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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

Upcoming Conferences

Volume to Value
Redefining Lab Services in a Changing Market
Feb. 25-27, 2013
The Westin Beach Resort & Spa
Fort Lauderdale, Fla.
www.G2Labvalue.com

Pathology Institute
Grow Your Practice in Turbulent Times: Pathology Business Models and Strategies That Work
Feb. 28-March 1, 2013
The Westin Beach Resort & Spa
Fort Lauderdale, Fla.
www.G2Path.com

www.G2Intelligence.com

2012 a Slow Year for Lab M&A; 2013 Could Be More of Same

Merger and acquisition (M&A) activity among laboratories barely topped $290 million in 2012, a fraction of the value of transactions that were consummated during 2011. Many of the acquisitions involved deals of less than $50 million.

Industry observers say uncertainty about a wide range of issues kept a lid on M&A activity. They do not anticipate a huge pickup in 2013, although toxicology, esoteric, and hospital laboratories could be ripe acquisition targets during the year.

For more on mergers and acquisitions in 2012 and the outlook for 2013, see *Inside the Lab Industry* beginning on page 4.

LabCorp, Quest CEOs Bullish on Future Growth

The annual J.P. Morgan Healthcare Conference held in San Francisco earlier this month offers the high finance equivalent of speed dating—placing companies face-to-face with venture capital firms and other potential suitors. But it is also a speed "road show" of sorts, where CEOs from virtually every health care niche give 20-minute, 30,000-foot presentations on the state of their companies.

The two big national laboratories—Quest Diagnostics and LabCorp—both gave presentations at the event, and their respective chief executive officers essentially said the same thing: The lab sector is growing, and both will play a key role in furthering its growth and their own.

Quest Diagnostics CEO Steve Rusckowski noted that the lab industry is valued at $72 billion and is growing at 4 percent a year. He considers the Patient Protection and Affordable Care Act (ACA) to be a "net positive" for the industry in 2014. And despite the opinion of some that Quest and LabCorp represent a duopoly, he said that together they share only 43 percent of what he calls a "highly fragmented market."

However, Rusckowski admitted that his New Jersey-based company is not pacing industry growth and needs to pick up volume. "Our company is not growing, and it needs to start growing," he said.

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■ **LabCorp, Quest CEOs Bullish on Future Growth**, *from page 1*

By contrast, LabCorp has had fairly solid revenue growth over the past five years, but CEO David King said he is not satisfied with the status quo. He believes there is a shift "in the fundamental center of gravity in health care delivery," with a lot more activity moving toward large hospital systems, physician practices, patient-centered medical homes, and accountable care organizations (ACOs). And while LabCorp is preparing to accommodate such shifts, he noted that the company would continue to deploy its capital evenly between acquisitions and share repurchasing. However, in the absence of attractive acquisition targets, share buybacks would likely receive more capital.

Rusckowski projected some organic growth from the ACA but said that the company will need to beef up its volume of molecular and genetic medicine, as well as accommodate the increased number of patients who will be insured under ACA but will also be coping with relatively high out-of-pocket costs.

King said LabCorp would invest in its IT infrastructure and robotics to make testing and specimen sorting more efficient and better integrate lab results into electronic health records—developments he considers crucial given the continued proliferation of ACOs. The company is also further building out its portal for patients to allow them to access tests and pay bills more easily. In addition, LabCorp is expanding its esoteric testing capabilities.

Quest will be focusing on providing more services to hospitals and likely acquiring some of their laboratories. It will also seek to expand its services outside of the United States, but Rusckowski did not provide specifics. Last fall, Quest announced a major reorganization that eliminated three layers of management and put the company's focus on diagnostic solutions and information services.

King also noted that hospitals would be a focus of LabCorp business as well. He said that up to 55 percent of the lab business is still controlled by hospitals, even though the national labs can perform the work for less.

"There's a great opportunity to shift share to the lowest possible provider," King said.

PathCentral Sells Lab to Ascend Clinical

Irvine, Calif.-based PathCentral has sold its diagnostic laboratory business to Ascend Clinical, a deal that will include the former company's chief executive officer.

Ascend Clinical, based in Redwood City, Calif., focuses primarily on laboratory testing for dialysis clinics and patients with end-stage renal disease.

"Ascend brings a wealth of laboratory business knowledge to the table and our acquisition of PathCentral's laboratory is a natural step for our company," said Paul Beyer, Ascend Clinical's chief executive officer. "This new addition to our service offering advances our vision of delivering broad spectrum clinical services."

Ascend Clinical said it would use the deal to help expand the tests it offers to clients.

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PathCentral said the divesting of its lab business would allow it to expand its anatomic pathology laboratory information system, or APLIS, which can connect providers across a Web-based platform. Through a deal struck by PathCentral in 2011 with a Chinese firm called KindStar GlobalGene Techonology, APLIS is widely used among providers in Southern China.

PathCentral also plans to launch its online professional network in the first half of 2013. It is designed to connect pathologists around the world with subspecialty expert consultants.

As part of the sale of the diagnostic lab business, PathCentral CEO Matt Watson will transition to an executive role with Ascend in order to provide continuity for lab clients. Current PathCentral Chief Financial Officer Jaye Connolly will succeed Watson.

"As a focused technology company, we now can advance our long-term vision, which is to enable pathologists around the globe to tap and harness powerful cloud-based solutions, share their findings, and collaborate on an unprecedented level," Connolly said.

Quest Sells OralDNA Unit to Access Genetics

Quest Diagnostics has divested itself of its salivary-based dental diagnostics business. Quest announced the sale late last year of its OralDNA business to Minnesota-based Access Genetics. The company primarily focused on cardiovascular and other risk assessment tests associated with periodontal disease, as well as a test for oral human papilloma virus (HPV).Terms of the sale were not disclosed.

Access Genetics has provided support and analysis for OralDNA's testing suite provided to dental professionals since 2008. OralDNA testing that has been conducted at Quest's lab in Brentwood, Tenn., will be moved to an OralDNA facility in Eden Prairie, a suburb of Minneapolis.

Access focuses on providing advanced molecular tests. Its Web-based plaform, TeleGene, provides testing results in real time to more than 80 laboratories in 30 states.

Quest noted that the transaction was part of its plan to streamline operations and improve its operational profitability. It announced a restructuring last fall that split the company into two divisions focusing on diagnostic solutions and diagnostic information services, while eliminating several layers of management and hundreds of jobs.

Quest originally acquired OralDNA in 2009, a low-key transaction for which it did not issue a press statement.

The stock analyst firm Zacks praised the divestment in a recent report. "We hold a favorable view about this divestment along with the organizational structure developed by the company's new CEO, Steve Rusckowski. We also expect this to run successfully adding synergies to the company's ongoing $500 million restructuring initiative associated with its Invigorate program," said Zacks.

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Uncertainty Slowed M&A Activity During 2012; Caution Expected to Continue in 2013

The year 2012 was filled with uncertainty about reimbursement, taxes, and a variety of other issues that impacted the laboratory sector. And as a result, lab mergers and acquisitions slowed dramatically compared to 2011.

There were 21 deals consummated during 2012, according to data from Haverford Healthcare Advisors in Paoli, Pa. That compares to the 30 that were undertaken during 2011, based on data gathered by *Laboratory Industry Report*. Haverford identified 34 deals (*see chart on page 6*).

The overall valuation of the 2012 lab deals was about $290 million. That was a fraction of the more than $3 billion valuation of the 2011 transactions.

"It was surprising," said Dennis Weissman, founder and executive editor of G2 Intelligence and president of Dennis Weissman & Associates. "The general sense was there would be a good many deals, particularly since it was likely taxes would go up in 2013, and you would probably want to get a deal through before that happened. But when all was said and done, it was a very mediocre year for mergers and acquisitions."

Weissman noted that uncertainties regarding coding reimbursement issues for both molecular and pathology testing were not settled by the Centers for Medicare and Medicaid Services (CMS) until the latter half of the year, which put many potential dealmakers on the sidelines.

"Buyers were dragging their feet," said Chris Jahnle, a Haverford managing director. He noted that the reasons were numerous. There were doubts about the outcome of the presidential election. "If Romney were elected, he was going to find a way to unwind Obamacare, even though systems were moving toward an ACA [Patient Protection and Affordable Care Act] model anyway," Jahnle said.

Prior to that, there were doubts about the constitutionality of the ACA, which were settled by the U.S. Supreme Court midyear. Like Weissman, Jahnle agreed there was much uncertainty about the coding issues. Moreover, Jahnle noted the accelerating trend of hospitals buying physician practices disrupted traditional lab traffic and created some uncertainties in valuations prior to making offers.

Tax Worries Pushed End-of-Year Deals

However, the pressure regarding the capital gains tax being raised in 2013 pushed many deals through just under the wire, according to Jahnle. Of the 21 transactions listed by Haverford, nine occurred in the fourth quarter. Eight of them closed in December.

Moreover, two big M&A players in 2011—Aurora Diagnostics and Solstas Lab Partners—stayed on the sidelines in 2012. Combined, they had accounted for nine of the 2011 transactions.

Aurora, which Weissman observed may have overpaid for some of the $78.1 million it laid out for its 2011 transactions, took significant write-downs during 2012, according to filings with the Securities and Exchange Commission, and

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posted a $111.4 million loss during the third quarter of 2012. It also put off a planned initial public offering. Jahnle, who is an Aurora shareholder, declined to comment on its operations. Sources have suggested that Solstas—which like Aurora is privately held but is not disclosing its earnings data because it is not planning an IPO—has also had issues digesting some of its deals.

The biggest deal of 2012 involved LabCorp's acquisition of Medtox Scientific Inc. in August for $241 million in cash, an indicator of the relative strength of the drug testing sector. However, that was a far cry from the biggest deal of 2011, when Quest Diagnostics bought Athena Diagnostics for $740 million.

Jahnle said the consolidation of the toxicology niche was the biggest M&A trend of 2012. Altogether, five deals in that sector were consummated.

Ongoing M&A Climate Mixed

Meanwhile, the M&A climate for 2013 remains mixed at best. Jahnle noted that of the 21 deals that took place in 2012, 15 involved anatomic pathology (AP) and other specialty laboratories, and he expects more consolidation to occur in these areas this year.

"There will be some deals, but they will be very selective."
— Dennis Weissman, G2 Intelligence

However, the recent 52 percent cut in reimbursement for the technical component of CPT code 88305 is expected to seriously devalue the worth of AP labs in the coming months. Weissman said when the cut was announced by CMS in late fall, it all but froze venture capital looking to make acquisitions in the AP space.

"There will be some deals, but they will be very selective. It will be tough for pathology practices to draw private capital, and if they do, it will be at very unfavorable valuations," Weissman said. Whereas valuations in prior years reached as much as three times annual revenue, Weissman believes it could drop to as low as 1.5 times revenue, or in some cases, attract no multiple at all. Should tailwinds begin to blow, Weissman believes it likely will be in specialty segments, such as molecular, genetic, or other forms of esoteric testing. But he added any movement would be reliant on more clarity emerging regarding the pricing of the more than 100 new molecular billing codes, payment of which will be determined by the gap-filling method.

Both Weissman and Jahnle believe that sales of laboratories by hospitals—such as the recent acquisition of the University of Massachusetts Memorial Medical Center's lab business—are likely to pick up some momentum.

Although terms of the Quest-UMass transaction were not disclosed, the size and breadth of the UMass lab and the fact that Quest is investing in a new lab to consolidate operations in the region suggest it was not only one of the biggest deals of 2012, but likely the one with the biggest long-term impact.

"Many hospitals are deciding they want to monetize their stake in labs and use that money to acquire physician practices. I haven't met a hospital yet that has not considered the reallocation of lab space for additional beds," Jahnle said. "And so I'm anticipating additional hospital lab divestitures."

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Clinical Laboratory Transactions - 2012

Date	Acquirer	Target	Target State	Purchase Price	Target Revenue	Target EBITDA	Price to Revenue
Jan-12	Quest Diagnostics	S.E.D. Labs	NM	NA	$75,000,000	NA	
Mar-12	PathGroup	Atlanta Dermato-pathology	GA	NA	$5,000,000	NA	
Apr-12	Laboratory Corporation of America	Millenium Laboratory	NC	NA	$25,000,000	NA	
Apr-12	Waud Capital	Sterling Reference Laboratories	WA	NA	$10,000,000	NA	
Apr-12	Bio-Reference Laboratories Inc.	InCellDx Inc. (a)	CA	$6,000,000	$1,121,000	NA	
Jul-12	Life Technologies Corporation	Navigenics Inc.	CA	NA	NA	NA	
Jul-12	Genova Diagnostics Inc.	Metametrix Inc.	GA	NA	NA	NA	
Aug-12	Laboratory Corporation of America	MEDTOX Scientific Inc.	MN	$241,000,000	$111,600,000	$14,400,000	2.16
Aug-12	Quintiles	Expression Analysis Inc.	NC	NA	NA	NA	
Sep-12	AccelPath Inc.	DigiPath Solutions LLC	TX	$2,400,000	$1,100,000	$561,000	2.18
Sep-12	Ampersand Capital Partners	Calloway Laboratories	MA	NA	NA	NA	
Oct-12	Laboratory Corporation of America	Genetica DNA Laboratories	OH	NA	NA	NA	
Dec-12	Pathology Associates Medical Laboratories	CellNetix Pathology and Laboratories (a)	WA	NA	NA	NA	
Dec-12	Quest Diagnostics	UMass Memorial Medical Center clinical outreach lab	MA	NA	NA	NA	
Dec-12	OPKO Health Inc.	Prost-Data Inc. d/b/a OURLab	TN	$40,000,000	NA	NA	
Dec-12	Laboratory Corporation of America	Pee Dee Pathology	SC	NA	NA	NA	
Dec-12	Bio-Reference Laboratories Inc.	Florida Clinical Laboratory Inc.	FL	$7,000,000	NA	NA	
Dec-12	Bio-Reference Laboratories Inc.	Meridian Clinical Laboratory Corporation	FL	$1,850,000	NA	NA	
Dec-12	Sterling Reference Laboratories	Graham-Massey Analytical Labs Inc.	CT	NA	NA	NA	
Dec-12	Sterling Reference Laboratories	SECON Laboratories	MA	NA	NA	NA	
Dec-12	InCyte Pathology	Eastside Pathology	WA	NA	NA	NA	

Source: Haverford Healthcare Advisors, with financial information from press releases, SEC filings and other publicly available sources.
EBITDA: Earnings before interest, taxes, depreciation, and amortization
(a) Acquisition of a minority interest

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Scripps Physicians Advocate for Changes in Cancer Specimen Handling

Three physicians at a prominent California hospital network are calling for reforms regarding the way tissue specimens are handled for cancer testing.

The doctors—Scripps Health pathologist Kelly Bethel, M.D., surgeon Laura Goetz, M.D., and cardiologist and Scripps Chief Academic Officer Eric Topol, M.D., believe the changes in cancer testing wrought by molecular pathology require changes in handling specimens.

Traditionally, tumor tissue specimens are preserved in a combination of formalin and paraffin. However, the trio argues in the most recent issue of the *Journal of the American Medical Association* that such preparation methods damage DNA, making gene sequencing difficult, if not impossible.

"We need to completely rethink the way we have collected and stored cancer tissue samples for decades," Topol said. "It's becoming increasingly clear that obtaining an accurate map of a tumor's DNA can be the key to determining the specific mutations that are driving a person's cancer, how best to treat it, and how likely it is to recur."

'Tipping Point'

In the article, the doctors argue that the practice of pathology has arrived at a "tipping point" when it comes to cancer testing. "Deciding how best to obtain samples and how best to process them for whole genome or exome sequencing is a pivotal yet unresolved issue with several layers of complexity," they wrote, adding that a "fundamental change in how cancer specimens are handled" may soon be at hand.

> ***"This type of change will require discussion about new operative standards."***
> ***—Stanley Robboy, M.D., CAP***

As an alternative, the doctors suggest that freezing specimens for preservation might be a better way to proceed, although they noted that process might require larger or more numerous biopsy samples. They also urged randomized clinical trials comparing the efficacy of current specimen collections and alternative methods.

The trio also suggested that the additional costs of freezing samples and collecting and storing more of them should be balanced against the patient benefits of complete genetic evaluations of tumors.

The article was praised by the College of American Pathologists, although President Stanley Robboy, M.D., urged a deliberative process.

"This type of change will require discussion about new operative standards, which will need the cooperation of surgeons, pathologists, ethicists, and, of course, appropriate patient consents. It's these types of implications we will need to consider and incorporate as a progressive health care agenda is moved forward," he said.

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INDUSTRY BUZZ

Partners and Illumina Form Gene Sequencing Network

Partners HealthCare and Illumina have entered into agreements with several major laboratories to share interpretation and support services for genetic sequencing.

Partners, a Boston-based health care system with nine hospitals in Massachusetts, and Illumina, a San Diego-based manufacturer and distributor of genetic sequencing equipment, have announced a network of laboratories that includes Salt Lake City-based ARUP Laboratories, Mount Sinai Genetic Testing Laboratory, the New York Genome Center, and their own two sites.

In a joint statement, Partners and Illumina said the network members are "committed to exploring and sharing knowledge, including variant level content and interpretations, through the formation of inter-laboratory collaborations."

"We're excited to bring together such a talented and diverse group of leading institutions who share a common vision and are passionate about the opportunities for collaboration to advance the field of clinical genetics," said Heidi Rehm, the chief laboratory director for Partners' Laboratory for Molecular Medicine.

Last September, Partners and Illumina announced a partnership to create support infrastructure for geneticists and pathologists and networking tools to improve interpretation and reporting. Partners and Illumina intended to fuse their products by installing the Partners-designed software, known as GeneInsight, into MiSeq, Illumina's gene sequencing hardware.

"Today's announcement represents a significant milestone toward achieving GeneInsight and Illumina's shared vision of enabling the market to apply sequencing technology to improve human health," said Matt Posard, an Illumina senior vice president and general manager of Illumina's translational and consumer business.

The members of the network, known as the GeneInsight Illumina Founding Network, will be used as pilot sites to test the combined software.

"As a user of the GeneInsight application, I look forward to participating in a network of leading genetic testing laboratories and academic institutions to curate genetic variants. This collaborative effort can greatly contribute to improving patient care," said Elaine Lyon, ARUP's medical director.

References

ARUP
800-522-2787

CAP
800-323-4040

Haverford Healthcare Advisors
610-407-4024

Illumina
858-202-4500

LabCorp
800-845-6167

New York Genome Center
888-415-6942

Partners HealthCare
617-278-1000

Quest Diagnostics
800-222-0446

Scripps Health
800-727-4777

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