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HIGHLIGHTS

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MolecularHealth Officially Opens Its Doors

After nearly a decade of legwork, MolecularHealth is now officially open for business.

The Texas-based MolecularHealth received its Clinical Laboratory Improvement Amendments certification for its laboratory, which is approximately 7,000 square feet and is based alongside the company's corporate headquarters in The Woodlands, about 30 miles north of Houston.

MolecularHealth will initially offer two tests under its Treatment-MAP brand: a gene panel that targets about 500 known cancer genes, and whole-exome sequencing of cancer tumors.

The gene panel will retail for $5,000, and the exome sequencing test will retail for $15,000, prices a company spokesperson said were "market competitive." MolecularHealth officials said they had opened talks with payers and hospitals to cover and carry the assays.

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Genetic Testing Drives Revenue Growth But Little Profit

Despite the fact harsh weather in the East and Midwest and a difficult reimbursement climate nipped at the bottom lines of several laboratories that issued recent earnings reports, most reported significant growth in revenue, if not their profits.

Although New Jersey-based Bio-Reference Laboratory reported a 12 percent increase in revenue for its fiscal quarter, ending Jan. 31, to $181.3 million from $161.3 million, net income dropped by two-thirds, to $3 million from $8.7 million.

Bio-Reference officials said the inclement weather snapped of 5 cents per share from its earnings, or about 30 percent overall. Another 30 percent of the drop was attributable to ongoing cuts in reimbursement from Medicare and other payers.

However, Bio-Reference noted that its molecular testing segment was growing steadily.

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MolecularHealth Officially Opens Its Doors, *from page 1*

A company official said in 2013 that MolecularHealth had planned to perform as many as 2,000 tests in calendar 2014, but a spokesperson declined earlier this month to provide any specific estimates.

In addition to providing the assays, MolecularHealth will provide logistical support, including potential treatment options for patients, and help in persuading insurers to cover such treatments.

MolecularHealth will be marketing its services through a five-person sales staff, which is expected to grow in the coming months. The company's commercial and business development staffs will be headquartered in the Boston suburb of Newtown, Mass., where it is currently recruiting a marketing director and a health economist.

"Boston is a hotbed of cutting-edge science, and a major biotech hub," said MolecularHealth Chief Commercial Officer Laura Housman, a longtime former executive with Novartis. "As we work toward generating adoption of our oncology treatment decision support offering over the coming months, it's important that we have a presence in Boston, where many of our current and potential partners and customers are located."

MolecularHealth has a third office in Heidelberg, Germany, that houses its European operations.

Much of MolecularHealth's top executive staff was formerly of U.S. Oncology, including its chief executive officer, Lloyd Everson, M.D. He served as U.S. Oncology's president and continues to serve on its board of directors.

The company, which was founded in 2004, is funded in part by Dietmar Hopp, a German software entrepreneur and billionaire. Company officials would not disclose how much Hopp or the company's other backers have invested in the venture.

Takeaway: Another molecular laboratory firm plans to address the cancer market in the United States. G2

Insight Genetics, Vanderbilt to Collaborate on Gene-Based Breast Cancer Assays

Insight Genetics has teamed with the cancer center at Vanderbilt University to produce and distribute a new molecular test that will drill down into the genetic makeup of a particularly aggressive form of breast cancer.

The test, which is being developed in conjunction with Vanderbilt-Ingram Cancer Center (VICC), will be used to diagnose what is known as triple-negative breast cancer. This specific form of the disease is negative for having an estrogen receptor, a progesterone receptor, or the HER2 gene.

Such a form of the cancer is diagnosed about 230,000 times each year in the United States. Triple-negative breast cancer can be difficult to treat because there are few targeted treatment options available and that form of cancer often recurs. The survival rate for the triple-negative form of cancer is about 30 percent worse than the overall average for the disease.

Insight Genetics contacted VICC after its researchers had used an algorithm on gene expression data on hundreds of triple-negative breast cancer cases to detect as many as six genetic subtypes of the disease.

The research "shows tremendous promise for identifying unique treatment options for each molecular subtype of triple-negative breast cancer," said Insight Genetics Chief Executive Officer Eric Dahlhauser.

VICC and Insight will work on developing tests that target the underlying biomarkers. The algorithm will be refined and moved onto a next-generation sequencing platform, an Insight spokesperson said. It is expected that research of the specific subtypes will lead to guided treatments, Insight officials said.

Insight has obtained worldwide rights to the method Vanderbilt has developed to detect the biomarkers and plans to distribute any assays that are developed from the collaboration. A spokesperson was unable to say when such tests would be available.

Takeaway: Insight Genetics will attempt to develop highly specific esoteric tests to better differentiate among forms of breast cancer. G2

Test Clearinghouse Receives Additional Financing

NextGxDx Inc., an online clearinghouse for CLIA-certified genetic laboratory tests, has secured a second round of financing.

The Nashville, Tenn.-based NextGxDx received an unspecified amount of series B funding from Voyent Partners and the Nashville Capital Network.

The company focuses on matching a specific test with a specific patient. Its database includes more than 220 laboratories across the United States that offer more than 17,400 tests. It provides information on the overall effectiveness of a test in relation to a patient's medical condition, as well as cost.

Officials with NextGxDx indicated the service is in response to trying to clear some of the product clutter surrounding the genetic tests that are currently available to clinicians. Its client base is primarily hospitals.

"The growth of genetic testing is overwhelming hospital budgets and their ability to manage the labor-intensive test ordering process, creating an opportunity for a solution like ours that lowers costs and addresses the workflow inefficiencies associated with genetic test ordering," said NextGxDx Chief Executive Officer Mark Harris. "We are excited about the opportunities we see in this market."

NextGxDx's business model allows it to collect a fee anytime its database is used to order a test directly from a laboratory. The test price is the normal retail rate the laboratory charges. The company currently has agreements in place with nine laboratories that cover about 4,800 tests—or about one-quarter of the genetic assays that are currently on the market.

Takeaway: A startup firm in Nashville aims to provide clarity to the huge number of genetic assays that are currently available. G2

Inside The Lab Industry

Recent Moves by Labs Suggest Tilt Toward Workplace Wellness

Is the increasing popularity of employee wellness programs creating a potential new revenue source for laboratories?

Quest Diagnostics, the nation's largest laboratory, and Health Diagnostic Laboratory (HDL), one of the largest regional labs in the northeast, may soon find out.

Quest just spent an undisclosed sum to acquire Summit Health, a Michigan-based provider of on-site employee wellness programs.

At nearly the same time the Summit acquisition was announced, HDL released an elaborate smartphone app that allows users of its lab services to check their test results and track their eating habits, among other options.

Whether or not Quest's and HDL's moves signal that labs will be piling into the wellness realm, there is little doubt that corner of health care delivery is growing fast.

More than 90 percent of companies with 200 or more employees offered such programs in 2009, according to a report conducted in 2012 by the Rand Corp. for the U.S. Department of Labor. Basic lab assays such as lipids and blood glucose are staples of such programs.

> ***"Disease prevention and wellness programs are critical to better outcomes and lower costs."***
>
> ***—Steve Rusckowski, Chief Executive Officer, Quest Diagnostics***

Meanwhile, vastly more money is being invested in these initiatives than even in the recent past. According to a survey released last month by the National Business Group on Health, corporations plan to spend $594 per worker on employee wellness programs in 2014, up nearly 15 percent from 2013 and more than double the $260 spent per employee in 2009.

The primary impetus is the endemic levels of obesity in the United States and accompanying chronic conditions such as heart disease and diabetes, which cost firms hundreds of billions of a dollars a year in additional health care costs and lost productivity.

Provisions in the Affordable Care Act are also prodding such programs forward by cutting employer premiums by as much as 30 percent if workers meet goals such as weight loss and reductions in cholesterol levels and blood pressure.

No doubt, Quest sees the ubiquity of such programs and the dramatic increase in cash being put into them as an alluring option. And one of the biggest motivators for such programs—the need for employees to keep health care costs in check—can also help labs in defining their role as the sector continues to shift from a volume to a value model.

"Disease prevention and wellness programs are critical to better outcomes and lower costs. Together, our two companies will give employers, health plans, and individuals greater access to a uniquely broad range of prevention and wellness services that use diagnostic insights to inform early intervention and preventive care and ultimately reduce health care costs," said Quest Chief Executive Officer Steve Rusckowski.

Summit provides on-site services to some of the largest corporations in the United States, including IBM, Merck, and Pepsi (ironically, its client roster also includes Quest rival LabCorp), and has substantial payer contracts with UnitedHealthcare, Aetna, and Cigna. Its trademark product is Single Station, a 15-minute health screening that includes tests for lipids and blood sugar. Another 1,000 lab tests are available through Summit's wellness program. The company also provides follow-up services such as lifestyle coaching and smoking cessation programs.

"It's a different trend for [Quest] to go in this direction."
—Peter Francis, President, Clinical Laboratory Sales Training

At the time Quest acquired Summit, it was growing dramatically. The firm projected revenue would top $103 million in 2013, more than double the $50 million it reported in 2012. It opened an office in Arizona last year to accommodate its expanding operations in the western United States and more than doubled the staff at its headquarters in Novi, Mich.

Aside from its primary work site business, Summit also has a burgeoning side business in home-based wellness testing, which accounted for about 2 percent of its overall revenue last year.

How the acquisition plays out remains to be seen. Roy Manning III, an analyst with Seeking Alpha, noted that Quest did not release any data about its impact on earnings.

"It's a different trend for [Quest] to go in this direction," said Peter Francis, president of Clinical Laboratory Sales Training in Woodstock, Md., adding that it was beyond the kind of straightforward lab acquisition in which Quest typically engages.

Regulatory Changes Helped Launch HDL App

Meanwhile, the recent changes in federal regulations that allow labs to directly transmit results to patients was one of the reasons HDL introduced its new app, called myHDL, which is available on both the iPhone and Android platforms. It allows users access to their biometric data (height, weight, and body mass index), as well as 42 different lab test metrics, including metabolic, renal, lipids, lipoproteins, myocardial function, inflammation, and platelets.

HDL spokesperson Jeff Kelley indicated the recent regulatory changes that allow labs to provide patients with results directly without prior physician approval will prove a boon to the employee wellness market.

That opinion is shared by ARCpoint Labs, the South Carolina-based workplace testing firm. "The quicker your employees can get their lab results, the faster they can pursue treatment for any abnormalities the lab tests reveal, including chronic illness, high levels of cholesterol, high blood pressure, and more. Armed with their lab results, your employees can also help you shape your workplace wellness programs to best fit your company's needs," said a recent entry on the company's blog. ARCpoint's chief executive officer, Felix Mirando, could not be reached for comment.

Kelley noted that patients who participate in HDL's wellness program, known as My Health Counts, are able to access their test results within seven days of a draw.

The HDL data provided via the smartphone app is color coded green, yellow, and red to indicate whether a patient is in the optimal, intermediate, or high testing range. Each test result is also explained to the patient, as well as the risks attached to being outside of the optimal range.

"Having a tool for our tech-savvy patients to engage in their own health was an important piece for us to offer as part of our mission."
—Tonya Mallory, Chief Executive Officer, HDL

Aside from accessing their lab results, users of the app can also communicate with HDL's clinical consulting team, keep daily diaries of their diets and food consumption, and trade photos of food with other users.

The app was developed in conjunction with MedHelp, a San Francisco-based firm that creates fitness and lifestyle apps and tracking software. It is compatible with wireless devices such as the Fitbit, which tracks calories consumed, and the smart scale manufactured by the French firm Withings, which can broadcast news of weight loss to Twitter and several weight loss support Web sites.

"We have always said that HDL is a health management company with advanced lab services, and having a tool for our tech-savvy patients to engage in their own health was an important piece for us to offer as part of our mission," said HDL Chief Executive Officer Tonya Mallory.

Mallory indicated that while the myHDL is not expected to significantly boost test volumes—tests cannot be ordered via the app—it is expected to better engage employees in wellness programs and hopefully bring down overall health care costs. And there are new iterations of the app currently in the pipeline.

Francis noted that the greater transparency around obtaining lab results may indeed prompt patients to communicate more proactively with their doctors and could even lead to more lab tests. However, he cautioned, it could also wind up leading to patients overwhelming doctors.

"It will create a different paradigm [surrounding] test results," he said.

Takeaway: The ever-growing employee wellness business and recent regulatory changes regarding how test results are transmitted may have created a new opportunity for labs both to grow their core business and to better prove their value in health care delivery.

■ **Genetic Testing Drives Revenue Growth but Little Profit**, *from page 1*

"Although companywide revenue per patient was flat (quarter-over-quarter), patient count for genetic testing increased by 70 percent," said Bio-Reference Chief Executive Officer Marc Grodman, M.D. "The revenue per patient for these services is substantially higher than the rest of our business."

Enzo Biochem Narrows Losses

New York-based Enzo Biochem narrowed its loss for its second fiscal quarter, ending Jan. 31, cutting it to $3.6 million. That's compared to a $5.7 million loss for the year-ago quarter. Revenue was up slightly to $22.9 million, compared to $22.2 million in the second quarter of fiscal 2013. However, the company said the poor weather reduced revenue by a minimum of $500,000.

For the first half of fiscal 2014, revenue dropped slightly, to $47.1 million, compared to $47.8 million during the first half of fiscal 2013. Revenues from laboratory services did rise to $28.7 million, from $28.5 million.

Like Bio-Reference, molecular and genetic testing is pushing Enzo Biochem forward, according to President Barry Weiner.

Opko Health Grows Revenues

The Miami-based Opko Health grew its revenue dramatically but widened its losses. For the fourth quarter of 2013, revenue increased 30 percent to $20.7 million, up from $16.2 million for the fourth quarter of 2012. However, the company lost $17.3 million, compared to a loss of $600,000 in the year-ago quarter. Company officials attributed the loss to investments in ongoing product development.

For calendar 2013, Opko more than doubled its revenue to $96.5 million, from $47 million in 2012. However, it lost $117.3 million for the year, nearly quadruple the $29.7 million loss it reported in 2012.

Opko booked a highly ambitious $1 billion in ongoing research and development and good will on its balance sheet, compared to $92 million in 2012, strongly suggesting it expects an ongoing upsurge in sales. Its assays focus on the use of immunoglobulin G autoantibodies as disease-specific biomarkers. Opko also expects to market in the coming months a new blood test for prostate cancer that it will eventually convert into a point-of-care test. The assay has been available in Europe since 2012.

Transgenomic Struggling

Omaha, Neb.-based Transgenomic continues to struggle, reporting a loss of $4 million for the fourth quarter, ending Dec. 31, up 70 percent from the $2.3 million loss it reported in the final quarter of 2012. Revenue was down to $6.2 million, compared to $7.3 million in the year-ago quarter.

For calendar 2013, Transgenomic reported a loss of $16 million on revenue of $27.5 million. For 2012, it lost $8.2 million on revenue of $31.5 million.

Although Transgenomic reported that its genetic testing business had increased, it did not release specific figures. Overall revenue from its laboratory services segment was down more than 20 percent for the calendar year.

Takeaway: Molecular testing appears to be fueling most of the laboratory sector's revenue growth, but margin growth remains elusive. G2

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INDUSTRY BUZZ

Boston Heart Introduces Test to Predict Short-Term Heart Attack Risk

Boston Heart Diagnostics Corp., the Massachusetts-based molecular cardiac laboratory, has launched an assay that is able to predict a patient's near-term risk of suffering a heart attack or stroke.

The test focuses on myeloperoxidase (MPO), an enzyme that is typically generated in conjunction with cardiac inflammation. Elevated levels of MPO presenting in a patient complaining of chest pain is considered a reliable indication of having a heart attack or stroke within one to six months of diagnosis.

"A high level of MPO in blood vessels increases risk in several ways. It modifies the primary protein in HDL—the 'good' cholesterol—so that it loses its protective properties. It also bruises and roughs up the wall of the blood vessel, making it more prone to rupture and increasing the likelihood that any plaque will become unstable or break off to form dangerous clots," said Boston Heart Chief Medical Officer Ernst J. Schaefer, M.D.

About 715,000 heart attacks occur in the United States every year, according to data from the Centers for Disease Control and Prevention. About three-quarters of those strike for the first time, without any prior warnings. Another 795,000 Americans also suffer strokes annually, with 75 percent of those considered first-time events.

A patient diagnosed with elevated MPO levels can be treated with statins, beta-blockers, and angiotensin-converting enzyme—or ACE—inhibitors, averting a catastrophic event.

Boston Heart's MPO assay retails for $125, compared to a cardiac angiography, an invasive procedure that can cost $10,000 or more. It can be performed as a standalone test or with other inflammation marker assays such as hs-CRP and LpPLA2. It also does not require aliquoting by medical office staff, which a Boston Heart spokesperson said differentiated the test from other MPO-related assays.

MPO test results are also provided in what the company called a "patient-friendly" manner, which includes color coding the specific results as red, yellow, and green in conjunction with various risk levels.

Takeaway: Boston Heart Diagnostics is providing a relatively low-cost test that could be highly predictive of future heart attacks.

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