Lab Sector

"It has already happened. Go to the village square, and ring the bell." That is not a vampire novel excerpt, but rather a recent observation of a senior executive at North Shore-Long Island Jewish Health, an 18-hospital health care system that serves the most heavily populated urban area in the United States. It was in response to an announcement by the U.S. Department of Health and Human Services late last month that it was going to rapidly accelerate the timetable for value-based payments to providers participating in the Medicare program.

Such payments are the virtual opposite of fee-for-service, where providers such as labs send a claim to Medicare and are paid a fixed amount. Instead, payments are based on the type of care the patient specifically needs, and the outcome of such care.

Providers usually share some risk regarding what they're paid. The sum can be reduced via financial penalties if a patient is readmitted to the hospital within 30 days of discharge, or increased via a bonus if the provider demonstrates it is improving overall outcomes. Or the payment can be "bundled" into a single amount intended to cover an entire episode of care. The accountable care organization movement was created specifically to address such changes in payments.

Currently, only about 20 percent of all Medicare payments are risk or value-based. Under the plan announced by HHS, it will rise to 30 percent by next year and comprise half of all Medicare payments by 2018.

"It is in our common interest to build a health care system that delivers better care, spends health care dollars more wisely and results in healthier people," HHS Secretary Sylvia Burwell said when the initiative was announced last month. She added that speeding payment reform "is about improving the quality of care we receive when we are sick, while at the same time spending our health care dollars more wisely. We believe these goals can drive transformative change, help us manage and track progress, and create accountability for measurable improvement."

### Finding and Defining Their Role

The problem for the laboratory sector is that while the roles of hospitals, physicians and outpatient clinics are fairly well defined in a value-based environment, the lab's role is not. Labs are, for better or worse, the purest form of fee-for-service health care. Perform more tests, and a lab generates more revenue. Perform fewer tests, and revenue shrinks.

"A call to action hasn't quite yet taken hold," said Susan Dougherty, vice president of operations and outreach services for Chi Solutions, a laboratory consulting firm in Ann Arbor, Mich. Dougherty noted that many lab operators are still

# Inside The Lab Industry

in a hunker-down mode due to ongoing cuts in reimbursement, such as the more than 50 percent cut in the technical component of CPT code 88305.

Indeed, a couple of prominent figures in the laboratory sector declined to comment on the announcement from the HHS—including one with extensive experience with labs in an ACO setting—saying they were not yet prepared to render opinions on how things will shake out.

However, Dougherty believes that the HHS announcement will create a new urgency for labs to begin to act. "You have 63 percent of (lab services) residing in hospitals and health systems. Those systems are already looking at the overall delivery of care. And knowing in reality that 70 percent of their clinical decisions are made relative to lab data, they would be hard-pressed not to have labs as part of this group."

## Data and Blood

The reams of data a lab generates on a single patient is a key opportunity for labs in an expanded value-based payment environment, according to James Crawford, M.D., senior vice president and executive director of laboratory services for the North Shore-LIJ Health System.

"How do labs generate value?" is the question that Crawford and other North Shore-LIJ officials ask when examining their options for making care more cost-efficient.

One of the first ways lab executives can find value is to use data to better manage perhaps one of the most crucial components of any health care system—its blood supply. Simply by dint of managing its blood supply more efficiently, North Shore-LIJ's laboratory services division was able to curb the system's blood costs per adjusted discharge by 54 percent–a savings of nearly $10 million a year. But it did not stop there. "How can you squeeze more blood from a stone?" is another question that Crawford said is continually being asked.

One way is to better manage patients with sickle cell illness—the New York City area has one of the highest rates of the genetic disease in the United States. Blood transfusions can ameliorate the symptoms in many cases. North Shore-LIJ labs used special antigen typing to ensure units of blood were kept in the right locale for speedy delivery and optimal transfusions. The cost of blood product utilization for sickle cell patients dropped 44 percent.

## Systematic Testing

Those are examples of how labs can use data to better manage some of their cost center components. But how about the direct use of testing?

North Shore-LIJ places a high priority on identifying patients in the early stages of sepsis, a serious infection that can not only ramp up costs but also lead to

# Inside The Lab Industry

organ failure and death. The sooner it is identified, the easier it is to mitigate. The system identifies it through the use of what is known as a sepsis bundle. A key element of this bundle is measuring serum lactate, which is both a strong predictor of risk for in-hospital mortality, and whether there should be a rapid escalation of the acuity of care.

Another laboratory test used for every hospital admission is serum creatinine. "There's a striking subset of patients being admitted with acute kidney injury," that often goes unnoticed, according to Crawford. Paying close attention to whether the creatinine levels on admission are elevated, or are rising within the first hours of admission, can optimize care for these patients by reducing complications, cutting their lengths of stay. Serum creatinine can also be used to identify patients with unsuspected chronic kidney injury, permitting medical intervention to slow the progress of their kidney problems.

The North Shore-LIJ Laboratories are also deploying its phlebotomy workforce in making about 200 daily blood draws from medically frail residents at their residences, to help providers better manage their chronic conditions and help avoid hospital admissions or readmissions.

Dougherty noted that such initiatives make perfect sense for hospital-based labs. "It's a department within a hospital that is being continually challenged to do more with less," she said.

Standalone reference laboratories will have their own challenges in a value-based payment environment. Whether or not they find their niche by managing more hospital-based labs using the kind of initiatives developed at North Shore-LIJ remains to be seen.

Meanwhile, many hospital systems have actually been selling their outreach businesses to standalone labs—a phenomenon Crawford believes could impede the goal of improving care while cutting costs.

"If the health system has given away its ability to have the lab data on their patients when they're not in the hospital, they are left with the ... highest part of the cost of managing their care," he said. "If you integrate your health system laboratories, you can not only achieve more competitive costing against national labs, but you also control your destiny."

***Takeaway: Laboratories will likely play an expanding role in optimizing the value-based payment system many Medicare providers will be shifting to in the coming years. Their executives should become more proactive in executing initiatives.*** G2

## Quest's Latest Earnings Report Suggests Growth Is Gaining Momentum, *from page 1*

Quest had gone nearly two years without reporting an increase in revenue, until it finally broke that trend with its second quarter of 2014 numbers reported last July.

Quest also issued a full-year forecast of earnings in the range of $4.70 to $4.85 per share—up nearly 10 percent from the analyst consensus of $4.41 per share. It projected revenue would grow this year by 2 to 3 percent, slightly higher than the consensus of 2 percent.

"We ended 2014 strong, and in the fourth quarter generated growth in revenues and EPS," said Steve Rusckowski, Quest's chief executive officer. "The 2015 outlook we are providing today is based on our expectations for strengthening operational performance and an improving business environment."

For the full 2014 calendar year, Quest reported net income of $592 million, down from $883 million for calendar 2013, although that was padded with an approximately $300 million profit from the company's sale of royalty rights of the anti-cancer drug ibrutinib.

In a conference call with analysts, Rusckowski said that there was a modest increase in test utilization, and that the benefits from the rollout of the Affordable Care Act were quickly accruing. "We are encouraged by the progress on exchange enrollment as the result of the ACA," he said.

According to data recently released by the U.S. Department of Health and Human Services, up to 9.9 million Americans are expected to be enrolled or re-enrolled in health plans through the state and federal health insurance exchanges. In the 28 states that have expanded Medicaid eligibility guidelines, enrollment is expected to jump 18 percent. The 22 states that have not opted into the program are still expected to see enrollment grow by 5.2 percent, according to data from the Kaiser Family Foundation.

Rusckowski also said that there is expected to be less pressure from government payers to make cuts to the clinical lab fee schedule in 2015.

Zacks Equity Research was fairly optimistic about Quest's prospects moving forward, noting that the company has been investing more resources into higher-end esoteric testing and that it is reaping a strong return from its diagnostic information services, which saw revenue grow by more than 7 percent in the fourth quarter.

"Although the recent volume improvement benefited the company's top line in the reported quarter, organic volume is still sluggish," Zacks noted in a recent report. "Moreover, lower health care utilization still acts as a major deterrent. Although the company has seen signs of modest increase in utilization, sustainability is still a matter of question."

However, Quest's stock price has risen more than 10 percent since the middle of December. And the company recently increased its quarterly dividend by 15 percent, to 38 cents a share.

***Takeaway: Quest Diagnostics appears to have broken out of its lengthy growth slump.*** G2

# INDUSTRY BUZZ

## 23andMe Motion Sickness Study May Be Part of Plan to Remake Company

23andMe, whose business model had taken a huge blow from the intervention of the U.S. Food and Drug Administration, may be gradually repositioning itself as a developer of new esoteric tests.

The California-based firm recently published research in the British journal *Human Molecular Genetics* suggesting there is a genetic link to what causes motion sickness in human beings.

23andMe used sequencing data from 80,000 of its customers to determine 35 such genetic linkages. According to the study, most of the genes are linked to balance and the development of the eyes, ears and cranium (PVRL3, TSHZ1, MUTED, HOXB3 and HOXD3, specifically).

"Until now there's been a poor understanding of the genetics of motion sickness, despite it being a fairly common condition," said 23andMe Scientist Bethann Hromatka, who served as the lead author of the study. "These findings could help provide clues about the causes of motion sickness and other related conditions, and how to treat them, which is very exciting."

That 23andMe undertook such research and published it may suggest that it is looking to develop some molecular tests to determine predisposition to motion sickness. A company spokesperson did not return repeated phone calls seeking comment.

23andMe, whose founder and Chief Executive Officer Anne Wojcicki was until recently married to Google co-founder Sergey Brin, started the company with the intent of performing full DNA analyses of its customers and reporting on their potential risk for hereditary diseases.

However, the Food and Drug Administration intervened in 2013 and insisted that 23andMe's testing be subject to pre-market approval because of the nature of the analysis being performed.

The company has since scaled back its testing service to focus solely on the ethnic and geographical origins of its clients. It submitted for FDA approval last June a potential genetic screening for Bloom's Syndrome, a relatively rare disorder characterized by short stature, over-sensitivity to sun exposure, and a higher risk for developing cancer. The agency has yet to make a ruling for that assay.

***Takeaway: 23andMe is looking for ways to refocus and restart its product pipeline.***

### References

**23andMe**
650-938-6300

**Ambry Genetics**
949-900-5500

**Chi Solutions**
800-860-5454
sdougherty@chisolutionsinc.com

**Claritas Genomics**
617-553-5880

**College of American Pathologists**
847-832-7000

**Myriad Genetics**
801-584-3600

**North Shore-LIR**
631-277-1035
JCrawford1@nshs.edu

**Palmetto GBA**
803-735-1034
mike.barlow@palmettogba.com

**Pathway Genomics**
858-450-6600

**Quest Diagnostics**
973-520-2700

**Note the change of address effective immediately.**
**© 2015 Plain Language Media, LLC, 15 Shaw Street, New London, CT, 06320, 1-888-729-2315**

**To subscribe or renew LIR, call now: 1-888-729-2315**
*(AAB and NILA members qualify for a special discount, Offer code: LIRNI1)*

**Online:** www.G2Intelligence.com/LIR
**Email:** customerservice@plainlanguagemedia.com
**Mail to:** Plain Language Media, LLC, 15 Shaw Street, New London, CT, 06320
**Fax:** 1-888-729-2315

*Multi-User/Multi-Location Pricing? Please contact Myra Langsom by email at myra@G2Intelligence.com or by phone at 1-203-227-0379.*

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

Kelly A. Briganti, JD, Editorial Director; Barbara Manning Grimm, Managing Editor; Ron Shinkman, Editor; Stephanie Murg, Managing Director of Conferences & Events; Kim Punter, Director of Conferences & Events; Myra Langsam, Corporate Licensing Manager; Jim Pearmain, General Manager; Pete Stowe, Managing Partner; Mark T. Ziebarth, 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 1-888-729-2315.***