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HIGHLIGHTS

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Ameritox Creates New Company to Focus on Testing for Anti-Psychotic Drugs

Ameritox sees a new business opportunity in mental illness. The Baltimore-based laboratory that focuses on drug testing primarily in the opioid and pain-management arena has established a new division solely devoted to testing for patient adherence to anti-psychotic medications.

Ingenuity Health is based at Ameritox headquarters and will use its existing testing facilities. Ingenuity Health President Jerry Vaccaro, M.D., a psychiatrist by training, was formerly president and chief operating officer of APS Healthcare, a White Plains, N.Y.-based firm that focuses on disease management, behavioral health, and informatics.

Ameritox officials say Ingenuity Health will try to leverage—and perhaps mitigate—a sad fact among those Americans with mental illness: that despite the fact there have been huge strides in recent years regarding advances in psychotropic medications, about half of those patients prescribed such drugs don't adhere to their regimens. Academic literature suggests that many patients consider themselves "cured" after the symptoms of their mental illness diminish, prompting them to stop taking the medication, or they are disturbed by the side effects. Partly as

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Labs Could Have Issues Reporting Payment Data to CMS

As the latest fix for the Sustainable Growth Rate (SGR) payment formula begins to be absorbed and analyzed by providers, it is becoming clear that laboratories will have enormous adjustments to make in the coming years, particularly as they have to begin submitting payment data to the Centers for Medicare and Medicaid Services (CMS).

"It's difficult to underestimate what Congress did," said Peter M. Kazon, a partner with Alston & Bird, during a webinar recently conducted by the American Association for Clinical Chemistry. He believes labs will be undergoing the biggest change in payment structure since the Clinical Laboratory Fee Schedule (CLFS) was created in the mid-1970s.

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Ameritox Creates New Company to Focus on Testing, *from page 1*

a result, about 13,000 suicides and about half of the mass killings in the United States every year are linked to untreated mental illness.

"Knowing whether a patient diagnosed with serious mental illness is taking their medication is an essential part of treatment and prevention of human tragedy," said Scott Walton, Ameritox's chief executive officer.

Lon Wagner, an Ameritox spokesperson, said that the company sees testing for anti-psychotic drugs as a "very big need," which is among the reasons for the creation of a new company. Such testing could "make a big difference with successful treatment," he added.

For now, Ameritox is playing its new business close to the vest. Wagner, who noted that the space has become very competitive very quickly, declined to disclose any information about projected test volumes, or even how many employees are with Ingenuity Health, only that new hires have occurred. He also declined to release any pricing for the tests.

Ingenuity Health is screening for eight different drugs used to treat patients with mental health issues, including Haldol, Risperdal, and Seroquel. They can be tested for absence or presence in a patient only.

However, Ingenuity Health will also use a proprietary test developed by Ameritox to detect the presence of Aripiprazole, which is used to treat schizophrenia and is marketed under the name of Abilify. Unlike the assays for the other drugs, the Abilify test can determine whether the levels of the drug in the patient's bloodstream are consistent with levels that suggest appropriate prescription adherence.

Wagner said that most of Ingenuity Health's clients would be psychiatrists treating patients and tracking their progress. The testing would allow them to take the guesswork out of whether their patients are taking the medications they have prescribed.

"What we would hope is that this leads to a good conversation with the doctor and the patient about what their circumstances are," Wagner said. It lets the clinicians be clinicians."

Takeaway: Testing for adherence to anti-psychotic drugs and other medications that treat mental illness could grow rapidly. G2

Diagnovus Collaborates With Cincinnati Children's Hospital for Assay Development

Diagnovus, a Nashville, Tenn.-based startup, has entered into an agreement with the Cincinnati Children's Hospital Medical Center to develop and distribute an assay that focuses on a chronic digestive disorder.

The test, known as ENGAUGE GI-EoE, focuses on the diagnosis of eosinophilic esophagitis, an inflammation of the esophagus that can make swallowing difficult and can even induce vomiting. Commonly known as EOE, it affects both children and adults, and research suggests it may be caused by an allergen. Data on how many Americans have the disorder are scant, as International Classification of Diseases codes for EOE were not approved until 2009.

The current pathway for diagnosing the disorder includes multiple biopsies of the esophagus. Oftentimes, patients diagnosed with EOE may actually be afflicted with gastroesophogeal reflux disorder, or GERD, or a variety of autoimmune diseases.

Diagnovus expects to develop a test that would analyze 96 specific genes associated with EOE. A biopsy would still be required, but diagnoses of the disorder would be far more accurate. Much of the genetic research required for the test has already been performed by Cincinnati Children's Hospital.

"We are proud to collaborate with Cincinnati Children's Hospital on this disease and believe the results from this partnership will help many children and adult patients battling this difficult illness," said James Stover, Diagnovus's president.

The parties have not disclosed a timeline for test development and distribution.

Founded in 2011, Diagnovus focuses on testing for diseases and disorders that have been difficult to diagnose using traditional testing methods. Last year, it introduced two esoteric assays. One test helped tailor treatments for patients diagnosed with diffuse large B-cell lymphoma, the most common subtype of non-Hodgkin's lymphoma. The other assay determined if patients with Barrett's Esophagus had a risk of developing cancer, and what form it might take.

Takeaway: Diagnovus is continuing to develop esoteric testing that focuses on medical conditions difficult to diagnose or treat. G2

NeoGenomics Enters Into Testing Deal With Aurora Diagnostics

NeoGenomics has entered into an agreement with Aurora Diagnostics to provide molecular testing at its various testing sites throughout the United States.

Under the terms of the agreement, the Fort Myers, Fla.-based NeoGenomics will provide molecular, fluorescence in situ hybridization (FISH), and immunohistochemistry testing at Aurora's 19 anatomic pathology labs.

"Our committee evaluated quality of testing, breadth and depth of services, information technology capabilities, managed care access, product development pipeline, and future partnership opportunities," said Aurora Executive Vice President Bruce Walton, who added that several molecular labs were evaluated for a potential joint venture.

The Palm Beach Gardens, Fla.-based Aurora Diagnostics is one of the largest independent anatomic pathology labs in the United States, with 110 physicians on staff. Its previous service agreement with NeoGenomics was regional in basis and much smaller than the current pact, said NeoGenomics Chief Executive Officer Douglas Van Oort.

NeoGenomics specializes in oncology testing. Earlier this year, it launched nearly two dozen new tests focused on the genetic sequencing and treatment development of a variety of hematological and solid tumor cancers.

The annualized value of the deal with Aurora and the projected test volumes were not disclosed.

Takeaway: NeoGenomics continues to expand its testing business by providing molecular testing to other laboratories that do not have widespread molecular capabilities. G2

Molecular Labs Continue to Report Robust Growth

As the two national laboratories scrap and grind to acquire seemingly every one of their competitors in a dogged attempt to rebuild vanished revenue momentum, the molecular labs have put on a master class in organic growth.

Virtually all of the publicly traded labs posted impressive, if not eye-popping, numbers for the quarter ending March 31.

Myriad Genetics has apparently suffered few ill effects from losing a landmark U.S. Supreme Court case last year regarding patents it held on BRCA gene testing. Although the Salt Lake City-based Myriad's net income declined slightly, its revenue bounded ahead 17 percent in its fiscal third quarter, ending March 31, to $182.9 million, compared to $156.5 million a year ago.

Myriad Chief Executive Peter D. Meldrum said the quarter came in better than expected. Partly as a result, the company bumped up revenue guidance for fiscal 2014 to between $770 million and $775 million, up from the previous estimate of $740 million to $750 million.

First-Quarter Revenue Comparisons, Major Molecular Labs

Lab	First-Quarter 2014 Revenue	First-Quarter 2013 Revenue
Myriad Genetics	$182.9 million*	$156.5 million*
Sequenom	$46.3 million	$38.5 million
Genomic Health	$67.0 million	$63.1 million
Foundation Medicine	$11.5 million	$5.2 million

**Company's fiscal third quarter*
Sources: Company reports

Myriad also inked a three-year pact with UnitedHealthcare to provide its enrollees its myRisk Hereditary Cancer assay. Meldrum told analysts that he eventually expects near-universal coverage for the test.

Amanda Murphy and J.P. McKim, analysts with William Blair & Co., observed in a recent report that the UnitedHealthcare deal may have been the most significant business development for Myriad in recent months.

"In our view, this contract is a meaningful positive that represents a clear validation of the myRisk assay," they wrote. "Even for those who pick apart a slowdown in sequential growth, in our view, it is hard to support an argument that this contract does not bode well for Myriad's ability to convert its BRCA franchise to myRisk while sustaining pricing."

For the first nine months of the fiscal year, Myriad's net income was $142.6 million. Excluding noncash charges related to its recent acquisition of Crescendo Biosciences, net income was $152.5 million, up 47 percent compared to the first three quarters of 2013.

Sequenom reported similar growth for its first calendar quarter of 2014, albeit on a smaller level than Myriad. Revenue for the San Diego-based company grew 20 percent, reaching $46.3 million, compared to $38.5 million for the first quarter of 2014.

Sequenom also entered into two new international contracts, bringing the total of overseas pacts for MaterniT21 PLUS to 27.

Although Sequenom officials said it was trying to cut off Medicaid-reimbursed testing in states that are not yet covering its assays, commercial test accessions grew by 12 percent. Its primary test, the MaterniT21 PLUS prenatal genetic screening, grew by 14 percent. Its contracts with commercial health plans cover 118 million lives, with another 24 million covered through government programs in the 18 states where reimbursement codes have been approved.

Sequenom also entered into two new international contracts, bringing the total of overseas pacts for MaterniT21 PLUS to 27. It is currently in the process of obtaining approval from the Food and Drug Administration for Impact DX, a sequencing platform that can be used in conjunction with the company's test for V Leiden and Factor II, although more tests are expected to be added to the platform in the future.

"This system will form the basis for transitioning the bioscience platform from basic research into clinical diagnostics," Chief Executive Officer Harry Hixson told analysts during the company's May 1 earnings call.

Sequenom, which primarily operates its accounting on a cash basis, also reported up to $46 million in receivables that have yet to be recorded. The company slashed its net loss by nearly half, to $15.7 million, compared to $29.3 million for the year-ago quarter.

Genomic Health's business was also on the upswing, although not as aggressively as Myriad's and Sequenom's. Revenue for the California-based company's first quarter was $67 million, up 7 percent from the first quarter of 2013, when it was $63.1 million. However, that was below the analyst consensus of $68.7 million.

The company reported a 13 percent increase in the volume of the Oncotype DX breast cancer assay, its primary test, topping 23,000 accessions during the quarter. Chief Operating Officer Bradley Cole said that the international market for its tests has grown 43 percent over the past year and now represents 20 percent of the company's overall volume and 17 percent of its total revenue. It provides the test in about 70 countries.

Chief Executive Officer Kimberly J. Popovits said the company was in a good position to report $1 billion in annual revenue by 2020, a projection that was not dismissed by analysts.

"Genomic Health is less than 10 percent penetrated for invasive breast cancer tests, which represents a large market opportunity," Murphy and McKim said.

The company did report a loss of $7.4 million, up sharply from the $900,000 loss it reported in the first quarter of 2013. Chief Financial Officer Dean L. Schorno told analysts during its recent earnings call that it had beefed up marketing for its prostate cancer test and for overseas sales. As a result, operating expenses increased to $74.2 million for the quarter, compared to $64 million a year ago.

Foundation Medicine also reported robust growth for the first quarter. The Massachusetts-based lab that focuses on sequencing of cancer tumors reported that revenue more than doubled, to $11.5 million, compared to $5.2 million in the first quarter of 2013, an overall increase of 125 percent.

In its 2014 guidance, Foundation Medicine projected it would perform between 22,000 and 25,000 tests during the calendar year and that revenue would be between $52 million and $58 million.

The company performed just over 4,700 tests during the quarter, up 25 percent from the fourth quarter of 2013 and more than triple the volume that occurred in the year-ago quarter. The company reported an average reimbursement of $3,400 per test.

In its 2014 guidance, Foundation Medicine projected it would perform between 22,000 and 25,000 tests during the calendar year and that revenue would be between $52 million and $58 million. Its 2013 revenue was $29 million.

"To meet the increasing demand in the clinical and pharmaceutical business areas, we are continuing to invest in our commercial and business development infrastructure and expanding our . . . sales force," said Foundation Chief Executive Officer Michael Pellini, M.D.

The company also said it had begun the arduous process of getting paid by Medicare for its tests, which have yet to receive specific codes. "We're appealing those claims through the normal channels and we're also continuing our broader dialogue with our local Medicare administrative contractor and with other regional contractors," Michael Ryan, Foundation's vice president of finance, told analysts. "We continue to believe that this process will play out over time, and we do think we're headed in the right direction with our overall approach to reimbursement."

Foundation Medicine lost $12.2 million for the quarter, compared to $7.2 million for the first quarter of 2013. And while the company is sitting on more than $110 million in cash, it has not yet provided any projections as to when it will become profitable.

Takeaway: In contrast to the larger general laboratories, many of the sector's publicly traded molecular laboratories are reporting robust growth in test volume and revenues. G2

■ Labs Could Have Issues Reporting Payment Data to CMS, *from page 1*

Kazon suggested there was little choice for the labs—the SGR fix was going to include a cut to reimbursement. But under the guise of the new bill, the Protecting Access to Medicare Act, CMS's technological change authority is eliminating, meaning the payment issues regarding the revised molecular codes and the use of gap-filling would be avoided, and the changes would be phased in over five years beginning in 2017.

The biggest change: a move away from fixed fees on a payment schedule to what Kazon says is a more market-based approach intended to ensure that Medicare reimburses at rates more similar to those of commercial payers.

Of particular concern for Kazon and other sector observers is the price reporting component of the SGR fix. In order to establish enough pricing data for CMS to set its own reimbursement rates, many labs will have to submit to the agency what private payers pay them for each test they perform in order to help establish a weighted median price. If the median price is more than 130 percent of Medicare's list price, CMS may recoup the payment difference.

"All of this is unknown territory from the data standpoint," said Charles Root, chief executive officer for CodeMap, who also spoke during the webinar.

Labs that obtain the majority of their revenue from the CLFS and the Physician Fee Schedule will have to undertake such reporting. Kazon said that covers the "typical" laboratory.

"A lot of labs probably don't know what their median price is," Root said, noting that even data from a single payer can vary due to out-of-network payments.

Labs do not have an enormous amount of time to prepare: Payment reporting begins in 2016, with the phase-in of new prices beginning the following year. Reporting will be required every three years for most tests.

"There is a big concern here, because it will be a tremendous amount of data. And it's not even known how most labs will be able to do this, to gather this information," Kazon said.

Richard Nicholson, chief executive officer of West Pacific Medical Laboratory, noted that labs in California already went through a dry run of sorts for the state's Medicaid program, which had requested data from labs on their five largest payers several years ago.

Although West Pacific was able to comply with the request, it required sifting through enormous numbers of explanation of benefit records.

"We probably sent in a Dumpster full of stuff," Nicholson said, adding that CMS has likely created a gargantuan task for most labs.

Kazon and Root suggested that it may make sense for CMS to ask for a shorter period for reporting payment data, as opposed to an entire calendar year.

Takeaway: Many labs will likely be scrambling in the coming years to establish the appropriate infrastructure to gather and report their pricing data to the CMS.

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INDUSTRY BUZZ

Clinical Reference Lab Purchases Part of Hooper Holmes

Kansas-based Clinical Reference Lab (CRL) and Hooper Holmes Inc. have agreed to swap some assets and services that will allow the latter to focus on workplace wellness initiatives.

CRL has come to terms to acquire Hooper Holmes's Heritage Labs International and its Hooper Holmes Services division for $3.7 million. The deal is expected to close by the third quarter of this year.

Heritage Labs focuses primarily on urine-based kit testing of HIV, cardiovascular, and other health disorders, primarily for due diligence work performed by life insurers screening policy applicants prior to writing coverage. Its most memorable feature may be its mascot, Heritage the Lab, a black Labrador dog who receives far more description on the lab Web site than the tests the company performs. The annual volume of tests performed by Heritage Labs was not available.

The transaction appears to be a good fit for CRL, which performs more than 100 million tests annually and has a sizable business performing testing for the life insurance sector.

Heritage will use the cash infusion from the sale to focus more on growing its health and wellness and clinical research. In turn, CRL will perform all of Heritage's lab testing after the sale is completed. It will also include Hooper Holmes in its provider network for wellness programs.

Health and wellness programs for medium-sized and large employers have been growing rapidly in recent years as those companies struggle to keep health care costs down and manage employees who may be struggling with their weight and other lifestyle issues. Quest Diagnostics indicated how important the business is to the lab sector after it announced the acquisition of Michigan-based corporate wellness giant Summit Health.

"Laboratory testing is an important and growing component of wellness programs and CRL is an industry leader," said Hooper Holmes Chief Executive Officer Henry Dubois in a statement. He did not respond to a phone call and e-mail requesting further comment.

Takeaway: Labs both large and small are taking aim at the wellness sector as a way to grow their business. G2

References

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CodeMap
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Diagnovus
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Foundation Medicine
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Genomic Health
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