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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

PAML Launches Hospital Lab Consulting Arm

Pacific Northwest powerhouse PAML has launched a program to provide enhanced consulting services to hospital laboratories.

The announcement by the Spokane, Wash.-based PAML comes just a couple of months after Austin, Texas-based Sonic Healthcare USA announced it was launching a similar service. As with the Sonic service, PAML officials indicated it was not a springboard toward acquiring hospital laboratories.

"We're not looking specifically at acquisitions," said Francisco R. Velázquez, M.D., PAML's chief executive officer. "This is a value-added service for clients and prospective clients that need assistance in certain areas of their operation.

"Labs are a great investment for hospitals," he added. "They're not very expensive to run, and they get a good return on them, but the lab staff has not always been trained well in how to leverage their services."

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Two Types of Red Ink for Sequenom, Transgenomic

Both Sequenom and Transgenomic posted losses for the fourth quarter and calendar 2012, but their numbers tell significantly different stories.

Sequenom started out primarily as a life sciences company, but it's most recent earnings report indicates it is hitting its stride as a molecular diagnostic laboratory. Last year, the San Diego-based company launched MaterniT21 PLUS, a noninvasive prenatal test for chromosomal abnormalities. It performed more than 61,000 of the assays during the year. By the fourth quarter, its annualized run rate topped 120,000, and it is projecting it will perform at least 150,000 of the tests in 2013.

"Results for both test unit volume and revenues for 2012 surpassed even our own optimistic expectations and the internal goals we announced for the beginning of the year," said Harry Hixson Jr., Sequenom's chief executive officer.

Although Sequenom has yet to achieve profitability, it is reporting rapid revenue growth. For the fourth quarter, ending Dec. 31, Sequenom reported a net loss of $32.8 million on revenue of $33.7 million.

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■ **Two Types of Red Ink for Sequenom, Transgenomic,** *from page 1*

That compares to a net loss of $22.2 million on revenues of $15.5 million—a 117 percent increase in sales.

For calendar 2012, the company lost $117.1 million on revenue of $89.7 million. For 2011, it lost $74.2 million on revenues of $55.9 million.

But Sequenom is not behaving like a venture anticipating the losses to continue indefinitely. It increased its sales staff from 20 to 75, hired medical affairs executives, increased the capacity of its laboratory in San Diego, and is ramping up operations of a second lab in North Carolina.

Eyeing the Bottom Lines

	2012 Revenues	2012 Net Income	2012 Revenues	2011 Net Income
Transgenomic	$31.5 million	-$8.3 million	$32 million	-$9.8 million
Sequenom	$89.7 million	-$117.1 million	$55.9 million	-$74.2 million

Revenue from diagnostic services increased more than fivefold between 2011 and 2012 and has surpassed genetic analysis. Gross margins for diagnostics during the first quarter turned positive for the first time in the company's history.

Although analysts have forecast that Sequenom will continue to operate in the red during 2013, losses are projected to narrow by about 30 percent. The company's stock price has appreciated 60 percent since last summer, closing at $4.45 on March 18.

Meanwhile, the Omaha, Neb.-based Transgenomic reported a net loss of $2.3 million on revenue of $7.3 million for the fourth quarter, ending Dec. 31. For the year-ago quarter, it had eked out a profit of $264,000 on revenue of $8.6 million.

Company officials pinned both the loss and the 15 percent decline in revenues primarily to a drop in its instrument sales. However, it also indicated its clinical laboratory revenues were also "modestly below" those of the fourth quarter of 2011. The company does not break out sales for specific segments.

For calendar 2012, Transgenomic reported a loss of $8.3 million on revenues of $31.5 million. That compares to a 2011 loss of $9.7 million on revenues of $32 million.

The company indicated that it expects lab sales to grow significantly in 2013, driven primarily by new molecular tests for assessing adolescent risk for scoliosis and sensitivity to the cardiovascular drug Plavix.

"We expect these activities will drive top-line revenue growth, especially as we progress throughout the year," said Craig Tuttle, Transgenomic's chief executive officer.

ARUP Develops Streamlined Huntington's Test

ARUP Laboratories has developed a new molecular test intended to expedite diagnosis of Huntington's disease as well as reduce its cost.

ARUP's test variant employs triple repeated primed polymerase chain reaction, or TP PCR. It allows for amplified scrutiny of the gene that carries the mutation that leads

to Huntington's when it is expanded for testing purposes. The test provided accurate results when compared to 246 prior tested samples using more traditional methods.

Huntington's, a neurodegenerative disorder, affects about 30,000 in the United States.

ARUP's testing variant, which is cataloged under CPT code 81401 for detecting cellular mutations, eliminates in most instances the use of southern blot reflex testing, CPT code 83912.

"A few patients with very large [gene] expansions still require southern blot testing for accurate sizing, but most cases, even apparent homozygous samples, will not need southern blot analysis," the Salt Lake City-based ARUP said in a statement.

In addition to reducing the need for additional testing, the turnaround on a diagnosis of Huntington's disease is reduced by nearly a week, according to Elaine Lyon, ARUP's medical director of molecular genetics.

Lyon did not project any increases in ARUP's volume of testing for Huntington's but did say it would lead to "a more efficient testing strategy." She declined to disclose how many Huntington's tests ARUP performs annually.

ARUP is offering the assay as a laboratory-developed test, meaning it is publicly available to all CLIA-certified laboratories.

Lawmaker Requests Exam of Palmetto MDx Pricing

A California congressman has asked the Centers for Medicare and Medicaid Services (CMS) to examine Medicare administrative contractor Palmetto GBA's pricing structure for dozens of Tier 1 molecular tests recently placed on the clinical laboratory fee schedule.

Rep. Duncan D. Hunter, a California Republican, sent a letter to acting CMS Administrator Marilyn Tavenner on Feb. 27 requesting a "comprehensive overview of the procedures utilized by Palmetto in establishing its fee schedule." Palmetto has jurisdiction in California, Nevada, and Hawaii, as well as some Pacific territories, and was one of the first MACs to announce its pricing under the gap-fill methodology mandated by CMS as a means of pricing new molecular pathology codes.

Hunter raised concerns that the fee schedule recently announced by Palmetto in early February reduced Medicare reimbursements for some high-volume molecular tests by 60 percent to 70 percent, while rates issued by another MAC he did not mention by name issued pricing more than double that of Palmetto's.

"This creates the appearance that the determination of these rates was arbitrary and performed at random," Hunter wrote.

More letters from members of Congress may be forthcoming. Michael Arnold, executive director of the California Clinical Laboratory Association, said his group is disseminating information to that state's congressional delegation on the Palmetto pricing issue.

Arnold sent a letter to Palmetto on March 11 stating that its process for arriving at the prices it did lacked transparency and asking for a disclosure of its methodology.

Two Pathology Practices, Two Routes to the Future

Vivek Khare, M.D., Delta Pathology Group

Karim Sirgi, M.D., Unipath/APP

To go it alone or to merge? That question, more than any other, seemed to hang over G2 Intelligence's annual Pathology Institute.

The attendees at the two-day gathering in Fort Lauderdale, Fla., Feb. 28-March 1 seemed palpably anxious about the future of their practices, particularly whether they could tough out recent deep cuts in reimbursement as the result of the Centers for Medicare and Medicaid Services' changes to payment for CPT code 88305, the recently imposed reimbursement cuts from budget sequestration, and the implementation of most provisions of the Affordable Care Act starting in early 2014.

Moreover, industry observers suggested that the financial turmoil in the lab industry has depressed the value of pathology practices, meaning that selling out is no longer a straight shot to long-term financial security and independence.

A joint session by two pathology executives provided some answers as to what courses could be taken toward finding firmer traction—whether or not a practice decides to go it alone or find a new partner.

Vivek Khare, M.D., business manager for the Delta Pathology Group in Shreveport, La., discussed options for those colleagues wishing to maintain independence. Karim Sirgi, M.D., president of UniPath/APP, in Denver, discussed the kind of merger that can take place if the practitioners keep as focused on their own independence as they do on the bottom line.

Both are midsized practices. UniPath has 28 pathologist, and Delta has 31.

Surmounting Louisiana's Market Challenges

Delta itself was founded 15 years ago through the merger of three Shreveport-area pathology practices. But consolidation within the Bayou State is not simple—it took five years for Delta to stabilize after the merger was consummated.

According to Khare, Louisiana is challenged by both demographics and geography. Forty percent of its population is located in rural regions with a high concentration of Medicaid patients.

"The presence of this high-cost, low-reimbursement market forces practices to consolidate but makes that consolidation very challenging," he said.

A SWOT analysis (strengths, weaknesses, opportunities, and threats) undertaken a decade ago concluded that while Delta had access to most of the providers in the Shreveport area, it fell short in terms of clinical, genetic, and molecular testing capabilities. Management also felt that Delta needed to have statewide reach to reflect overall consolidation of businesses with the health care sector. Delta leaders decided to position the path lab as a homegrown alternative to national and out-of-state labs. The expansion was undertaken without incurring debt or taking on an outside partner.

Delta decided to segment its services. Delta Pathology focuses on anatomic and molecular pathology. It performs about 990,000 billable tests a year, along with 195,000 accessions. An affiliate company known as Omega Diagnostics, founded in 2005, focuses on clinical pathology and markets the hospital side of the business. It performs about 1.4 million billable tests annually.

A third segment, Pathology Resource Network, provides services such as courier work, audits, accounts payable, CLIA compliance consultation, logistics, information technology (IT), and lab consolidation. Those services led to the purchase of two labs in Louisiana that Khare described as being "in crisis" regarding their ability maintain CLIA compliance.

As a result of its diversification, Delta now has attained much of that statewide reach, including a strong presence in New Orleans, and is now Louisiana's second-largest Medicaid lab. Revenue has tripled over the last decade. Net income has increased by about 75 percent.

But not all is rosy. Delta is still fending off incursions by outside labs, including a move by an unnamed national player that took 7,000 Pap smear tests a year from Delta. Another 4,500 accessions were lost due to the ongoing economic downturn and the growth of insurance policies with high patient deductibles.

At a Crossroads

"We decided to take a slightly different turn," Sirgi from UniPath observed.

In some ways, UniPath had an ancestry similar to Delta's, with its formation traced to the successful merging of three pathology groups—two with a hospital-based business, and one more dependent on outpatient work.

Path Groups at at Glance

Delta Pathology Group
Based: Shreveport, La.
Pathologists: 31

UniPath, PC
Based: Denver
Pathologists: 28

And UniPath was also facing similar market pressures: By 2007, it faced an increased need for subspecialization, reimbursement risks, increased in-sourcing pressures, and the need to invest in expensive pieces of equipment to improve its molecular capabilities, IT, and overall work flow.

At the same time, UniPath's position as the dominant lab in the Denver region had put it on the radar for bigger players, primarily regional and national organizations.

"When people come to you with business propositions, it is never not tempting to listen to them. You always want to listen to them," Sirgi said. As a result, UniPath's leaders took meetings with a variety of interested parties.

However, Sirgi and his colleagues always returned to a familiar worry: Making a too-hasty decision that could impact the quality of UniPath's work—and patient care—down the line.

In other words, the perfect long-term solution for UniPath would allow it access to financing for maintaining its infrasucture and other needs required for further growth, without ceding control.

"We were at a crossroads. Business is not static, business was dynamic, and we wanted to take it to the next level," Sirgi said.

Then American Pathology Partners (APP) came seemingly "out of nowhere" as Sirgi described it—a Nashville, Tenn.-based organization that has fused a variety of practices into a nationwide network of pathology practices while allowing their practitioners a high level of independence.

Although APP received an initial funding commitment of $75 million from the venture capital firm New Enterprise Associates six years ago, it was still a startup. No one within UniPath had heard of the organization.

"We got a phone call from them and thought it was a hoax," Sirgi said.

Marriage of Reason

But as talks commenced and then progressed, it became clear to UniPath that APP was offering what Sirgi termed a "marriage of reason." APP was committed to growing the practice—and compensating the pathologists accordingly—while at the same time not interfering with how they operated.

UniPath closed a deal with APP in late 2008, making the group its first acquisition. It was agreed most governance matters would be conducted via a joint strategy board with equal representation from both parties.

Despite the unfolding of the economic crisis, UniPath's pathologists received everything they wanted, including a commitment from APP to provide UniPath a brand new molecular lab. The $1.4 million facility opened in 2010. It also upgraded its existing flow cytometry capabilities and IT. The pathology assistant and grossing staff was doubled from seven employees to 14.

The sales and marketing team also expanded from four employees to 21. That was not only enough to grow the business organically but also to neutralize threats from competitors, Sirgi noted.

UniPath has grown significantly in the intervening years. Its pathology staff has expanded by a third, to 28 in total, and it has added service lines such as renal and gastrointestinal pathology. In 2012, net income grew by 17 percent.

But, like Delta, challenges remain for UniPath. Sirgi said that a business model predicated on continued volume growth may not be sustaining in the long run, and asked the rhetorical question many principals involved in a merger ask: How long will I remain individually relevant to the larger organization?

"A business transaction is like a marriage . . . you need to find the right partner," Sirgi said. And it appears to UniPath's management that they succeeded in doing so.

"Would we do it again? Absolutely, yes," Sirgi said. "We have challenges, but they are good challenges. And we are still alive as a business." G2

■ PAML Launches Hospital Lab Consulting Arm, *from page 1*

PAML's decision to burnish its hospital consulting services comes at a time when larger laboratories are under pressure to organically grow their revenue sources, as most opportunities for deal-making among midlevel and small labs have been consummated. Hospital labs present a new opportunity.

"With the current climate of lower reimbursements and higher costs, hospitals are focused on driving costs down and developing revenue-generating departments," said Bill Remillard, PAML's technical operations director.

Martha Robbins, a clinical laboratory consultant in Oswego, Ill., who previously directed the national laboratory practice for Coopers & Lybrand in the 1990s, agreed that hospital consulting can provide new business inroads for the larger labs. "It's a way for them to make more money," she said. Robbins added that such consulting relationships can not only in bring in more clinical business but also help solidify relationships with existing clients.

Although Velázquez noted that PAML's program is being marketed primarily through word of mouth, it has already signed up three clients. Moreover, it has received a half-dozen queries from other hospitals. Some of them are located in Florida and the Eastern Seaboard, which are outside of PAML's traditional operating area.

"These are places where traditionally we have no market concentration," he said.

Similar Issues

Although each hospital lab is different, Velázquez observed that their operational issues tend to have a shared heritage about 65 percent of the time.

Among the biggest issues: Multiple lab sites have created problems of managing the various locales, supply chain management, and, perhaps most significantly, billing and collections. Bad debt for hospitals has been on the rise, and some part of it is attributable to laboratory, Velázquez noted.

"Hospital lab testing is a lot of small claims, and our particular expertise is capturing reimbursement—particularly when you have a lot of smaller claims in high numbers," he said. "Hospitals will pay attention to the billing for an open heart procedure because it brings in a lot of money. But when you have a half million bills of $100 apiece, they may not. And that adds up to money."

Robbins did strike a note of caution for such deals. Although she observed that PAML is well regarded in the industry, that it already provides clinical laboratory services places it in a delicate position.

"If I were going to hire someone as a lab consultant to come in, I wouldn't hire a firm that has something to gain from what I tell you," she said. "I would hire someone with no bias at all."

Velázquez said such a concern has been addressed.

"The consulting teams are focused on a specific task; they're not there to solicit business," he said. "We keep a firewall between the two. We don't want anyone to think we have an ulterior motive."

INDUSTRY BUZZ

Provista Teams With Lpath to Improve Ovarian Cancer Tests

Provista Diagnostics has entered into an agreement with Lpath to create new laboratory tests targeting significant gaps in early ovarian cancer detection.

The Scottsdale, Ariz.-based Provista, which focuses on molecular-based cancer diagnostic testing, said the parties would focus their collaboration on a bioactive known as lipid lysophosphatidic acid, or LPA, which can be an indicator of cancer. It plans to enter into a pilot project study with Lpath, where the latter would conduct measurements of LPA levels in the plasma of ovarian cancer patients and use the data for test development.

The San Diego-based Lpath has created a technology platform for generating therapeutic antibodies, but Chief Executive Officer Scott Pancoast said "it also has potential utility in diagnostic settings."

Provista said it would provide the San Diego-based Lpath with an up-front payment, research funding, and development milestone payments, as well as royalties for any tests that are developed from the collaboration.

"Provista is committed to advancing the standard of diagnostic care for women at risk or suffering from ovarian and other cancers, and LPA is a potential biomarker that could be critical to achieving this goal," Provista Chief Executive Officer David Reese said in a statement. The company declined to answer specific questions.

Ovarian cancer kills 14,000 women in the United States every year, while 22,000 new cases are diagnosed. The rates of diagnosis have risen about 10 percent over the past 15 years. Although long-term survival rates top 90 percent if diagnosed early, there are few laboratory tools to assist in doing so.

"There is a huge demand for a better, more decisive test," said Peter Francis, president of Clinical Laboratory Sales Training LLC in Woodstock, Md. "The problem is that the early stages of the disease have no obvious symptoms and no screening tests have proven to be effective . . . due to the complex biology of this disease."

Francis added that while there are some molecular-based tests on the market, they are most effective in monitoring the progression of the disease or its recurrence.

References

ARUP Laboratories
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