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HIGHLIGHTS

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Quest Stock Gets a Big Temporary Bump From Social Media Burp

It appeared on the lazy Friday before Memorial Day that Quest Diagnostics was on the block. Until it wasn't. And social media played a far larger role in the tale than salient facts.

The New Jersey-based laboratory, the nation's second largest, saw its stock shoot upward from $74 to $89 a share on May 22 after speculation that it may have been preparing for a sale and that it had retained the investment banking giant Goldman Sachs to handle the details. The potential sales price: $95 a share, or more than a 30 percent premium to its recent share price.

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CardioDx Releases More Studies Validating Use of Its Assay

CardioDx, the California-based molecular laboratory, has issued two new studies connecting its blood-based assay to the reduction of further cardiac interventions.

The most recent study, which was published in *Circulation: Cardiovascular Quality and Outcomes*, concluded that the use of the company's Corus CAD test to determine the risk of cardiac obstructive disease led to far fewer referrals for often pricey—and inconclusive—cardiovascular diagnostics and procedures.

The study focused on 718 medically stable and non-acute adults without a history of obstructive coronary artery disease from 21 primary care practices who underwent the Corus CAD assay from September 2012 to August 2014. Those who scored on the lower end of the risk spectrum were 82 percent less likely to be referred for additional testing, according to the data.

"Data from recent studies suggest that physicians have a challenging time accurately risk stratifying patients presenting with stable symptoms suggestive of obstructive CAD," said Joseph A. Ladapo, M.D., an assistant professor of medicine at the New York University School of

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CardioDx Releases More Studies Validating Use of Its Assay, *from page 1*

Medicine and lead author of the study, in a statement. "Our analysis ... demonstrates that using the score that incorporates age, sex, and gene expression in a primary care setting in patients with symptoms suggestive of obstructive CAD can help clinicians safely and efficiently rule-out low-risk patients."

Oftentimes, patients are referred for cardiac stress tests and other workups for symptoms such as unspecific chest pains or tightness. The practice was highlighted in a recent article in the *New Yorker* magazine by physician Atul Gawande, who noted that procedures such as cardiac ultrasounds, the placements of cardiac stents and even heart bypass procedures are commonplace in patients whose medical history and complaint show little need for such interventions, which can cost tens of thousands of dollars and place the patient in other perils. This even happened to Gawande's mother, who received a carotid ultrasound and cardiac catheterization after fainting. It turned out that Gawande's mother had fainted due to dehydration and lack of food.

The second CardioDx study focused specifically on women patients and was published online by *Menopause: The Journal of The North American Menopause Society*. The study focused on 320 women who were medically stable but had symptoms suggesting they might have obstructive coronary artery disease. Of those women, 77.5 percent had Corus CAD test results suggesting they had a low risk for the disease. Only 4 percent of those women were referred for additional diagnostics and treatments.

CardioDx officials indicated the test can prove especially useful in women, who are often more difficult to diagnose as having obstructive coronary artery disease than men and therefore are often subject to more testing and other procedures that may be medically unnecessary.

Commercial health insurers Aetna and Coventry Health began covering the assay last year for any non-diabetic adult enrollees without a history of coronary artery disease who are experiencing chest pain or equivalent symptoms. CardioDx also raised $35 million in financing late last year from the Alberta Investment Management Corporation.

Takeaway: CardioDx is providing more clarity as to when interventions are required in patients with some symptoms suggestive of a cardiac issue.

Sequenom to Shut Michigan Lab, Discontinue Rhesus Test

San Diego-based Sequenom has decided to shutter its laboratory facility in Michigan and will move its operations to another facility in North Carolina.

The laboratory in Grand Rapids, Mich. had performed the company's genomic test to detect carriers of the cystic fibrosis gene. That test will now be performed at the company's lab in Raleigh Durham, N.C. That lab will also perform the company's newest assay, HerediT.

"The expansion of our North Carolina laboratory operations to include our HerediT CF carrier screen test will enable us to continue to provide high quality and meaningful test offerings to physicians and their patients while continuing to build value for our shareholders," said Sequenom Chief Executive Officer William Welch in a statement.

In addition to the Michigan lab closure, Sequenom also said it would discontinue its Fetal RHD Genotyping test, which it began offering in 2010. The company indicated that the test, which is used to detect the Rhesus D gene in fetuses, had not contributed significantly to its revenues. It noted that the test may be introduced at a later time.

The announcement of the Michigan lab's closure comes six-and-a-half years after Sequenom acquired it for $4 million in stock and cash from regional hospital operator Spectrum Health and the Van Andel Institute. Sequenom also received a tax incentive package valued at $20 million through 2018 in exchange for a $20.2 million investment in the community.

The company said in a statement that it would "provide transition services and outplacement assistance to affected employees," but declined to provide any specifics about how many jobs would be cut.

"This move enables Sequenom to consolidate locations, and affects a small number of employees," a spokesperson said in response to an email query.

Takeaway: Sequenom is focused on creating efficiencies through facility and test elimination. G2

Illumina Files More Patent Infringement Lawsuits

Illumina continues to pile up the patent infringement lawsuits against Roche Molecular Systems and its laboratory subsidiary.

The San Diego-based Illumina filed a new suit in mid-May against San Jose, Calif.-based Ariosa Diagnostics, claiming the microarray-based version of its Harmony prenatal assay infringes on a patent for "multiplex nucleic acid reactions."

The Harmony assay tests for Down's Syndrome and other potential prenatal genetic issues and helps avoid the use of amniocentesis, which can place a fetus at risk of physical harm. Illumina offers a similar test under its verifi® brand. Ariosa has said the test relies on a proprietary methodology that focuses on cell-free DNA.

Illumina and its Verinata subsidiary have previously filed two other patent infringement suits against Roche and Ariosa, both of which are still pending.

There is some prior bad blood between Roche and Illumina. The latter rejected two hostile takeover bids from Roche's parent company in 2012, including one worth $6.7 billion. Illumina was later sued by one of its larger institutional shareholders for adopting a poison pill provision in order to thwart the takeover bid.

However, Illumina has been particularly aggressive in protecting its testing technology. It sued British firm Premaitha Health earlier this year, saying its prenatal test infringed on its patent in the United Kingdom. It also has sued Sequenom in the past, but late last year the two companies settled their litigation and agreed to pool their intellectual property in order to jointly develop new tests moving forward.

Takeaway: Illumina is ratcheting up pressure on Roche and Ariosa regarding its prenatal tests. G2

Inside The Lab Industry

Quarterly Numbers for Niche Labs Indicate a Maturing Market

As personalized medicine and molecular testing have established themselves in the health care sector, it is leading to more mature growth patterns for the publicly-traded specialty laboratories. Translation: Smaller annual revenue growth, but promising outlooks for future earnings and performance.

Sequenom

Sequenom reported revenue of $37.8 million for the quarter, up just 2 percent from the $37.1 million it reported during the first quarter of 2014. But the company leaped into the black for the quarter, reporting net income of $14.3 million. That's compared to a $15.7 million loss during the year-ago quarter. The company attributed the dramatic shift in part to a $21 million profit through its pooled patents agreement with another local company, Illumina. It also cut operating expenses.

Additionally, Sequenom launched two massive prenatal genomic screening tests, HerediT, which scans for more than 250 genetic conditions, and VisibiliT, a version of the assay for international markets. Overall test volumes were up 6 percent for the quarter compared to a year ago, but volume for Sequenom's most popular test, MaterniT21, was up 12 percent.

Illumina boosted its 2015 earnings forecast by about 2 percent, to around $480 million.

Illumina

Illumina was one of the few labs to report fairly dramatic growth. Revenue for the quarter was up 28 percent for the quarter, to $539 million, compared to $421 million during the first quarter of 2014. But net income truly skyrocketed, to $136.7 million, compared to $60 million a year ago. That was about 25 percent higher than the consensus among analysts. Illumina boosted its 2015 earnings forecast by about 2 percent, to around $480 million. It projects revenue growth for the year to be about 20 percent, to just around $2.2 billion.

In a report discussing the company's earnings, AtonRa Partners commented that "Illumina's addressable market is expected to expand significantly thanks to developments in oncology and non-invasive prenatal testing," and that it was on the right track continuing to expand into liquid biopsies.

Foundation Medicine

Another big growth spurt was reported by Massachusetts-based Foundation Medicine, albeit on a smaller scale than Illumina. Foundation's revenue for the first quarter reached $19.3 million, up 68 percent compared to a year ago. Test volume for its cancer assays was up 67 percent. Revenue per test was $3,400, slightly lower than the year before but still healthy for any laboratory test.

Inside The Lab Industry

However, the company reported a loss for the quarter of $17 million, up from $12.2 million during the first quarter of 2014. Costs and expenses were up nearly 40 percent quarter over quarter.

> *"We're continuing to build a transformational business for the long-term, and we believe we made significant progress in that direction during the first quarter"*
>
> — Michael Pellini, M.D.
> CEO, Foundation Medicine

Foundation CFO Jason Ryan said during the company's earnings call that revenue was projected to be in the $105 million to $115 million range for the calendar year. That's about a 70 percent increase on the low end compared to calendar 2014. However, no projections were made regarding when the company would become profitable. The company did close a development deal with pharmaceutical giant Roche that will bring in about $250 million in capitalization and ensure that its developing product pipeline remains robust.

"We're continuing to build a transformational business for the long-term, and we believe we made significant progress in that direction during the first quarter," Foundation CEO Michael Pellini, M.D., said in a statement.

Genomic Health

With help from its Oncotype prostate cancer detection test, Redwood City, Calif.-based Genomic Health reported revenue of $68.2 million for the first quarter ending March 31, up 2 percent from the first quarter of 2013 and 3 percent when currency fluctuations are taken into account.

The company said volume for its prostate cancer test tripled year-over-year, while the breast cancer test showed moderate growth.

The company reported a loss of $15 million, up from $7.4 million during the first quarter of 2014, slightly more than the consensus. Chief Financial Officer G. Bradley Cole told analysts that the company took a $5.5 million non-recurring charge associated with winding down some of its breast cancer research operations. Instead, the company would be focusing on liquid biopsy testing—i.e., blood over tissue samples. It also missed about $800,000 in revenue associated with breast cancer testing due to payer delays in implementing a new CPT code for the procedure. That revenue is expected to be recouped over the next couple of quarters, he added.

"Looking ahead we believe we are well positioned to deliver key reimbursement milestones and clinical data presentations to drive further test utilization and revenue growth, returning us to profitability by the end of the year, while strengthening our position at the forefront of precision medicine with our liquid biopsy pipeline," said Kim Popovits, Genomic Health's chief executive officer, in a statement.

Inside The Lab Industry

That shift in focus has cheered some stock analysts. Amanda Murphy of William Blair & Co. in Chicago said that Genomic Health should fare well down the line. "We believe that given the company's meaningful commercial infrastructure and strong brand reputation, Genomic Health is well positioned to be a key player in genetic-based testing," she wrote in a recent report.

The overseas market remains relatively small for Myriad, but it grew 63 percent quarter over quarter, primarily through sales of its EndoPredict breast cancer prognostic assay.

Myriad Genetics

Salt Lake City-based Myriad Genetics continued to be hurt by the loss of its legal battle over the BRCA gene patents, and reported revenue of $180 million for its fiscal third quarter ending March 31. That's down from $182.9 million for the year-ago quarter.

The company remained profitable, with net income of $21.5 million, compared to $36.8 million for the third quarter of fiscal 2014, and actually beat analysts consensus by a penny a share.

For the first nine months of its fiscal year, Myriad reported net income of $61.5 million on revenue of $516.6 million. That compares to net income of $142.6 million on revenue of $565.3 million during the first three quarters of last fiscal year.

The company did report a significant gain in rheumatology testing through its Crescendo Bioscience affiliate, but that remains a small part of its business. It also announced the purchase of a clinic in Germany that will allow it to be reimbursed by the payers in that nation for tests. The purchase avoided a regulatory process that can take years to complete before being able to accept revenue from payers.

The overseas market remains relatively small for Myriad, but it grew 63 percent quarter over quarter, primarily through sales of its EndoPredict breast cancer prognostic assay. Switzerland recently accepted the test into its health care system, after a study indicated it saved $3,500 per patient in health care costs compared to older diagnostic approaches.

But as a result of Myriad's quarterly numbers, Blair's Murphy lowered fiscal 2015 revenue estimates to $720 million from $739 million and fiscal 2016 revenue to $754 million from $813 million. Its fiscal 2014 revenue was $778 million.

Trovagene

San Diego-based Trovagene, by far the smallest of the niche labs, reported revenue for the first quarter of $127,000, up from $111,000 in the first quarter of 2014. It reported a loss of $7.2 million, compared to $3.2 million a year ago. The company said it had entered into collaborations with both the City of Hope and University of California San Diego to test its platform for detecting certain lung cancer mutations.

Takeaway: Earnings reports for the niche molecular labs are mixed, but generally reflect the growth curve of a more mature market. G2

Quest Stock Gets a Big Temporary Bump From Social Media Burp, *from page 1*

On the face of it, Quest pulling a massive deal makes some sense. It recently lost its number one position to LabCorp after it acquired the pharmaceutical giant Covance. And while the company is growing, it will do so only modestly for the foreseeable future.

Quest's stock dropped back rapidly—but not completely to its pre-rumor price.

However, the announcement did not come from official channels, but a Twitter posting from a would-be Master Of The Universe named Joe Kunkle. He runs a company in Pennsylvania called OptionsHawk, which sells a subscription service to investors wanting to make money on options, a chit that allows you to be able to buy a stock at a certain price at a certain time, regardless of what its trading price is. Options are priced far lower than the stocks they permit you to buy, and they are much more volatile.

Kunkle, however, quickly backpedaled on the rumor and deleted the tweet. "All I did was pass along what was said across the Internet on the market," he told *Bloomberg News* not long afterward. Kunkel also said he had no position in Quest stock or options.

Quest's stock dropped back rapidly—but not completely to its pre-rumor price. On the Tuesday after Memorial Day weekend, it was trading at $77 a share, up about 4 percent from the pre-Kunkle bump.

If the rumor proved an embarrassment to Kunkle, it nonetheless made some day traders extremely happy. "Woke up late, and made $800 shorting (Quest) in my first 5 mins in the market," tweeted one trader. "Covered Quest. Nice profit and & i didn't even have to subscribe to the service," wrote another trader, in reference to Kunkel's subscription business.

While the Twitterverse was yapping about Quest spiking and falling, less ethereal parties—such as the actual company and the stock analysts who cover it—were much more closed-mouthed.

"We do not comment on rumors or speculation," Quest spokesperson Wendy Bost said in an email.

Amanda Murphy, an analyst who covers Quest for William Blair & Co. in Chicago, gave a similar response. "Unless there's substantiated news, we can't comment on it," she said, adding that the behavior of the stock price should suffice as to the authenticity of the takeover news.

One analyst, Wells Fargo Securities' Gary Lieberman, actually stuck his neck out in a research note he issued not long after the furor subsided. Quest, he said, is not likely to combine with another large lab, although he did say the company going private is "more feasible." However, Quest's lack of hard assets relative to other health care companies going private and the need to finance some $9 billion in debt to execute a deal at $95 a share to go private may prove obstacles, he wrote.

Lieberman is one of the tougher analysts of Quest, and he maintains an underperform rating with a future target price of $60 to $65 a share. Whether that's Quest's actual future or another one may be formulated remains to be seen.

Takeaway: Rumors swirling around the future of Quest appear to be just rumors. G2

INDUSTRY BUZZ

LabCorp Launches Hepatitis C Drug Resistance Tests

LabCorp has launched two new tests to determine patient sensitivity to extremely pricey drugs that treat hepatitis C.

The North Carolina-based LabCorp has introduced the HCV NS5A and NS5B assays. Those tests, which use next-generation sequencing, are intended to determine how a patient would respond to a treatment regimen of sofosbuvir, ledipasvir, or a combination of the two drugs.

Sofosbuvir and ledipasvir have roiled the U.S. health care and pharmaceutical sectors over the past couple of years. They can cure more than 90 percent of the cases of hepatitis C over several weeks with few side effects. Prior to the introduction of the drugs in 2013 and last year, the primary way to treat the disease was with a liver transplant. Altogether, the U.S. Food and Drug Administration has approved a half-dozen direct acting antiviral drugs for hepatitis C since 2011.

About 3 million Americans have been diagnosed with hepatitis C. Prior to the introduction of the drugs, up to 5 percent of them would eventually die from chronic liver inflammation.

However, a dose of the drugs in single or cocktail form can cost $90,000 or more—a price that has forced some insurers and state Medicaid and prison medical programs to place caps on how much they could spend on regimens for enrollees. However, resistance to the drugs also means some patients could receive a treatment that is as expensive as it is futile. The new tests mostly eliminate that risk.

Although LabCorp would not disclose the current or potential market for the new tests, F. Samuel Eberts, the company's senior vice president of corporate affairs, said in an email that "we are very pleased with physician interest and use of our industry leading assays."

Those two tests, in addition to an assay LabCorp introduced in 2011, HCV GenoSure NS3/4A, allows the company to provide a "complete (hepatitis C) portfolio," Eberts wrote.

Takeaway: LabCorp's new assays will likely eliminate expensive and futile treatments for some sufferers of hepatitis C. G2

References

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CardioDx
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Foundation Medicine
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Genomic Health
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