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LABORATORY INDUSTRY REPORT™

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HIGHLIGHTS

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PAML Launches AION Laboratories Division

PAML's long-awaited specialty testing program catering to the Baby Boomer generation was introduced last month, and its chief executive officer has high hopes for its first full year of operation.

PAML's AION Laboratories division (Greek for the word "eternal") debuted at the Annual World Conference on Anti-Aging, Regenerative & Aesthetic Medicine held in Las Vegas in mid-December.

The new lab division will focus on the nation's 77 million Baby Boomers and offer a suite of tests intended to forecast and preserve their health in the long-term.

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Smaller Esoteric Labs Struggle With Losses, Product Growth

Earnings reports for some of the smaller esoteric labs trickled in during the latter part of November and December, and they presented a mixed bag.

The largest of the labs, Redwood City, Calif.-based Genomic Health, dropped into the red for the third quarter ending Sept. 30, reporting a loss of $6.1 million, compared to net income of $604,000 for the third quarter of 2013. Revenue was up 5 percent, to $69.1 million compared to $66 million a year ago. Although the company reported rapid growth of its breast and prostate cancer tests, operating expenses increased more than 15 percent. For the first nine months of 2014, Genomic Health has posted a loss of $18 million on revenue of $206.6 million, compared to a loss of $3.2 million on revenue of $192.1 million a year ago.

New York-based Enzo Biochem also operated in the red for its fiscal 2015 first quarter ending Oct. 31. It posted a loss of $3.7 million on revenue of $24.8 million. That compares to a net loss of $2.8 million for the fiscal 2014 first quarter on revenue of $24.1 million. Legal fees were up more than 70 percent, to $2.5 million, due to what the company said was increased litigation.

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■ **Smaller Esoteric Labs Struggle With Losses, Product Growth,** *from page 1*

Omaha, Neb.-based Transgenomic was able to reduce its flow of red ink even as revenue continues to shrink. It reported a loss of $80,000 on revenue of $6.4 million for the third quarter ending Sept. 30, compared to a year-ago quarterly loss of $5.6 million on revenue of $6.6 million. The company attributed the dip in part to the sale of rights to its Surveyor line of assays and a large testing contract that ended in 2013. Chief Executive Officer Paul Kinnon said the loss of revenues is expected to be replaced with other testing in the coming quarters.

Miami-based Opko Health also narrowed its quarterly losses, but they remained significant. It reported a loss of $48.7 million on revenue of $19.8 million for the third quarter, compared to a loss of $60 million on revenue of $20.6 million for the third quarter of 2013.

The company said its 4KScore prostate cancer test was gaining a toehold in the European market, and had a new pharmaceutical in late-stage testing. It also had some $120 million in cash on hand in order to continue its focus on new product growth.

Takeaway: Many of the smaller esoteric labs are struggling to achieve significant revenue growth and profitability. G2

After Another Legal Setback on BRCA Testing, Myriad Considers Other Options

Myriad Genetics is continuing to legally duke it out with some of its competitors in breast and ovarian cancer genetic testing, but it is appearing increasingly likely that it will have to accept that the space will be crowded for the foreseeable future.

A federal appeals court in Utah ruled in December that three patents held by Myriad for BRCA testing (it markets its own test as BRACA) should never have been issued in the first place, as they covered products that weren't eligible for legal protection.

The appellate ruling follows on a 2013 U.S. Supreme Court ruling that barred companies from holding patents on single genes. That effectively opened up the market for BRCA testing, meaning Myriad's $4,000 list price for the test could be undercut by other labs.

However, Myriad sued two of its would-be competitors, Ambry Genetics Corp. and Pathway Genomics, claiming their sequencing processes infringed on its existing patents. The decision issued last month involved the Ambry lawsuit. It not only upheld a trial court's decision to permit Ambry to continue marketing its own BRCA test, but went beyond the question originally posed and invalidated the patents Myriad had held.

Myriad said it was disappointed in the decision and was considering its options. The company announced last month that it received FDA approval to use its BRACA assay as a companion diagnostic in conjunction with determining the use of the chemotherapy drug Lynparza for treating ovarian cancer patients.

"The potential for Myriad to become a companion diagnostic could be meaningful," wrote William Blair & Co. Analyst Amanda Murphy in a recent report. Murphy noted that Myriad tests about a quarter of the nation's ovarian cancer patients, and that using the test as a companion diagnostic could double that market for the lab in the coming years.

Takeaway: After another legal setback regarding its BRACA test, Myriad may have other avenues to grow that line of business. G2

Foundation Medicine Joins Lung Cancer Testing Campaign

Massachusetts-based Foundation Medicine has joined forces with the Bonnie J. Addario Lung Cancer Foundation and the Friends of Cancer Research to push individuals who suspect they have lung cancer to undergo the appropriate testing to better assess their options.

The campaign, known as "Don't Guess. Test," was launched late last year and includes 16 health care advocacy organizations and Foundation, which specializes in cancer testing at the genomic level. They have been working to distribute literature to would-be patients about the benefits of genomic profiling of their lung cancers, and the potential treatments that are available.

Lung cancer is the deadliest form of the disease in the United States, killing about 160,000 Americans every year. Even patients suffering from the disease in the intermediate stages have less than a one in three chance of surviving five years. Among the reasons for the disease's high rate of fatalities is few instances are diagnosed in the earliest stages, when the survival rates approach 50 percent.

Bonnie Addario, who created her California-based foundation after surviving stage 3 lung cancer, noted that the primary reason for the campaign was to provide more options for patients facing a tough diagnosis.

"The purpose is really to get patients tested, so they get the right drug at the right time," Addario said. "Too many times, they are put on radiation without testing, and they receive a treatment that is very toxic," while not necessarily providing therapeutic effects.

"Our understanding of cancer and lung cancer specifically has changed dramatically in the last decade, from a single disease, to a diverse set of diseases defined by their underlying genomic drivers," said Vincent Miller, M.D., Foundation Medicine's chief medical officer. "The diversity of genomic alterations found to drive lung cancer and the positive outcomes commonly resulting from use of the respective targeted therapy means that lung cancer is a disease that must be addressed by a precision medicine approach, and one where a 'one-size-fits-all' standard of care is no longer appropriate."

Addario said that other cancer-focused laboratories have been supportive of the campaign, and expect others to join it in the future.

Takeaway: Laboratories are beginning a push for more comprehensive testing for cancer patients in order to optimize their treatment. G2

Inside The Lab Industry

A 2015 Preview for the Laboratory Sector

The year 2014 was a challenging one for laboratories. They continued to confront cuts in reimbursement even as the Affordable Care Act brought millions of more Americans into the insurance fold for laboratory testing.

The second half of the year also signaled a turnaround — or turning point — for the two biggest labs. Quest Diagnostics finally was able to successfully combat shrinking revenues, while LabCorp's bold acquisition of Covance for $5.6 billion may signal its transition from the Avis of the sector to the largest player overall by a significant margin, and with the diversification to maintain and grow a commanding lead over Quest.

But with the lab sector entering 2015, questions remain about developing trends, reimbursements and companies. Where will the new year head?

Regulation of LDTs

The U.S. Food and Drug Administration began taking the first major steps in 2014 toward the regulation of laboratory-developed tests as medical devices. Not surprisingly, the laboratory sector immediately pushed back, with the American Clinical Laboratory Association retaining two of Washington's most prominent attorneys, Lawrence Tribe and Paul Clement, to represent its interests.

"It's quite serious," said Lâle White, chief executive officer of XIFIN, a San Diego-based laboratory software and consulting firm that works extensively in the regulatory realm. Although White believes the ACLA and other lab interests may sue the FDA if it does not back down on its current proposed regulatory plan, she also believes a compromise could be reached.

"There's a danger of slowing down innovation in the sector, and the FDA does not want to be responsible for that," she said, adding that the regulations could also create a two-tiered pricing scheme for tests that have and do not have FDA approval.

As for compromise, White believes it will come in the form of strengthening the Clinical Laboratory Improvement Amendments, or CLIA — a path that is being suggested by the ACLA and other laboratory lobbies.

Bundled Pathology Payments

The practice of pathology has been hit hard in recent years, most notably by the Centers for Medicare & Medicaid Services' decision in late 2013 to cut payments for the technical component of CPT code 88305 by 52 percent. It was an act that devastated many smaller pathology practices, forcing some to close and others to seek buyers at prices at a fraction of what they were just a few years prior.

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Now, independent pathology practices are facing another potential change in their reimbursement through the bundling of payments to those that provide services to hospitals. "There is no doubt payments are going to go down," White said.

But Barry Portugal, chief executive officer of Florida-based Health Care Development Services, believes it will not impact too many labs, mostly the independent ones that provide services to hospitals.

"The real question is if you're a hospital and you don't have a histology lab at all — and typically those are really small hospitals — then it becomes a contractual issue you have to resolve," he said.

That means both pathology practices and hospitals will have to do their own cost calculations in order to determine how to eke out the appropriate margins in a bundling scenario.

LabCorp vs. Quest Diagnostics

With annual revenue of about $6 billion, North Carolina-based LabCorp has always been the smaller of the two national laboratories, about three-quarters the size of New Jersey-based Quest Diagnostics. It was also the favored lab on Wall Street, exhibiting organic growth at a time Quest's revenues were stalled for nearly two years.

But with LabCorp's recently announced acquisition of drug testing firm Covance, whose annual revenues approach $3 billion, LabCorp is poised to overtake Quest in terms of size.

"(LabCorp CEO) Dave King has called this a transformational transaction. It makes them bigger than Quest in most categories, and it puts LabCorp very strongly into the clinical trials business," observed Dennis Weissman, former executive editor of G2 Intelligence and the company's founder. But Weissman cautioned that LabCorp had to borrow fairly heavily to pull off the $5.6 billion deal, and that it would be under pressure from shareholders to perform moving forward.

Deutsche Bank moved to a buy from hold action on LabCorp stock not long after the deal was announced. "Although we do believe LabCorp is buying a top-tier pharma services company in Covance, based on our significant interactions with investors of all stripes, we conclude the deal lowers LabCorp's appeal to most traditional health care services investors," analyst Darren Lehrich wrote in a mid-November report. He added that LabCorp may have also created a Quest-like problem of stagnant growth as a result of the deal, as its leadership had yet to make a compelling argument for revenue synergies from the transaction moving forward.

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Conversely, Lehrich also upgraded his hold recommendation for Quest Diagnostics to a buy rating. "In an environment where pricing looks more stable, volumes are improving and cost savings remain visible due to Quest's "Invigorate" initiative, we believe its ability to generate operating income and (earnings) growth above consensus makes it a more compelling idea right now," he observed.

In other words, swapping places at the top of the heap leads to problems of their own.

Will Theranos Pop?

No doubt the single most intriguing company in the lab sector in 2015 is Palo Alto, Calif.-based Theranos. Its 30-year-old founder and chief executive officer Elizabeth Holmes was not only anointed Silicon Valley's latest world conqueror by dint of a recent $9 billion valuation of the company (Holmes owns half of Theranos' stock), but was also the subject of a recent lengthy profile by well-known author Ken Auletta in the New Yorker magazine. Holmes, who has raised some $400 million from investors after dropping out of Stanford University a decade ago, was portrayed as a soft-spoken visionary who has dismissed any thoughts of a personal life in order to grow her company. All the while, she deflected Auletta's questions about the technology Theranos has developed to conduct patient draws without the use of needles and perform assays with just a few drops of blood. In keeping with the company's tendency toward secretiveness, a spokesperson did not respond to a request seeking comment.

There was one salient fact about Theranos in the New Yorker: Despite an unfolding partnership with pharmacy chain Walgreens, Holmes projects a mere 1 million tests will be performed by the company in 2015. That would place Theranos in the realm of a regional lab as opposed to the Fortune 500.

"She's done an unbelievable job in terms of getting the Theranos name out there, and the way they do things could be a game-changer," Weissman said, noting that its business model fits well with the major pharmacy chains vying to provide primary care services. "But they have to prove it first."

And aside from carefully curated locations inside a convenience retailer, Theranos has not divulged how it intends to wrestle business away from the draw stations already firmly ensconced in the doctors' offices, hospitals and medical groups where Americans routinely receive their health care services. That may be something that will be revealed in 2016 and beyond.

Takeaway: 2015 could be a year of big changes—and big questions—for the laboratory sector. G2

PAML Launches AION Laboratories Division, *from page 1*

"AION is dedicated to scientific excellence, a premium product line, and proactive client service protocols," said PAML CEO Francisco Velázquez, M.D. "We understand that discerning physicians and their well-informed patients have very high expectations, and AION is structured to deliver the rapid, reliable results required."

AION Laboratories offers a dozen testing panels and about 120 assays in total that focus on establishing baseline health for the patients, hormone levels, inflammation levels, allergy risks and cardiac risks, among others. The panels range in price from about $15 for a comprehensive metabolic panel to more than $850 for a panel that gauges a patient's cardiac risk. There is also a $290 test that determines the length of telomeres, sections of DNA at the end of each chromosome. The length of the telomere can be an indicator of the cellular age of the patient and may be able to provide information regarding the remaining lifespan.

Up to 80 percent of AION's patients are expected to be cash pay, with panel prices ranging from the hundreds to the thousands of dollars. PAML has contracted with a network of mobile phlebotomists that operate in the continental 48 states to perform in-home blood draws if requested. The service is being offered through about 15 medical groups and other providers, but that number is expected to grow fairly rapidly, according to Velázquez. AION has a single national sales person, although another may be hired in the near-term. Demand is projected to be most brisk in the Eastern U.S., Southeast and West.

Velázquez has high hopes for AION. Along with the high cash-pay rate, he noted that the typical age management patient would utilize tests at a rate of about two to three times higher than a younger patient just engaged in wellness management. As a result, he projects AION will show a profit by the end of 2015, and that the net margin for the year will be around $1 million.

AION's launch took a little longer than projected (PAML originally announced its introduction in the fall of 2013). "We tried to do a proof of concept test before we invested more time, money and effort, and we did that in the spring of this year," Velázquez said. "That gave us a really good understanding of the product."

AION's launch also complements PAML's launch earlier this year of Cinch, another division that focuses on the testing of younger cash-pay patients. Cinch's panels focus on women's and men's health and chronic conditions such as diabetes. The Cinch concept focuses on younger patients who may be too busy to come in personally for testing, and provides in-home and office testing kits. Unlike AION, prices for each assay are posted on the Cinch website.

The two divisions aside, PAML has been on a bit of a roll, with overall test requisitions between September and November up 14 percent compared to the same period a year ago, although revenue per requisition has been more of a challenge to grow.

Takeaway: AION Laboratories launch appears to cement consumer product lines for PAML that service both younger and older patients, and will likely provide a consistent source of cash-pay revenue. G2

INDUSTRY BUZZ

Loosening of Marijuana Laws May Be Contributing to More Positive Test Results

A new report by the Maryland-based drug testing lab Ameritox concluded that a significant proportion of its patients have issues with their prescription drug regimens. Ameritox's National Drug Report was based on the compliance testing of 400,000 patients undertaken by the testing lab in 2012.

The study concluded that 39.3 percent of those patients had a positive test result for other drugs not prescribed by their physician, and 11.6 percent tested positive for an illicit drug other than the one they were prescribed. In the latter category, 78 percent of patients tested positive for marijuana, 16.7 percent for cocaine, and 4.6 percent for heroin. Another 32.2 percent of samples indicated that the drug being prescribed was not ingested by the intended patient.

The use of opioid painkillers has increased in the U.S. in recent years, along with the consequences. According to the Centers for Disease Control and Prevention (CDC), accidental drug overdoses kill more than 41,000 Americans a year — more than the number who perish in automobile accidents. Such deaths have more than doubled between 1999 and 2012, according to CDC data.

A significant black market exists for opioid painkillers, prompting some patients to sell their pills. And the legalization of marijuana for recreational use in four states (Washington, Oregon, Alaska, Colorado) and the District of Columbia, along with the loosening of criminal penalties for its possession in many other states, may be encouraging more widespread use.

According to a drug testing survey of the U.S. workforce conducted by New Jersey-based Quest Diagnostics, positive tests for marijuana increased 6.2 percent between 2013 and 2012, but by more than 20 percent in states where the drug is approved for recreational use.

"Treating pain is a major challenge in our society, and so is the potential for misuse of prescription medications and the abuse of illicit drugs," said Ameritox Chief Executive Officer Scott Walton. "We need a concerted, dynamic approach – one that uses monitoring and additional insights at the clinical level – to address this problem."

Takeaway: Opioid drug compliance testing continues to turn up the presence of other illicit substances in many patients. G2

References

Ambry Genetics
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Ameritox
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Health Care Development Services
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LabCorp
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Myriad Genetics
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PAML
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Quest Diagnostics
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