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LABORATORY INDUSTRY REPORT™

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HIGHLIGHTS

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Upcoming G2 Events

Lab Revolution
April 6-8, 2016
Sheraton Wild Horse Pass Resort & Spa, Chandler, AZ
www.labrevolution.com

Sequenom Remakes Fiscal, Operational House

Struggling to remake its fiscal house and gain some traction, Sequenom is putting its laboratory in North Carolina on the blocks and will cut its total workforce by more than 20 percent.

Sequenom, which focuses on noninvasive prenatal laboratory tests, announced that it would sell the facility in Research Triangle Park, NC and consolidate its testing operations at its San Diego headquarters by the first half of this year.

It's the second operations consolidation by Sequenom in less than a year. It merged its Michigan laboratory with North Carolina last May and cut a fetal RHD genotyping assay from its menu.

In addition to the latest consolidation, the company will also cut 110 jobs, out of 500 in total, a 22 percent reduction.

"Our employees have always displayed a remarkable passion for innovation and a strong commitment to delivering the highest quality

Continued on page 7

Pathway Genomics Will Use Watson Supercomputer to Analyze Test Results for Consumers

Eight years ago, IBM supercomputer Watson gained global fame for eviscerating two legendary "Jeopardy!" contestants. Now, it will assist Pathway Genomics in the more benign task of drawing consumers to a pending wellness smartphone app.

Watson will crunch information obtained by Pathway through its FIT test, a $159 assay that provides a genetic "fitness profile" for patients looking to gain insights in how to better manage their weight, lifestyle, and in some instances, improve control of their diabetes. It analyzes 75 different genetic markers related to weight, metabolism and other indicators of overall health and fitness. Although the test is technically not offered directly to consumers, they can order it online and have it requisitioned by a Pathway-affiliated physician. Pathway also provides consultations with dietitians for those looking to make changes in what they consume.

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Pathway Genomics Will Use Watson Supercomputer, *from page 1*

But according to Pathway officials, the use of Watson through a new app known as OME will further analyze test results and imbue them with more granularity and clarity. For example, a patient might have a genetic variation specific to how sated they feel depending on what kinds of foods they eat, or they metabolize a specific fat more efficiently. Watson would be able to provide this kind of analysis.

"With access to health information via mobile Internet, today's consumers are taking charge of their health and well being more than ever before. But at the same time they are overwhelmed with understanding and interpreting the massive amounts of information that specifically impacts their health and well-being," said Michael Nova, M.D., Pathway's chief innovation officer in a statement. "With Watson cognitive computing leveraged by our technology we are able to deliver real-time, highly personalized insights to empower people to change unhealthy behaviors."

> *"Affiliating with IBM's Watson technology provides even more credence that Pathway Genomics is at the cutting edge of personalized wellness."*
>
> — Peter Francis, President, Clinical Laboratory Sales Training

Nova noted by email that Pathway "trained Watson on a proprietary corpus of basic medical, nutritional, exercise, wellness, genetics, and many other health related datasets. The corpus/Watson will then be used (in part with our own artificial intelligence) to answer or push personalized content to the user via the OME app."

He added that for the moment, the use of the OME app in conjunction with the FIT test will likely not incur any additional charges. The app is currently in beta stage and limited in its availability, but likely will be widely available by the third quarter of this year, according to Nova.

"We have many different channel opportunities that have expressed interest in offering the OME service, including retail clinics," Nova said.

Pathway has other reasons to bring Watson in to analyze its test data aside from providing patients with more actionable data. The company noted that the bioinformatics market is expected to reach a value of nearly $13 billion by the end of the decade, while the mobile health market will top $59 billion. And Watson is much more of a household name–and therefore a more reliable marketing tool–than the Pathway name alone.

Peter Francis, president of Clinical Laboratory Sales Training, a Maryland-based consulting firm, said the move was far more than a marketing gimmick.

"Affiliating with IBM's Watson technology provides even more credence that Pathway Genomics is at the cutting edge of personalized wellness," Francis said. "(The company's) vision must be applauded for not only diving deep into the precision medicine world by offering state-of-the-art assays, but also for aligning state-of-the-art information methodologies to enable the general public to use the data to improve their health.

Takeaway: Pathway Genomics will take personal health and the related assays a step further by having a computer system that is a household name to analyze the results. G2

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Two Prominent Senators Push CMS to Make Changes on PAMA Rules

The Congressional pressure on the Centers for Medicare & Medicaid Services to make changes to its proposed final rules on the Protecting Access to Medicare Act (PAMA) have been ramped up, with two powerful U.S. Senators from both sides of the aisle asking for significant changes.

Sen. Orrin Hatch, a Utah Republican and chair of the Senate Finance Committee and Sen. Ron Wyden, the Oregon Democrat who is its ranking member, urged acting CMS administrator Andrew Slavitt to change both payment calculation methodologies and the timeline of implementing PAMA.

"The March 31 deadline is particularly unrealistic given that a final rule containing all of the information that laboratories will need to report has yet to be published."

— Sen. Orrin Hatch and Sen. Ron Wyden

The letter comes on the heel of another letter from more than 40 members of the U.S. House of Representatives asking CMS to make changes to PAMA's final rules.

The biggest change requested in the Jan. 6 letter is how laboratories will report reimbursement data from payers so Medicare can set its own payment rates moving forward. Currently, labs that hold individual taxpayer ID numbers (TIN) who receive $50,000 or more in annual Medicare revenues are required to report their average rates from private payers.

In their letter, the senators noted that using TINs only would exclude hospital outreach laboratories.

Instead, both Hatch and Wyden suggested using the more widely held CLIA registration numbers as a more "expansive" alternative. "We ask CMS to analyze whether there is a way to use these numbers while still meeting the statutory intent of only including laboratories that receive a majority of their Medicare revenues from the clinical laboratory or physician fee schedules," they wrote.

Hatch and Wyden also asked for an extension of the current reporting deadline for pricing data. Under the proposed rule, labs would have to gather private payer data relevant to testing performed between July 31 and Dec. 31 of last year. That data would then have to be submitted by this March 31.

"The March 31 deadline is particularly unrealistic given that a final rule containing all of the information that laboratories will need to report has yet to be published," the letter said. Instead, Hatch and Wyden asked for a non-specific extension of the reporting deadline.

The requests are in line with what laboratory sector lobbies have been asking for in their comments submitted to the CMS on the proposed rule late last year. Some have asked for an extension of the reporting period into 2018.

There is no specific timeline for CMS to publish its final rule, although it is widely expected to occur within the coming weeks. The agency has not made any indication as to whether it is heeding the intense lobbying efforts for the changes.

Takeaway: The pressure on CMS to make changes to PAMA's reporting requirements continues to be ratcheted up with a letter coming from two powerful U.S. Senators. G2

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Inside The Lab Industry

Laboratory M&A in 2015: Flat but With Possibilities Moving Forward

When it came to mergers and acquisitions in the laboratory arena, 2015 has proven to be pretty much more of the same.

Altogether, there were 29 transactions announced during the 2015 calendar year, according to data provided to *Laboratory Industry Report* by Tampa, Fla.-based Crosstree Capital Partners. That compares to 27 deals in 2014.

Momentum picked up during the second half of the year. There were just five deals announced during the first five months of the year; the remainder were announced on June 1 or afterward.

> *"It's a bit of an anomaly, and I think the trends (over both years) are fairly consistent."*
>
> — Jeff Ellis, Crosstree Capital Partners

While the deals remained about the same, the value of the deals announced last year were significantly smaller than they were in 2014. Total volume for the 12 transactions where a price was announced equaled $2.12 billion. That compares to $7.87 billion for the 14 deals where a price was disclosed in 2014.

Jeff Ellis, a Crosstree managing director, said that the numbers for 2014 were skewed by its largest announced deal: LabCorp's acquisition of Covance for nearly $6 billion, or about 80 percent of the value of all deals announced that year.

"It's a bit of an anomaly, and I *think* the trends (over both years) are fairly consistent," Ellis said.

There is a toss-up for the biggest deal of 2015. By dollar amount, Roche's acquisition of Foundation Medicine was the biggest. However, that was not a full acquisition per se; Roche merely took a majority stake in the Cambridge, Mass.-based Foundation.

Lisa Phillips, an editor with Irving Levin & Associates, a Connecticut-based research firm that studies merger activity in the health care sector, said that OPKO Health's $1.5 billion acquisition of Bio-Reference Laboratory—an odd transaction where the acquirer was much smaller than the acquired—was the biggest completed deal of 2015. According to Levin, the sector that includes labs saw 52 deals announced in 2015, up from 33 in 2014. However, that also includes imaging clinics and dialysis clinics. The company does not break out labs specifically.

According to Levin, the (slight) bump up of deals in the lab sector may have to do with the overall bottom line. "I think more (acquirers) targeted diagnostic labs because of the cash flow" that many of them were generating.

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Inside The Lab Industry

More Outreach Deals

Hospitals are continuing to sell their outreach operations, and Quest Diagnostics, the second-largest national laboratory, continues to be an eager acquirer.

Quest closed three outreach deals during the second half of last year: It picked up the outreach operations of MemorialCare Health System, a six-hospital system in California in late June. Toward the end of the year, it picked up the outreach operations of the five-hospital Hartford HealthCare. In Mid-December, it entered into an agreement to manage the seven hospital laboratories operated by Barnabas Health, New Jersey's largest hospital chain. Terms of all three deals were not disclosed.

"Hospitals are increasingly focusing on their core business and turning to Quest to help them evaluate and execute their lab strategy so they can do what they do best—deliver great patient care," Quest Chief Executive Officer Steve Rusckowski said in a statement. "This partnership follows a model for delivering high-value diagnostic information services for our nation's cost-pressured health systems."

"Hospitals are increasingly focusing on their core business and turning to Quest to help them evaluate and execute their lab strategy so they can do what they do best—deliver great patient care."

— Steve Rusckowski, CEO, Quest

As for the outreach or other hospital-based laboratory businesses, Ellis is unsure if there are many more targets that are left for Quest and other larger players to acquire.

"It's not due to limited demand, but there are a limited number of hospitals with outreach operations that have the scale or size" to attract a big national lab, he said. Moreover, should hospital labs be excluded from the reimbursement calculations under PAMA, their attractiveness to have all or part of their operations acquired will be limited.

Although rival LabCorp has also acquired its share of outreach operations in recent years, it was not nearly as active on this front as Quest was last year. Instead, it focused on bread-and-butter acquisitions of other labs, such as North Carolina-based ILS Genomics, Physicians Reference Laboratory and Pathology, Inc.

LabCorp's most intriguing acquisition was Safe Foods International Holdings, which provides food testing services for large companies, and two affiliated firms, International Food Network and The National Food Laboratory.

"It represent(s) our first major expansion in this important area, and we are delighted that these high-quality companies and their outstanding teams are joining our company," said LabCorp CEO Dave King in a statement. "With this acquisition, we extend our capabilities to offer a full range of product-development and product-integrity services to food and beverage manufacturers and retailers, industry organizations, and academic institutions."

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Inside The Lab Industry

Laboratory Acquisitions in 2015			
Date Announced	**Company Acquired**	**Buyer**	**Deal Value**
01/06/15	Diagnovus	Aegis Sciences	NA
01/12/15	Foundation Medicine	Roche Holdings	$1.6 Billion
04/09/15	CynoGen	Rosetta Genomics	$4.6 Million
04/15/15	Brazos Valley Pathology/Trinity Pathology	Aurora Diagnostics	NA
05/19/15	Innovative Diagnostic Laboratory	GeneNews Limited, Cobalt Healthcare Consultants	$12 Million
05/29/15	Anapath Diagnostics	Summit Pathology	NA
06/01/15	Diatherix Laboratories	Eurofins Scientific	$50 Million
06/04/15	Bio-Reference Laboratories	OPKO Health	$1.5 Billion
06/16/15	Physicians Reference Laboratory	LabCorp	NA
06/29/15	Emory Genetics Laboratory	Eurofins Scientific	$53.3 Million
06/30/15	MemorialCare Health Outreach	Quest Diagnostics	NA
07/21/15	Main Street Clinical Laboratory	Schryver Medical Sales	NA
07/28/15	Homeland Health Specialists	Undisclosed	NA
07/31/15	ILS Genomics	LabCorp	NA
08/10/15	Response Genetics	Cancer Genetics	$13.8 Million
08/24/15	B.O.N. Clinical Laboratories	Schryver Medical Sales	NA
09/04/15	Health Diagnostic Laboratory	True Health Diagnostics	$37.1 Million
09/17/15	IGeneX	4C Capital LLC	NA
10/01/15	Strata Pathology Services	Indvidual Investors	NA
10/13/15	DNA Diagnostics	GHO Capital Partners	$118.3 Million
10/21/15	Clarient	NeoGenomics	$299.7 Million
10/23/15	Safe Foods International Holdings	LabCorp	NA
10/29/15	Consultants In Laboratory Medicine of Greater Toledo	Aurora Diagnostics	$9.3 Million
11/10/15	Hartford HealthCare/Clinical Laboratory Partners	Quest Diagnostics	NA
11/13/15	Dermpathology Institute of New Jersey	Titanium Healthcare	NA
12/10/15	Barnabas Health Outreach	Quest Diagnostics	NA
12/10/15	Pathology, Inc.	LabCorp	NA
12/16/15	National Reference Laboratory For Breast Health	NRL Investment Group	$10.1 Million

Source: Crosstree Capital Partners

> *"There are companies overseas with unique assays and test menus that want to access the U.S. market, and see (an acquisition) as a viable route."*
>
> — Jeff Ellis, Crosstree Capital Partners

Another significant operator that made some big deals is Eurofins Scientific SA, the Luxembourg-based health care conglomerate. It acquired Diatherix Laboratories and Emory Genetics Laboratory in June in separate deals for $50 million and $53.3 million respectively. Those deals came right on the heels of its late December 2014 acquisition of Boston Heart Diagnostics for $200 million.

Ellis believes that Eurofins and other foreign operators will be acquiring more U.S. labs in the coming years. He noted that interest is beginning to grow from larger labs in Asia.

"There are companies overseas with unique assays and test menus that want to access the U.S. market, and see (an acquisition) as a viable route," he said.

Takeaway: Mergers and acquisitions in the laboratory sector were relatively level in 2015, and while the momentum of deals picked up during the second half, 2016 is not expected to have a huge number of surprises. G2

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Sequenom Remakes Fiscal, Operational House, *from page 1*

products in support of women's health," said Sequenom CEO Dirk van den Boom in a statement. "In making the difficult decision to sell our North Carolina facility, we are working hard to find a buyer that may be able to employ some or all of our team, thereby minimizing the effect on our employees and their families."

The company said the moves are expected to save about $20 million a year on an ongoing basis. Filings with the Securities and Exchange Commission suggest Sequenom will spend about $4 million severance and lease termination costs.

"We have less confidence in Sequenom's ability to achieve self-funding status and believe deteriorating fundamentals may limit potential interest from strategic buyers."

— Brandon Couillard, Analyst

Van den Boom also announced that Sequenom would refocus its priorities moving forward. It plans to shift research and development to include more tests that serve obstetricians, gynecologists and maternal fetal medicine specialists and expand its sales force in the obstetrics and gynecological arenas. It will also push to commercialize its liquid biopsy assay for oncology patients and seek strategic partners to accomplish that goal.

"In making these changes, we are committed to unlocking the value that already exists in the business," van den Boom said.

Sequenom's past year has been a struggle to maintain a grip on its revenue, which it has attributed to growing competition and price cuts in the noninvasive prenatal test market. For the third quarter of 2015, it reported a drop of 21 percent, from $37.9 million to $29.9 million, while test samples accessioned dropped by 12 percent. Its losses also widened, to $9.4 million for the quarter, compared to $6.1 million for the third quarter of 2014. For the first nine months of last year, it reported a loss of $4.2 million on revenue of $94.3 million, compared to a loss of $17.3 million on revenue of $113.5 million.

Former CEO William Welch abruptly left Sequenom in September, replaced by van den Boom, the company's longtime chief scientific and strategy officer. Little more than a week later, an analyst and investor day conducted by Sequenom led to three brokerage firms downgrading their ratings for the firm.

"We have less confidence in Sequenom's ability to achieve self-funding status and believe deteriorating fundamentals may limit potential interest from strategic buyers," Jefferies analyst Brandon Couillard wrote at the time, adding that Welch's abrupt departure did not help matters.

The company's stock, which was trading at as much as $4.65 a share in the spring of 2015, has plummeted to less than $1.25.

For calendar 2015, Sequenom said its revenue will be about $128 million, down more than 15 percent from the $151.6 million reported for 2014. That places it on the lower range of its prior forecast of between $127 million and $131 million.

Takeaway: Sequenom faces significant challenges in trying to regain market momentum in a competitive area of esoteric laboratory testing. G2

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INDUSTRY BUZZ

AltheaDX Raises $30 Million, Announces New Tests

AltheaDX, a California-based lab that focuses on pharmacogenetic testing, has raised $30 million in a third round of financing. The money comes from several investors, including WUXi Healthcare Ventures, a Chinese venture capital firm with a significant presence among U.S. companies.

"The era of pharmacogenetic testing is now and AltheaDx has all the crucial components to be a major player in the field," said Wei Li, WuXi's managing partner, in a statement. "We look forward to working with the management team and supporting the company to become a leading provider of such tests."

The company said the financing will be used for product enhancements, to pursue business opportunities overseas and investments in long-term growth.

AltheaDX has introduced several new assays and panels in recent weeks. They include an expansion of an existing panel to test for the effectiveness of neuropsychiatric medications. The panel now tests for patient sensitivity and reaction to medications that are prescribed to treat both bipolar disorder and seizure disorder. The company's NeuroIDgenetix panel now tests for medications used for six different disorders, including depression, anxiety, psychosis and ADHD.

"These new Idgenetix tests provide a comprehensive approach using genomic profiling and medication therapy management to guide treatment decisions in an attempt to avoid unnecessary and potentially toxic therapies," said Jorge Garces, AltheaDX's chief operating officer. "There is a clear need to expand the use of pharmacogenetic testing beyond psychiatric care and into other clinical areas which often manifest as co-morbidities in these patients."

In addition to the expansion of the panel for psychiatric medications, the company also introduced a new next-generation sequencing panel focused on the development of new drugs for oncology care.

Takeaway: AltheaDX is ramping up its product pipeline and is taking in the required capital to continue to grow. G2

Clarification: In the Nov. 19, 2015 issue of *Laboratory Industry Report*, an article about T2 Biosystems' test for candida-related sepsis said that such cases of sepsis are caused by a fungal virus. Candida-related sepsis is a fungal infection.

References

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