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# LABORATORY INDUSTRY REPORT™

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[www.labinstitute.com](http://www.labinstitute.com)

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Dec. 9, 2013

Union League Club of New York  
New York City

### Laboratory and Diagnostic Investment Forum

Dec. 10, 2013

Union League Club of New York  
New York City

## Bio-Reference's Acquisition of Hunter Labs Gives It Presence on West Coast

**H**unter Laboratories has been hunted down. The Campbell, Calif.-based Hunter was acquired earlier this month by Bio-Reference Laboratories, the fast-growing, publicly traded outfit looking to expand beyond its primary operations on the East Coast.

The specific terms of the deal, which was consummated after eight months of negotiations, were not disclosed. Chris Riedel, Hunter's outspoken founder, retained rights to a nascent cardiac testing business that he will spin off into another company.

Riedel, who agreed to a noncompete clause as part of the sale, also informed *Laboratory Industry Report* that he has no plans to abandon his role of legal gadfly to Quest Diagnostics—he will continue suing the nation's largest laboratory operator in a variety of venues.

"Bio-Reference wanted nothing to do with the litigation, but it is absolutely continuing," Riedel said enthusiastically.

Partly as a result, Bio-Reference did not appear eager to parade its trophy around before nailing it to the wall. The receptionist at Hunter's former Bay Area headquarters began answering the phone as Bio-Reference almost immediately after the deal closed on Aug. 9.

*Continued on page 2*

## Illumina, Sequenom Report Dramatic Revenue Growth For Second Quarter

**A**lthough national labs Quest Diagnostics and LabCorp struggled with boosting their sales during the second quarter, San Diego-based specialty players Illumina and Sequenom had no such problems, although concerns about the latter's eventual profitability persist.

Illumina reported net income for the second quarter ending June 30 of \$36 million, up 55 percent from the \$23 million reported during the second quarter of 2012. Revenue jumped 23 percent, to \$346 million from \$281 million. The company revised earnings guidance upward for 2013 as a result.

Illumina Chief Executive Officer Jay Flatley reported strong growth among all product platforms, which included both equipment and various assays. Consumer demand for personal genetic testing has

*Continued on page 7*

### ■ BIO-REFERENCE'S ACQUISITION OF HUNTER LABS, *from page 1*

"I think it is important for people to know there are new owners," Bio-Reference Chief Information Officer Richard L. Faherty dryly observed.

Faherty said the acquisition of Hunter for cash and assumption of debt gives Bio-Reference two things it wanted: a laboratory on the West Coast to more quickly process work for its growing book of business in the western United States and a license to participate in Medi-Cal, California's Medicaid program.

"It was an important consideration," Faherty said.

The California Department of Health Care Services, which oversees Medi-Cal, issued a moratorium against new licenses for labs back in the late 1990s. Initially expected to last only six months, the agency has never lifted the new license ban, although existing licenses can be transferred.

California is in a minority of states planning to expand Medicaid coverage as part of the Affordable Care Act. As many as 1.5 million Californians could wind up obtaining coverage as a result, providing what could be a healthy boost in volume for those labs that are Medi-Cal providers.

Hunter itself is a relatively small operation, believed to generate revenue of \$15 million to \$20 million a year, compared to the nearly \$800 million in revenues Bio-Reference is likely to report for all of fiscal 2013. Analysts Amanda Murphy and J.P. McKim with William Blair & Co. in Chicago said the transaction will add about 2 cents per share to its fiscal 2013 earnings estimates for Bio-Reference, a bump of about 1.5 percent.

Faherty noted that Hunter had been under pressure to sell after losing a key contract three years ago with Blue Shield of California. It was a state of affairs confirmed by Riedel, who noted that growth at Hunter came to a halt after that loss transpired.

### Riedel to Continue Litigation

Despite appearing as the smaller fish swallowed by a much larger one, Hunter and Riedel's perception in the sector has been closer to piranha or barracuda than minnow. That has been driven by almost relentless litigation in recent years against Quest, initially for Medicaid billing practices but more recently for anti-competitive business tactics. Although a federal suit against Quest for interfering with Hunter's operations was recently tossed out of federal court in California, Riedel said the complaint has recently been modified and refiled.

Riedel also filed a qui tam lawsuit against Quest and LabCorp in 2005, claiming they overbilled California's Medicaid program. The two labs eventually settled the suit for a combined \$290.5 million. Riedel and Hunter would have been entitled to as much as \$43.8 million of that sum under federal whistleblower laws.

In 2011, Riedel was named whistleblower of the year by the organization Taxpayers Against Fraud.

Riedel says he currently has five lawsuits against Quest pending in Michigan, Massachusetts, Georgia, Virginia, and Nevada that are no longer under seal, suggesting that more litigation is pending in other states. All of the suits make similar claims: Quest overcharged for laboratory services for Medicaid enrollees.

The Nevada suit is scheduled to go to trial later this year, Riedel said. Michigan State Attorney General Bill Schuette has joined the litigation in that state as a co-plaintiff, Quest acknowledged in a recent 10-Q filing with the Securities and Exchange Commission.

"Once the government intervenes, there is almost always a settlement," Riedel said.

*Takeway: Bio-Reference Labs pursued Hunter in order to expand its processing capabilities to the West Coast. Chris Riedel has left the company in order to spend more time pursuing litigation.* 

### Gene By Gene Buys Sequencing Startup

**G**ene By Gene, the ambitious Texas laboratory focusing on personal genomic testing, has acquired Arpeggi, a startup firm that is expected to greatly expanding its ability to perform sequencing in-house.

Terms of the deal for Arpeggi, which is based in Austin, Texas, were not disclosed. Founded last year, Arpeggi was financially backed by GE's health care ventures division.

All six of Arpeggi's employees immediately relocated to Houston, where Gene By Gene is based. Three of them were named the company's chief business, technology, and scientific officers.

Gene By Gene President and Managing Partner Bennett Greenspan said the acquisition of Arpeggi's proprietary sequencing software would make it much easier to expand product offerings and reduce turnaround times for testing. Some of the company's tests take three weeks or more to turn around.

"By having in shop a group of guys with a lot of next-generation sequencing and scoring knowledge, it basically means we can tackle almost anything in the human area," Greenspan said. "If we want to put together a panel for 40 genes or exomes, we will be able to do it in-house."

The company had previously used licensed software for sequencing, but it was painfully slow. Using the Arpeggi product will cut down turnarounds as well as the use of reagents, according to Greenspan.

The pricepoints for the firm's tests won't go down immediately, but Greenspan indicated the acquisition could accomplish that in the future.

### Still Battling Myriad

Meanwhile, Gene By Gene also announced it was joining California testing firm Ambry Genetics to defend against patent infringement litigation brought by Utah-based Myriad Genetics against both firms earlier this summer. Although Myriad's claim to have held a patent on specific human genes was defeated by the U.S. Supreme Court in June, it immediately sued Ambry and Gene By Gene when both firms announced they would offer gene-based breast cancer tests. Gene By Gene's announced pricing was a fraction of the \$3,000 Myriad charges.

*Takeway: Gene By Gene is making moves to streamline its turnaround times, a crucial development to serve its consumer business.* 

# Inside The Lab Industry



## Reimbursement Cuts Have Led to New Lab Mantra: Cost Control and Efficiency

**F**or a venture doing as well as West Pacific Medical Laboratory, its leadership is taking no chances.

A startup little more than three years ago, the Southern California-based West Pacific performed 12 million tests last year. It is projected to more than double that total in 2013, reaching a volume of 27 million, according to Richard Nicholson, its chief executive officer.

Nonetheless, West Pacific is also striving relentlessly to cut down costs even as volumes have grown dramatically. Nicholson wants the company to reduce the cost of a requisition by 10 percent—about \$2 to \$3 apiece. West Pacific is about halfway there.

"Every lab has been doing cost cutting," Nicholson said, adding that he is trying to balance dramatic growth with cost control.

The obsession with costs has been confirmed by interviews with several laboratory executives. Their operations have been nipped by repeated cuts from Medicare and exclusions from private payer networks. They are also concerned by the future the Affordable Care Act holds for them. As a result, many labs have been wringing out costs and introducing efficiencies to every corner of their business.

### Labs Must Change

Tom Tiffany, the former chief executive officer of PAML Laboratories in Spokane, Wash., and now an industry consultant, said that labs and pathology practices are confronting an array of cuts. They include deep reductions in reimbursement for the technical component (TC) of the 88305 CPT code, the end of the Medicare grandfather protection that allowed independent labs to bill Medicare directly for the TC of pathology services provided to hospital patients, and the elimination of code stacking for molecular testing (and resulting delayed payments). As a result, labs have no choice but to make changes.

"They essentially have to start increasing their technical work and take it in-house," Tiffany said. "They have to cut down on their sendouts and go to higher-paying CPT codes. It's not an easy task."

It's also not cheap. According to Tiffany, a small lab or pathology group that decides to take flow cytometry and fluorescence in situ hybridization testing in-house may have to invest \$500,000 or more in order to do so.

Meanwhile, he is seeing pathologists cutting their pay by 20 percent or more to try to keep operations going.

### Options for Labs

Even among medium-sized labs with revenue in the tens of millions of dollars, investment in a doctorate-level employee and some pieces of equipment

are not likely to reap the savings and efficiencies they are seeking. Instead, larger operations are taking a more holistic approach.

West Pacific itself has taken back in-house several tests it had been outsourcing, celiac and reverse T3 among them. That's added between \$300,000 and \$400,000 annually to its bottom line, according to Nicholson. Meanwhile, Pacific West's forecast for torrid growth is being used as leverage with suppliers. "If we tell them we anticipate a growth rate of 20 percent, we can get a response," Nicholson said, adding that supply prices can be negotiated downward as a result.

West Pacific has also explored going overseas for some supplies—it is regularly contacted by Chinese firms—but it has yet to cross that threshold.

"If we switched from a recognized vendor, and we had a disruption . . . it is a big concern," Nicholson said. "We can't have an interruption like that, and we can't be the guinea pig" for testing a foreign supply market.

### Even Bigger Labs Are Tightening Up

PAML, which has been moving boldly from a large regional to a national player, is also taking a close look at efficiencies, with a goal of cutting costs by a double-digit percentage as part of a three-year plan. It has made some recent dramatic changes as a result.

According to PAML CEO Francisco Velázquez, M.D., although the company's volumes have grown, reimbursements per test have eroded.

"Our approach has been a little more strategic than reactive," he said.

The lab is wrapping up the consolidation of all nine of its supply depots into a single locale—the underground parking garage at its company headquarters in Spokane. That will be completed in October and is expected to translate into six-figure annual savings.

Moreover, PAML is seeking partnerships with hospitals to perform basic testing such as lipids locally. "A lot of routine testing is better done in the community," Velázquez said.

Among the advantages is a lower transportation cost while turnaround times are shortened. But it also helps to expand PAML's reach without having to construct additional laboratories, according to Velázquez.

PAML has also streamlined its agreements with the delivery companies that make its shipments—entering into a single tentative pact with FedEx. "This is not typically a core competency for a lab—shipping things all over creation," Velázquez said. The deal also allows PAML couriers to focus on picking up and delivering specimens as opposed to juggling that task with transporting supplies.

The company is not finished, however. PAML recently established a product innovation and improvement group that will scrutinize the entire enterprise for efficiencies. Although it has only two employees to start, Velázquez said it will expand in the future.

***"Our approach has been a little more strategic than reactive."***  
***—Francisco Velázquez, M.D., CEO, PAML***

### Employees Not on Table

Despite the focus on keeping costs in control, few of these changes have involved what has become a common refrain across corporate America: cutting jobs. Nicholson has eliminated a couple of employees in the billing department but has otherwise been hiring, particularly sales staff. There have been seven sales hires so far this year at West Pacific, with two let go because they couldn't cut it.

"You have to take risks with salespeople," Nicholson said, with their performance the indicator of whether to keep them on.

And while PAML is in the middle of revamping its primary laboratory in order to make it more efficient, there are no layoffs planned for the moment. "It is not about downsizing people—it's about giving them better tools and a better [work] space," Velázquez said, adding that it's tough to recruit and hold on to qualified employees.

### Doesn't Work for All

Although both PAML and West Pacific have been success stories in a tough environment, cost cutting and efficiencies are not the magic bullet for every laboratory. Hunter Laboratories, located in California's Bay Area, recently

sold out to the much larger Bio-Reference Lab after three years of struggles, according to former CEO Chris Riedel.

After Riedel's lab was shut out of the Blue Shield of California's provider network, "the company was the walking dead," he said. A lab that previously had 45 percent annual growth no longer had any.

During that time, Riedel tried every option to stay afloat, investing about \$10 million in the process. They included expanding to include cardiovascular testing and esoteric testing, the shutting down of unprofitable patient-service centers, and hard-line negotiations with vendors. The staff was reduced 10 percent.

Riedel expects many other smaller and regional labs to eventually succumb to such pressures, and either find a buyer or file for bankruptcy.

"You have these nationwide specialty labs, and tons of molecular labs, and most are losing money," Riedel said. "They have no choice but to run as lean as they possibly can."

But even the labs that have growth and bright futures ahead are in a similar mind-set.

"There is not going to be any end," to keeping focus on costs and efficiencies, Velázquez said.

***Takeaway: Medium-sized and large regional labs are undertaking cost cutting and streamlining operations in order to counteract revenue cuts from the elimination of code-stacking, the changes in the technical component of 88305, loss of commercial payer network participation, and other reimbursement cuts.***



### ■ ILLUMINA, SEQUENOM REPORT DRAMATIC REVENUE GROWTH, from page 1

been strong, and the company says consumer sales will approach \$50 million for the calendar year. Overall, 2,500 genomes were sequenced during the quarter, more than triple the figure from a year ago. Genotyping and sequencing revenue grew 50 percent compared to the second quarter of 2012, due in part to the recent acquisition of Verinata.

Net income for the first half of 2013 was \$13.3 million, compared to \$49.6 million for the first half of 2012. The decline is mostly attributable to a \$115 million verdict against the company in June related to a patent infringement case.

#### Sequenom Reports Loss

Sequenom reported a loss of \$31 million for the quarter ending June 30, up from the \$29.6 million loss reported during the second quarter of 2012. However, revenue nearly doubled, to \$34.9 million, compared to \$18.3 million for the year-ago quarter. Although the genetic analysis book of business mostly remained unchanged, diagnostic services revenue more than tripled and now accounts for about 75 percent of the company's business.

#### Illumina and Sequenom Earnings

	Sequenom	Illumina
Second Quarter 2013 Revenues	\$34.9 million	\$346.0 million
Second Quarter 2013 Net Income	-\$31.0 million	\$36.0 million
Six Month 2013 Revenues	\$73.3 million	\$677.1 million
Six Month 2013 Net Income	-\$60.4 million	\$13.3 million

Sources: Company Reports

However, Sequenom Chief Financial Officer Paul V. Maier said the lack of concrete payment methodologies for molecular testing hampered revenue significantly during the quarter, although the company declined to give specific figures. Revenue is expected to grow more once all the pricing for new molecular codes is finalized, company officials said.

For the first six months of 2013, Sequenom reported a loss of \$60.4 million, up from the \$54 million loss reported for the first half of 2012. However, revenues more than doubled, to \$73.3 million from \$33.2 million.

Analysts are unsure when Sequenom will reach profitability, a goal it has yet to reach in more than a decade of operation. Five of the eight analysts covering the company rate the stock as a hold or buy. Standard & Poor's rates the stock as a "c"—its lowest ranking for a company that is not in financial reorganization.

Analysts are more bullish regarding Illumina. Seven of 25 analysts have buy ratings for its stock. S&P analyst Jeffrey Loo projects earnings per share to reach \$1.74 but noted that the company was rocked by a recent hostile takeover bid by pharmaceutical giant Roche. "We would not be surprised if Roche makes another bid for the company," Loo said.

**Takeaway:** *Although national laboratories are struggling with flat growth, some specialty players are experiencing rapid increases in revenues; still, profitability is elusive for some.*



## Quest, HDL Sign Deals With NFL Teams

The Obama administration was unsuccessful in a recent attempt to get the National Football League to promote the Affordable Care Act. But the nation's largest laboratory and an emerging regional player have had no such difficulties inking branding deals with two NFL teams.

Quest Diagnostics and Health Diagnostic Laboratory (HDL) have recently inked marketing deals with the New York Giants and the Washington Redskins, the nearest teams to their respective headquarters in Madison, N.J., and Richmond, Va.

Such deals have been fairly common among sports teams, hospitals, and other high-profile providers, but they have been less common with ancillary providers such as laboratories.

The HDL deal will focus on the players using the company's cardiometabolic testing panel. A number of Redskins underwent testing by HDL recently, although the results are being kept confidential. A 2008 study of 233 retired NFL players by the Mayo Clinic discovered more than 80 percent of that population under the age of 50 was at increased risk for heart disease when compared to non-NFL players.

The Quest deal is more general—it will work with the Giants to develop sports-related diagnostics assays. "We see our relationship with Quest as the next step in the process of achieving a healthier and safer game during our players' careers and after their playing days," said Giants President John Mara.

Quest spokesperson Wendy Bost said the relationship will be used to create and market assays for both professional and amateur athletes, although no specific details were available. There are no plans to develop tests for one of the biggest health problems in the NFL right now—the effect of repeated concussions on cognitive abilities.

Quest officials have suggested its deal with the Giants would help raise consumer awareness about laboratory testing—the cost of which has been systematically shifted over to individual patients in recent years.

However, one laboratory industry observer didn't think such deals would help labs in terms of increased brand awareness. "Consumers won't care about this," said Kathleen Murphy, chief executive officer of Chi Solutions, a laboratory consulting firm in Ann Arbor, Mich.

**Takeaway:** Some labs are entering into branding opportunities with NFL teams, but their effectiveness remains to be seen. 

### References

Bio-Reference Laboratories 201-791-2600	Hunter Laboratories 408-341-8609	Quest Diagnostics 973-520-2700
Gene By Gene 832-381-5410	Illumina 858-202-4500	Sequenom 858-202-9000
Health Diagnostic Laboratory 804-343-2718	PAML 509-755-8600	Tom Tiffany 509-939-1585

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