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HIGHLIGHTS

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Quest Collaborates With French Researchers to Provide BRCA Variants Data

Quest Diagnostics wants to crack the BRCA gene wide open. The New Jersey-based national laboratory has joined forces with a French research institute to create a wide-ranging, data-sharing initiative on the gene, which can often predict cases of breast cancer.

Quest and Inserm, the French National Institute of Health and Medical Research, have launched BRCA Share, which will provide labs and researchers access to a large accumulation of research into the variants of the BRCA1 and BRCA2 genes.

The database is already of a significant size, the result of test data gathered by 16 laboratories throughout France that participate in the Unicancer Genetics Group (UGG). It will be used to help clarify test results for patients whose BRCA assay identifies a gene variant of uncertain significance. There are more than 3,900 unique variants in the database, of which about 57 percent are classified as being an unknown variant.

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Veracyte Obtains $40 Million in a Private Placement

Veracyte, the California-based lab that focuses on genomic tests to help make clearer decisions for lung, thyroid and other forms of cancer, has raised $40 million in a private placement.

The company sold 4.9 million shares at a price of $8.15 per share to several venture capital firms, including venBio, Broadfin Capital, Camber Capital, Deerfield, and Longwood Capital Partners, in late April. They represent both existing and new investors, Veracyte said in a statement.

Veracyte said the money will be used to fund research and development, for product commercialization, and for working capital and general corporate purposes.

The additional paid-in capital significantly beefs up Veracyte's cash reserves. It had reported $25.8 million on hand at the end of March.

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Veracyte Obtains $40 Million in a Private Placement, *from page 1*

In 2014, Veracyte reported robust growth. For the fourth quarter of 2014 ending Dec. 31, revenue was $12.2 million, up 78 percent in contrast to the $6.8 million in the fourth quarter of 2013. For calendar 2014, revenue was $38.2 million, up nearly 75 percent compared to full-year 2013 revenue of $21.9 million. However, it lost $8.1 million in the fourth quarter of last year and $29.4 million for 2014, both higher than in 2013.

For 2015, the company forecast revenues of $48 to $53 million, another significant uptick. It did not provide any forecast for profitability.

Veracyte launched its first commercial test, Afirma, in 2011. It is used to type thyroid cancers and suggest non-surgical courses of treatment. Veracyte said in a recent filing with the Securities and Exchange Commission that the test had helped patients avoid some 15,000 thyroid surgeries and $200 million in related medical expenses as a result.

Veracyte recently launched Percepta, a molecular assay intended to provide clarity to patients with nodes on their lungs who have unclear results from a bronchoscopy. The intent of the test is to avoid invasive lung biopsies.

Veracyte Chief Executive Officer Bonnie H. Anderson said in a statement that Percepta would complement recently issued federal guidelines that provide annual low-dose CT scans for about 8 million Americans who are considered to be at high risk for contracting lung cancer.

The company also recently entered into a collaboration with GE, another Veracyte investor, to use its digital imaging technology to improve disease diagnosis.

Takeaway: Veracyte has significantly beefed up its cash on hand as it releases a new test.

Pathway Genomics Introduces Comprehensive Colorectal Cancer Panel

San Diego-based Pathway Genomics has launched new testing panels that provide in-depth analyses of the risks for colon cancer.

The panel known as ColoTrue zeroes in on pathogenic variants in 15 genes that suggest a higher risk of contracting colon cancer, particularly for those 5 percent of patients who are at much higher risk of contracting the disease through the passing down of mutated genes.

"ColoTrue allows providers to test several high-risk colorectal cancer genes at once, rather than testing gene by gene," said Ardy Arianpour, Pathway Genomics chief commercial officer, in a statement. "This saves time and provides valuable personalized information about other potential cancer risks and options for management."

Colon cancer is the third most common version of the disease diagnosed in the United States, with about 93,000 new cases reported every year, according to data from the American Cancer Society. It is the second leading cause of cancer deaths, with about 50,000 patients dying every year, although the death rate has

been dropping in the past decade due to more aggressive preventive screenings for the disease.

Along with identifying particular risks to colon cancer, Pathway officials said the panel can also potentially raise red flags for risks of other forms of the disease.

"A pathogenic variant in a cancer susceptibility gene can have tremendous impact on a patient, not only for their own health management but for their family's health," said Julie Neidich, M.D., Pathway Genomics laboratory medical director, in a statement. "It's important for providers to consider genetic testing in cases of colorectal cancer, especially where the patient is younger or has a strong family history of cancer."

In addition to ColoTrue, Pathway Genomics also introduced a panel that tests for the five genes associated with Lynch Syndrome, an inherited condition that increases the risk for both colon and rectal cancer, as well as many other forms of the disease. That assay can be flexed to ColoTrue if no pathogenic variants are found.

Takeaway: Pathway Genomics is diversifying its assays for colorectal and associated cancers.

Highmark Blue Shield Will Make Metamark Assays Available to Enrollees

Massachusetts-based Metamark Genetics has reached a deal with Highmark Blue Shield to make its urology assays available to its enrollees.

The agreement with Highmark provides Metamark's tests to 5.2 million enrollees in Delaware, Pennsylvania and West Virginia.

Metamark's ProMark assay uses tissue biopsies to determine treatment options for patients who have been diagnosed with prostate cancer. The test focuses on patients with intermediate Gleason scores where it may be difficult to chart a specific course of action, and it can determine more than 90 percent of the time whether the prostate cancer is indolent and would be best treated through watchful waiting, or aggressive and should be addressed through an immediate intervention. Metamark made the test available to clinicians last year after completing validation studies.

In addition to Promark, Metamark also distributes the Progensa PCA3 assay, a urine-based molecular test developed by Hologic that provides additional confirmation to men who have already had several negative biopsies.

"There is increasing awareness among payers regarding the potential for new diagnostic tools to improve patient care and decrease health care costs," said Metamark Chief Executive Officer Shawn Marcell in a statement. "Metamark is at the forefront of this transformation, taking a comprehensive approach to the disease that combines our deep uropathology expertise with tests that help urologists to make more personalized treatment decisions for their patients. We ... look forward to working with Highmark to expand availability of Metamark's novel tests."

Takeaway: Metamark's prostate cancer assay is making inroads into the commercial payer market.

Inside The Lab Industry

Repeal of the SGR Brings Some Uncertainty to the Future Practice of Pathology

The Sustainable Growth Rate formula, or SGR, had a trajectory not unlike that of a child actor who offended the wrong director or studio executive.

Passed into law in 1997, it broke into the business of regulating Medicare reimbursements to providers at the age of 5. It did not receive favorable reviews. SGR's mechanistic acting style—based on complex formulas that relied primarily on the overall volume of procedures performed—led to a 4.5 percent reimbursement cut in 2002. That caused an uproar in the provider community.

> *"There was some anxiety regarding a sudden 21 percent decrease in Medicare payments, and a certain complacency that it would not happen."*
>
> — George Kwass, M.D.

After that, the SGR was permanently sidelined. It was replaced with a series of 17 different payment patches authorized by Congress, which dithered about coming up with a bankable replacement. Had Congress not acted on either a patch or SGR replacement, the Medicare Physician Fee Schedule would have dropped more than 21 percent this year as a result of the SGR formula.

But a replacement for the SGR was finally completed last month, after the House and Senate displayed extremely rare bipartisan support by passing a bill containing SGR's repeal and providing a replacement observers say in the lab sector is fairly vague by comparison.

At 18, SGR's career is now completely over. And there were open celebrations of its demise—President Barack Obama held a ceremony in the White House Rose Garden, inviting leaders of the various physician lobbies to the event.

"On behalf of our patients, America's physicians thank the U.S. House of Representatives and the U.S. Senate for their bipartisan and bicameral successful work to build the stable and sustainable Medicare program that will secure high-quality, cost-effective health care," said James L. Madara, M.D., chief executive officer of the American Medical Association, in a statement.

But now that the celebration of SGR's demise has come and gone, the focus has shifted to its replacement, the *Medicare Access and CHIP Reauthorization Act of 2015*, which has quickly acquired the acronym MACRA.

Some Surprise at Repeal

That Congress actually acted to replace the SGR after a dozen-year wait took the pathology community by some surprise.

"There was some anxiety regarding a sudden 21 percent decrease in Medicare

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payments, and a certain complacency that it would not happen," said George Kwass, M.D., laboratory director at the Holy Family Hospital at Merrimack Valley in Haverhill, Mass. Kwass also chairs Council on Government and Professional Affairs for the College of American Pathologists. "But there was much less complacency that the actual repeal would occur. On the whole, this is better than the alternative. People seem to be pleased about that."

Pleased, but apparently uncertain about what the future holds.

"The MIPS is designed to be a more accurate scorecard of each practice's actual quality of care, and to relieve physicians from the onerous burden of current requirements."

— AMA fact sheet

"It is kind of early in the game," said Barry Portugal, president of Health Care Development Services, a Florida-based pathology and hospital laboratory consulting firm. "We know certain things, and we know we have some time."

That time frame is about five years. Through 2019, providers will receive a modest 0.5 percent annual payment increase, at which point it will be eliminated in 2020. There will then be no automatic increases for the next five years.

Although the pay bump is significantly lower than most of the increases that came with the Congressional patches, it provides some certainty for the next several years—until the next portion of MACRA phases in.

Physicians—including pathologists—will be encouraged to move into what is known as the Merit-Based Incentive Payment System, or MIPS. It will replace and consolidate three existing programs: The Physician Quality Reporting System, the value-based payment modifier model and Meaningful Use for the deployment of electronic medical records. There are also other payment mechanisms that could be developed in the future.

"The MIPS is designed to be a more accurate scorecard of each practice's actual quality of care, and to relieve physicians from the onerous burden of current requirements," the AMA said in a fact sheet about MACRA.

If the pathology profession had been rattled by the steep cuts in the technical component of CPT code 88305 a couple of years ago, the tiny payment bumps over the next several years—which Portugal believes will not cover the inflation trend inherent in running a pathology practice—and the changeover to MIPS should prove a wakeup call to truly change the way they practice medicine. If doctors don't participate, they will face future cuts in reimbursement and a large proportion of the mandatory pay increases for Medicare Physician Fee Schedule that will be reinstated starting in 2026.

"It will dramatically force pathologists to reassess operational workflow and productivity in both clinical and anatomic pathology," Portugal said.

Inside The Lab Industry

MIPS Deployment a Mystery for Now

But exactly how MIPS will be deployed in the coming years is a matter for debate. And there are many questions as to the role pathologists would have in creating the more efficient delivery of care. "As far as outcomes go, they are difficult to measure for diagnostic specialties," Kwass said.

> *"As far as what pathologists can do, there is no one-size-fits-all formula. Every practitioner practices with a certain level of efficiency or not efficiency. It becomes a judgment call."*
>
> — George Kwass, M.D.

As a result, the CAP lobbied successfully to put into MACRA a provision that measures the quality of care delivered by pathologists and other medical specialties that do not interface directly with patients using different guides than other specialties. Kwass noted that how different those actual measures will be will hinge on how the regulations mapping out MACRA are promulgated by the U.S. Department of Health and Human Services over the coming years.

"As far as what pathologists can do, there is no one-size-fits-all formula. Every practitioner practices with a certain level of efficiency or not efficiency," Kwass said. "It becomes a judgment call." He added that measuring how physicians practice for efficiency and quality can become a self-fulfilling prophecy, wherein those who do the measuring are determined to measure a specific item, while other more subtle factors can be overlooked.

In the meantime, MACRA will provide funding for physicians and practices to help with the transition. That includes $100 million for technical assistants for small practices. A significant portion of that sum is likely to go to pathology practices, as two-thirds of them have five or fewer physicians.

And while SGR's career was killed in its adolescence, Portugal believes any pathologist over the age of 50 will have to make some hard decisions in the next decade about what to do next, as its demise is also ushering in the end for fee-for-service medicine.

"Can you imagine the craziness in 2026?" Portugal asked, adding that many pathologists will be at a crossroads. "Maybe I am exaggerating, but I think it is going to be terrible and confusing, even though there is a decade between now and then."

Takeaway: It will be a lengthy process to determine how SGR's replacement will impact the pathology community financially.

Quest Collaborates With French Researchers, *from page 1*

"BRCA Share is a new model for public and private collaboration in an age of scientific openness and genomics discovery," said Quest Chief Executive Officer Steve Rusckowski in a statement. "This initiative will harness the power of diagnostic insights to illuminate the role of genetics in inherited cancer. It reflects Quest's value as a provider of insights into disease that enable people to take actions to improve their health. Inserm and UGG's experience in BRCA data curation and excellence in BRCA science make it eminently well suited to co-lead this initiative with Quest."

The initiative received praise from one stock analyst. "This collaboration aiming to improve BRCA variant knowledge is the most robust to date," wrote William Blair & Co. analyst Amanda Murphy in a recent report. "We believe this initiative supports the view that BRCA variant data has value and is a critical component of delivering high-quality clinical interpretation—particularly given that those who want to access the database for commercial purposes will have to pay license fees."

BRCA Share has already picked up a significant client: North Carolina-based LabCorp, which rivals Quest in size as a national laboratory.

However, the initiative has also created some volatility among the other labs offering BRCA testing. The Utah-based Myriad Genetics, which had held a patent on the BRCA gene until the U.S. Supreme Court ruled in 2013 that single genes were not proprietary, saw its stock drop by about 5 percent shortly after Quest made the announcement on April 21. Murphy also noted that the BRCA market was further thrown into turmoil by the announcement of a small California lab that it would introduce a low-cost version of the BRCA test (see Industry Buzz, page 8).

But when it comes to data testing, Murphy noted that BRCA Share is of intermediate size, similar to the Breast Cancer Information Core (BIC) database operated by the National Human Genome Research Institute, but about half the size of ClinVar, another database operated by the National Center for Biotechnology Information.

And she also observed that while the Quest collaboration may present a blow to Myriad, it is not out of the game. Murphy said that Myriad has moved forward with combining BRCA testing into panels that also test for ovarian and colon cancer risk, and that it is refining its current tests to make them more sensitive.

"As data has apparently become more of a focus and labs working together could erode this advantage over time, we continue to believe that Myriad's vast database—amassed since it began offering BRCA1/2 in 1996 and which now includes some of the newer genes it is testing on the MyRisk panel—represents an advantage," Murphy wrote.

Takeaway: Quest Diagnostics' initiative to open up research into BRCA gene variants, is introducing uncertainty into a portion of the molecular testing market. G2

INDUSTRY BUZZ

Color Genomics Offers $249 BRCA Test

An upstart California laboratory is trying to further alter the already shaken-up genomic testing market by introducing a $249 BRCA test.

The test, offered by Burlingame-based Color Genomics, analyzes 19 genes that are currently linked to an inherited predisposition to breast and ovarian cancer. Those include the BRCA1 and BRCA2 genes.

"We founded Color because we want to give every person the opportunity to understand their genetic risk of cancer. This important information gives people the opportunity to work with their physician to manage their risk and make key life choices," said Elad Gil, the company's CEO, in a statement.

BRCA testing for a low three-figure price is a far cry from the $4,000 or so that had been charged for a BRCA assay by Myriad Genetics prior to a 2013 U.S. Supreme Court decision that eliminated its patent on the gene. Competing labs almost immediately began offering their own versions of the test, but usually their price tag remained in the four figures.

"It is no surprise that following the Supreme Court decision on gene patents, commercial laboratories have jumped into the (BRCA) testing world," said Peter Francis, chief executive officer of Clinical Laboratory Sales Training, a Maryland-based consulting firm. "It's a natural business progression for labs to attempt to lower costs/pricing in order to attract new customers."

But whether or not Color Genomics' pricing will create a specific demand remains to be seen.

Francis noted that Color Genomics did not post any data on its corporate website regarding the clinical trials data it may have gleaned from its own BRCA test.

"Physicians typically want to see how the test performs before they subscribe to its clinical accuracy—and, therefore, start ordering the test," he said. "Clinicians need to weigh a lab's price against the test's clinically proven scientific data using a specific methodology. In the current world, $250 sounds very inexpensive. The price alone may make clinicians wary."

Takeaway: Color Genomics' pricing could shake up the BRCA testing market even further.

References

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