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Lab Leaders' Summit 2013
Dec. 9, 2013
Union League Club of New York
New York City
www.lableaderssummit.com

Laboratory and Diagnostic Investment Forum
Dec. 10, 2013
Union League Club of New York
New York City
www.labinvestmentforum.com

What's Next for Hospital Laboratories: Operations, Outreach, and Business Models
Jan. 30, 2013
Westin Atlanta Airport
www.G2Intelligence.com/HospitalLabs

A Bankrupt MedLab Will Sell Itself Off

When a group of investors founded MedLab in 2007, the intent was to morph a small group of laboratories in Midwest enclaves such as Cincinnati and Terre Haute, Ind., into a national presence.

Although MedLab stretched itself into eight states and the District of Columbia and grew its workforce to more than 1,000 employees, reality snapped it back down to earth.

Relentless cuts in reimbursement from the Medicare program caused a cash flow crunch and missed debt payments. That prompted MedLab to shed its physician outreach business last summer as part of an intended restructuring. LabCorp quietly snapped up the business last June for $10.7 million and additional payouts that may total $1.2 million.

Much of MedLab's leadership departed right afterward due to a disagreement with its board of directors—the company's current chief

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PAML Aiming for Boomer Market With New Lab Division

There are 77 million baby boomers in the United States, and they control about three-quarters of the nation's wealth. And as business segments from cruise ships to fitness centers have tweaked their business models to cater to them, it seems logical laboratories should do so as well.

That is among the reasons Spokane, Wash.-based national laboratory PAML, LLC has created a new subsidiary business division to provide what is known as age management: a clinical glimpse into the crystal ball to help the boomer generation to decide the best way to preserve their health for the next 30 years or beyond.

Age management typically is focused on patients beginning in their mid-40s and often extending into their 80s. Its focus is to go beyond ensuring absence of disease, creating a holistic sense of good health. Although it is not considered a specific medical specialty, the number of physicians who offer age management services is growing rapidly.

The division, subsidiary known as AION Laboratories ("aion" is the Greek word for eternal), is headed by existing PAML executives and

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■ **A Bankrupt MedLab Will Sell Itself Off**, *from page 1*

executive officer suggested the sale price was lower than what had been envisioned. Its investors also decided they could no longer continue funding expansion.

As a result, MedLab's parent company, Laboratory Partners, and its subsidiaries filed for Chapter 11 bankruptcy protection on Oct. 25. It listed about $32 million in secured and unsecured debts.

While it appeared on the face of it that MedLab was going to use bankruptcy filing in federal court in Delaware to regroup and reorganize, Chief Executive Officer Bill Brandt said that's not actually the case. Instead, MedLab's last two significant assets are on the block. They include its long-term care testing business and significant lab operations in Terre Haute, where it services Union Hospital. Both are in such high demand that Brandt expects the long-term care piece to be sold by next month and the Terre Haute operations sometime in January.

"Everything will be sold; we're assembling the proceeds and performing a Chapter 11 liquidation plan," said Brandt, who is also chief executive officer of Development Specialists Inc., a prominent Chicago-based firm that specializes in corporate turnarounds and workouts and was retained by MedLab earlier this year.

One of MedLab's original lenders, Marathon Special Opportunity Fund LP, is providing a $5 million debtor-in-possession line of credit for the company to continue operations. Some $2.85 million was drawn down immediately, in part to make the Nov. 1 payroll, according to the legal publication *Law360*. Brandt said Marathon is owed slightly more than $20 million.

"Everything will be sold; we're assembling the proceeds and performing a Chapter 11 liquidation plan." —Bill Brandt, chief executive officer, MedLab

The story of MedLab's demise is not uncommon these days, as labs are facing declining utilization, cuts in reimbursements from payers such as Medicare, and steerage to preferred labs from private payers, according to Michael Snyder, principal with Clinical Lab Business Solutions, a New York-area consulting firm.

Add to that MedLab's business concentration: "They were heavily into testing for nursing homes, which is a high-service, low-profit business," Snyder said. Other industry observers noted that the cuts in skilled nursing facility payments have been so steep that it is unclear whether that segment will be appropriately serviced in the future.

As to why MedLab's assets are in high demand when it couldn't cut it as a whole entity, Brandt attributed it to economies of scale.

"We started out in a regional footprint and tried to staff out for a national footprint, and we never got there," he said. As a result, the remaining assets would be attractive to a national player looking to add on for minimal cost, or a smaller regional player that could use cash flow to cover its overhead and try to expand. With MedLab "between and betwixt" those two scenarios, it could not continue making a go of it, according to Brandt. He suggested that a "household name" in the lab business would play a role in the pending transactions.

The only other alternative for MedLab was to continue to contract, eventually ceasing operations and putting all of the employees out of work, Brandt observed. Dismantling was the preferable legacy for everyone—except the company's original founders.

"A great number of jobs will be preserved," Brandt said.

Takeaway: The current business environment for labs is stifling the growth and dreams of newer players.

Genova Diagnostics Purchased by Los Angeles Equity Firm

Genova Diagnostics, the Asheville, N.C.-based esoteric laboratory, has changed hands from one set of private equity firms to another.

Nautic Partners and Ferrer Freeman & Co. LLC (FFC) sold Genova earlier this month to Los Angeles-based Levine Leichtman Capital Partners (LLCP) and some of Genova's executives for an undisclosed sum. Currently, it is the only health care venture in the Levine Leichtman portfolio.

"I'd like to thank Nautic and FFC for their partnership in building the company to where it is today," said Ted Hull, Genova's chief executive officer, in a statement. "We operated as partners and succeeded together. We believe the company is well positioned to continue on its growth trajectory into the future under LLCP's ownership."

Nautic, Ferrer Freeman, and Levine Leichtman declined to comment about the sale. A statement issued by the parties indicated Hull and his team of senior executives would remain in their current position and retain a significant ownership stake in the firm.

> ***"I expect this partnership will contribute meaningfully to the continued growth of our franchise."***
> ***—Sarah Martin, chief financial officer, Genova Diagnostics***

Genova was founded in 1986 and has focused primarily on testing for chronic complex diseases. It began branching out into nutritional and digestive-related testing with the acquisition of Metametrix last year for an undisclosed sum.

Genova recently obtained a patent for a universal test not only for irritable bowel syndrome, but also for imbalances in levels of gut bacteria, records show. Introducing new forms of bacteria into the digestive tract is becoming an emerging form of treatment for some patients with gastrointestinal conditions.

The statement issued by Genova suggested its new co-owner would be investing significantly in its future product lines and expansion.

"As the company continues to grow and diversify its product offering, having a partner with the financial means and experience of [Levine Leichtman] is very attractive," said Sarah Martin, Genova's chief financial officer. "I expect this partnership will contribute meaningfully to the continued growth of our franchise."

Takeaway: The full development of a diagnostic laboratory may require the investment of several outside equity firms over a period of years, if not decades.

Inside The Lab Industry

Big Growth, Little Profit Is the Current Story for Esoteric Firms

While traditional reference laboratory testing has been under pressure due to cutbacks in reimbursements from government and commercial payers, it has been a different story for the publicly traded labs that perform specialty molecular and esoteric testing.

That was borne out in the most recent earnings reports, which indicated a broad section of esoteric and molecular labs reporting significant growth in their revenue.

However, the bottom lines of these labs remained a mixed bag. Virtually all of the companies reported ongoing losses, some of which have doubled over the past year. None have provided guidance as to when they might enter profitability.

On the Way Up

One of the biggest performers of the third quarter was Redwood City, Calif.-based Genomic Health, which saw revenue for the third quarter increase 13 percent, to $65.7 million from $58.4 million from the third quarter of 2012. The company attributed the growth to a widespread acceptance of its tests for prostate and breast cancer. It was also among a few of the smaller esoteric testing firms to report a profit, although it was a minuscule $488,000, down from $3.7 million in the year-ago quarter.

> ***"We are very encouraged by the commercial traction as the utility of FoundationOne and the information it delivers garners growing recognition among oncologists, pathologists, and pharmaceutical companies."***
>
> ***—Michael Pellini, M.D., chief executive officer, Foundation Health***

Despite the narrowed profit—and a loss of $3.4 million for the first nine months of 2013—the numbers still beat expectations of some stock analysts. Analysts Amanda Murphy and J.P. McKim of the firm William Blair had forecast revenue of $64 million and a loss of about $500,000. As a result, they upgraded Genomic Health to outperform and predicted the company would report year-end revenue of $263 million, about $5 million higher than their original forecasts.

Another firm that performed strongly was San Diego-based Sequenom. It reported a near doubling of revenues for the third quarter to $44 million, up from $22.9 million in the third quarter of 2012. Revenue for its diagnostic tests nearly tripled, to $33.3 million from $12.5 million. Test volume increased 87 percent from quarter over quarter due to the increased uptake of the company's MaterniT21 PLUS noninvasive prenatal test. The assay can be used in lieu of amniocentesis, which can place some fetuses at risk.

Sequenom's rise in revenue came despite a warning issued by the company that it is still not getting paid in a timely manner from some payers due to the Centers for Medicare and Medicaid Services still not putting a cogent payment system for molecular tests into full effect. It reported a net loss for

the quarter of $28.1 million, down slightly from the $30.2 million loss reported for the second quarter of 2012. The company has not issued any forecasts as to when it would become profitable.

Another company that reported a big gain in revenue was Miami-based OPKO Health. It reported third-quarter revenue of $20.6 million for the quarter, compared to $11.8 million in the third quarter of 2012. However, it also reported a net loss for the quarter of $60.2 million, up considerably from the $10.2 million loss reported in the year-ago quarter.

Esoteric Lab Results, First Nine Months of 2013

Company	Revenue, First Nine Months of 2013	Revenue, First Nine Months of 2012	2013 Net Income for Period	2012 Net Income for Period
Genomic Health	$192.8 million	$174.7 million	-$3.3 million	$6.3 million
Interleukin Genetics	$1.8 million	$1.9 million	-$5.2 million	-$3.9 million
Sequenom	$117.3 million	$56 million	-$88.5 million	-$84.3 million
OPKO	$75.8 million	$30.8 million	-$98 million	-$30.2 million
Foundation Medicine	$19.3 million	$5.5 million	-$30 million	-$16.8 million
Atossa Genetics	$585,345	$383,346	-$8 million	-$3.4 million
Transgenomic	$21.3 million	$24.2 million	-$12 million	-$6 million

Sources: Company Reports

OPKO, which plans to launch a test early next year to more reliably predict the risk for prostate cancer, attributed more than $47 million of the loss to accounting changes linked to the early conversion of senior notes that were not set to mature until 2033.

Cambridge, Mass.-based Foundation Medicine also reported a big increase in revenue, which jumped to $8.2 million for the quarter from just $3 million during the third quarter of 2012. The company said the health care sector was quickly adopting FoundationOne, its biomarker assay for solid cancerous tumors.

"We are very encouraged by the commercial traction as the utility of FoundationOne and the information it delivers garners growing recognition among oncologists, pathologists, and pharmaceutical companies," said Michael Pellini, M.D., Foundation's chief executive officer.

However, Foundation also posted a loss of $12.5 million for the quarter, more than double the $5.6 million loss it reported in the year-ago quarter.

Treading Water—Or Worse

Not every one of the esoteric firms that recently reported earnings has been experiencing dramatic growth. Waltham, Mass.-based Interleukin Genetics reported revenue for the third quarter of $419,000, unchanged from the third quarter of 2012. The company reported a loss of $2.2 million, nearly double from the loss of $1.3 million reported in the year-ago

quarter. The company focuses primarily on genetic testing for dental and oral diseases. It expects its latest test will be covered by dental payers beginning in early 2014.

Omaha, Neb.-based TransGenomic reported a drop in revenue for the third quarter, to $6.6 million from $7.9 million in the third quarter of 2012, including a reduction in laboratory service volume. It also reported that its loss had doubled, to $5.6 million from $2.8 million.

Partly in response to its ongoing struggles, TransGenomic replaced its chief executive officer in September, appointing Paul Kinnon, a longtime consultant to the firm. Kinnon said he would focus on boosting sales of its diagnostic tests, which focus on genetic anomalies. The company recently inked deals with PerkinElmer to distribute its oncology assays outside of the United States and PDI Inc. to market its tests to better predict the efficacy of certain cardiac drugs.

"We are addressing the FDA's regulatory requirements so that we can resume the national rollout of the ForeCYTE test at the earliest possible date."
—Steven C. Quay, M.D., chief executive officer, Atossa Genetics

"The new commercialization agreements . . . highlight our renewed vigor and corporate strategy, which aims to optimize, through channel partnerships, the commercial potential of these strong assets while focusing our internal resources on our areas of strength," Kinnon said.

Atossa Genetics, the Seattle-based firm that has developed a breast cancer detection test, said in its most recent earnings report that it is inching toward obtaining Food and Drug Administration (FDA) reapproval for its assay, which is known as ForeCYTE.

The ForeCYTE assay and another Atossa product, the Mammary Aspiration Specimen Cytology Test, was voluntarily recalled early last month after the FDA raised concerns about marketing claims made in connection with the tests, as well as some of the accompanying instructions.

The company reported revenue for the quarter of $76,597, down nearly 30 percent from the $105,576 reported for the third quarter of 2012. Its net loss of $3.5 million was more than triple the $1.1 million net loss reported in the year-ago quarter.

Atossa recently renegotiated a deal with one of its investors, Aspire Capital LLC, to obtain additional capital. The two parties reached terms on a $25 million stock buyback deal, helping to more than Atossa's cash balance compared to the second quarter of 2013.

"With cash and cash equivalents of $7.7 million on our balance sheet at the end of the third quarter and a new financing agreement in place with Aspire Capital, we believe we are well positioned going into 2014," said Steven C. Quay, M.D., Atossa's chief executive officer. "We are addressing the FDA's regulatory requirements so that we can resume the national rollout of the ForeCYTE test at the earliest possible date."

Takeaway: Although growth among the labs focusing on esoteric molecular testing is widespread, it could be an indefinite period of time before they begin entering profitability. G2

■ **PAML Aiming for Boomer Market With New Lab Division**, *from page 1*

scientists, although a few hires have been made in the customer service and sales divisions. Most of the testing will be performed at PAML, LLC's reference laboratory in Spokane, with its existing network of phlebotomists performing draws in the offices of patients' doctors or in their homes or offices. Company officials have described the service as "concierge-level," meaning they do not expect many patients to visit draw centers.

"The goal of age management by definition is for individuals to be at their peak physiologic performance," said PAML, LLC Chief Executive Officer Francisco R. Velázquez, M.D., S.M. He added that many middle-aged Americans believe they can take years off of their bodies and minds with the right balance of diet and exercise, and lab testing can provide the appropriate guidance to do so.

Although Velázquez said the expansion dovetails with PAML's dedication to patient wellness, it is also expected to help PAML remain at peak performance in terms of its bottom line. Citing statistics from age management advocacy groups, Velázquez projected as much as 80 percent of AION's business will be cash-pay, with panels running from hundreds to well into the thousands of dollars. And while PAML's organic business is continuing to grow, Velázquez noted that a business segment where reimbursements are unlikely to come under pressure is a good hedge against existing books of business.

> ***"It seems to be a marketing spin on currently available assays. It will be hard to tell if this will take hold."***
>
> ***—R. Scott Liff, president of business development, Kellison & Co.***

"It's fairly lab intensive, and these patients get monitored several times a year," he said.

The diagnostics being offered by AION included baseline assessments for males and females, thyroid and lipid panels, comprehensive cardiovascular and risk assessment, hormone and menopause testing, inflammation testing, and diabetes/metabolic testing. Some genetic and molecular tests are also being offered, primarily to determine specific major health care risks for patients.

R. Scott Liff, president of business development at Kellison & Co. in Cleveland, believes the move by PAML, LLC makes business sense, but he was not without skepticism.

"It's a logical step for labs to look at the middle-aged folks going into their senior years," he said. But Liff later added that AION is not really offering any new tests. "It seems to be a marketing spin on currently available assays. It will be hard to tell if this will take hold."

The creation of the AION subsidiary division means PAML, LLC has expanded its laboratory offerings to both ends of the demographic spectrum. Earlier this year, it invested in Health123, a Seattle-based virtual health technology startup that is offering in-home diagnostic tests that are aimed primarily at the XRs and millennial generation.

"We've always intended to cover all segments of wellness testing in the market," Velázquez said.

Takeaway: In order to make up for unpredictable volumes and revenue in general reference testing, PAML, LLC is expanding to other segments where cash-pay patients are abundant. 

INDUSTRY BUZZ

LabCorp Distributes Improved HIV Detection Test

LabCorp, the Burlington, N.C.-based national laboratory, has launched a more sophisticated test and algorithm for the detection of the HIV virus.

The test is the fourth-generation HIV test that has been made available by LabCorp, which is the nation's second-largest laboratory firm.

LabCorp said in a statement that the new test allows for the detection of the HIV virus about seven days earlier than the previous generation of the test. In addition to confirming an infection, the new test can confirm which of the two HIV antibodies and whether or not the p24 antigen is present in the patient. Levels of the p24 antigen correlate to how long ago the patient was infected with the virus.

According to the Centers for Disease Control and Prevention, about 1.1 million Americans have been diagnosed with HIV, which is a precursor to AIDS. Another 207,000 Americans are estimated to have been infected with the HIV without yet being diagnosed.

Altogether, 50,000 HIV infections are diagnosed in the United States every year, and 32,000 people are diagnosed with having AIDS. The disease is most common among gay and bisexual men, although African Americans are infected at a rate significantly higher than other ethnic groups.

Although HIV and AIDS was once an eventual death sentence, it can be kept in check with a combination of anti-retroviral drugs and is now mostly considered a chronic condition. However, the intensity of the drug regimen—and its accompanying side effects—can be lessened with a quicker diagnosis of HIV infection.

"Fourth-generation HIV screening and associated supplemental testing is a valuable addition to the tools available to achieve early diagnosis of HIV," said Mark Brecher, M.D., LabCorp's chief medical officer. "Detection of acute infections using the fourth-generation assay provides an improved opportunity for early intervention and the potential to affect transmission rates."

A LabCorp spokesperson did not to respond to a request seeking comment.

Takeaway: Improved laboratory testing for viruses such as HIV can lead to a more comfortable treatment regimen for the patient.

References

AION Laboratories
509-720-2466

Genomic Health
650-556-9300

Genova Diagnostics
800-522-4762

LabCorp
336-584-5171

Levine Leichtman Capital Partners
310-275-5335

MedLab
800-522-7556

PAML
509-755-8600

Sequenom
858-202-9000

TransGenomic
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