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LABORATORY INDUSTRY REPORT™

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HIGHLIGHTS

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Illumina Teams With Equity Firms to Create Consumer Genomics Data Company

Illumina is betting big on the consumerization of medicine and molecular data. But it isn't going it alone.

Along with private equity firms Warburg Pincus, Sutter Hill Ventures and both a clinical and financial hand from the Mayo Clinic, the San Diego-based Illumina has created Helix. Based in San Francisco, the new company will create and provide consumer-friendly sequencing and database services.

The move comes as more laboratories are positioning themselves to not only provide test results directly to consumers, but also crunching genomic data to help predict any health issues they might encounter as they age, or provide guidance for treating cancers or other serious medical issues that might arise during their lives.

Altogether, Illumina and its partners have committed more than $100 million to get the company off the ground, although no one at Helix would disclose the amount each party invested.

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Cleveland Clinic Teams With Cleveland HeartLab, Procter & Gamble to Develop Heart Disease Biomarker Test

Sensing a big diagnostic business possibility, the Cleveland Clinic wants to learn the tao of TMAO.

That's short for trimethylamine-n-oxide. It is a metabolite that originates in the human digestive system. However, levels of TMAO in the blood are a strong indicator of heart disease in a patient—and therefore could make for a useful diagnostic tool.

As a result, the Cleveland Clinic is teaming up with the Cleveland HeartLab and consumer products giant Procter & Gamble to create not only a test for detecting TMAO in patients, but develop a therapeutic product that would be sold directly to consumers.

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Cleveland Clinic Teams With Cleveland HeartLab, Procter & Gamble, *from page 1*

"The objective of the collaboration with (Procter) is the development of a consumer over-the-counter product that would help manage TMAO levels," said Mary Kander, who is coordinating the project on behalf of Cleveland Clinic's innovations arm.

"We knew early on that this discovery was of profound importance and could impact the lives of patients everywhere for the better."

— Thomas Graham, Chief Innovation Officer, Cleveland Clinic

According to Kander, both the Cleveland Clinic and Procter & Gamble are investing in the initiative. Any therapeutic that is developed would be distributed by Procter under a license from the Cleveland Clinic. Cleveland HeartLab, which is a Cleveland Clinic spinoff, will develop the diagnostic and offer it to patients as an advanced cardiovascular test. It is expected to be available before the end of the year, according to Kander.

The linkage between TMAO and heart disease and the risk of heart attacks was discovered by a Cleveland Clinic research arm four years ago. Its presence can determine whether the consumption of eggs, red meat and other foods high in cholesterol makes it more likely a patient will develop heart disease and its associated problems, or not.

"We knew early on that this discovery was of profound importance and could impact the lives of patients everywhere for the better," said Thomas Graham, the Cleveland Clinic's chief innovation officer, in a statement. "All stakeholders sought to find the right partnership to help realize the potential advancements in health and wellness promised by this discovery."

Graham noted in a statement issued by the Cleveland Clinic that Procter was chosen as a product development partner because of its experience marketing and selling over-the-counter health devices. The company recently retooled the Metamucil fiber beverage to include an entire line of food and probiotic products intended to increase the intake of fiber, which can be used to stave off heart disease.

Any therapeutic medication or device intended to manage TMAO levels could take longer to develop than the TMAO assay, as it would require approval by the U.S. Food and Drug Administration. Kander noted that there was a likelihood that the diagnostic could be available to consumers before any therapeutic.

Takeaway: The Cleveland Clinic is working to make available a consumer-friendly diagnostic and therapy to better manage heart disease. G2

Medium-Size Labs Report Mixed Earnings Bag

For some medium-sized molecular laboratories, robust growth in revenue for the first half of 2015 continues to carry the day. For others, they are searching for the elusive catalyst that will take them to the next fiscal level.

NeoGenomics, the Florida-based laboratory that focuses on a variety of molecular cancer assays, reported robust revenue growth but has had trouble breaking into the black.

For the second quarter ending June 30, NeoGenomics reported an 18 percent growth in revenue, to $24.4 million compared to $20.7 million a year ago. But the company posted a loss of $176,000, compared to net income of $274,000 for the second quarter of 2014. For the first half of 2015, NeoGenomics reported a loss of $937,000

on revenue of $47.4 million, compared to net income of $376,000 on revenue of $38.9 million a year ago. In a call with analysts, Chief Executive Officer Douglas Van Oort said that test volumes grew 21 percent year-over-year, with molecular profiling assays growing 130 percent.

Van Oort reported delays in integrating the products of Sacramento-based PathLogic into its sales pipeline. "We do have concrete plans in place to expand this business and are managing it closely. However, we now expect it will take until about the end of the year to increase revenue at PathLogic to achieve breakeven level of profitability," he said. Van Oort also noted that the proposed increase in reimbursement for FISH testing from the Centers for Medicare & Medicaid Services could lead to an overall positive impact in revenue of $4 million to $6 million in 2016, more than offsetting proposed payment cuts for performing flow cytometry.

San Diego-based Illumina, which performs lab tests and also distributes testing platforms, also reported strong revenue growth, along with an explosive growth in earnings. For the second quarter ending June 28, it reported net income of $102.2 million on revenue of $462.8 million. That compares to net income of $46.6 million on revenue of $390.8 million—growth rates of 120 percent and 20 percent, respectively. The company not only reported significant increases in testing volumes, but a backlog in shipping its testing platforms. However, Illumina has not updated its guidance for the remainder of the year. For the first half of 2015, it has reported net income of $238.9 million on revenue of $921.9 million. That compares to net income of $106.6 million on revenue of $753 million for the first half of 2014.

"We believe we are well positioned to deliver profitability and double-digit revenue growth by the end of the year."

— Kim Popovits, CEO, Genomic Health

Although it reported an 8 percent increase in total test volume during the second quarter, Redwood City, Calif.-based Genomic Health is stuck in a revenue plateau. It reported a loss of $9.2 million on revenue of $70.6 million, compared to a net loss of $4.6 million on revenue of $70.5 million for the first half of 2014. While Genomic Health reported strong volume growth in its OncotyeDX test for ductal carcinoma in situ and prostate cancer and an overall 12 percent increase in orders during the quarter, the company is still struggling to receive commercial payer coverage for its assays in the U.S., although Palmetto GBA just approved coverage of its prostate cancer test for Medicare.

"We believe we are well positioned to deliver profitability and double-digit revenue growth by the end of the year," CEO Kim Popovits said in a conference call with analysts.

Salt Lake City-based Myriad Genetics has mostly gotten past the fallout of an adverse 2013 U.S. Supreme Court decision that essentially dissolved its monopoly on BRCA testing. For the company's fiscal fourth quarter ending June 30, it reported net income of $18.7 million on revenue of $189.9 million. That compares to net income of $33.7 million on revenue of $188.8 million for the year-ago quarter. For fiscal 2015, it reported net income of $80.2 million on revenue of $723.1 million. For fiscal 2014, it reported net income of $176.2 million on revenue of $778.2 million.

Takeaway: The smaller molecular laboratories are grappling with either stagnant revenue growth or keeping strong demand for its products under control. G2

Inside The Lab Industry

Laboratory M&A: Most of the Smaller Players Have Been Absorbed, Leading to Fewer, But Bigger Deals

Fewer deals. Bigger pricetags. That in a nutshell sums up the merger and acquisition activity in the laboratory sector during the first half of 2015.

Altogether, there were 10 deals involving labs during the first half of 2015 in the U.S. That compares to 15 during the first half of 2014, according to data from Crosstree Capital Partners, a health care investment bank based in Tampa Bay, Fla. There were 26 deals consummated in all.

Although there were significantly fewer deals completed so far during the first half of this year compared to last year, their enterprise value is far larger: $2.6 billion among the deals where transaction terms were disclosed (six) versus the $1.25 billion among the seven disclosed deals from the year-ago period, according to the data from Crosstree.

"My sense is that demand among the big commercial labs is strong, and the valuations are high, but I think the supply of candidates is low."

— Christopher Jahnle, Managing Director, Haverford Healthcare Advisors

The smaller number of deals and the larger enterprise total is a reflection of a specific trend: There has been enough merger activity in the lab space that there are fewer entities who can actually join forces in a way that will enhance their bottom lines.

Another study of the market by Connecticut-based Irving Levin & Associates more or less confirmed Crosstree's data. Altogether, the company confirmed eight pure laboratory deals taking place during the first half of this year, with a total enterprise value of $1.47 billion, according to Lisa E. Phillips, who edits the Levin publication *Health Care M&A News*. Her data excludes dental laboratories, which Levin also tracks.

But Christopher Jahnle, a managing director with Haverford Healthcare Advisors, charted only four lab deals that took place during the first half of 2015. His company excludes esoteric laboratories and focuses primarily on medical labs and pathology practices.

"My sense is that demand among the big commercial labs is strong, and the valuations are high, but I think the supply of candidates is low," Jahnle said. He added that there's a shortage of candidates, primarily because 20 years of steady consolidation within the laboratory sector has weeded out a lot of potential takeover targets. And although there remain thousands of independent labs, Jahnle said they tend to service portions of the health care business that are less fiscally desirable, such as skilled nursing facilities.

Inside The Lab Industry

Jeff Ellis, a Crosstree managing director, concurred with Jahnle regarding the lack of candidates. "There are fewer smaller deals due to a dearth of assets out there. There are just fewer smaller independent laboratories," he said.

The biggest deal during the first half was the much smaller OPKO Health's acquisition of Bio-Reference Laboratories for $1.52 billion in company stock.

Nevertheless, the environment to cut a deal has been healthy. "Equity valuations are very strong, and valuations have been on the rise for years now," Ellis said, noting that low interest rates play an interrelated role because they not only help drive valuations but provide an abundance of capital to make purchases.

As a result, the deals have been among somewhat larger players that had tended to acquire smaller labs in the past. The biggest deal during the first half was the much smaller OPKO Health's acquisition of Bio-Reference Laboratories for $1.52 billion in company stock. The deal is expected to lend synergies to OPKO's point-of-care testing business.

Laboratory Transactions During The First Half Of 2015

Announced Date	Target	Buyer	Enterprise Value
6/30/2015	MemorialCare Health System, Laboratory Outreach Service Business	**Quest Diagnostics Inc.**	-
6/29/2015	Emory Genetics Laboratory	**Eurofins Scientific SA**	$40.0
6/16/2015	Physicians Reference Laboratory, L.L.C.	**Laboratory Corp. of America Holdings**	-
6/4/2015	Bio-Reference Laboratories Inc.	**OPKO Health, Inc.**	$1,516.0
6/1/2015	DIATHERIX Laboratories, Inc.	**Eurofins Scientific SA**	$50.0
5/29/2015	AnaPath Diagnostics, Inc.	**Summit Pathology**	-
5/19/2015	Innovative Diagnostic Laboratory, LLP	**GeneNews Limited, Cobalt Healthcare Consultants, Inc.**	$4.0
4/9/2015	CynoGen Inc.	**Rosetta Genomics, Ltd.**	$3.6
1/12/2015	Foundation Medicine, Inc.	**Roche Holdings, Inc.**	$957.9
1/6/2015	Diagnovus, LLC	**Aegis Sciences Corporation**	-

* Target's primary focus is pharmaceutical and biotechnology clientele

Source: Crosstree Capital Partners

Inside The Lab Industry

"It is a very interesting combination of two companies, somewhat of a surprising announcement, and very exciting news for the lab industry," Jahnle said, noting that such transactions suggest that labs are looking to expand their businesses beyond bread-and-butter testing.

Phillips noted that deals such as LabCorp's acquisition last year of pharmaceutical testing firm Covance falls along such lines as well, suggesting that labs are beginning to think outside of the box for their expansion plans.

> *"In fact, July dollar volume has already surpassed $157 billion, which should put the third quarter at a new record. We'll have to wait and see if the Federal Reserve raises interest rates in September, which could slow down deal volume again."*
>
> — Lisa E. Phillips, Editor, Health Care M&A News

"The climate on the diagnostic testing side has been difficult, whereas the clinical research side has been fairly healthy and growing and more profitable," Ellis said.

Another significant deal was Quest Diagnostic's acquisition of the outreach business of MemorialCare Health, a hospital system in Southern California. Although Ellis believes there will be fewer outreach deals moving forward because a significant number of deals have been consummated and they tend to take a very long time to execute, Jahnle thinks they will continue to trickle in as they have over the past half-dozen years.

Meanwhile, there appears to be a consensus that the second half will perk up a little. Jahnle noted that there have been a few deals consummated right after the end of June, and his company has entered into letters of intent with a couple of other labs.

Ellis believes that there will be some pickup of sales of pathology labs and practices, after reimbursement slashes that drove down valuations and ground transactions in that arena to a halt. However, both he and Jahnle noted that Aurora Diagnostics has been one of the few active players acquiring pathology businesses. In July, Aurora acquired Texas-based Brazos Valley Pathology, which provides services to several hospitals in Southeast Texas.

Phillips also noted that there has been an upsurge of overall health care deals in the third quarter, prompted in part by the recent settlement of the *King v. Burwell* case by the U.S. Supreme Court.

"In fact, July dollar volume has already surpassed $157 billion, which should put the third quarter at a new record," she said. "We'll have to wait and see if the Federal Reserve raises interest rates in September, which could slow down deal volume again."

Takeaway: Mergers and acquisitions in the laboratory sector are growing in value but appear to be slowing down overall. G2

Illumina Teams With Equity Firms to Create Consumer Genomics Data Company, *from page 1*

"Genomics is reaching an inflection point in cost, volumes, and knowledge, creating a significant opportunity to unlock information that is currently not widely accessible to individuals," said Illumina CEO Jay Flatley in a statement. "Helix and its founding investors are committed to creating a neutral platform at the highest quality standard that will work with partners to accelerate consumer adoption of genomics."

Mayo's Center for Individualized Medicine will work with Helix to develop applications initially focused on educating consumers and satisfying queries they make about their health. North Carolina-based LabCorp will also lend a hand in the new company, providing analytic and interpretation services focused on genetic conditions that can be medically treated or addressed. LabCorp is not investing in the new venture.

According to Justin Kao, a Helix senior vice president, the company will begin offering services to consumers by the second half of next year. Although he declined to provide specifics about the services that will be offered directly to consumers in an interview, he was certain they would be priced in a highly competitive manner.

"We want these to be consumer-friendly prices," he said, adding that partners would drive pricing, but that prices in the $99 to $199 range per service would be likely for initial products, and the potential for much lower cost applications also exist.

Flatley will serve as Helix's chairman. Helix will be run from San Francisco, but its laboratory team will be based in San Diego. It is currently trying to fill nearly 20 positions, including a director of business development and marketing. Kao believes there will be as many as 100 employees hired during Helix's first year of operations.

While the company will be semi-autonomous, its operations will be consolidated into Illumina's financial statements. It is initially expected that the Helix venture will lose money, as Illumina has forecast it will dilute its own earnings by about 10 cents per share in 2016, or roughly $15 million.

"We view (the) announcement as similar to a reasonably sized venture investment in a central/clinical lab ... with the hope of further catalyzing demand for consumer-based genomics (while also retaining distinct control over the ecosystem)," Analysts Ross Muken and Michael Cherny wrote in a report for Evercore ISI detailing the new venture. "Long-term we see partnering with leading clinical organizations such as LabCorp and Mayo as well as well recognized financial backers such as Warburg Pincus and Sutter Hill as a clear positive as the market developments (first mover advantage in potentially sizeable market), although we also see a complicated regulatory landscape ... as the key limiting factor near-term.

Kao would not say whether Helix planned to offer any prognostic services, which would likely require approvals from the U.S. Food and Drug Administration.

Takeaway: Illumina, which has had huge success with laboratory testing and product distribution, has made an ambitious leap into the direct-to-consumer testing market. G2

INDUSTRY BUZZ

Johns Hopkins Develops Point-Of-Care Test for Chlamydia

A new low-cost point-of-care test for chlamydia that can be performed in conjunction with a smartphone has been developed by researchers at Johns Hopkins University.

Details about the test were presented at the American Association of Clinical Chemistry annual conference in late July.

Currently, most chlamydia testing is performed through nucleic acid amplification testing, or NAAT. Although the test is extremely accurate, it is too complicated to provide in a point-of-care format. Chlamydia has no symptoms initially, but it leads to pelvic inflammatory disease in about a third of all cases because it goes undiagnosed, according to data from the U.S. Centers for Disease Control and Prevention.

The new test platform, known as mobiLab, also employs NAAT technology, but in a point-of-care platform that's about the size of a coffee mug. It requires a specimen swab and a microfluidics cartridge to perform an assay. Test data can be processed via a specialized smartphone app.

The cost per test is about $2, Johns Hopkins officials said. That compares to the current $10 per test cost using traditional NAAT technology. The hope is that the lower price and the convenience of the test could drive up test rates for chlamydia if the mobiLab ever makes it to market.

"We now have these pretty accurate, sensitive, and specific molecular assays to detect very few numbers of organisms in biological samples," said Dong Jin Shin, one of the abstract's authors and a doctorate student at Johns Hopkins, in a statement. "But a lot of these technologies are confined to being used in centralized lab settings. If we're able to bring molecular diagnostic technology closer to the clinic and deliver accurate results to clinicians sooner, then we'll be able to improve our standard of care for patients with chlamydia while also saving costs."

It remains to be seen if the mobiLab will come to market anytime soon. Unlike laboratory developed tests, all point-of-care assays require review and approval by the U.S. Food and Drug Administration.

Takeaway: A point-of-care test for chlamydia is in development and could eventually reach market. G2

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