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LABORATORY INDUSTRY REPORT™

Vol. 14, Iss. 22, November 20, 2014

HIGHLIGHTS

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Arizona Lab Develops $99 Molecular Lung Cancer Test

A small laboratory in Arizona has brought to market a product the cancer community is sorely in need of: a low-cost molecular test that can detect all forms of lung cancer at all stages of the disease.

The firm, Tempe, Ariz.-based Global Cancer DX, last month introduced a primarily direct-to-consumer assay simply called The Lung Cancer Test. It retails for only $99 and is focused on groups at high risk for the disease, current and past smokers over the age of 50. That's about 47 million people nationwide. The test is available in 45 states, 26 of which allow direct ordering by consumers without a physician's order.

Global Cancer Chief Executive Officer and founder Will Gartner—who previously developed a low-cost breast cancer test for another of his startups, Provista Life Sciences (now part of Provista Diagnostics)—is playing his cards close to the vest regarding this new assay. Claiming that a firm in China infringed on his breast cancer testing patent, he will only say that The Lung Cancer Test uses the enzyme-

Continued on page 7

Foundation Medicine Strikes Deal for Testing in China

Foundation Medicine has struck a deal with an overseas firm to offer some of its assays in China.

Under the terms of the deal reached with Shanghai-based WuXi PharmaTech Inc., the Cambridge, Mass.-based Foundation has licensed its FoundationOne assay to be performed in China. The FoundationOne assay forms complete genomic profiling of solid tumor cancers. The testing will be performed at WuXi Genome Center. Foundation Medicine will also offer other products to Chinese biopharmaceutical firms to assist them in their research.

"The development and use of targeted therapies and comprehensive diagnostic tests in oncology are expected to grow significantly in China," said Michael J. Pellini, M.D., Foundation Medicine's president and chief executive officer. "WuXi's leadership position in China makes it an ideal partner as Foundation Medicine expands its global reach to support targeted drug development and clinical entry into this rapidly growing market."

Continued on page 2

Foundation Medicine Strikes Deal for Testing in China, *from page 1*

The terms of the transaction were not disclosed.

Although the standalone laboratory sector in China is growing by some estimates as rapidly as 70 percent per year as more of its consumers demand cutting-edge health care services, the WuXi Genome Center is the only CLIA-certified facility in the country.

According to Foundation officials, the company is working with more than 20 biopharmaceutical firms and is providing genomic profiling services to more than 100 studies this year.

In another business development, Foundation announced it has struck a deal to capture and analyze comprehensive genomic, clinical outcome, and cost data from patients. New Jersey-based COTA will provide the analysis for patients who have undergone testing with the FoundationOne assay.

"Eliminating inefficiencies and improving patient care requires actionable insights supported by complete, integrated data," said Eric Schultz, COTA's chief executive officer. "This unprecedented collaboration with Foundation Medicine incorporates the most comprehensive genomic profiling data with COTA's unique real-world, longitudinal clinical outcomes and cost of care data to provide insights that enable both physicians and payers to move toward value-based treatment and reimbursement practices."

The analysis will begin initially for patients who are suffering from non-small cell lung cancer but will eventually expand to other cancer patients as well, according to company officials.

"The capture of clinical outcomes resulting from treatment selection informed by our comprehensive genomic profiles is essential to demonstrating the clinical and economic value of FoundationOne and to expanding utilization and access for these tests," Pellini said.

Takeaway: Foundation Medicine is expanding its overseas reach by tapping into one of the largest markets outside of the United States.

Aurora Diagnostics Acquires West Georgia Pathology

Aurora Diagnostics, the Florida-based pathology operator, has entered the Georgia market with the acquisition of West Georgia Pathology LLC. The hospital-based practice is located in Carrolton, Ga., about an hour's drive west of Atlanta.

West Georgia Pathology, which has four physicians, provides pathology services to Tanner Health System, a nonprofit that operates three hospitals in western Georgia.

"West Georgia is a well-known provider of pathology services in the local region," said Daniel D. Crowley, Aurora's chief executive officer in a statement. "Aurora can provide West Georgia with the resources and structure it needs to continue its growth in the region while maintaining focus on its local patients."

Crowley added that "we are a natural fit for local pathology practices that want a corporate home as industry consolidation continues."

Terms of the transaction were not disclosed.

"We look forward to beginning this partnership with Aurora Diagnostics, and we know that the corporate support it provides will advance and improve our practice in West Georgia," said Lawrence M. Alligood, M.D., of West Georgia Pathology. "As part of a national network, we are eager to work alongside many other exceptional pathologists while remaining a locally based provider."

Standalone pathology practices have been hit hard by numerous reimbursement cuts in recent years, leading many practices to merge or even close, industry observers say.

Aurora spokesperson Bill Halldin said the company is currently negotiating to acquire other pathology practices but disclosed to comment further.

The purchase now has Aurora operating pathology practices in 15 states, including Alabama, Georgia, Florida, Texas, and the Carolinas in the South and Southeast.

Takeaway: Aurora Diagnostics continues to take advantage of a soft market to acquire more pathology practices in various parts of the country. G2

IBM's Watson Division Invests in Pathway Genomics

The Watson supercomputer first made a splash three years ago when it dominated a special *Jeopardy!* tournament against two legendary former champions. Now, its backers are getting into the laboratory business.

The IBM division that manages the supercomputer, the IBM Watson Group, has invested in Pathway Genomics, the San Diego-based molecular laboratory.

The two companies will work to create a consumer-oriented application that will draw on a variety of data sources to help them focus on making healthier choices in their daily lives. The investment is part of $100 million the Watson Group is putting into companies to help develop cognitive applications.

"The medical industry is undergoing a dramatic and systemic change, giving consumers and their physicians a powerful tool built upon cognitive learning, and Watson will make the change even more transformative," said Michael Nova, M.D., Pathway Genomics' chief medical officer.

The specific size of the investment was not disclosed. Pathway Genomics has received some $80 million in startup funds over the last half-dozen years.

The application will be called Pathway Panorama and will be a variation of the mobile application Pathway Genomics released last month for consumer use. It will blend the available health care literature with the user's specific wellness biomarkers to create answers to questions posed by the user. For example, the user can ask Pathway Panorama how much exercise it should do or how much coffee they should drink during the day. The app would then provide an answer based on both the available data and the user's specific biomarker data and vital signs at the time they made the query.

Takeaway: Pathway Genomics and IBM's Watson division are taking steps together to create a high-tech, consumer-oriented approach to personalized medicine. G2

Labs' Ability to Obtain Payer Contracts Limited, Observers Say

Gregory Solak expects to have an answer soon. The vice president for laboratory services for Kaleida Health has helped to painstakingly craft a relationship between the upstate New York hospital system and national player LabCorp not only to address their respective business interests but also to help secure a long-desired preferred provider organization (PPO) contract with BlueCross BlueShield of Western New York, the region's predominant payer.

Its PPO, Community Blue, has long had a laboratory relationship with Quest Diagnostics. And Kaleida, in need of millions of dollars of infrastructure improvement for its lab system, could not compete for the health plan's lives.

"In order to have a competitive bid, we needed to have the resources of a large publicly traded lab for infrastructure for the benefits they can provide," Solak said. He added that Kaleida expects to hear what direction the Western New York Blues will go any day now.

Although Buffalo is in upstate New York, its location on Lake Erie makes it significantly closer to Cleveland, Akron, Ohio, and Detroit than New York City. Along with the financial issues affecting health care nationwide, it has suffered all the economic pressures that have descended on Rust Belt cities over the past five decades, such as the loss of shipping and manufacturing. The city's population is less than half of what it was in 1950 and is continuing to shrink.

Under Financial Duress

Kaleida, which operates five hospitals in the Buffalo area, including the 501-bed Buffalo General Medical Center, is the largest system in the region. But its size has not exempted it from financial duress. According to its 990 tax returns, it reported net income of $12 million in 2012, the most recent year available, on revenue of $1.1 billion. That's a profit margin of just over 1 percent. While it comes on the heels of a $12 million loss in 2011, it's still a fraction of the profits Kaleida posted earlier in the decade. The financial pressures have been compounded by recent capital projects, such as a replacement facility for its Women & Children's Hospital of Buffalo.

Kaleida's lab system has been stuck at around 4.5 million tests performed annually for the past several years. Its outreach revenue, at around $16 million a year, has also been growing relatively little.

"We were looking at a $20 million investment (in our laboratory services) over the next three to five years to make sure we have all the emerging technologies, but access to capital given Kaleida Health's focus on expanding its market share and replacing facilities has been a big concern," Solak said.

The supply chain agreement with LabCorp, which was engineered in 2012, sends most of Kaleida's reference testing to LabCorp's facility in Raritan, N.J.

However, it allows access to LabCorp's economies of scale, giving Kaleida access to what the national giant pays for key products and services.

Huge Cuts in Supply Chain Procurement Costs

"I have joked that Quest and LabCorp are the Wal-Mart, and we saw double-digit reductions in costs [for supply chain procurement]," Solak said.

The deal also allows for Kaleida to receive new equipment at a discount as well that is baked into the agreement, according to Solak. As a result, the deal has cut the costs of operating Kaleida's laboratory system enough that bidding for the Blues contract in a manner that is competitive with Quest Diagnostics finally made sense. And that likely makes a difference regarding Kaleida's future.

"We were able to survive and thrive by handling all the other [insurance carriers in the region], but not having the Blues is a big deficit," Solak said.

But the access to capital labs such as Kaleida's is often a catch-22, as it often has to go hand in hand with access to revenues. Many medium-sized and smaller players are increasingly being shut out by commercial payers, say sector observers, and they need to find ways to gain entree in order to remain competitive.

"We were able to survive and thrive by handling all the other [insurance carriers in the region], but not having the Blues is a big deficit."
—Gregory Solak, Vice President, Laboratory Services, Kaleida Health

Cost is always going to be at the forefront. Richard Gentleman, a senior director of national ancillary contracting for Aetna, the Connecticut-based health insurer, noted that it has manifested specific purchasing power as a national payer. As such, Aetna considers clinical laboratory services to be a commodity. "The price point for services should be similar in Spokane and Georgia," he said. And contracting labs should also have the IT infrastructure in order to provide Aetna with the ability to improve the medical management of its payers and spur wellness initiatives.

"It's the integration and information of packaging, and taking all that information and feeding it back to the plan [that we expect from labs]," Gentleman said.

Meanwhile, with more cost-shifting over to patients, Aetna has been promoting price transparency tools for its enrollees so they will have an idea what their health care services will cost before they receive them, adding an additional layer of cost pressure on labs.

According to Mike Snyder, president of Clinical Lab Business Solutions in New Jersey, population health initiatives—the linkage of testing data to the ultimate health care improvements and outcomes of patients—is where labs will have to prove their mettle to payers. "It's the next big battle that's brewing," he said.

Meanwhile, Snyder observed that the current environment for small and medium-sized labs to obtain payer contracts is "abysmal." And while he acknowledged that Kaleida's joint venture with LabCorp is one way to achieve traction with a payer, it has limited applicability in other regions of the country.

"LabCorp was completely locked out [of the Buffalo market]," Snyder said. "If you go to other markets where both LabCorp and Quest have a dominance and are entrenched, they're not as interested in joint venturing. Where it makes sense for them to cozy up to the hospital, they are absolutely doing it." Otherwise, it makes more financial sense for Quest and LabCorp to purchase hospital outreach services than engage in joint ventures.

The Messenger Model

Another potential collaborative effort for labs, Snyder suggested, is a "messenger" agreement. Such agreements originally surfaced in the oil industry in the 1980s, but they are slowly gaining traction in other industries.

Under a messenger agreement, hospitals or standalone labs (primarily the former) are grouped under a single taxpayer identification number, meaning any revenue received under the agreement flows to a single entity. However, they all make bids and negotiate for a nonhospital ancillary payer contract separately. Information sharing among the entities is barred so as to avoid collusion.

"Not everyone has a seat at the table, and those that are the most vulnerable are the independent labs."
—Mike Snyder, President, Clinical Lab Business Solutions

Carent Laboratory Solutions, which includes 21 hospital-based lab facilities in Colorado and another lab in Nebraska, is an example of the messenger agreement model and has been in operation since the late 1990s. According to Snyder, the Mayo Clinic has been using the messenger model on behalf of its own clients.

But for the most part, the messenger agreement model remains relatively rare. Snyder estimates there are perhaps a half-dozen such models throughout the country, and most primarily involve hospital labs. And standalone labs have been knocking on the door of these messenger groups to see if they can gain admission. Instead, it may be time for some labs to come to terms with the fact that contracts with big payers are not going to materialize and either explore other models, sell, or close down.

"Not everyone has a seat at the table, and those that are the most vulnerable are the independent labs," Snyder said.

Takeaway: With the payer contracting environment for labs becoming increasingly straitened, many have to consider joint venturing or other forms of collaboration in order to remain competitive.

■ **Arizona Lab Develops $99 Molecular Lung Cancer Test**, *from page 1*
linked immunosorbent assay method and focuses on biomarkers relevant to detecting the disease.

Global Cancer is also keeping the price of the test low due to Gartner's previous work trying to get payers to cover the breast cancer assay. "I just swore . . . I would never develop another test that would require medical insurance reimbursement," he said.

> ***"They can screen for cancer, and then do a CT scan, and know they're finding growths."***
> ***—Will Gartner, CEO, Global Cancer DX***

The company has conducted four validation studies for The Lung Cancer Test, and the numbers are impressive: a 92 percent overall accuracy rate for detecting lung cancer, although false positives have been a relatively high 19 percent and false negatives register at a 15 percent rate. However, the data suggest it works at a consistently high rate detecting cancers even at the earliest stages of the disease.

Lung cancer has the highest death rates of all cancers in the United States, killing about 160,000 people a year, up 3.5 percent between 1999 and 2012, according to the American Lung Association. Although survival rates are relatively high when detected in the earliest stages of the disease, most patients are diagnosed only when they become symptomatic, at which point the cancer is usually at an advanced stage.

But perhaps more crucially, the Lung Cancer Test is able to detect small cell carcinomas at an overall 90 percent rate, including 67 percent at stage I and 100 percent at both stages II and III. There has been a lack of any test to detect small cell carcinoma, which kills at a higher rate than other forms of lung cancer.

Gartner said the lab has already received a variety of orders through the Internet from individual customers. His business plan predicts that Global Cancer will generate a substantial profit from the test by the end of next year.

Global Cancer is processing the assay at its own facility, with a turnaround time of 48 hours. It has a draw facility contract with Any Lab Now, which operates in Arizona and North Carolina. It is currently negotiating a pact with Medix Exams—which collects samples for disability and life insurers—to draw blood from patients in other states. The company is also getting feelers from national labs such as Quest Diagnostics and LabCorp, according to Gartner.

Gartner added that a variety of imaging companies—who do a significant business in lung cancer screening—have contacted his lab about the test.

"They can screen for cancer, and then do a CT scan, and know they're finding growths," he said. "They very strongly get the picture."

Takeaway: A low-priced test may now be able to detect the single deadliest form of cancer, even in its earliest stages. G2

INDUSTRY BUZZ

PDI Acquires RedPath Integrated Pathology

New Jersey-based PDI has acquired RedPath Integrated Pathology, a Pittsburgh-based firm that specializes in developing tests that focus on diagnosing and managing gastrointestinal cancers.

The deal will give PDI exclusive rights over one test that RedPath has already developed, PathFinderTG. It determines the risk among patients of developing cancer for pancreatic cysts, which generates about $10 million a year in revenue, officials said.

"PDI's deep go-to market expertise and commercialization infrastructure can deliver the resources needed for the development and promotion of this innovative technology," said Dennis Smith, M.D., RedPath's chief executive officer.

Another test RedPath has in the late stages of development will assess the cancer risk for Barrett's Esophagus, a tissue change that usually occurs in people who suffer from chronic gastroesophageal reflux disorder, or GERD. Although Barrett's Esophagus raises the risk for developing esophageal cancer, the risk has not been specifically quantified in individual patients.

About 45,000 Americans are diagnosed with pancreatic cancer every year, and another 37,000 die from the disease.

"The PathFinderTG testing platform has tremendous untapped potential to deliver a much-needed improvement in diagnostic options for oncologists, gastroenterologists, pathologists, and patients—particularly in pancreatic cancer and other gastrointestinal-related cancers," said Nancy Lurker, PDI's chief executive officer. "This acquisition further demonstrates PDI's commitment to building a growth-oriented portfolio of proprietary molecular diagnostics that serves unmet medical needs in the oncology space."

RedPath will operate as part of the PDI subsidiary Interpace Diagnostics.

PDI paid $12 million in up-front cash for RedPath and an $11 million four-year subordinated note. The deal also includes future payments based on reaching specific performance milestones and revenue.

Takeaway: PDI's acquisition of RedPath is expected to ramp up the visibility of its pancreatic cancer testing platform.

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Clinical Lab Business Solutions
908-237-2807
Foundation Medicine
617-418-2200
Global Cancer DX
602-908-9604
Kaleida Health
716-859-5600
LabCorp
336-584-5171
Pathway Genomics
877-505-7374
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