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LABORATORY INDUSTRY REPORT™

Vol. 15, Iss. 12, June 18, 2015

HIGHLIGHTS

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Health Diagnostic Laboratory Files for Bankruptcy Protection

It seemed just a brief time ago Health Diagnostic Laboratory (HDL) was a company on a swift and seemingly stratospheric rise. It fell back to earth even more rapidly than it had ascended.

Facing lawsuits from both private payers and the federal government, its revenue dropping precipitously, in default of lending covenants and even the ability to pay its employees in question, HDL filed for bankruptcy protection earlier this month.

The Virginia-based HDL entered into the Chapter 11 filing on June 7 in the Eastern Virginia district of U.S. Bankruptcy Court.

"While we regret the necessity of seeking protection under Chapter 11, it is the right path for us to take, and we see it as an opportunity to better position our company for continued growth and success while strengthening our finances—ensuring our viability as a company for decades to come," said Chief Executive Officer Joseph McConnell in a statement. "As we have seen in any number of industries—the

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OPKO's Hunt for a Big Fish Leads to Bio-Reference

There is an inherent risk when a smaller company acquires a bigger one, but that is exactly what happened when OPKO Health announced it planned to acquire Bio-Reference Laboratories earlier this month in a $1.47 billion stock deal.

Miami-based OPKO's 2014 annual revenue of $91.1 million was less than an eighth of the $832.2 million generated by Bio-Reference—the nation's third largest clinical laboratory. But OPKO is seen by many industry observers as an up-and-comer. Its specialty pharmaceutical development is expected to lead to a nearly tripling of revenue for calendar 2015. As a result, its stock price more than doubled over the past year (although it dipped significantly below that threshold after the deal was announced).

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OPKO's Hunt for a Big Fish Leads to Bio-Reference, *from page 1*

"Recent appreciation in OPKO shares has enabled OPKO to fund this deal," Amanda Murphy, an analyst with William Blair & Co., said in a recent report.

> *"We're trying to make the component parts be more successful than the entity itself."*
>
> — Mark Grodman, M.D.
> CEO, Bio-Reference

OPKO Chief Executive Officer Phillip Frost, M.D., believes that Bio-Reference can help with the marketing and distribution not only of its 4Kscore prostate cancer test—which can help avoid biopsies to make diagnoses—but a credit card-sized point-of-care test for diagnosing analytes. That device could be used to perform a variety of assays developed by OPKO.

"In both cases, Bio-Reference can add greatly to the velocity of uptake of these products," Frost said in a recent call with analysts to discuss the acquisition. He praised Bio-Reference's sales force and penetration with commercial payers. That is an important point for the 4Kscore test, which has yet to obtain coverage from big insurers. Frost added that Bio-Reference's existing genomics business was also quite healthy and complementary, particularly its women's health tests.

> *"This deal is certainly unique and seems to be continuing the trend of other deals announced in the space with the intention to leverage lab data for biopharma drug development and clinical trials."*
>
> — Amanda Murphy
> Analyst, William Blair & Co.

"We're trying to make the component parts be more successful than the entity itself," said Bio-Reference CEO Mark Grodman, M.D. He added that OPKO's product line has the opportunity to transform some facets of clinical care, particularly the 4Kscore test. Grodman said that test could eventually anchor a product line of men's health diagnostic products.

Frost indicated that some portions of Bio-Reference would operate independently of OPKO, but neither he nor Grodman have yet to provide specifics about the post-merger management structure.

"This deal is certainly unique and seems to be continuing the trend of other deals announced in the space with the intention to leverage lab data for biopharma drug development and clinical trials," Murphy wrote, citing recent transactions involving LabCorp and Covance, Quest Diagnostics and Quintiles and Roche and Foundation Medicine. "Based on the stock reactions (to the deal) the strategic rationale seems to be somewhat unclear—at least to investors."

OPKO's stock dropped by more than 15 percent after the deal was announced and remains depressed. Bio-Reference's stock rose about 20 percent and has held that position.

The deal is expected to close later this year, and the financial pressure is on the much larger Bio-Reference to close it. Murphy reported that it would have to pay OPKO $54 million in termination fees to back out voluntarily; $40.5 million if there is some change in events that led to either board making a recommendation against the deal. And if OPKO kills the deal and Bio-Reference merges with another entity within a year, it will still have to pony up $13.5 million.

Takeaway: Despite the revenue asymmetry between OPKO and Bio-Reference, both companies believe they complement each other well. G2

Pathway Genomics Introduces Test That Focuses on Latino Community

Pathway Genomics has brought a new twist to the burgeoning BRCA testing market: An assay directed at the Latino community.

The San Diego-based laboratory has introduced a limited version of the BRCA assay that focuses on eight variants of the gene that are found specifically in Latino patients. The $399 assay is being called the BRCATrue Hispanic and will allow its users to project their risk of contracting breast or ovarian cancer. According to Pathway, the number of BRCA gene variants is higher than average among women of Latin-American/Hispanic descent.

The marketplace for BRCA testing has been extremely competitive since the U.S. Supreme Court ruled in 2013 that a patent could not be held on a single gene.

Although Latinas have lower-than-average mortality rates from breast and ovarian cancer, their screening rates for such diseases are significantly below white women. Health policy experts have suggested the lower levels of health insurance in the Latino community are among the reasons for the disparity.

"The BRCATrue Hispanic (8-Site) test gives providers the option to test specific BRCA1 and BRCA2 pathogenic variants that are recurrent in the Mexican and Hispanic populations," said Pathway Genomics' Chief Commercial Officer Ardy Arianpour in a statement. "This targeted testing provides a more cost-effective testing option for individuals in these populations, and will allow for quicker delivery of results to patients and their providers."

The marketplace for BRCA testing has been extremely competitive since the U.S. Supreme Court ruled in 2013 that a patent could not be held on a single gene. That eliminated the BRCA testing monopoly for Utah-based Myriad Genetics, prompting many laboratories to offer the test at a fraction of the $4,000 Myriad charged. But the multitude of labs offering tests has also prompted some to seek new versions of the tests that can attract a specific audience in order to stand out.

Peter Francis, chief executive officer of Clinical Laboratory Sales Training, LLC, a Maryland-based consulting firm, said the Pathway test is the first assay he has seen that targets a specific ethnic group outside of Jews of eastern European descent. That group is vulnerable to genetic conditions such as Tay-Sachs and Fragile X Syndrome.

Although Francis said Pathway's price tag for the test is very competitive, he questioned whether the company would be able to market it to the Latino community to great effect. Pathway does not have extensive coverage with commercial insurers, he noted.

"I question the number of Hispanic patients that will be educated on/offered BRCA testing by a healthcare provider and able to afford the potential out-of-pocket expense of meeting a deductible or paying outright due to no insurance despite the test's relative low cost," he said in an email response. "Scientifically justifying the R&D expense to institute a terrific test is one thing; getting appropriately reimbursed for it sits on the other side of the equation."

Takeaway: Pathway Genomics is creating a new marketing niche in the burgeoning field of BRCA testing. G2

Inside The Lab Industry

Veracyte Makes Rapid Inroads into Genomic Cancer Testing

Even if the fast-growing Veracyte, Inc. makes its numbers for 2015, it will be about one 200th the size of LabCorp and one 150th the size of Quest Diagnostics.

Nevertheless, the news and buzz surrounding Veracyte these days is outsized, suggesting the South San Francisco, Calif.-based laboratory is capable of punching classes above its weight.

"Veracyte was founded on the premise that we would always start by identifying the right clinical question—the question that reduces unnecessary surgeries and associated costs."

— Bonnie Anderson, CEO, Veracyte

Founded in 2008, Veracyte has focused on creating tests that essentially prove the economic proposition laboratories must make these days: Their work must verifiably reduce health care costs and improve clinical outcomes. That was the intent of company co-founder and Chief Executive Officer Bonnie Anderson from the beginning.

"Veracyte was founded on the premise that we would always start by identifying the right clinical question—the question that reduces unnecessary surgeries and associated costs," said the 57-year-old Anderson. Prior to co-founding Veracyte, she spent more than a decade and a half at Beckman Coulter, where she initially focused on strategic marketing and then focused on creating products for overseas markets and eventually led the startup of the firm's Immunomics Operations.

In those latter roles, Anderson observed that she "really learned about creating, assessing and drawing conclusions around unmet needs in order to formulate those products."

That leads directly to Veracyte, which was started after Anderson took a year off to live with her husband on a sailboat. The company is currently focused on two areas of diagnostics that are of particular concern in the health care sector: Thyroid cancer and lung cancer. The former is perhaps the most overdiagnosed malady on the planet. Even a near microscopic presence of disease prompts millions of people a year to undergo a delicate surgery to remove an organ that could be kept in place—sentencing them to a lifetime of hormone therapy. Lung cancer issues are the polar opposite: Although smokers are the most likely to contract the disease, much tumor growth can occur without symptoms. When cancer is finally detected, it is often a struggle to keep the patient living beyond five years—and that discovery is often at the business end of a painful and invasive biopsy.

Anderson said the company operates on four premises, or pillars. They include being certain Veracyte is informing on the right clinical question; delivering clear value and clinical utility from its products; getting data published in peer-reviewed journals; and making the case to payers so they will write coverage policies to include the products.

Inside The Lab Industry

"It's been a pretty exciting ride. We've clicked off a lot of boxes."

— Bonnie Anderson, CEO, Veracyte

Those pillars appear to be bearing their weight competently. Veracyte brought its first test to market within three years of its founding, had Medicare coverage a year after that, and went public just five years after it opened its doors.

Amanda Murphy, an analyst for William Blair & Co. in Chicago, noted in an interview that Veracyte's biggest strength is that it is able to "attack an underserved market with an opportunity to improve care." She added that the company's initial focus on the scientific evidence and need for patients—as opposed to creating a product first and then seeking a market—is one of its biggest engines of success.

There are also the spectacular growth numbers for 2014. Revenue was up 75 percent compared to 2013. Guidance for 2015 suggests another big growth spurt this year, although the company posted a $29.4 million loss in 2014 and doesn't expect to become profitable in the immediate future.

"Too often, the reverse happens because companies are so married to their own technology," said Heather Creran, a laboratory consultant in Atlanta. "That bias is not conducive to good customer discovery or problem solving."

Meanwhile, the past year—and the last few months in particular—have been so brimming with news that it would seem wise for Veracyte's website to use a separate server for press releases. It has secured a $40 million private placement, had a positive study published in the *New England Journal of Medicine* for a product it acquired just months before, and Anderson was named one of *Fast Company* magazine's most creative people in business for 2015.

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"It's been a pretty exciting ride," Anderson said. "We've clicked off a lot of boxes."

The *New England Journal of Medicine* study focused on Percepta, Veracyte's lung cancer product that it obtained through the purchase of tiny Allegro Diagnostics last year for $21 million. The test was brought to market this past April.

Percepta can complement a bronchoscopy and lavage of a patient's airways. Inconclusive bronchoscopies are commonplace, and typically require patients to undergo a far more invasive lung biopsy. According to the American Society of Clinical Oncology, biopsies are the most costly tool used for lung cancer diagnosis. A recent study of 761 Medicare patients who underwent lung cancer diagnostics determined that $38.3 million was spent on the procedures. Of that sum, 43 percent, or $16.5 million, was spent on biopsies that were negative.

Inside The Lab Industry

The Percepta studies focused on a similarly sized group: 639 patients in AEGIS I and AEGIS II clinical trials who underwent bronchoscopies to investigate lung nodules. Percepta was able to rule out cancer 91 percent of the time, compared to 75 percent for just the bronchoscopy. Combined, the two tests could make accurate predictions 97 percent of the time. In the study, 43 percent of bronchoscopies were non-diagnostic for lung cancer; 64 percent of that group underwent biopsies, and more than a third had benign nodules or lesions.

Most thyroid cancer analysis occurs via fine needle aspiration of nodules, but that leads to an inconclusive determination in up to 30 percent of all cases, prompting a full surgical biopsy to obtain more information.

According to Murphy, Veracyte anticipates Medicare coverage for Percepta by next year, and meaningful contribution to company revenue by 2017. Based on the volume of inconclusive bronchoscopies performed annually, the market in the U.S. could be $300 million or more.

Similar studies have helped to validate the clinical case for Afirma, Veracyte's test for thyroid cancer. Thyroid cancer is fairly easy to detect, and five-year survival rates for all but the most advanced stages of the disease are nearly 100 percent. But treatment for the disease has been extremely aggressive, with many patients having their thyroids removed even with the presence of tiny cancer-like nodules—a phenomenon recently documented by surgeon Atul Gawande, M.D. in *The New Yorker* magazine.

Most thyroid cancer analysis occurs via fine needle aspiration of nodules, but that leads to an inconclusive determination in up to 30 percent of all cases, prompting a full surgical biopsy to obtain more information. The Afirma test analyzes 142 genes associated with thyroid cancer. A 2012 study in the *New England Journal of Medicine* concluded that the test had a negative predictive value of 94 to 95 percent for various forms of thyroid cancer.

Afirma retails for $4,875. It's reimbursed by Medicare at $3,200. But each test that is performed saves an average of $2,600 in other clinical costs for patients. That doesn't even include the cost of lifelong hormone therapy, according to Anderson.

Veracyte's 2015 guidance is between $48 million and $53 million in revenue. Its 2014 revenue was $38.2 million, representing at least a 30 percent increase year-over-year. Murphy forecasts that that growth rate is sustainable for now, "aided by realization of Veracyte's lung franchise in 2017 and beyond."

Takeaway: Veracyte is on the cusp of becoming a significant player in the field of thyroid cancer and lung cancer testing. G2

Health Diagnostic Laboratory Files for Bankruptcy Protection, *from page 1*

airlines, automakers and retailers—Chapter 11 can lead to bright, self-sustaining and competitive futures.

"Through this process, we will secure a better future for HDL, Inc. by better aligning our balance sheet obligations with our operations while ensuring that business will continue as usual," he added.

The bankruptcy filing said HDL would obtain debtor-in-possession financing and negotiate with its creditors. It owes $18.3 million to several lenders, and at least one called in the outstanding balance and did not honor checks to vendors written on the line of credit.

In April of this year, the company entered into a $47 million settlement with the U.S. Department of Justice regarding how it would process samples.

Just a year ago, HDL appeared to have had that bright future without seeking protection from creditors. But the storm clouds gathered quickly.

On June 25, 2014, the U.S. Department of Health and Human Services' Office of the Inspector General issued a fraud warning regarding the payments by laboratories to physicians to process samples, warning those payments could constitute an illegal kickback. It seemed to address directly HDL's business model of paying physicians a $20 processing fee for drawing blood and sending in samples for lab testing.

Less than three months later, the *Wall Street Journal* published a front page story highlighting the fraud alert and putting HDL in the spotlight. Not long after that, HDL co-founder and CEO Tonya Mallory resigned. In April of this year, the company entered into a $47 million settlement with the U.S. Department of Justice regarding how it would process samples.

"The confluence of these events and associated media coverage, as well as certain payer issues and changes in billing practices in certain states that affected the fees earned by HDL from each sample test, caused significant disruption to the Company's business and negatively impacted HDL's recent financial performance," the company said in its bankruptcy filing.

Last year's revenue of $320 million was 15 percent below 2013's $375 million, and net income declined by two-thirds, from $45.2 million to $15.3 million. By the first quarter of this year, the average daily sample test volume dropped to half of what it was in 2013. The eroding numbers broke a covenant with at least one of HDL's lenders, causing a credit squeeze and necessitating the filing.

In addition to the issues with its creditors, HDL is also fighting lawsuits from Cigna, Aetna, its former sales/marketing arm, as well as a whistleblower suit filed by Chris Riedel, a California-based lab owner who now specializes in *qui tam* lawsuits against competitors, claiming they are gaming how contracts are negotiated with private and public payers.

Takeaway: Health Diagnostic Laboratory will attempt to remake itself and restore sliding sales after filing for bankruptcy protection.

INDUSTRY BUZZ

Study Suggests Racial Disparities in Accessing Genomic Test Data

There have long been documented health care disparities by race, but a new study by UCLA researchers zeroes in on how data from a molecular test for breast cancer informs minority patients about their treatment options. According to Ninez Ponce, associate director for the UCLA Center for Health Policy Research and the senior author of the study, the test is OncoTypeDX, which was created and is distributed by Pathway Genomics in Redwood City, Calif.

According to the mail and online survey of 890 Californians who had been diagnosed with early stage breast cancer and took the test, 90 percent were aware that they had taken the blood-based assay, which undertakes gene expression profiling of their tumor. But 20 percent of the patients in the study were unaware of the results of that test.

Ninety-eight percent of Asian-American women and 94 percent of white women were aware that they had been tested. But only 78 percent of Latinas and 85 percent of African-American women were aware they had been tested.

And while 7 percent of all women who tested for breast cancer that had a low risk for recurrence underwent chemotherapy, 15 percent of Latinas and 11 percent of African-Americans underwent such treatment, which can have adverse side effects such as extreme nausea and the loss of hair. About 7 percent of white patients underwent chemotherapy as well, but only about 2 percent of Asian-American women did.

The results are a concern to researchers, who not only believe the disparities are preventing some women of color from receiving appropriate care, but should raise some worries among labs, which are designing such tests specifically to reduce unnecessary utilization and health care costs.

"No one should have to go through the stress and discomfort of chemo without understanding the personal risks and benefits," Ponce said. "At the very least, patients should know their options. Right now, some women may be making treatment decisions based on incomplete information."

Ponce suggested a customized educational campaign may be needed to eliminate such disparities.

Takeaway: Even with equal access to genomic tests, some minority women may not be receiving actionable data.

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