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HIGHLIGHTS

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UnitedHealthcare, BeaconLBS Launch Florida Preauthorization Pilot Program

LabCorp's Beacon Laboratory Benefit Solutions laboratory management system is touted as a way for smaller laboratories to better manage their operations. But the nation's largest health insurer apparently sees Beacon as a way to potentially ratchet down costs throughout a large chunk of its provider network.

That is how Minnesota-based UnitedHealthcare is employing Beacon in Florida, where it will launch a lab benefit management program starting Oct. 1. Beacon will serve as its administrator.

In a letter sent to its network of independent and hospital labs last May, UnitedHealthcare said the use of the Beacon system is "to help improve quality of care and manage appropriate utilization for outpatient laboratory services."

The pilot pertains only to UnitedHealthcare's fully insured commercial members, which excludes its huge Medicare Advantage business, Medicaid managed care, and a variety of subsidiaries. Nevertheless, it is fairly sweeping. More than 80 tests—including virtually all ana-

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NeoGenomics Acquires Path Logic, Expands NGS Cancer Profiles

NeoGenomics has enhanced its recent dramatic organic growth with a significant acquisition.

The Florida-based NeoGenomics announced earlier this month it had completed the acquisition of Path Logic, an anatomic pathology laboratory based in West Sacramento, Calif. It has a second lab in Santa Ana in Southern California. And in what is becoming an increasingly rare event in laboratory mergers and acquisitions (M&A), NeoGenomics announced the purchase price: $6 million. The lab itself has annual revenue of about $10 million. Analysts Amanda Murphy and J.P. McKim of William Blair & Co. estimate that the deal was paid for in equal amounts of cash and debt.

"Path Logic has earned a reputation as one of the highest-quality anatomic pathology laboratories in California. The staff of outstanding

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UnitedHealthcare, BeaconLBS, *from page 1*

tomic pathology assays and even basic thyroid and urine panels—require preauthorization by submitting a request through Beacon's platform and waiting for approval.

Moreover, many tests also require that the pathologist have certification from the College of American Pathologists. And a second review by another appropriately certified pathologist may also be required, both for premalignant and malignant diagnoses. For dermatopathology cases, one of the pathologists involved in the diagnosis must have a subspecialty in dermatopathology; ditto for cytopathology and hematopathology.

If the preauthorization and other protocols are not followed, the pathologists will not be paid for the services rendered.

Laboratory Industry Report attempted to reach about a dozen independent pathologists practicing in Florida for comment. Most either declined to comment or did not respond. But the one clinician who did go on the record felt the pilot project was an overreach.

"It's a very sophisticated business strategy on the part of LabCorp to increase market share for [its] outpatient business and for United to boost profits disguised as a 'quality initiative,'" said Pedro Carmona, M.D., a pathologist who practices in Titusville, Fla.

Carmona is concerned about having to retain—and possibly pay— subspecialists for second reviews, particularly for work that he believes is often unnecessary. As an example, he believes that after 25 years of practice, he can accurately diagnose about 70 percent of hematopathology cases without a review from a subspecialist.

"We've received training for diagnosing a lot of hematopathology and dermopathology cases," he said. "Does that experience and training not count anymore?"

Carmona does not believe the UnitedHealthcare-Beacon initiative will have a large impact on his practice, as he does not treat a large number of United enrollees. But he is concerned that it could impact the community hospitals involved in the Titusville area and elsewhere in Florida.

A LabCorp spokesperson did not respond to repeated requests for comment. A UnitedHealthcare spokesperson said the program helps providers choose the most appropriate tests using evidence-based guidelines.

At the same time, a report released earlier this month by the Office of Inspector General of the U.S. Department of Health and Human Services concluded that more than 20 percent of all of the laboratory claims submitted to the Medicare program in 2010 are tied to questionable billing patterns. That may provide the leverage for UnitedHealthcare to eventually expand the program into other states and insurance plans.

Takeaway: LabCorp appears to be expanding its Beacon subdivision beyond laboratory management and into the realm of private payers and utilization management.

Study Details Sensitivity of clonoSEQ Assay

Seattle-based Adapative Biotechnologies has released a study concluding that its clonoSEQ molecular assay is far more accurate in identifying relapses of b-cell acute lymphoblastic leukemia (B-ALL) compared to standard flow cytometry.

B-ALL, a pediatric form of leukemia, is diagnosed in about 6,000 children in the United States every year. It is far more treatable than the adult form of the disease, and survival rates are higher if caught in a timely fashion and relapses are aggressively addressed. The clonoSEQ assay focuses on detecting minimal residual disease (MRD), considered an accurate predictor of relapse.

According to a comparison test between clonoSEQ and the flow cytometry equipment at the University of Washington on 99 children with B-ALL 29 days after the first round of chemotherapy, the assay identified 28 relapses that flow cytometry did not catch. The presence of MRD was at levels 10 to 100 times lower than where both flow cytometry and clonoSEQ were able to accurately diagnose its presence.

"Accurately measuring minimal residual disease is a critical component of patient care in acute leukemias," said David Wu, M.D., an associate professor of laboratory medicine at the University of Washington. "Next-generation sequencing is a very promising technology that could greatly improve on current approaches."

The study was published in the online edition of the journal *Clinical Cancer Research*.

Takeaway: Molecular assays are continuing to demonstrate far greater diagnostic sensitivities than many other forms of testing.

AutoGenomics, Genomas Team to Develop Statins Stress Test

AutoGenomics and Genomas have entered into a strategic alliance to develop assays and test platforms to better guide physicians in properly dosing statins.

Statins, which are used to regulate cholesterol levels in patients to reduce their risk of developing cardiovascular disease, are among the most prescribed medications in the United States. About 57 million Americans are currently prescribed the medication. A study published earlier this year by researchers from Duke University in the *New England Journal of Medicine* suggested that another 13 million should take the medication under expanded eligibility guidelines.

Although statins are mostly safe, they do pose the risk of muscle pain and damage in a significant subgroup. The collaboration between the California-based AutoGenomics and the Connecticut-based Genomas, which is based at Hartford Hospital, is intended to address that issue. The two companies would merge their existing products in order to create a test that would predict the risk of muscular issues in individual patients.

"Growing evidence indicates that genetics determines who develops muscle complaints with statins," said Paul D. Thompson, M.D., chief of cardiology at the Henry Low Heart Center at Hartford Hospital in Hartford, Conn. "The partnership will allow us to pursue the final implementation studies of the multigene biomarker system to personalize cardiovascular therapy."

Neither company issued a timeline regarding development of a specific test or how their collaboration is structured. A spokesperson for AutoGenomics did not respond to a request for comment.

Takeaway: Common treatments can be further refined through the use of genomic testing.

Inside The Lab Industry

Laboratory M&A Heating Up Again—On a Smaller Scale

Laboratory transactions have simmered down over the past couple of years, due to a dearth of still-available acquisition targets and reimbursement cuts that have hit the pathology sector—and the value of its individual practices—particularly hard.

The biggest blow was the Centers for Medicare and Medicaid Services' 52 percent cut in the technical component of Current Procedural Terminology code 88305 that was implemented last year, which led to overall reimbursement for 88305 dropping by a third. This caused many pathology practices to suffer double-digit percentage drops in their revenues. That dramatically dropped overall practice valuations, taking many pending deals off the table and prompting other pathologists who were pondering selling their practices to change their mind.

But evidence is now emerging that mergers and acquisitions (M&A) are perking back up again, particularly in the realm of pathology. However, they are being driven by deals on a significantly smaller scale than in the past, and possibly at lower valuations.

That's the assessment of Jeff Ellis, the managing director of Crosstree Capital Partners, a Florida-based investment banking firm that provides mergers and acquisitions advisory services to diagnostic laboratories.

Ellis's firm has estimated that 16 mergers and acquisitions in the laboratory realm took place during the first half of 2014, compared to just 10 in the first half of last year, an increase of 50 percent. That includes two deals that occurred in Canada, meaning 14 overall took place in the United States. There were also two deals reported in the first part of July, putting the year-to-date total at 16 in the United States and 18 overall.

If you add the acquisition of employee wellness firm Summit Health by Quest Diagnostics last March (which is not on Crosstree's list) the total in the United States rises to 15.

By comparison, another transaction list kept by the Pennsylvania-based Haverford Healthcare Advisors toted only eight laboratory deals that took place in the United States during the first half of 2013.

Moreover, six of those transactions involved a lab either focused on the practice of pathology or that offers pathology services. The first two deals that were recorded in the second half of 2014 also involved anatomic pathology laboratories.

"Last year, we tracked one or two. The reimbursement cuts had hamstrung the market, but we are now seeing signs of stabilization," Ellis said.

Haverford's list confirms that—there was only one pathology deal during the first half of the year. That was Ascend Clinical's acquisition of Path Central.

Clinical and Pathology Laboratory Transactions, First Half of 2014

Number	Date	Acquirer	Target	Segment	Target State	Value of Deal	Multiple of Revenue	Multiple of EBITDA
1	January	LabCorp	Covance Genomics Laboratory	Specialized	NJ	NA	NA	NA
2	January	Health Enterprises Medical Laboratory	Skiff Medical Center	Outreach	IA	NA	NA	NA
3*	January	Gamma-Dynacare	Lab Bio-Medic	Clinical	Canada	NA	NA	NA
4*	January	Quantum Genetix	GenServe Laboratories	Specialized	Canada	NA	NA	NA
5	February	LabCorp	Laboratory Partners Inc./Talon	Anatomic/ Clinical	OH	$10.5 million	NA	NA
6	February	Myriad Genetics	Crescendo Bioscience	Specialized	CA	$270 million	9.3	NA
7	March	Quest Diagnostics	Solstas Lab Partners Group	Anatomic/ Clinical	NC	$570 million	1.6	NA
8	March	ABRY Partners	Aegis Sciences Corp.	Toxicology	TN	NA	NA	NA
9	March	Quest Diagnostics	Summit Health	Specialized	MI	NA	NA	NA
10	April	Quest Diagnostics	Steward Healthcare System	Outreach	MA	NA	NA	NA
11	May	Cellnetix	Highline Pathology Associates	Anatomic	WA	NA	NA	NA
12	May	Incyte Diagnostics	Medical Center Laboratory	Anatomic	WA	NA	NA	NA
13	May	American Health Associates	Medlab Nursing Home Labs	Clinical	OH	$5.5 million	NA	NA
14	May	BelHealth Investment Partners	Precision Toxicology	Toxicology	CA	NA	NA	NA
15	June	Aurora Diagnostics	Hallmark Pathology	Anatomic	MA	NA	NA	NA
16	June	Aurora Diagnostics	Mid-Atlantic Pathology Services	Anatomic	VA	NA	NA	NA
17**	June	Cancer Genetics	Gentris Corp.	Specialized	NC	$6.25 million	NA	NA
18**	July	Incyte Diagnostics	Accupath Laboratory Services	Anatomic	WA	NA	NA	NA
19**	July	NeoGenomics	PathLogic	Anatomic	CA	$6 million	0.6	NA

Source: Crosstree Capital Partners
**Transaction is limited to Canada only. **Occurred in second half of 2014*

Aside from the stabilization of the pathology market, Ellis noted that some regional players are making their own moves, figuring that acquiring a smaller nearby practice can help them add scale easier than growing business organically. One example of that is Seattle-based InCyte Diagnostics. It has acquired two local practices so far this year: Medical Center Laboratory and AccuPath Laboratory Services. Ellis also cited Aurora Diagnostics, which acquired Hallmark Pathology and Mid-Atlantic Pathology Services, both regional labs in Massachusetts and Virginia. Aurora was previously fairly active in M&A but had been on the sidelines for about the past 18 months.

"Our sense is that the smaller anatomic pathology groups are in a defensive mode given all the cuts, and the likelihood of further reimbursement cuts in the future," Ellis said. "They have concerns about their sustainability and profitability at their size, and they are looking for ways to combine or continue their operations."

They are also apparently resigned to smaller asking prices than in the past.

"The company may have done 10 million in revenue [before the 88305 cuts] and had $5 million in EBITDA [earnings before taxes, depreciation and amortization]," Ellis said. "Now, they're doing $7 million in revenue with $2 million in EBITDA with the same volume" and are therefore cutting the potential sales prices for their practices.

Anatomic pathology groups "are looking for ways to combine or continue their operations."
—Jeff Ellis, Managing Director, Crosstree Capital Group

While more deals have taken place in 2014, there has also been slightly more disclosure of financial terms. Five purchase prices have been disclosed to date, for a total of $866.25 million. That does not include the $6 million price NeoGenomics paid to acquire California-based Path Logic, a July transaction that applies to the second half of this year.

The biggest deal according to Crosstree's list was New Jersey-based Quest Diagnostics' acquisition of Solstas Lab Partners from a private equity fund for $570 million. At the time the deal was announced, Quest Chief Executive Officer Steve Rusckowski described the deal as in support of the company's strategy, which includes "restoring growth and driving disciplined capital deployment through strategically aligned, accretive acquisitions."

Quest did not disclose the price it paid to acquire Summit Health.

Another substantial deal in the first half of the year was Utah-based Myriad Genetics' acquisition of Crescendo Bioscience for $270 million. Those were the only deals recorded so far this year with a valuation of more than $100 million.

Takeaway: Since the reimbursement for pathology practice has stabilized, the market for practices has as well, helping drive overall laboratory M&A. G2

■ **NeoGenomics Acquires Path Logic, Expands NGS Cancer Profiles,** *from page 1*

specialized pathologists, with capabilities in dermatopathology, nephropathology, women's health, and GI/GU pathology, will further build and diversify NeoGenomics' specialized testing as a 'one-stop shop' for highly specialized AP testing services," said Douglas Van Oort, NeoGenomics' chief executive officer. "With this expanded capability, both our clinical trial clients and our hospital and pathology-based clients will have access to an expanded product line and consulting expertise."

Van Oort estimated that the acquisition would add between $3 million to $4 million of revenue synergies in the short term, as customers on both of their lists have access to the merged testing menus. After a period when redundant operations are eliminated, he projects that the transaction will be accretive to NeoGenomics' bottom line within six months.

The deal sent NeoGenomics' stock soaring about 15 percent, rising from about $3.65 a share just before it was announced to more than $4.20 a share. The stock was trading at little more than $3 a share in late June.

"We believe that these small targeted profiles of driver genes are the most clinically justifiable approach to cancer testing."
—Maher Albitar, M.D., Chief Medical Officer, NeoGenomics

Last month, NeoGenomics bumped up its estimates for second-quarter revenues by 7 percent, from between $18.8 million and $19.3 million to $20 million and $20.5 million. However, it did not increase its earnings estimates, which are currently at around breakeven.

As a result of the transaction, Murphy and McKim upgraded revenue projections for NeoGenomics by $5.7 million for 2014 and $13.3 million for both 2015 and 2016. And while they are cutting their prior earnings per share estimate by a penny a share, they are increasing it by 3 cents in 2015 and 4 cents in 2016.

Meanwhile, NeoGenomics also announced the release of 23 new cancer profiles using next-generation sequencing. They can be used for both solid tumors and hematological forms of the disease.

"These new profiles are designed to provide information that clinicians can utilize in the management of their patients. They provide information on clinical behavior, prognosis, and potential response to currently approved drugs and investigational therapies undergoing clinical trials," said Maher Albitar, M.D., NeoGenomics' chief medical officer and its director of research and development. "While each profile covers, on average, less than 20 different actionable molecular abnormalities, physicians can customize each profile and add additional genes from a list of validated genes. We believe that these small targeted profiles of driver genes are the most clinically justifiable approach to cancer testing given the targeted drugs that are currently available."

Murphy and McKim noted that the expansion of NeoGenomics' product offerings "enables pathologists to further broaden their test menu options [and thus compete against larger independent labs] while being able to retain the sample to benefit from the professional component of FISH and flow [cytometry]." They also noted that the company should be able to expand its scale and reach through additional M&A activity. It reiterated an "outperform" rating for NeoGenomics' stock.

Takeaway: NeoGenomics' organic growth is being supplemented with a significant outside acquisition. G2

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INDUSTRY BUZZ

Foundation Medicine Teams With Patient Advocate Foundation

The Massachusetts-based Foundation Medicine has joined forces with a health care consumer group with the intent of assisting in the sometimes onerous cost of providing cancer care.

The alliance, known as FoundationOne CareLine, is between Foundation Medicine and the Virginia-based Patient Advocate Foundation (PAF). It is the expansion of a previous pilot program that began in late 2012. It offers case management services to uninsured and underinsured patients facing obstacles in identifying and obtaining specific therapies for their tumor types.

PAF focuses on providing financial relief to consumers who need medical care, including coverage of copayments, assistance in navigating health insurer bureaucracy, and medical debt relief.

"Rapid developments in genomics and the scientific understanding of cancer in recent years have fundamentally changed the way cancer can be treated, yet at times, the advances evidenced by new medical and scientific data have outpaced access to treatment," said Deborah Morosini, M.D., Foundation's vice president of clinical development. "Through this partnership with Patient Advocate Foundation, FoundationOne CareLine connects patients to case management resources that help them navigate the appropriate channels to secure treatments by leveraging peer-reviewed literature supporting their use."

Cancer care is among the most expensive forms of health care delivery in the United States, costing about $125 billion annually. That number is projected to reach $175 billion by the end of the decade. At the same time, most Americans are experiencing dramatically increasing out-of-pocket costs, even when they have insurance coverage. Some covered treatments leave patients with bills of $5,000 or more. Meanwhile, a genomic assay to determine the makeup of a tumor can cost $3,000 or more.

The caseworkers for Foudation and the PAF are trained as either nurses or social workers, with a background in insurance coding and billing. Foundation spokesperson Dan Budwick said they will help determine whether individuals are eligible for insurance coverage for FoundationOne's tests and assist in appeals involving coverage, enrollment in clinical trials, and obtaining discounts or compassionate use waivers for pharmaceuticals.

Takeaway: Advances in personalized molecular medicine often do not take into consideration the often high costs of such care.

References

Aurora Diagnostics 866-420-5512	Foundation Medicine 617-418-2200	NeoGenomics 239-768-0600
AutoGenomics 760-477-2248	Genomas 860-545-4574	Quest Diagnostics 973-520-2700
Crosstree Capital Partners 813-774-4750	LabCorp 800-845-6167	UnitedHealthcare 800-328-5979

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