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HIGHLIGHTS

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Survey Finds Most Hospital Outreach Businesses Not on Block

There have been three large deals involving hospital outreach businesses in the past year. They included Quest Diagnostics' acquisition of UMass Memorial Medical Center's pathology outreach business in Massachusetts and two California deals: Quest's acquisition of Dignity Health's outreach business and LabCorp's acquisition of John Muir Health's outreach operations.

Despite grabbing their share of headlines and suggesting national labs are on an earnest conquest of outreach, those deals apparently have had little overall effect on outreach's structure and operations on the whole, according to a new report on outreach by Michigan-based consulting firm Chi Solutions, Inc. It may be obtained at *www.chisolutionsinc.com*.

Chi's 13th annual national laboratory outreach survey—which queried 136 labs throughout the United States—has concluded that while the nationals are a formidable presence in outreach, much of the competition remains between independent labs and hospitals with outreach programs.

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23andMe Begins to Rebuild With New Business Model

Just months ago, it appeared 23andMe was down for the count. The laboratory had been stopped in its tracks last fall, when the Food and Drug Administration (FDA) ordered it to stop offering genetic interpretations of the DNA kit it was selling directly to consumers.

The FDA had considered the test—which analyzed the saliva of customers and assessed their risk of contracting some 200 medical conditions ranging from digestive disorders to cancers—as an unregulated medical device. As a result, 23andMe required regulatory approval in order to market it to the public, which the Mountain View, Calif.-based business had not pursued.

This not only led to 23AndMe suspending its sending of results to consumers who had already purchased the kit but also relegated it to providing general ancestral background for those customers still willing to shell out $99 for the test—all the while posting vague

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"It is becoming more and more common for one hospital outreach program to become a competitor with another. They start to bump into one another," said Kathy Murphy, Chi's chief executive officer.

And despite the three big deals, Murphy does not believe most hospitals are looking to dump their outreach businesses. That the survey indicated the average net margin for an independent lab's outreach business is nearly 11 percent and the average contribution margin for a hospital-based laboratory is more than 28 percent may have something to do with this.

Murphy noted that since hospitals are able to charge more for tests and have only incremental costs for their operations, outreach is often a moneymaker. And that economic advantage also makes them very competitive with the national labs, she added.

"Whether hospital executives view outreach as good business often depends on their prior experience with outreach," Murphy said. "If they had a good experience in the past, they are likely to be more supportive. If they had a poor experience, for any reason, they tend to think the opposite and it becomes a self-fulfilling prophecy." She noted that hospitals that need short-term cash or whose management team is overwhelmed with other priorities tend to be the likeliest candidates for a sale.

That does not mean that hospitals and independent labs are not keeping their eyes out for deals. The survey noted that while the large majority of respondents have not yet been approached about selling their outreach program and more than 70 percent said they would not accept an offer, 29 percent did say they were somewhat likely to accept one. Nearly half also said they were approached about forming a partial equity relationship, and 56 percent said they were likely or somewhat likely to consider the offer.

"In my experience, executives are looking at their options more as a matter of due diligence," Murphy said. She noted that a sticking point in many proposed deals is giving up day-to-day control of laboratory operations. "They're concerned about any change in service and quality provided," she observed.

Meanwhile, there are areas where hospital outreach businesses are not keeping their eyes on the ball. Remarkably, more than two-thirds of respondents do not know their level of bad debt. And more than three-quarters of those queried were unaware of their average days sales outstanding. Murphy said that data was "shocking." She added that it was a reflection of how many hospitals conduct their business.

"They perform adjustments to revenues on a hospitalwide basis, and outreach revenue is usually commingled with other hospital revenue. They cannot see the financial performance of outreach when all the information is aggregated together," Murphy said.

Takeaway: Hospital lab outreach programs are enjoying relatively healthy margins despite the continued financial pressure on the lab sector. G2

Strong Revenue Growth Continuing for Esoteric Labs, But Bottom Line Is Mixed

Revenues for esoteric testing labs have made large gains this year, though the overall financial picture for many of these companies is mixed.

Genomic Health, the Redwood City, Calif.-based laboratory that focuses on testing for prostate, breast, and other forms of cancer, reported an 11 percent increase in revenue for the second quarter, ending June 30, reaching $70.5 million, compared to $63.7 million a year ago. It reported that test volumes were up 17 percent.

For the first half of 2014, Genomic Health's revenue was $137.5 million, up from $126.4 million a year ago. However, the company remains in the red, posting a loss of $4.6 million for the quarter and $12.1 million for the half—both larger than the year-ago figures.

South San Francisco, Calif.-based Veracyte, which focuses on molecular thyroid analysis, reported a dramatic increase in revenue for the quarter—at $8.7 million it was up 71 percent for the second quarter, while accessions were up 32 percent. For the first half of the year, revenue was $16.2 million, up 70 percent from the first half of 2013. But it made little headway in cutting its net losses: $6.7 million for the quarter and $13.3 million for the half, similar to last year's numbers. The company announced an improved deal with Genzyme regarding the copromotion of its assays.

But perhaps the biggest quarterly results were reported by Cambridge, Mass.-based Foundation Medicine with its genomic profiling of cancer tumors. As of June 30, test volumes were up 263 percent year over year.

As a result, the company reported second-quarter revenue of $14.5 million, up 145 percent from the $5.9 million it reported in the year-ago quarter. The company's net loss widened to $13.8 million, compared to $10 million a year ago. For the first half of the year, revenue was $26 million, more than double the $11.1 million for the first half of 2013. But its net loss was $25.9 million, compared to $17.4 million during the first half of 2013.

Despite the fact that all three of the labs reported losses that were either larger or the same as a year ago, brokerage firm William Blair & Co. had decidedly different predictions for the stock performance of the three labs.

William Blair analysts were most bullish on Foundation, forecasting full-year revenue of $58.1 million, an increase of about 1.5 percent. For Genomic Health, it increased its 2014 revenue forecast to $283 million, a bump of about 1 percent. However, it lowered revenue forecasts on Veracyte by about 2.5 percent because it missed projections for the second quarter.

Takeaway: Although they have yet to achieve profitability, the major esoteric molecular labs are continuing to book ever-growing revenue.

Will Lab Sector Develop a Test for the Deadliest Form of Lung Cancer?

Molecular testing in combination with the practice of oncology has made great strides in the past decades. There are assays for tumor evaluation and even those that predict risk for some of the most common forms of the disease.

In many ways, these tests have revolutionized the way oncology care is delivered. Based on test results, doses of chemotherapy have been adjusted accordingly or abandoned altogether for other treatments. The prophylactic mastectomy, for example, is a direct result of the BRCA test. Celebrities such as Angelina Jolie have raised the awareness of such testing by undergoing a preventive operation herself.

But there remains a conspicuous absence in oncology-related testing for small-cell lung cancer. Lung cancer is the deadliest form of the disease both in the United States and the rest of the world. And the small-cell form is perhaps the deadliest cancer of all.

> ***"The prevailing state-the-art [for diagnosis and treatment is] from the early 1980s."***
> ***—National Cancer Institute***

The five-year survival rate of small-cell lung cancer is just 31 percent if detected in the earliest stage of the disease—less than a third the rate for breast cancer. Survival rates are less than 20 percent for stage 2, and a decidedly bleak 2 percent for those in the late stage of the disease. According to the American Cancer Society, the overall five-year survival rate for all small-cell lung cancer patients is a mere 7 percent.

And like most lung cancers, the small-cell form of the disease is rarely detected in the earliest stages because patients are usually asymptomatic at its onset. It also spreads much more rapidly than its non-small-cell counterpart.

Despite the fact that only about 15 percent of lung cancer cases diagnosed are of the small-cell variety, 30,000 Americans still die each year die from that form of the disease. That's well over 20 percent of the total lung cancer fatalities, an outsized proportion of all deaths given the prevalence of small-cell lung cancer.

The National Cancer Institute (NCI) noted in a recent report to Congress that little progress has been made in battling the disease over the past three decades.

"Avoidance of the use of tobacco is the only known way to prevent the disease; no screening method has proved effective . . . and life expectancy after diagnosis tends to be very short," the report said.

The typical treatment is chemotherapy and radiation therapy, with no guidance as to how a specific patient might respond—"the prevailing state-of-

the-art from the early 1980s," the report noted. Most patients also quickly develop resistance to chemotherapy.

Despite the need for sharper diagnostic tools, none currently exist. "I am not aware of any current, commercially available molecular assays used to diagnose patients with small-cell lung cancer," said Peter Francis, president of Clinical Laboratory Sales Training, a Maryland-based consulting firm.

Little Infrastructure for Development

Meanwhile, the infrastructure for developing a similar test for small-cell lung cancer is all but nonexistent. Most esoteric tests are based on prior genetic research and preservation of the relevant cell lines.

"We don't have proper modern systems to study the disease at all, no cell lines or animal models, and no patient samples," said Guneet Walia, director of research and medical affairs at the Bonnie J. Addario Lung Cancer Foundation. Since surgery is useless for treating small-cell lung cancer patients, most tissue samples are from biopsies and are too small to perform extensive genetic research. The NCI report noted that this is hindering research on determining biomarkers for chemotherapy resistance.

Partly as a result, the NCI has created a new framework for combating small-cell lung cancer, including improving the collection of small-cell lung cancer tissues, creating new tumor profiles for the disease as it progresses, and the investigation of "new diagnostic approaches for populations at high risk of developing small-cell lung cancer." In other words, a predictive risk assay for the millions of Americans who smoke or are former smokers—the cohort with the greatest probability of developing the disease.

"We don't have proper modern systems to study the disease at all, no cell lines or animal models, and no patient samples."
—Guneet Walia, Director, Research and Medical Affairs, Bonnie J. Addario Lung Cancer Foundation

The framework, which was announced last month, drew mostly praise from anti-cancer advocacy groups. "Our long sought effort to devise a national strategy to improve lung cancer's survival rate has taken a concrete step forward," said Lung Cancer Alliance President Laurie Fenton-Ambrose.

But whether the laboratory sector develops any sort of diagnostic tools for small-cell lung cancer anytime soon remains to be seen.

Not Much Available From Labs

Why the laboratory sector hasn't developed a specific test for small-cell lung cancer when it has developed esoteric assays is a matter for debate. The vast majority of cancer victims have the non-small-cell variety of the

disease. As a result, much of the research and test development have been on that form of cancer.

Pinpoint Genomics, a small lab in Northern California, developed a polymerase chain reaction test that determined whether patients with the non-small-cell variety were at high risk of having the disease progress to a late stage after undergoing surgery to remove the tumor, which is the typical intervention to treat the disease. That surgery is often performed for non-small-cell lung cancer patients means far more tissue has been available to conduct the research to develop lab tests.

Pinpoint was acquired by Life Technologies, a division of Thermo Fisher Scientific, in 2012. Life Technologies markets the assay as Pervenio Lung RS.

"Our long sought effort to devise a national strategy to improve lung cancer's survival rate has taken a concrete step forward."
—Laurie Fenton-Ambrose, President, Lung Cancer Alliance

Life Technologies officials estimated that the market for a comprehensive molecular lung cancer assay would be as much as $120 million a year in the United States and $500 million worldwide. A company spokesperson did not respond to a query regarding the development of a predictive or diagnostic test for small-cell lung cancer.

If there is a test developed in the near future, it may come from outside of the United States. Walia of the Addario Lung Cancer Foundation noted that most of the relevant research is currently being performed in Europe. Researchers in the Netherlands are working on developing avatars of lung cancer tumors, while researchers in the United Kingdom are focused on isolating circulating tumor cells. Such cells have been the basis for many esoteric molecular laboratory tests.

"This has the obvious advantage of being noninvasive, since it is a blood test," Francis said.

Walia also noted that researchers may also be able to link levels of volatile organic compounds in a patient's body to their risk for developing lung cancer. Such compounds have been used to determine the level of exposure an individual has had to tobacco smoke.

"The scientific community is very aware of the fact that more needs to be done, and the NCI is putting more money into research," Walia said, noting that the establishment of the framework for fighting non-small-cell lung cancer will soon spur more research—and perhaps an eventual molecular assay.

"Time and research will tell," Francis said.

Takeaway: There may be a market for a molecular test for small-cell lung cancer, but no laboratory has yet to take advantage of the opportunity, and the economies of scale for supporting such a test remain uncertain. G2

■ **23andMe Begins to Rebuild With New Business Model**, *from page 1*

announcements on its Web site that it was working with federal regulators to resolve any outstanding issues. Those issues have yet to be resolved.

But just a few months later, the company is counting its contracts. Having already screened some 650,000 people before it stopped issuing test results, 23andMe used that data in part to remake itself as a facilitator of the gathering of genetic and population health data for both the government and private sector. It also has made several significant additions to its executive staff in recent months, hiring a chief medical officer, a chief legal and regulatory officer, and a vice president of corporate communications.

Toward the end of July, 23andMe announced that it had secured a two-year, $1.37 million grant from the National Institutes of Health (NIH). The money will be used to conduct Internet-based surveys to identify novel genetic associations, allow outside researchers to access deidentified data from 23andMe's databases, and beef up its ability to collect phenotypic data.

And earlier this month, 23andMe entered into a contract with drug manufacturer Pfizer. It will enroll up to 10,000 people into a study of inflammatory bowel disease (IBD). The data will be used for a study of the genetics of ulcerative colitis and Crohn's disease. IBD, which affects about 1.4 million in the United States, often leads to ulcerative colitis and Crohn's.

"Pfizer is committed to bringing forward new treatments for patients suffering with IBD," said Jose Carlos Gutierrez-Ramos, Pfizer's senior vice president of biotherapeutics research and development. "By enhancing our understanding of the underlying biology of the disease, we hope to better support our clinical research activities and development programs."

The financial terms of the deal with Pfizer were not disclosed.

In addition to the NIH and Pfizer deals, 23andMe is also trying to develop a new assay that would test patients for their risk of passing down Bloom syndrome, an inherited disorder that leads to stunted growth and weight and an enhanced risk of contracting cancer at a young age. It is going through the normal FDA approval process for that test.

A 23andMe spokesperson did not respond to e-mail and telephone requests seeking comment.

In a recent interview with *Forbes* magazine, company co-founder and Chief Executive Officer Anne Wojcicki indicated that her management team moved quickly to rebuild after the issues with federal regulators.

"We've made mistakes. When you try new things, you will make mistakes. That's OK. We will make mistakes again in the future," she said. "The best thing you can do is to understand how you quickly recover. A lot of companies would shut down in this situation, but we looked at how do we double down."

Takeaway: After getting slapped down by the FDA, 23AndMe appears to be getting on its feet. G2

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INDUSTRY BUZZ

HDL Uncovers More Reliable Markers for Diabetes

You may be at risk for diabetes and not even know it, Health Diagnostic Laboratory (HDL) has concluded in a new study.

A biomarker screening of nearly 1,700 patients by the Virginia-based HDL determined that testing insulin resistance and dysfunctions in their pancreatic beta cells are more accurate ways of determining the risk of contracting diabetes than measuring blood sugar levels.

Of that group, 20 percent were already considered diabetic, with another 25 percent considered prediabetic based on their blood sugar levels.

However, another 46 percent of the patients screened who would be considered at low risk for diabetes based on their blood sugar levels showed signs of insulin resistance and dysfunctional pancreatic cells.

A large bulk of the patients reduced their risk for contracting the disease after several months of lifestyle interventions and other treatments. The study was published in the most recent issue of the *Journal of Cardiovascular Translational Research*.

"The findings represent a substantial increase in sensitivity of diabetes risk detection, and earlier detection allows appropriate interventions to be administered when they are likely to be most effective," said Szilard Voros, M.D., HDL's chief clinical strategy officer and one of the study's co-authors.

Finding early ways to confront diabetes is becoming a growing challenge in the United States, where numbers of the type 2 version of the disease have reached epidemic levels. About 30 million Americans have diabetes, close to 10 percent of the entire population. But nearly a quarter of those cases have not been officially diagnosed.

Perhaps more troubling is that another 86 million Americans have shown symptoms of being prediabetic based on traditional blood sugar readings alone, meaning tens of millions more may also be at risk based on HDL's screening methods.

Whether the study findings will be a boon for HDL's bottom line remains to be seen. The company provides screening services and disease management for individuals with cardiac and chronic conditions, including diabetes. An HDL spokesperson did not respond to a request seeking comment.

Takeaway: HDL's screening methods may turn up more patients at risk for developing diabetes and eventually contribute to its bottom line.

References

23andMe
800-239-5230

Bonnie J. Addario Lung Cancer Foundation
650-598-2857

Chi Solutions Inc.
800-860-5454

Clinical Laboratory Sales Training
410-203-1023

Foundation Medicine
617-418-2200

Genomic Health
650-556-9300

Health Diagnostic Laboratory
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