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LABORATORY INDUSTRY REPORT™

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HIGHLIGHTS

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LabCorp Acquires Molecular Lab From Covance

In an attempt to bolster its molecular offerings and its clinical trials business, national player LabCorp has purchased a Seattle-based genomics laboratory from New Jersey-based drug development giant Covance for an undisclosed amount.

"The platforms and capabilities available at this laboratory are complementary to and broaden LabCorp's existing global clinical trials service offerings, and we will continue to work further to develop and expand these capabilities in the future. The addition of scientific, technical and sales team members is also an important aspect of this transaction," the Burlington, N.C.-based LabCorp said in a statement. "The acquisition enhances LabCorp's existing biomarker development and companion diagnostics capabilities and it confirms our commitment to advance our industry-leading genomic services."

Additionally, LabCorp has entered into a five-year contract to continue to provide Covance with specialty genomics services it can offer to its clients.

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PAML, CellNetix Create Joint Venture Focused on Molecular Oncology

When Spokane, Wash.-based PAML purchased a minority stake in Seattle-based CellNetix almost a year ago, the deal was intended to raise the game in merged anatomic and clinical pathology services.

Now, the two labs will use that mission to make a go at molecular oncology. They have formed a new joint venture, known as Symbiodx.

The fledgling venture has 15 full-time employees and is being headed by Anna Berry, M.D., who was previously a professor of pathology at the University of California San Francisco. Symbiodx's roster also includes two molecular scientists, a bioinformatics expert, physicians focused on production and research and development, and a three-member sales staff.

"This is a very intentional national oncology product. It is molecular and genetics, and it is a fully integrated portfolio," said Francisco R. Velázquez, M.D., PAML's president and chief executive officer.

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Upcoming Events
One-Day Workshops

Becoming a Value-Driven Lab: Innovative Models and Winning Strategies
April 10, 2014
Hyatt Regency O'Hare
Rosemont, Ill.
www.G2Intelligence.com/ValueDrivenLab

New Compliance Red Flags for Labs: How to Minimize Legal Risks in an Evolving Market
May 22, 2014
Hamilton Crowne Plaza
Washington, D.C.
www.G2Intelligence.com/RedFlags

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LabCorp Acquires Molecular Lab From Covance, *from page 1*

The Pennsylvania-based investment banking firm Fairmount Partners assisted Covance in the sale of the lab, which closed on Jan. 31. David Windley, an analyst with Jeffries, noted that the lab had been an underperforming asset for Covance and that the company would rely more on its central labs for future product development.

Covance had acquired the facility in 2009 from Merck. It has been in operation since 2001. Based on a statement issued by Covance in 2011, the lab runs about 45,000 tests per year. It has 50 employees, according to a Covance spokesperson, who declined to provide additional information.

Neither LabCorp Chief Executive Officer Dave King nor Covance officials have suggested in recent earnings calls that the transaction will have a significant impact on their bottom lines.

"If their growth is being impeded by declining reimbursement and economic conditions, they will turn their attention towards alternate growth strategies."
—Susan Dougherty, Vice President of Operations, Chi Solutions

However, King, in a presentation at the J.P. Morgan Healthcare Conference in San Francisco in January, stressed the importance of molecular testing to the company's future.

"The movement toward companion diagnostics and personalized medicine is a long-term opportunity for growth," King said at the presentation, later adding that the company is focused on making smaller, strategic acquisitions.

LabCorp did not respond to repeated requests seeking comment.

Although LabCorp controls roughly 10 percent of the U.S. lab testing market, like many other labs it is facing declines in reimbursement from public and private payers and is struggling with flat growth. Its 2013 revenue grew slightly more than 2 percent, from $5.67 billion to $5.8 billion, while net income was down slightly.

"If their growth is being impeded by declining reimbursement and economic conditions, they will turn their attention towards alternate growth strategies. This type of acquisition will afford them an opportunity to grow and it will complement and augment their existing operations and distribution systems," said Susan Dougherty, Vice President of Operations at Chi Solutions Inc, a Michigan-based laboratory consulting firm. "If LabCorp believes in the molecular testing market estimates and continues to focus on the evolving dynamics of medicine, this type of acquisition strategy can better position them for the future."

In addition to the Covance acquisition, LabCorp also announced that it was making available Thermo Scientific's ImmunoCAP allergy testing panel. The company noted that allergies affect about 60 million Americans and that there is a well-documented link between allergies and asthma.

"We will develop customized panels to improve treatment practices and enhance patient outcomes," said Mark Brecher, M.D., LabCorp's chief medical officer.

Takeaway: Struggling with organic revenue growth, LabCorp is continuing to focus on strategic acquisitions in the molecular arena and other forms of specialty testing.

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Study Shows Economic Utility of CardioDx Assay

CardioDx, the Palo Alto, Calif.-based laboratory that focuses on cardiovascular genomics testing, has issued a study concluding that its primary assay can save even a modestly sized health plan millions of dollars a year.

The study focuses on Corus CAD, a molecular test that examines the 23 genes and their expressional changes related to the development of arteriosclerosis, the hardening of the arteries that can lead to heart attacks. It is 96 percent accurate in terms of ruling out obstructive coronary artery disease as a cause of chest pains and other potential symptoms related to heart disease.

Coronary artery disease kills about 600,000 Americans a year and costs $109 billion in terms of health care delivery and lost productivity, according to data from the Centers for Disease Control and Prevention.

The study, "Economic Utility of a Blood-Based Genomic Test for the Assessment of Patients with Symptoms Suggestive of Obstructive Coronary Artery Disease," was published in the journal *Population Health Management*. The lead author was Louis Hochheiser, M.D., chief executive officer of St. John's Medical Center in Jackson, Wyo., and a former medical director with health insurance giant Humana.

The study concluded that use of the Corus test provides clearer treatment options for patients, leading to a cost savings of 9.4 percent compared to a less definitive path of care. Most of the savings was associated with the avoidance of noninvasive imaging and invasive diagnostics, such as myocardial perfusion imaging and cardiac angiography. The cost of both procedures can run well into the four figures for a single test.

Employing the typical coronary care pathways in a health plan with 500,000 lives would cost $49.07 million a year. By employing the Corus test to provide a more accurate diagnosis, the savings is 77 cents per member per month, or $4.59 million a year, inclusive of the cost of administering and interpreting the assay. The cost savings includes nearly $5 million in avoiding unnecessary coronary angiographies and $1.7 million for stress myocardial perfusion imaging.

"The results of this cost analysis indicate that the Corus CAD gene expression score, when used in primary care patients with symptoms suggestive of obstructive CAD, may reduce the economic burden associated with cardiac imaging and invasive coronary angiography, and allow patients to avoid unnecessary radiation exposure and complications associated with procedures," said Joseph Ladapo, M.D., a professor at the New York University School of Medicine and co-author of the study.

A variety of observers say such research is crucial for laboratories to make the case to the payer community regarding the economic utility of the tests they're providing. Many are experiencing declining reimbursements from both public and private payers and often lack the leverage required to negotiate on equal terms with large insurers.

In addition to its Corus test, CardioDx is also developing genomic tests related to congestive heart failure and cardiac arrhythmia.

Takeaway: As clinical laboratories strive to prove the value of their services, the clinical and economic utility of laboratory tests can be made more clear with clinical research published in academic journals. G2

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Inside The Lab Industry

Genomic-Oriented Labs Continue Swift Growth

While the national laboratories and labs performing routine testing continue to struggle with flat test volumes and revenue growth, those labs focused on genomic and molecular medicine are seeing their revenues grow steadily.

Fourth-quarter and final year earnings reports from four publicly traded molecular-focused enterprises—NeoGenomics, Genomic Health, Foundation Medicine, and Sequenom—showed that all enjoyed significant year-over-year revenue growth. Those that are in the black saw their bottom lines grow.

Indeed, the financial landscapes between molecular and traditional labs are stark. Amanda Murphy and J.P. McKim, analysts with William Blair & Co., issued an outperform rating for several molecular specialty labs, including NeoGenomics and Genomic Health, even though they noted uncertainty remained regarding the full resolution of payment for molecular tests using new molecular pathology codes.

> ***"Despite continued pressure on reimbursement, we achieved strong revenue growth and sharply increased gross margins."***
>
> ***—Douglas VanOort, Chief Executive Officer, NeoGenomics***

In the meantime, Murphy and McKim kept in place market perform ratings for LabCorp, Quest Diagnostics, and Bio-Reference Labs.

"Labs have also given weaker-than-expected fiscal 2014 guidance, primarily as a result of government-driven reimbursement challenges, while volume growth expectations suggest a continued muted (albeit not worsening) environment," they wrote. "No company is incorporating a meaningful utilization benefit from reform and most are assuming an increase in bad debt as a result of increased patient cost sharing."

Cambridge, Mass.-based Foundation Medicine showed particularly strong business growth. For the fourth quarter, ending Dec. 31, it reported a net loss of $13.1 million. However, revenue was $9.7 million, nearly 90 percent higher than the $5.2 million reported for the year-ago quarter. The company lost $42.9 million for calendar 2013 on revenue of $29 million. The loss was much higher than the $22.4 million reported in 2012. However, revenue was up more than 180 percent compared to the $10.6 million reported in 2012.

Foundation Medicine Chief Executive Officer Michael J. Pellini, M.D., noted that the company also reaped additional revenues from its second molecular test product, FoundationOne Heme, which provides a genomic profile for hematological cancers such as leukemia, lymphoma, and myeloma. "The response from hematologists and oncologists indicates this product will be important in providing comprehensive genomic profiling for patients with hematologic malignancies, sarcomas, and pediatric cancers," he said.

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The Fort Meyers, Fla.-based NeoGenomics turned a corner on profitability. It reported net income of $857,000 on revenue of $18.3 million for the fourth quarter of 2013, driven by a 28 percent growth in test volume. That compares to a loss of $113,000 on revenues of $14.9 million for the year-ago quarter.

For all of 2013, NeoGenomics reported net income of $2 million on revenue of $66.5 million. That compares to essentially breakeven—$65,000 in income—on revenue of $59.9 million in 2012.

"Despite continued pressure on reimbursement, we achieved strong revenue growth and sharply increased gross margins," said NeoGenomics Chief Executive Officer Douglas VanOort. "Our stream of innovative new tests and consistently high service levels is attracting new clients, and we are gaining market share. We have also been successful at increasing productivity and reducing costs." That's despite revenue per test declining by 3.7 percent.

Stock Prices of Genomic/ Molecular Oriented Laboratories

Company	Stock Price, March 2014	Stock Price, March 2013
Sequenom	$4.36	$2.37
Foundation Medicine	$3.30	$3.50
Genomic Health	$29.03	$26.41
NeoGenomics	$3.30	$3.58
Illumina	$52.22	$171.49

Source: Financial Reports

However, there are some potential clouds on the horizon. William Blair's Murphy and McKim noted that uncertainties regarding how Medicare will allow labs to bill for multiple fluorescence in situ hybridization procedures could cut NeoGenomics' revenue by $3 million, or as much as 4 percent, in 2014.

Redwood City, Calif.-based Genomic Health reported a loss of $9.4 million for the fourth quarter on revenue of $67.1 million. That compares to net income of $2.1 million for the year-ago quarter, on revenue of $60 million. The loss was attributable in part to a $9 million up-front licensing payment. For calendar 2013, Genomic Health lost $12.4 million, compared to net income of $8.2 million in 2012. However, revenue increased 11 percent to $259.2 million, from $233.5 million.

Genomic Health Chief Executive Officer Kim Popovits said test volumes had grown 15 percent last year. "Given the strength in our core business, the successful launch of our Oncotype DX prostate cancer test, and recent international progress, we plan to accelerate our investment to further the clinical practice of genomic medicine in cancer," Popovits said.

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Genomic Health forecasts it will perform between 98,000 and 102,500 Oncotype DX tests for the calendar year, up slightly from the Wall Street consensus of about 93,000.

San Diego-based Sequenom reported a net loss for its fourth quarter of $18.9 million. However, that was a significant improvement over the $32.8 million loss in the fourth quarter of 2012. Revenue for the quarter was $45.1 million, compared to $33.7 million for the year-ago quarter.

For the entire calendar year, Sequenom reported a net loss of $107.4 million on revenue of $119.6 million. For 2012, the company lost $117 million on $46.5 million. A restructuring that took place last August cut selling and marketing expenses significantly.

"We made significant progress in our performance during 2013, with 157 percent growth in diagnostic services revenue as our collections and revenue improved during the year and our overall cash burn declined in the last half of the year," said Sequenom Chief Financial Officer Paul V. Maier. "We look forward to continued growth in 2014 as we improve our collection results following the coding changes adopted at the beginning of 2013 and continue to increase our volume of tests performed." The company informally projects reaching breakeven and positive cash flow by the end of the calendar year.

"We made significant progress on key research and development programs, which allowed us to introduce new products in early 2014 that will once again redefine the trajectory of sequencing."
—Jay Flatley, Chief Executive Officer, Illumina

Other firms with a more peripheral role in genomic assays are also benefiting from the testing boom. San Diego-based Illumina, which mostly provides the sector with sequencing equipment but also offers a handful of assays, reported significant growth. It reported net income of $80 million on revenue of $336.4 million for the fourth quarter, up from net income of $71.9 million on revenue $279 million. For 2013, its net income was $125.3 million, down from the $151.2 million in 2012, related primarily to $25 million in impairment charges for shutting down a noncore product line. But revenue grew more than 20 percent, from $1.06 billion to $1.26 billion.

"We made significant progress on key research and development programs, which allowed us to introduce new products in early 2014 that will once again redefine the trajectory of sequencing," said Jay Flatley, Illumina's chief executive officer. "We plan to leverage this momentum in 2014 to more broadly enable the adoption of genomics."

Takeaway: Although esoteric molecular laboratories have had their own encounters with reimbursement issues, their ability to grow organically currently outstrips more traditional laboratories' ability to grow.

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■ **PAML, CellNetix Create Joint Venture Focused on Molecular Oncology**, *from page 1*

Symbiodx will sell its services to cancer centers throughout the United States, focusing initially on serving PAML's partners, owners and existing clients through what Velázquez called a "soft launch" and eventually migrating east. He added that it would be similar to the business model that powers Massachusetts-based oncology laboratory Foundation Medicine.

The demand for cancer-related diagnostics is high, particularly in relation to targeting therapies based on the genetic composition for tumors. More than 1.6 million Americans are diagnosed with some form of cancer every year; nearly 600,000 die from the disease annually. The American Cancer Society estimates that nearly 41 percent of the population will be diagnosed with the disease during their lifetime.

According to the World Economic Forum, global health care expenditures on cancer are growing at a rate of 10 percent per year, far higher than those for other chronic conditions such as diabetes, cardiovascular disease, and chronic obstructive pulmonary disorder.

"Change is necessary. Anatomic pathology has not been a top priority for many of the national laboratories," said Don Howard, M.D., CellNetix's chief executive officer.

Altogether, Symbiodx is able to sequence some 200 clinical mutations and offers about 275 different tests. Its next-generation sequencing (NGS) capabilities—which the two labs spent nearly a year developing—extend to 68 different genes.

"Change is necessary."
—Don Howard, M.D., Chief Executive Officer, CellNetix

Cytogenetics and other genetic assays will be performed at PAML's main laboratory in Spokane, with other panels performed at CellNetix's lab in Seattle. CellNetix's 50 pathologists will provide the interpretative services.

Velázquez noted that Symbiodx will focus on customer service, turning around tests within two to seven days depending on their complexity. Results will also include detailed pharmacogenomic data.

The expansion of PAML and CellNetix's abilities speaks to the growing use of genomic medicine in fighting cancer, which is among the most complex of diseases to treat. But it also is expected to generate a substantial amount of revenue as well. Velázquez said Symbiodx's NGS-related tests retail for between $2,000 and $2,400 apiece, with payers reimbursing about 80 percent of their prices on average.

"It's more premium pricing" compared to PAML and CellNetix's other panels, according to Velázquez.

Molecular oncology also has a substantial overseas market. Velázquez noted that in China, with a population nearly five times that of the United States, cancer is the leading cause of death among its urban population and second-leading among more rural dwellers. That country, like others in the developing world, has a high rate of smoking and its population tends to be exposed to significant levels of pollution.

Symbiodx will focus on the United States for now. However, Velázquez said it would make sense to explore China and other overseas markets in the next few years.

Takeaway: Molecular medicine with a focus on oncology services may drive the future growth of many regional laboratories. G2

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INDUSTRY BUZZ

Illumina Launches an Incubator for Genomic Startups

Illumina, the San Diego-based sequencing equipment firm and laboratory, has launched a new venture: an incubator for new businesses.

The company has launched the Illumina Accelerator Program, a six-month business incubator that will provide funding and support services to up to six startup companies each year that are "working on scientifically and commercially promising next-generation sequencing applications," the company said in a statement.

Companies will be selected for the program through a competitive application process. Those selected will receive up to $100,000 in sequencing services, reagents, technical support, and laboratory space at a new research and development center Illumina is building in the Mission Bay section of San Francisco. Illumina is also providing financial modeling, forecasting, and legal and human resource assistance, as well as support in product licensing and technology transfer.

Technology investor Yuri Milner is also offering $100,000 in working capital in exchange for convertible notes capped at $5 million in value. The Silicon Valley Bank will provide credit lines up to $20,000 and other financial services.

"Next-generation sequencing has reached the lift-off stage. I'm excited to support this endeavor promoting innovation and entrepreneurship in the genomics ecosystem," said Milner, whose best known investment in the lab space is the personal genomics firm 23andMe.

Participating startup companies will hone their product, make pitches to venture capitalists and angel investors, and will receive help in opening their company headquarters after the incubator session is concluded. Illumina will retain a 10 percent stake in the companies that go through the incubator process.

"The dramatic reduction in the cost of sequencing has enabled the scientific and business communities to address an increasingly broad range of research and clinical opportunities. We've only begun to scratch the surface, however, and we're excited to foster the next generation of genomics innovators . . . the Illumina Accelerator Program will make it easier for them to validate and create NGS applications and bring these solutions to market," said Mostafa Ronaghi, Illumina's chief technology officer.

Takeaway: The laboratory sector and Silicon Valley are joining forces to speed up development of genomic companies and products.

References

CellNetix 206-215-5960	Illumina 858-202-4500	PAML 509-927-6250
Covance 888-268-2623	LabCorp 800-845-6167	Quest Diagnostics 973-520-2700
Foundation Medicine 617-418-2200	NeoGenomics 239-768-0600	Sequenom 858-202-9000
Genomic Health 650-556-9300		

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