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HIGHLIGHTS

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XIFIN Acquires PathCentral, Plans to Use Technology to Expand Services

XIFIN, the San Diego-based revenue cycle management firm, went above and beyond the call of duty for one of its clients: It acquired it in a deal that closed last month.

XIFIN will use the acquisition of Irvine, Calif., PathCentral to expand its technological capabilities, according to Lâle White, XIFIN's chief executive officer.

The terms of the deal, which was completed on Aug. 9, were not disclosed. Ten of PathCentral's 14 employees were retained by the 210-employee XIFIN, although CEO Jaye Connolly was not among them, according to White. PathCentral will maintain its current corporate office, which is about a 90-minute drive from XIFIN's.

White said that PathCentral became attractive to XIFIN after PathCentral sold its laboratory to Ascend Clinical late last year.

"At that point, they only had the technology piece remaining," White said, adding that XIFIN has no interest in acquiring its lab.

PathCentral's cloud-based laboratory and anatomic pathology and molecular diagnostics laboratory information system was particu-

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Fueled by Genetic Testing, Bio-Reference Reports Strong Earnings, Revenue Growth

While the larger national labs have been grappling with stagnant revenue and earnings, swiftly growing regional player Bio-Reference Laboratories continues to demonstrate vibrant growth.

For the fiscal third quarter, ending July 31, Bio-Reference reported net income of $14.7 million on revenues of $185.4 million. That compares to year-ago net income of $12.6 million on revenues of $172.3 million, increases of 17 percent and 16 percent, respectively.

For the first nine months of fiscal 2013, net income was $34.7 million on revenues of $523.1 million, compared to net income of $29.3 million on revenues of $450.8 million for the year before, up 19 percent and 16 percent, respectively.

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■ **XIFIN Acquires PathCentral**, *from page 1*

larly attractive to XIFIN, as well as its information exchange system that allows medical specialists to upload and share files for electronic consultations and second opinions. XIFIN had provided consulting services to PathCentral in setting up its network and servicing its laboratory.

"Many of our molecular clients are on [PathCentral's network], and it's the only product that works extremely well for molecular testing, as well as anatomic pathology clients. This product suits them both extremely well," White said.

PathCentral's client list included Johns Hopkins University School of Medicine, University of Nebraska Medical Center, Massachusetts General Hospital, Penn Medicine, the University of Southern California, and Kindstar Global, a Chinese laboratory, which provides services to about 3,300 hospitals in China. PathCentral launched its online network back in March.

The eventual goal of the acquisition is to integrate PathCentral's data-sharing capabilities with XIFIN's own portal, according to White.

"Our long-term objective is to use a portal not just for revenue cycle management but physician collaboration," she said. "It will help in the decision support arena."

Takeaway: XIFIN is seeking to create an all-in-one portal solution for its clients with its acquisition of PathCentral's technology.

Insight Genetics Receives Federal Grant To Develop Lung Cancer Biomarker Panel

Nashville, Tenn.-based molecular testing firm Insight Genetics has received a $1.5 million contract from the National Cancer Institute (NCI) to continue to develop assays to better detect lung cancer.

The money is part of a series of small business innovation and research grants the NCI has made to advance research. Insight began working with NCI earlier this year as part of the organization's clinical assay development program.

Lung cancer is the deadliest of cancers in the United States, with the disease killing about 150,000 Americans annually. Another 228,000 are diagnosed with the disease every year. Five-year survival rates are about 15 percent.

Insight's assays focus on how diagnosed non-small-cell lung cancer patients respond to certain treatments. Its primary test, ALK Screen, helps determine if patients will respond to therapies that inhibit anaplastic lymphoma kinase (ALK). The ALK biomarker is associated with a small percentage of small-cell lung cancers.

The grant will be used by Insight to expand its panels, focusing on the ROS1, RET, and DEPDC1 biomarkers for patients who have tested negative for the ALK, KRAS, and EGFR mutations. These biomarkers are found in a significantly larger portion of lung cancer patients than ALK, and their prognoses tend to be among the grimmest.

"Cancer therapies targeting these genetic markers have shown great promise, but we need effective and robust diagnostics to help identify the patients who can benefit from these treatments," said David Hout, Insight's vice president of research and development.

The need for focused treatment is especially crucial for lung cancer patients, who are typically diagnosed at an advanced stage of the disease because it is usually asymptomatic in the earlier stages.

Along with focusing on the new panel of assays, Insight will also continue working with the NCI on the development of real-time screenings for ROS1, RET, and DEPDC1. Such tests would have a 24-hour turnaround time, compared to the three to seven days to perform a fluorescence in situ hybridization detection assay.

Takeaway: Public-private partnerships between the National Cancer Institute and private laboratories are being used to develop assays to better form treatment plans for lung cancer.

National Kidney Foundation Recommendation Could Boost Volume of Urinalysis Assays

The National Kidney Foundation (NKF) has called for a significant expansion of the number of Americans who should be tested for kidney disease, a recommendation that could be a boon for urinalysis tests.

The NKF recommended that all Americans over the age of 60 who have been diagnosed with high blood pressure and diabetes undergo testing for kidney disease by undergoing a urine albumin test as part of annual medical examinations.

The recommendation came out of a recently published study by Johns Hopkins University researchers that concluded that more than 59 percent of Americans would eventually develop at least moderate kidney disease. That is about 190 million people.

"If caught early, the progression of kidney disease can be slowed with lifestyle changes and medications. This underscores the importance of annual screenings," said Beth Piraino, NKF's president.

Should the recommendations be embraced by Americans and their physicians, it could lead to a larger volume of albumin urinalysis tests. Medicare pays for the test at a national rate of $7.33 or $8.19, depending on how it is coded.

Although it's unlikely that labs will be inundated with urinalysis tests over the next few years, at least one national laboratory sees promise in NKF's recommendation. Burlington, N.C.-based LabCorp noted in a statement that providers can request chronic kidney disease (CKD) testing in their routine patient chemistry profiles.

"These expanded screening guidelines will assist in the detection of CKD in more individuals that are currently undiagnosed and untreated, and should help more patients get treatment before serious CKD complications arise," said Mark Brecher, M.D., LabCorp's chief medical officer.

Takeaway: Routine screenings for chronic kidney disease could boost volumes of routine testing.

Inside The Lab Industry

Lab, Pathology Sectors Campaign for CMS To Rethink Changes to Medicare Physician Fee Schedule

A proposed rule by the Centers for Medicare and Medicaid Services (CMS) to cap payments for many anatomic pathology services at outpatient rates has elicited an especially strong response from the laboratory and pathology lobbies.

The reaction has included the hiring of an outside firm to conduct an extensive pricing study and a vigorous electronic grassroots campaign to contact CMS leadership directly.

"In all my years in this industry I have never seen such unity among all the groups—laboratories, pathologists, hospitals, academic medical centers, suppliers, device manufacturers—to rally against the proposal," said Marc D. Grodman, M.D., chief executive officer of New Jersey-based Bio-Reference Laboratories.

The activity appears to be the direct result of a sector that has experienced multiple reimbursement cuts in recent years and has become fearful of weathering more. The cuts range from Medicare reductions that affect all providers, cuts in technical component (TC) of CPT code 88305, cuts and delays in payments for molecular tests, and the end of the TC grandfather protection.

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> ***—Marc D. Grodman, M.D., CEO, Bio-Reference Laboratories***

In this case, CMS proposed in July that any services under the Medicare Physician Fee Schedule (MPFS) whose total payments are higher than the Outpatient Prospective Payment System (OPPS) be capped at the OPPS rates. The proposed changes would apply to the TC and global payments for both pathology and laboratory services.

CMS claimed in its rationale that inaccurate data was used to establish practice expense values under the MPFS. Altogether, it wants to revalue 211 different physician tasks in this manner, including 38 pathology services.

It's unclear if media reports earlier this year about the American Medical Association (AMA) possibly exaggerating the amount of physician labor required to perform specific tasks had anything to do with the CMS proposal.

Altogether, the cuts to laboratory services would average about 26 percent, according to the American Society for Clinical Pathology (ASCP), although it and the AMA have reported cuts to individual services that would be much deeper.

One example cited by the AMA is CPT code 88367, automated in situ hybridization. Reimbursement under Medicare is currently $258.53; it would be cut 79 percent, to $54.92, under the new methodology, even though it is almost never performed in a hospital setting on an outpatient basis.

"The cost of supplies is at three to four times the reimbursement CMS is proposing," said Joanne Glisson, an American Clinical Laboratory Association (ACLA) senior vice president.

The general feeling is that additional reductions on this scale could not be absorbed without the sector undergoing a major reconfiguration.

"If these regulations were implemented next year, it would have a significant negative impact on independent laboratories," said Barry Portugal, president of Health Care Development Services, a pathology consulting firm in Nokomis, Fla. "It doesn't mean they would close, but there might be mergers of independent labs to effect greater economies of scale, and it could mean joint ventures and acquisitions, with either other independent labs, or with hospitals."

Moran Report

Last month, ACLA released a 13-page report compiled by the Moran Co., a Washington-based health care research firm, that extensively rebuts the CMS proposal to move some anatomic pathology services to the OPPS. The report included a survey of 10 different laboratories, which provided pricing on 154 specific codes. "Because our sample included all of the nation's largest laboratory companies, we believe the data we received may well typify the economic reality of performing these procedures across the industry," the report said.

Current Medicare Test Pricing vs. Potential HOPPS Pricing

Code, Description	Median Price Among Labs Surveyed	Median Under HOPPS
88104, Cytopath Flow	$51.80	$21.61
88182, Cell Marker Study	$72.37	$47.54
88184, Flow Cytometry/tc 1	$39.11	$24.91
88307, Tissue Exam	$133.63	$66.81
88313, Special Stains	$55.04	$25.38
88323, Microslide Consultation	$115.33	$46.28
88329, Interoperative Pathology Consult	$73.62	$16.26
88348, Electron Microscopy	$691.40	$189.58
88360, Manual Tumor Immunohistochem	$124.51	$67.72
88365, FISH	$132.96	$72.16

Sources: American Clinical Laboratory Association, The Moran Co. All CPT codes copyright American Medical Association.

At about the same time, ASCP created a template on its Web site that allows customized letters to be composed and sent directly to CMS Administrator Marilyn Tavenner and Deputy Administrator Michelle Snyder. Although ASCP has used these kind of templates for the better part of a decade, it has primarily used them to contact individual lawmakers rather than agencies.

The results have been eyebrow-raising: In the first couple of days after the template debuted, more than 1,700 letters were submitted. Matthew

Schulze, ASCP's director of government relations, said the response has been far greater than its typical letter-writing campaigns. In an interview just before the Labor Day weekend, he expected at least 2,000 letters would be sent to the CMS through the template before the public comment period on the proposal ended on Sept. 6.

Schulze, like Portugal, believes if the cuts are implemented, they would have the potential to change the fundamentals of pathology practices and laboratory operations.

"The smaller labs, the midsized labs, they have cut out all the fat. If their margins are already low, [further cuts] become very problematic," he said.

Methodology Questioned

The Moran report funded by ACLA made some troubling conclusions: that CMS arbitrarily shifted away from its traditional price-setting methodology—which focused on determining resource intensiveness of a procedure—to a new focus on determining exact costs.

"It is certainly a radical departure for anatomic pathology [pricing] on the physician fee schedule," said ACLA President Alan Mertz.

At the same time, the Moran report claims CMS's pricing rationale is not granular enough to accurately capture precise costs.

"It is certainly a radical departure for anatomic pathology [pricing]."
—Alan Mertz, President, ACLA

One example is the way capital costs are allocated by hospitals in determining outpatient care costs. "Such costs may not be fully captured in the associated cost center, but instead spread over all the cost centers as part of overhead costs," the report said. "Expensive lab equipment may fall into this category, and if so, the [cost-to-charge ratios] associated with laboratory departments may be artificially low."

Add to that the fact that low-cost, high-frequency procedures such as 88305 are grouped together with higher-cost, less-utilized procedures, which also tends to drag down the prices, according to the report.

The End Game

Despite the deep concern the CMS proposal has engendered, there is a general feeling that it will not implement the changes wholesale, particularly given the response it has received.

"I would hope that CMS has realized they have used the wrong methodology and would change its mind on this," Portugal said.

Schulze is also optimistic that the agency will not move forward. "I would like to believe the CMS will abandon the proposal," he said, although he added he is not sure it will.

If that's the case, expect the campaign to be ratcheted up to yet another level of intensity.

Takeaway: Lab and pathology lobbies see the proposed payment changes, when taken in context with other cuts, as a potential game-changing threat to the way they do business. G2

■ **Bio-Reference Reports Strong Earnings**, *from page 1*

Revenue per patient increased 7 percent, while patient count was up 8 percent. The latter number was slightly below analyst projections of 9 percent.

"The operations and financial results of the company met or exceeded our expectations for the quarter while our industry and health care in general were in a state of flux. Despite these extrinsic pressures, we were able to sustain our growth," said Marc D. Grodman, M.D., Bio-Reference's chief executive officer.

According to Grodman, growth has been coming through its GeneDX genetics testing division, as well as recent acquisitions. That includes Hunter Laboratories in Northern California and EdgeBio, a Maryland-based laboratory that will be folded into its GeneDx operations.

Bio-Reference also announced it would begin performing BRCA1 and BRCA2 testing, a diagnostic realm that was opened up by a recent U.S. Supreme Court decision that unaltered genes could not be patented. Grodman also announced Bio-Reference has been investing heavily in tumor sequencing and a new initiative that focuses on inherited cancers.

Altogether, esoteric testing comprised about 64 percent of the company's volume, up from 61 percent a year ago.

"The company has clearly established a leadership position in genetic testing, with about 65 sales reps dedicated to genetics [and half of these dedicated to inherited cancers], 50 [medical doctor or doctorate-level] geneticists, and 50 genetic counselors," wrote William Blair analysts Amanda Murphy and J.P. McKim in a report released just after Bio-Reference announced its earnings.

Bio-Reference did note a six-day increase in outstanding sales, which Grodman attributed to a billing dispute with Blue Cross Blue Shield of New Jersey. However, he also said that Bio-Reference has contracts with the nation's five largest commercial insurers and a growing number of Blues plans.

"We believe that the total number of lives that we cover rivals any laboratory in the country," Grodman said during a conference call with analysts.

Murphy and McKim kept William Blair's market perform rating of Bio-Reference in place, noting that it expects the company to continue to feel the same reimbursement pressures as other laboratories.

Startups Struggling

Two laboratories that are still in startup mode also recently announced earnings. Seattle-based Atossa Genetics, which focuses on testing for precancerous cells in the breast, reported a net loss for the second quarter, ending June 30, of $2.6 million on revenue of $326,078. That compares to a net loss of $1.2 million on revenues of $223,097 for the second quarter of 2012. Waltham, Mass.-based Interleukin Genetics reported a net loss of $1.8 million on revenues of $852,158 for the second quarter, ending June 30. That compares to a net loss of $1.2 million on revenue of $777,549 for the second quarter of 2012.

Takeaway: Genetic testing appears to be the future for Bio-Reference Laboratories, while startup firms are still struggling to find traction in that arena. G2

INDUSTRY BUZZ

Quest Will Distribute Thermo Fisher's Molecular-Based Peanut Allergy Test

Thermo Fisher Scientific has entered into a nonexclusive deal with Quest Diagnostics to have the nation's biggest laboratory distribute and market its test for peanut allergies.

The assay, known as the ImmunoCAP Peanut Component Test, measures a patient's level of immunoglobulin e, which is an indicator as to how the person will react to the five peanut proteins that can trigger an allergic reaction. Allergies to a specific protein can give clinicians a clear picture about how severe the allergy might be.

The ImmunoCAP test is considered a more accurate indicator of a person's level of allergy than the skin scratch test, which exposes the patient to a tiny amount of the potential allergen. However, skin testing has its drawbacks: A 2011 study of the method concluded that as many as 75 percent of subjects who test positive do not have a true allergy to peanuts.

"Traditional allergy testing measures sensitivity to an entire allergen, but component testing takes the next step by testing for sensitivity to each individual protein in peanuts, some of which cause more severe reactions than others. This gives doctors much more information when making a diagnosis and establishing a treatment plan," said Robert Reinhart, M.D., ThermoFisher's chief medical officer for its immunodiagnostics division.

Nut allergies are relatively uncommon in the United States, affecting anywhere from one-half to 1 percent of the population. However, the number of people who have such an allergy has been increasing in recent decades among children. Children who are allergic to nuts may die if their allergy is undetected or undiagnosed prior to exposure or consumption.

As a result, Reinhart noted that the demand for accurate allergy testing is on the rise, both from patients and doctors.

Treatment plans for patients determined to be allergic to peanuts include incremental exposures to desensitize the patient's immune system, although this can pose risks of overexposure to an allergen.

Thermo Fisher officials did not release any projected volumes for the test, which is also being offered by other labs.

Takeway: The laboratory sector is responding to a desire for more accurate and less invasive food allergy testing.

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202-637-9466

Atossa Genetics
206-588-0256

American Society for Clinical Pathology
312-738-1336

Bio-Reference Laboratories
800-229-5227

Health Care Development Services
847-498-1122

LabCorp
800-845-6167

Quest Diagnostics
973-520-2700

Thermo Fisher Scientific
781-622-1000

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