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HIGHLIGHTS

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LabCorp Expands DNA Testing With Acquisition Of Bode Technology

The DNA of LabCorp has changed significantly over the last year as it has made some huge purchases in order to diversify. And as a result of its latest wade deeper into the lab sector gene pool, it will begin testing DNA itself.

The North Carolina-based LabCorp quietly closed a deal earlier this month for Virginia-based Bode Technology, a subsidiary of New York City-based Solution Point International. Terms of the deal were not disclosed.

Bode focuses on DNA collection products, specialized DNA forensic analysis, and relationship (paternity, maternity, and other forms of familial) testing. The company works closely with law enforcement agencies, providing DNA analysis in as little as 90 minutes to match or eliminate specific criminal suspects or establish possession of evidence. It also operates some limited DNA databases and has been of-

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Health Diagnostic Laboratory Releases Patient Efficacy Study for Its Tests

As it continues operating under a regulatory microscope, Health Diagnostic Laboratory (HDL) is making some of the boldest claims to date regarding the efficacy of its cardiac and diabetic health monitoring services.

HDL released a study earlier this month of 7,400 of its patients who received its testing services. According to the study, which was conducted in conjunction with analytics company Optum Health and the University of Richmond, the incidence of heart attacks dropped by 41 percent, ischemic strokes by 17 percent, and complications associated with diabetes dropped by 15 percent. Inpatient hospital admissions were also 21 percent lower compared to the non-HDL cohort.

Using HDL's services increased the total cost of care per patient by $7 per month compared to the non-HDL cohort. Costs for laboratory testing were also $98 per month higher per HDL patient. However, ambulatory care costs were 13 percent lower, emergency care costs

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■ **Health Diagnostic Laboratory Releases Patient Efficacy Study for Its Tests,** *from page 1*

were 19 percent lower, and inpatient costs were 17 percent lower for those using HDL's services.

"Improvements in outcomes emerged in a relatively short time frame [and] although laboratory costs increased, the costs were entirely offset by an expenditure shift away from other medical costs such as emergent care," said Steve Thompson, an associate professor of management at the University of Richmond's Robins School of Business.

According to an HDL spokesperson, Thompson was not available for comment regarding the composition of the non-HDL cohort or other specifics of the study, which has not yet been published in a peer-reviewed scientific journal.

"It is extremely rewarding to see independent data that validates our model and the hard work that all of us put into this organization," said Joseph McConnell, HDL's chief executive officer.

HDL, which grew rapidly between its founding in 2009 and 2012, when its annual revenue peaked at more than $400 million, has been under federal investigation for paying physicians who use its services a $20 shipping and handling fee for patient blood draws. Such payments could be construed as violating federal anti-kickback laws. HDL, which discontinued the practice in June, said it was cooperating with an ongoing investigation by the U.S. Department of Justice. Its founder and former chief executive officer, Tonya Mallory, stepped down earlier this year, replaced by McConnell.

Last month, HDL laid off about 15 percent of its total workforce, about 132 employees in all—the second round of layoffs conducted by the lab this year.

Takeaway: In the midst of a federal investigation, HDL continues to press the fiscal case for using its laboratory services. G2

Are Prenatal Screening Tests Being Oversold by Labs?

Prenatal screening tests offered by several major esoteric laboratories may be prompting some women to terminate their pregnancies based on incomplete information, according to an article published earlier this week by the New England Center for Investigative Reporting.

The article focused on several esoteric labs that offer prenatal screening assays, including the MaterniT21 blood test offered by California-based Sequenom, Natera's Panorama assay, Illumina's verifi, and Ariosa's Harmony assay. Such tests can screen for relatively rare genetic abnormalities such as Edwards syndrome, which is associated with significant birth defects. The labs market the tests as a much safer and less invasive alternative to amniocentesis-based tests.

However, as the article noted, there is a significant difference in the accuracy of screening assays such as the MaterniT21 that can indicate elevated risks of giving birth to an abnormal child and tests that can accurately diagnose whether a fetus has such a condition. For example, an Edwards syndrome screening may be accurate only 64 percent of the time, and other tests less than 85 percent of the time, according to a survey recently published by Quest Diagnostics.

The New England Center article claimed some labs may be overselling their tests while not properly educating patients on the potential for false positives—which rise when screening for particularly rare syndromes. As many as 800,000 screening tests have been conducted in the United States since 2011, and that many mothers are waiting later to have children means demand for such tests is on the rise.

As a result, more expectant mothers may be terminating pregnancies of healthy children. The New England Center cited at least three aborted pregnancies reported by Stanford University as the result of high-risk screening results in which the fetus was perfectly normal. It also cited cases of mothers who received negative results on screening tests who wound up giving birth to children with serious health issues.

The article also cited research commissioned by Natera that 22 mothers out of 356 who received an initially positive screening result terminated their pregnancies without conducting further testing. Natera's assay successfully predicts a genetic abnormality 84 percent of the time.

Takeaway: Esoteric labs offering prenatal testing may be overselling their assays and increasing the risk of the termination of healthy fetuses. G2

JAJ International Developing High-Speed Ebola Detection Test

San Diego-based JAJ International has reported promising results in creating a fast-acting diagnostic test for confirming the presence of the Ebola virus in patients.

Such a test would be considered crucial in containing the spread of Ebola, which has devastated parts of western Africa in recent months—killing some 6,400 people—and has even led to occasional cases being reported in the United States. There is no vaccine against the disease, although researchers in the United States and elsewhere are developing one at a rapid clip. In November, the World Health Organization called for the development of a rapid, low-cost test in order to better combat the epidemic.

According to test trials of JAJ's 10-Minute Ebola Rapid Test, the assay had a sensitivity of 82.4 percent and a specificity of 80 percent during field testing in Sierra Leone. The test has a 10-minute turnaround time and requires just a drop of blood. The current reverse transcription polymerase chain reaction testing can take a day or more and require a tube of blood to make an accurate diagnosis. It costs about $100 to perform. JAJ has not indicated what its test would cost or sell for.

"We understand the difficult physical constraints facing medical professionals in remote clinics," said James Lu, a JAJ vice president.

The company said it would consider a 96 percent sensitivity and specifity as a goal prior to making the test available for general use in Africa. It said it would continue to conduct trials in both Sierra Leone and Ghana.

Takeaway: JAJ may be close to developing a rapid field test for the Ebola virus. G2

Laboratory M&A: Volume of Deals Mostly Unchanged From a Year Ago

As 2014 comes to a close, the volume of mergers and acquisitions in the laboratory sector during the calendar year is hewing close to what transacted in 2013, although there is more movement in the once vapor-locked pathology niche.

According to data from the Florida-based Crosstree Capital Partners, 26 deals have been consummated so far this year, compared to 29 in 2013. One of those 26 deals involved a Canadian laboratory, bringing the U.S. total down to 25.

However, another source in the lab M&A realm has indicated as many as three other deals are in the works and could close before the end of the year.

That's in fairly stark contrast to 2013, when the deal-making essentially ended in the week before Thanksgiving.

"I think it has been an interesting year. There has been a lot of activity on the clinical side, particularly toxicology and direct testing labs, both [being traded] by private equity firms and strategic buyers and what looks to be some consolidation," said David Cox, a partner in the Nashville law firm of h3gm who specializes in mergers and acquisitions. Cox added that he has at least five lab deals currently on his plate.

There have been two deals closed in December alone—LabCorp's acquisition of Bode Technology (see page 1) and Eurofins Scientific's acquisition of Boston Heart Diagnostics Corp. for $200 million, which was announced on Dec. 8. The deal includes $140 million up front and a projected $60 million in future earn-out payouts to its owner, Bain Capital Ventures, based on the company meeting certain milestones.

"We couldn't be more excited to become part of the Eurofins family," said Boston Heart Chief Executive Officer Susan Hertzberg. "Boston Heart will continue to provide our breakthrough testing and services to clinicians and patients under the Boston Heart name and in the same manner our customers have come to expect." The company will operate as a wholly owned subsidiary, and its entire workforce of about 350 employees will be retained.

The deal by the Luxembourg-based Eurofins is the second in 2014 (it acquired Viracor-IBT in May for $255 million). The company was primarily focused on food, consumer product, and environmental testing, but it has been diversifying as of late.

Jeff Ellis, a managing director at Crosstree, said that Eurofins has been particularly active in the U.S. market, although it was not an indication that other foreign laboratories would swoop in on American properties.

"Eurofins is very much a global business, and what is unique about them is that they didn't have presence in clinical diagnostics," which was the primary impetus behind the two deals. "A lot of their general philosophy overall is

that they acquire in a number of different industries, keep labs intact, and continue to build the business further with some financial and parental support."

Ellis added that Eurofins had "some fairly robust revenue goals" and that the company needed to be active in mergers and acquisitions in order to meet them.

Laboratory M&A in 2014 to Date

Announced Date	Target	Buyer	Enterprise Value
Dec. 8, 2014	Boston Heart Diagnostics Corporation	Eurofins Scientific SA	$200 million
Dec. 5, 2014	Bode Technology Group Inc.	Laboratory Corporation of America	-
Nov. 3, 2014	Covance Inc.*	Laboratory Corporation of America	$5.7 billion
Nov. 3, 2014	RedPath Integrated Pathology Inc.	PDI Inc.	$34.8 million
Oct. 31, 2014	West Georgia Pathology LLC	Aurora Diagnostics Holdings LLC	-
Sept. 25, 2014	LipoScience Inc.	Laboratory Corporation of America	$58.3 million
Sept. 22, 2014	Arizona Dermatopathology	Aurora Diagnostics Holdings LLC	-
Sept. 4, 2014	Allegro Diagnostics Corporation	Veracyte Inc.	$20.2 million
Aug. 28, 2014	Epinex Diagnostics Laboratories Inc.	Medytox Diagnostics Inc.	-
July 8, 2014	Path Logic Inc.	Neogenomics Inc.	$6 million
July 3, 2014	Accupath Laboratory Services Inc.	Incyte Diagnostics	-
June 26, 2014	Hallmark Pathology P.C.	Aurora Diagnostics Holdings LLC	-
June 23, 2014	Gentris LLC*	Cancer Genetics Inc.	$6.3 million
June 2, 2014	Mid-Atlantic Pathology Services Inc.	Aurora Diagnostics Holdings LLC	-
May 23, 2014	Laboratory Partners Inc., MedLab Long-Term Care Division	American Health Associates Inc.	$5.5 million
May 12, 2014	Highline Pathology Associates Inc.	CellNetix Pathology & Laboratories	-
May 9, 2014	Viracor-IBT Laboratories Inc.	Eurofins Scientific SA	$255 million
May 1, 2014	Precision Toxicology Inc.	BelHealth Investment Partners LLC	-
May 1, 2014	Medical Center laboratory	Incyte Diagnostics	-
March 4, 2014	Aegis Sciences Corporation	ABRY Partners LLC	-
Feb. 19, 2014	Centogene AG, Canadian Business	LifeLabs Inc.	-
Feb. 4, 2014	Covance Genomics Laboratory LLC*	Laboratory Corporation of America	$10.4 million
Feb. 4, 2014	Crescendo Bioscience Inc.	Myriad Genetics Inc.	$398.3 million
Jan. 28, 2014	Laboratory Partners Inc., Talon Division	Laboratory Corp. of America Holdings	$11.9 million
Jan. 22, 2014	Solstas Lab Partners Group LLC	Quest Diagnostics Inc.	$563 million
Jan. 16, 2014	Lab Bio-Medic	Gamma-Dynacare Medical Laboratories Inc.	-

**Target's primary focus is pharmaceutical and biotechnology clientele.*
Source: Crostree Capital Partners

LabCorp vs. Quest

If there has been one dramatic change in the composition of deal-making, it is the involvement of the two major publicly traded national laboratories. In 2013, seven of the 29 deals—nearly a quarter of the total—involved Quest Diagnostics or LabCorp acquiring a lab. In 2014, those two were involved in six of the transactions—but five of them were consummated by LabCorp. Quest's only deal took place in January, when it acquired Solstas Lab Partners Group LLC for $563 million. Quest did also acquire Summit Health in April for an undisclosed sum, but that company focuses on wellness rather than laboratory services.

Sector observers suggest the dearth of deals on Quest's side this year illustrates a divergence with LabCorp. Quest, which announced a quarterly cash dividend of 33 cents a share earlier this month, may be more focused on cutting costs and building share price, while LabCorp is moving more aggressively in diversifying its portfolio.

"I would expect Quest and LabCorp will compete aggressively, but LabCorp is a much more diversified company at this point," Ellis said.

Pathology Heats Up

Meanwhile, there has been some fairly robust activity in the realm of pathology, which has been beaten up by a steady drumbeat of reimbursement cuts. The most devastating was the 52 percent cut in the technical component of Current Procedural Terminology code 88305 that was implemented last year. It led to overall reimbursement for 88305 dropping by a third, damaging the values of pathology practices and labs.

"Pathology labs had really been on life support on a while, but I think you are starting to see some pickup in that space as well," said Cox, who added that pathology lab owners are becoming more accepting of the fiscal realities of their niche and are making peace with exiting the space.

According to the Crosstree list, there were eight transactions during the year involving the acquisition of pathology labs and practices. The only transaction where a dollar figure was disclosed was Path Logic's acquisition by NeoGenomics for $6 million, among the smallest deals where the terms were announced.

The reimbursement cuts have indeed had an impact on sales prices. According to Cox, deals are being predicated on one to 1.5 times revenue, whereas before the flood of reimbursement cuts, sales were more likely to be based on two to 2.5 times revenue.

Meanwhile, 2015 is expected to have about the same number of deals as in the prior two years.

"I would expect M&A to probably maintain in 2015. I don't expect to see a flood of deals," Ellis said.

Takeaway: The 2014 M&A picture in the laboratory sector is all but unchanged in terms of volume, but the easing up in the pathology market is making deals more diverse. G2

■ **LabCorp Expands DNA Testing With Acquisition of Bode Technology**, *from page 1*

fering highly specialized services, such as clearing up the backlogs of thousands of untested rape kits collected in some jurisdictions.

DNA testing has exploded since it was first used for criminal evidence analysis in the 1990s. Such testing, which initially focused on violent crimes such as murder, has become so ubiquitous it is now routinely used in less serious crimes, such as burglaries and auto thefts, under the theory that the majority of such crimes are committed by a small number of professional criminals, and that identifying their DNA would not only cut down the volume of property crimes dramatically but also potentially link those identified to previously unlinked crimes as well.

LabCorp said in a statement that Bode and its affiliate, Chromsomal Labs, would be folded into its specialty division, working in combination with its existing DNA Identity and Cellmark Forensics businesses, which have operations in both the United States and the United Kingdom. The combined ventures will provide DNA testing to federal and state governments, law enforcement agencies, crime laboratories, disaster management organizations, and to consumers both in the United States and other parts of the globe.

"We are very pleased that Bode Technology is joining the LabCorp family," said LabCorp Chief Executive Officer Dave King. "Bode Technology's capabilities strengthen our range of forensics and DNA identification testing services, furthering . . . our strategy by continuing our leadership in scientific innovation." King added that the transaction is expected to be accretive to LabCorp's overall bottom line within the first year of the acquisition and cover the cost of financing the deal within three years.

Sector observers say the deal is a continuation of LabCorp's strategy to diversify—typified by its daring $5.6 billion acquisition of Covance earlier this year—and that DNA testing would provide a reliable stream of income from law enforcement and other governmental entities.

"You can see that LabCorp is really trying to diversify themselves with deals such as this," said Lâle White, chief executive officer of XIFIN, a San Diego-based laboratory software and consulting firm. "This kind of testing is a very niche type of business, but it is probably contractually price-protected in many ways."

However, as the cost of DNA testing has dropped dramatically—from thousands of dollars in the 1990s to hundreds of dollars or less today—margins tend to be fairly thin.

"My guess is that it could be growing because law enforcement needs this type of testing to proceed with cases, but governments will be price-sensitive and the margins may not be reasonable based on the contracts that would be involved," said Jim Root, a senior consultant with Chi Solutions, a Michigan-based laboratory consulting firm. However, Root stressed that he was not overly familiar with this specific lab segment.

Takeaway: LabCorp continues to diversify its portfolio of lab services via acquisition. G2

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INDUSTRY BUZZ

Saladax Releases Gleevec Companion Diagnostic

Pennsylvania-based Saladax Biomedical has launched a new test intended to better gauge cancer patients' receptivity to a well-known chemotherapy drug.

The blood-based companion diagnostic assay, known as MyImatinib, measures patient sensitivity to imatinib, which is marketed in the United States as Gleevec. That drug is used to treat leukemia, gastrointestinal stromal tumors, and other forms of cancer.

However, determining Gleevec dosage—as with other chemotherapy medications—has been a challenge. Most dosing methodology has been based on determining the surface of the patient's body based on their height and weight. That methodology is nearly 100 years old and has been used since chemotherapy drugs were introduced a half-century ago. Some studies have suggested that with some forms of cancer, underdosing approaches 70 percent. In the United States, about 65 percent of cancer patients undergo chemotherapy regimens during the course of their treatment. Large percentages of those patients will eventually wind up visiting hospital emergency rooms or be admitted as inpatients, according to data from the health care research firm Milliman.

For Gleevec, dosages for patients can range from 100 milligrams to 800 milligrams a day depending on their particular affliction, according to Novartis Pharmaceutical Corp., the company that manufactures and markets the drug. In some cases, such as for gastrointestinal stromal tumors, the regimen can last for years. Side effects for the medication can range from nausea to edema, although in some cases large doses of the Gleevec have been linked to congestive heart failure.

"Our own analysis shows that, in general, 50 percent of patients are not receiving an optimal chemotherapy dosage, which reduces the effectiveness of the treatment or causes significant toxicity," said Saladax Chief Executive Officer Kevin Harter.

Along with the MyImatinib test, Saladax also has marketed assays to determine appropriate dosages for 5-fluorouracil, pacilitaxel, and docetaxel. The company has said that it is developing at least nine other blood-based companion diagnostic tests for cancer patients to be released in the near future.

Takeaway: Saladax is continuing to expand its portfolio of drugs intended to pinpoint chemotherapy treatments.

References

Bode Technology
703-646-9740
Boston Heart Diagnostics
508-877-8711
Crosstree Capital Partners
813-774-4750
Eurofins Scientific
515-280-8378
h3gm
615-256-0500
Health Diagnostic Laboratory
804-343-2718
JAJ International
858-792-6468
LabCorp
336-436-5076
Quest Diagnostics
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