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LABORATORY INDUSTRY REPORT™

Vol. 14, Iss. 4, February 13, 2014

HIGHLIGHTS

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LabMD Shuts Down After Lengthy Battle With FTC

LabMD has shut down after a years-long tangle with federal regulators regarding the safeguarding of its patient records.

The Atlanta-based laboratory, which focused on uropathology assays, received a formal complaint from the Federal Trade Commission (FTC) last August regarding security breaches involving the personal health information of about 9,000 of its patients.

The incident was traced to a breach of LabMD's computer firewall when an employee had downloaded a peer-to-peer music-sharing application to listen to songs while she worked. The data appeared on the music-sharing service's own network and was eventually accessed by identity thieves, the FTC claims.

The breach is an unusual one; most involving employees are tied to their losing or having had stolen unencrypted laptop computers or smartphones containing sensitive data. According to statistics from the U.S. Department of Health and Human Services (HHS), only 38 of nearly 800 large patient data breaches reported to the agency have been tied directly to hacking incidents involving a health care provider's server.

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Growth Continues to Remain Elusive For Quest, LabCorp

Quest Diagnostics and LabCorp remain highly profitable companies and are by far the biggest players in the clinical laboratory sector, but they have bumped up against a growth ceiling. And if that ceiling is glass, it is a lot thicker than expected.

Although Quest's restructuring program under Chief Executive Officer Steve Rusckowski is now bearing fruit in the terms of a fatter bottom line, revenues continue to shrink. Meanwhile, LabCorp's growth has almost come to a complete halt and failed to meet earnings estimates.

"It is clear to us that health care utilization declined broadly in 2013. And it is conceivable that this trend could continue through 2014 based on the acceleration of employer-to-employee cost shifting and benefit plan design," Rusckowski told investors during a call to discuss earnings late last month, adding that the slow rollout of the Affordable Care Act means it will take longer than expected for benefits to accrue.

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LabMD Shuts Down After Lengthy Battle With FTC, *from page 1*

The FTC had been investigating LabMD and several other companies since 2010 about failures to safeguard consumer information. According to the FTC, the breaches constituted a deceptive and unfair trade practice.

LabMD officials have argued that the HHS is the appropriate agency to oversee potential breaches involving patient data, and that while it wanted to cooperate with the FTC, the agency has never provided a specific road map for complying with its demand to protect patient privacy.

Although the issue is one of compliance, the tangle over how to satisfy regulators led to the closing of a lab that had 25 employees and had been in operations for nearly 20 years.

"LabMD's wind down is largely due to the FTC's abuse of power," the company said in a statement. "Absent any established or uniform data security standards; absent Congressional approval to regulate data security practices; absent a consumer victim from any alleged LabMD security breach; all without alleging that LabMD violated HIPAA privacy regulations, the FTC has spent untold taxpayer dollars investigating LabMD, destroying jobs and usurping power over patient information from the [HHS]."

LabMD's chief executive officer, Michael Daugherty, has claimed that a company wanting to provide it cybersecurity services tipped regulators about the incident when he chose not to contract with that firm. He has written a highly critical book about the FTC and has been making speeches about the topic. A nonprofit, self-styled government watchdog called Cause of Action has also been providing legal counsel to LabMD.

Takeaway: An investigation by the FTC into a data breach at LabMD in Atlanta has forced the lab to shut its doors. G2

LabCorp Acquires MedLab's Terre Haute Operations

LabCorp is playing white knight in the ongoing saga of the MedLab bankruptcy, riding in on a stalking horse to purchase its Terre Haute, Ind., operations.

A stalking horse is a fancy name for an entity placing a price floor for bidding in an asset auction. It has guaranteed that it will pay a set amount for the asset unless it gets outbid by another party.

In this case, Wilmington, N.C.-based LabCorp paid $10.5 million at auction on Feb. 10 to acquire Terre Haute Medical Laboratory and Pathology Associates of Terre Haute. Both assets belong to Laboratory Partners, which primarily operates under the name of MedLab. There were no other bidders, according to Laboratory Partners Chief Executive Officer Bill Brandt. Under the stalking horse guidelines, LabCorp could have been outbid and would have received a $300,000 fee for its troubles.

Brandt said that LabCorp was a logical buyer for the business, which performs about 1.2 million tests and 500,000 accessions annually. LabCorp already pur-

chased MedLab's laboratory outreach business last year for $10.7 million, the sale part of the company's plan to restructure and streamline. But a continued deterioration of its business prompted MedLab to file for bankruptcy last October and engage in a plan to sell off its assets. The company has a significant stake in lab testing in the skilled nursing facility sector, a highly competitive sector that has been hit hard by cuts in reimbursement.

Pending approval by a bankruptcy judge later this week, Brandt said he expects the deal to close by early March. It does not include a contract to operate a nuclear testing laboratory for Union Hospital in Terre Haute. Brandt said those operations will likely be returned to Union in the form of a reversion sale.

MedLab, which operates in eight states and the District of Columbia, was also close to completing a deal to sell its long-term care laboratory business to Florida-based American Health Associates (AHA). Brandt said the first phase of that deal is also expected to close in March, with separate future closings this spring as AHA obtains licensure to operate in all the states where MedLab does business.

Takeaway: MedLab is edging ever closer to liquidating all of its assets.

PGDx Licenses Cancer Detection Technology From Johns Hopkins

Personal Genome Diagnostics, a Baltimore-based molecular testing firm that focuses on oncology diagnostics, has licensed a technology from Johns Hopkins University to increase its ability to detect cell-free cancers.

PGDx has obtained rights to use a technology called PARE, an acronym for personalized analysis of rearranged ends. It allows the lab to detect tumor DNA free of any cells in a patient's bloodstream. It also allows for the detection of structural changes in the cancer DNA that would assist oncologists in developing a treatment protocol. The tests may be performed without having to perform biopsies, which can be particularly extensive and painful for some kinds of organ cancers.

Terms of the licensing arrangement were not disclosed.

"Our success in routinely using cell-free circulating DNA from cancer patients to conduct advanced genomic analyses is a prime example of how our ongoing access to world-class genomics research, proprietary technologies, and clinical expertise is benefiting our growing customer base," said Antony Newton, PGDx's chief commercial officer.

PGDx was launched in 2010 as a spinoff from Johns Hopkins, headed by two cancer genomics professors, Luis Diaz, M.D., and Victor Velculescu, M.D. The company's primary products are CancerSelect, which can detect genetic alterations in 120 specific cancer genes, and CancerComplete, which detects specific mutations in cancer genes to better target treatments. The firm has grown from just the two physicians to more than a dozen employees.

Takeaway: Companies spun off from academic research may have an advantage in obtaining cutting-edge sequencing technologies.

Inside The Lab Industry

Direct-to-Patient Lab Results: Who Will Benefit?

For decades, it has been a given throughout much of the laboratory industry that test results go directly to the doctor who has ordered them.

Only nine states have laws on the books specifically allowing the patient to receive test data. Most states have no law at all, simply defaulting to the federal rules, which require direct transmission to a physician.

But much has changed in delivery and financing of health care in recent years. Significant cost-shifting to patients by payers—accompanied by slow but ever-gathering momentum toward price transparency and consumerism—has nudged patients closer to the center of their own health care delivery and the relevant decisionmaking processes.

As a result, the U.S. Department of Health and Human Services (HHS) issued a rule earlier this month that essentially upends how laboratories deliver the results of the hundreds of millions of assays they perform every year. In a significant revision of the Clinical Laboratory Improvement Amendments rules that have governed the sector for more than a quarter of a century, labs will soon be required to send test results directly to patients should they request it.

The change did not come easily. The rule was originally proposed in 2011, and there was more than two years of back-and-forth between the government and the lab sector as to how its final version should read. Labs had resisted parts of the new rule during the review process, particularly the HHS's estimation they would have a relatively easy time formulating methods for delivering results to patients.

In the end, though, lab groups are supportive of the new rule, although they urge caution.

"AACC strongly supports patient empowerment and health literacy and believes that patients should have greater access to their test results so that they can take a more active role in managing their health," said Janet Kreizman, president of the American Association for Clinical Chemistry.

"ACLA applauds HHS and the Centers for Medicare and Medicaid Services (CMS) for making a clear, unequivocal statement that the rule will now preempt more restrictive state laws that previously limited patient access," said Alan Mertz, president of the American Clinical Laboratory Association.

But both Kreizman and Mertz warned that patients should not go it alone in interpreting the esoteric names and numbers that comprise a good many tests results, suggesting that to do so would cause unnecessary anxiety.

"ACLA encourages patients to work closely with their physicians and health care providers to understand the meaning of what is often very complex medical information," Mertz said.

And now that change has arrived, what does it mean for the laboratory business as it moves forward?

Although the rule change should not have a significant impact on laboratory test volumes—those assays will have to be performed no matter what—it could mean changes for some of the sector's long-held business models. That means potential opportunities for those labs already aiming for a more consumer-oriented audience. It could also prompt many labs having to quickly reconfigure how they deliver test results.

But observers say it will be a mixed bag as to whether labs will actually benefit from the new rule or figure out means to exploit it.

Chance for Revenue Questioned

Susan Dougherty, vice president of operations and outreach services for Chi Solutions, a Michigan-based consulting firm that specializes in laboratories, believes there is little opportunity for traditional labs to take advantage of the new rule.

> ***"Labs are not set up to effectively and efficiently deliver results to patients."***
>
> ***—Susan Dougherty, Vice President, Chi Solutions***

"As far as creating new revenue opportunities, what I mostly see is if there was a charge associated with a delivery of results to patients," Dougherty said, but added that likely would be offset by the cost of actually delivering that data in a timely manner. "There would have to be some sort of investment in order to do so . . . labs are not set up to effectively and efficiently deliver results to patients."

Current Demand Questionable

Even those labs already equipped to deliver test results to patients report little demand from them to do so. PAML, a large regional laboratory based in Spokane, Wash., has experienced that firsthand. Although PAML's home state specifically bars test sharing with patients, it also has operations in neighboring Oregon, which specifically permits such sharing.

Nevertheless, demand from patients in Oregon for their test results has been minimal, according to PAML Chief Executive Officer Francisco Velázquez, M.D.

"I don't think we're inundated," said Velázquez, who was unable to provide any specific data on result requests from patients. Under Oregon regulations, patients who want their test results have to appear at a physical site operated by PAML, fill out a request form, and provide identification.

But Velázquez believes there will be a bump in demand for test results in the coming years. In particular, cost-shifting is driving more curiosity as to what patients are getting for their money. "We're also seeing a more educated consumer patient base interested in participating in their care," he said.

One company is definitely looking forward to the implementation of the new data-sharing rule. Theranos, the Silicon Valley startup that has

patented a number of ways to draw minute amounts of blood in order to perform scores of assays, has been opening outlets within the Walgreens retail pharmacy chain to deal directly with consumers. The company charges 50 percent of Medicare rates for items on its test menu.

"We are excited by this announcement and encouraged by the progress being made at the federal level to encourage individuals to play an active role in their health care," said Elizabeth Holmes, Theranos's founder and chief executive officer. "The best solution to our rising health care costs is to empower individuals to play a bigger role in managing their and their families' health."

When providers do furnish easy patient access for tests, demand tends to follow.

The University of Pennsylvania Health System has been delivering test results from routine assays via an electronic patient portal since 2010. Although UPenn Health's 14 labs perform about 6 million tests each year, results are sent to patients within a couple of days after a physician has reviewed them.

"I can pretty much bet we're way ahead of the curve on this."
—Irving Nachamkin, Director, Division of Laboratory and Pathology Medicine, Hospital of the University of Pennsylvania

"It's very popular," said Irving Nachamkin, director of the division of laboratory and pathology medicine at the Hospital of the University of Pennsylvania. The portal also includes some interactive features, such as allowing patients to graph their blood sugar levels over specific periods of time. The online access to records has played some role in UPenn Health patients requesting manual pulls of paper records. Paper records are also provided to hospital lab outreach patients, although that too will soon be shifted over to an electronic process, according to Nachamkin.

"I can pretty much bet we're way ahead of the curve on this," he said.

Both Velázquez and Dougherty believe that if there is mounting demand for tests results, it likely will be split by generation, with younger patients likely more eager to see their data than their elders. And emerging providers such as retail clinics will also likely create many patients who want to get their results transmitted or mailed to their homes.

But labs will not only have their work cut out for them in creating a delivery infrastructure, but also by providing interpretative services so when the patients get their tests, they can figure out what it all means.

"We have to build a model for consumer interpretations," Velázquez said. "But it will be good for the lab industry. Most patients don't understand what we do. This will go a long way in highlighting pathology and labs in the lives of consumers."

Takeaway: Although the change in the test-sharing rules is a major shift for laboratories, it remains to be seen whether it will be a business opportunity or an operational burden. G2

Growth Continues to Remain Elusive for Quest, LabCorp, *from page 1*

As a result, Quest projects that revenue for the year will be flat or down as much as 2 percent, excluding the earnings boost expected from its recent acquisition of Solstas Lab Partners for $570 million. Rusckowski said such deals are expected to grow the company's revenue by 1 percent to 2 percent per year, although industry observers have noted that there are few large targets remaining to acquire that would generate such growth.

The Madison, N.J.-based Quest reported net income for the fourth quarter ending Dec. 31 of $151 million on revenue of $1.76 billion. The bottom line was more than double the $66 million net income reported for the fourth quarter of 2013, but revenue was down slightly, from $1.77 billion.

For full-year 2013, Quest reported net income of $883 million, up more than 53 percent from 2012's $556 million. But revenue was down nearly 3 percent to $7.14 billion, compared to 2012's $7.4 billion.

LabCorp, meanwhile, also reported an uptick in net income, but it was far less dramatic than Quest's: $126.3 million for the fourth quarter ending Dec. 31, compared to the year-ago's $120.6 million—an increase of 5 percent. But revenue barely budged, reaching $1.44 billion, compared to $1.41 billion for the fourth quarter of 2012.

LabCorp recently increased its allowance for doubtful accounts by $5 million due to an increase in patient responsibility.

For all of 2013, LabCorp's net income was $573.8 million, down from 2012's $583.1 million. Revenue was $5.8 billion, up slightly from 2012's $5.7 billion.

As for its 2014 outlook, LabCorp expects revenue to grow no more than 2 percent for the year, with operating cash flow projected between $780 million and $820 million, essentially unchanged from 2013 and down about 2.5 percent from 2012. Although test volume was up 5 percent for the fourth quarter, revenue per requisition was down 2.6 percent.

The company cited factors similar to those holding back Quest: decreased reimbursement from government payers (including payment for molecular diagnostics testing), uncertainty from the ACA, and more cost-shifting to patients. As a matter of fact, LabCorp recently increased its allowance for doubtful accounts by $5 million "due to an increase in patient responsibility," Chief Financial Officer William Hayes told analysts during the company's recent earnings call.

For the most part, LabCorp's expectations were slightly below the expectations of stock analysts. And many remain skeptical of Quest in particular.

"We believe organic volume growth will remain weak and reimbursement headwinds will continue to pressure growth and margins throughout the year," wrote Kevin Ellich and Bradley Maiers of Piper Jaffrey in a recent report on Quest. "While cost-cutting initiatives helped drive slightly better fourth quarter margins, we do not believe reductions in 2014 will be enough to offset the aforementioned headwinds.

Quest's stock has dipped about 10 percent in price since late January, while LabCorp's price has generally been unaffected in recent weeks. However, its current price of around $90 a share is down significantly from the $107 a share it commanded in late November.

Takeaway: Quest Diagnostics and LabCorp have yet to find the way to sustained and robust growth.

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INDUSTRY BUZZ

Myriad Genetics Acquires Crescendo Bioscience

Salt Lake City-based Myriad Genetics has acquired the up-and-coming Crescendo Bioscience Inc. for $245 million in cash.

The full price is $270 million, but $25 million will be subtracted from the final purchase price to repay a loan Myriad previously made to Crescendo.

Crescendo, based in South San Francisco, Calif., specializes in molecular testing for patients with autoimmune disorders. It was founded in 2002. Last year it was ranked the second-fastest-growing health care company in the United States on Deloitte's Technology "Fast 500" list.

The acquisition gives Myriad a chance to diversify its product offerings, particularly in light of a recent U.S. Supreme Court ruling that barred it from holding patents over single genes. That essentially opened the door to other laboratories to offer tests similar to one Myriad offered for diagnosing the genetic likelihood of a patient developing breast cancer.

"This acquisition diversifies our business into a new high-growth, multibillion-dollar market opportunity," said Peter D. Meldrum, Myriad's chief executive officer.

One of Crescendo's most well-known molecular tests, Vectra DA, tests for the presence and progression of rheumatoid arthritis. It affects as many as 1.5 million people in the United States, including tens of thousands of children. The numbers afflicted by the disorder are expected to rise as the baby boomer population continues to age.

In addition to Vectra DA, Crescendo has been developing a variety of molecular assays focused on autoimmune disorders that are expected to be released in the coming years.

"We envision multiple opportunities over the next several years where, as a combined company, we can expand our presence into international markets and provide new innovative products that help improve the lives of patients suffering from autoimmune diseases," said William Hagstrom, Crescendo's chief executive officer. "I believe Myriad will enable us to move to the next level in terms of scale and growth."

Takeaway: Myriad's setback by last year's Supreme Court decision on gene patents appears to be only temporary, as it uses the Crescendo acquisition to diversify its product offerings.

References

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Crescendo Bioscience
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LabCorp
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LabMD
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MedLab
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Myriad Genetics
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February 13, 2014 **www.G2Intelligence.com**

 Laboratory Industry Report (ISSN 2332-3884) 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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