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# LABORATORY

# INDUSTRY REPORT®



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Issue 09-12/September 2012

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## LabCorp Denies Reports of a Leveraged Buyout; Completes Medtox Acquisition

**L**abCorp (Burlington, N.C.) is denying reports of a potential leveraged buyout (LBO) by a private equity consortium.

In a statement released Aug. 1, the company said it was aware of recent reports regarding a buyout, but “the company has no knowledge of any such plans and is not in current discussions with any firms to effect such a transaction.”

The comment came in response to a July 31 report by Debtwire, which said that at least two private equity firms were working to assemble a financing package. “BofA Merrill Lynch is spearheading the consortium’s effort to raise LBO capital and would likely have to partner with other banks to help underwrite a multibillion deal,” said the report, which did not identify the source of the information.

*Continued on page 2*

## InCyte and Eastside Pathology to Merge; New Groups Will Cover Major Areas in Washington

**P**arties in long-distance relationships often negotiate for months or years or explore more conveniently located suitors before taking the final plunge.

Although that description applies to people, it can also be used to discuss the pending union between Bellevue-based Eastside Pathology and Spokane-based InCyte Pathology, located 375 miles from one another in Washington state.

Executives with the two labs had been in on-and-off discussions dating back to 2008. Eastside had even discussed a merger with Cell-Netix, which has been fairly aggressive in terms of recent regional acquisitions and is in nearby Seattle.

However, Eastside and InCyte ultimately preferred the long-distance option. They announced plans early last month to merge after a year of serious negotiations. The deal is expected to be finalized by Jan. 1.

The transaction not only brings geographical breadth to the two labs—they essentially will cover all of the major population centers in Washington state—but potential economies of scale to its individual businesses.

*Continued on page 8*



## Upcoming Conferences

**MDx NEXT: Reimbursement Realities, Payment Priorities, and the Future of Genomic Medicine**

Sept. 13-14, 2012  
University Club of Chicago  
Chicago

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

**Lab Institute 2012  
Separating the Best From the Rest**

Oct. 10-12, 2012  
Crystal Gateway Marriott  
Arlington, Va.

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

[www.G2Intelligence.com](http://www.G2Intelligence.com)

### ■ **LABCORP DENIES REPORTS OF A LEVERAGED BUYOUT**, *from page 1*

With a market capitalization of \$8.1 billion based on the July 31 closing price of \$84.09, the company has an enterprise value of about \$12.3 billion, according to Kevin Ellich, senior research analyst with Piper Jaffray & Co., an investment bank based in Minneapolis.

Private equity buyers would need to put up \$3 billion to \$4 billion of equity capital for the purchase, according to a report by Bloomberg. Among firms with deep enough pockets to make a bid for LabCorp are TPG Capital and Bain Capital Partners, said the report. Other potential acquirers include Blackstone Group and KKR & Co.

Private equity firms have been the most active acquirers of laboratory, medical testing, and research service companies in the past five years, accounting for almost \$6 billion of the \$19 billion in takeovers in the sector, data compiled by Bloomberg show.

Ellich believes LabCorp is an attractive asset for financial buyers given its strong cash flow. With the pullback in the stock following second-quarter 2012 earnings, the company has a free cash flow yield of about 9 percent to 10 percent, with free cash flow expected to be about \$800 million in 2012. If the deal were consummated at around \$102 per share, Ellich estimates the internal rate of return for a financial buyer at about 20 percent.

### **Rumor Could Be Fueled by Note Offering**

LabCorp's denial of plans for a buyout of the company does call into question whether the Debtwire reports are accurate, notes Ellich, who mentioned that a recent offering by LabCorp of \$1 billion in senior notes could have led to the speculation.

The company announced the offering Aug. 20 and said it intends to use the net proceeds of the offering to repay certain amounts outstanding under its existing credit facility and for general corporate purposes. The active joint book-running managers for the offering are BofA Merrill Lynch and Credit Suisse.

It's possible that someone from Debtwire learned that BofA Merrill Lynch was looking into LabCorp's debt as part of the note offering and made assumptions regarding a leveraged buyout, says Ellich. "You never really know where the speculation comes from sometimes," he notes.

### **LabCorp Completes Medtox Acquisition**

In separate news, LabCorp said July 31 that it had completed its acquisition of Medtox (St. Paul, Minn.). The all-cash deal, announced in June, valued the toxicology testing company at approximately \$241 million, or \$27 per share, a premium of about 37 percent over the closing share price on the previous trading day.

Medtox operates a SAMHSA-certified drug testing laboratory, a CAP- and CLIA-certified clinical laboratory, and a diagnostics division. The company reported 2011 revenues of \$108 million, driven by sales of diagnostic tests and instruments, new business for its drugs-of-abuse testing services, and a move into clinical trials services. 

## Divided Appeals Court Again Upholds Myriad's Gene Patents; Company Reports Fourth-Quarter Results

In a 2-1 decision issued Aug. 16, the U.S. Court of Appeals for the Federal Circuit once again partially reversed a lower court's ruling in a case challenging patents held by Myriad Genetics on two human genes, BRCA1 and BRCA2, associated with hereditary breast cancer and ovarian cancer.

The court ruled that the company can obtain patents on the genes but cannot patent methods to compare those gene sequences.

This is the second time the court has considered this lawsuit, brought by a group of patients and scientists represented by the American Civil Liberties Union (ACLU) and the Public Patent Foundation and including the American Society for Clinical Pathology, the Association for Molecular Pathology, and the College of American Pathologists. Last year, the U.S. Supreme Court ordered the case to be reheard in light of its ruling in *Mayo v. Prometheus* that patents cannot be issued on natural processes. The same three appeals court judges reheard the case, upholding Myriad's gene patents but not its method claims comparing or analyzing gene sequences.

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"It is extremely disappointing that despite the Supreme Court's ruling, the appeals court has failed to fully reconsider the facts of this case," said Chris Hansen, a staff attorney with the ACLU Speech, Privacy, and Technology Project, in a statement. "This ruling prevents doctors and scientists from exchanging their ideas and research freely. Human DNA is a natural entity like air or water. It does not belong to any one company."

The lawsuit against Myriad Genetics and the University of Utah Research Foundation, which hold the patents on the BRCA genes, charged that the challenged patents are illegal and restrict both scientific research and patients' access to medical care, and that patents on human genes violate the First Amendment and patent law because genes are "products of nature."

The case could be appealed again to the Supreme Court, which could extend a final decision into mid-2013 (both parties have 90 days to appeal).

### **Better-Than-Expected Revenue**

The ruling is a positive for Myriad, which on Aug. 15 reported fiscal fourth-quarter 2012 results, with better-than-expected revenue in earnings per share. Revenue for the quarter was \$133 million, an increase of 24 percent over the same period the prior year, and above Wall Street analysts' estimates of \$132 million. Fourth-quarter diluted earnings per share were 34 cents, an increase of 14 percent over the same period in 2011 and consistent with analysts' estimates.

Molecular diagnostic testing revenue in the fourth quarter was \$127.5 million, an increase of 21 percent. Revenue from the oncology segment was \$87 million, an increase of 16 percent over the same period the previous year. Women's health revenue totaled \$40.5 million, an increase of 32 percent.

Revenue from the BRCAAnalysis test, which represented 81.7 percent of total revenue in the fourth quarter, was \$108.7 million, a 17 percent increase over the same period of the prior year. Revenue from the COLARIS AND COLARIS AP tests, which repre-

sented 8.7 percent of total revenue during the quarter, was \$11.5 million, an increase of 51 percent. Myriad's other molecular diagnostic tests contributed \$7.3 million to fourth-quarter revenue, or 5.5 percent of total revenue, an increase of 47 percent.

Myriad expects revenue in fiscal 2013 to be \$550 million to \$565 million (11 percent to 14 percent growth) versus the consensus estimate of \$554 million. Guidance assumes a stable physician office visit environment in 2013 and incorporates an incremental \$4 million in operating income dilution from the international business over fiscal 2012, no additional buybacks, and a slightly higher effective date rate of 40 percent. **G2**

## Genomic Health Revenues Show Lag Between Volume, Collections

**G**enomic Health (Redwood City, Calif.) reported second-quarter results of \$57.6 million, a little light compared to consensus estimates of \$58.3 million. Results were driven largely by an accelerated lag between volume growth and collections, say industry analysts.

Total revenue increased 13 percent compared to the same period last year. Net income was \$1.8 million for the second quarter of 2012, compared with \$2.3 million in the second quarter of 2011. Net loss related to InVitaе Corp., a wholly owned subsidiary, was approximately \$800,000 for the quarter. Net income, excluding InVitaе, was \$2.6 million.

Basic and diluted net income per share applicable to common stockholders was 6 cents in the second quarter of 2012, compared with 8 cents in the same period in 2011.

During the quarter the company delivered more than 19,020 Oncotype tests (16 percent growth), exceeding analysts' expectations. However, realized average sales price per test was just over \$3,000, below expectations of \$3,100.

"The lag in collections suggests more of the company's volume growth has been driven by traction in newer (and less well-reimbursed) markets, including DCIS, colon, and international, which has driven a wider-than-expected disparity between volume growth and revenue growth relative to our model," says Amanda Murphy, an analyst with equity research firm William Blair. "During the quarter, 67 percent of revenue, or 59 percent of tests, were recorded on an accrual basis, roughly in line sequentially."

Kim Popovits, Genomic Health's chief executive officer and president, says the company is on track to report topline results from its prostate cancer clinical validation study later this year with the goal of launching an Oncotype DX test for prostate cancer patients in 2013.

The company has updated guidance for the year, given the shift of InVitaе's performance from fully consolidated results to minority interest (Genomic will own less than 20 percent after another \$5 million investment the company has committed to make). Management has increased full-year net income guidance up to \$4 million loss to breakeven, to \$4 million to \$7 million of profit (including a \$1 million loss from InVitaе). Management is maintaining revenue guidance of \$230 million to \$240 million and test volume of 75,000 to 77,000 tests. **G2**

# Inside The Lab Industry



## The Role of Labs and Pathologists in ACOs

**A**ccountable care organizations (ACOs) have been one of the most widely discussed payment models for controlling health care costs since the rise of managed care in the 1990s. Because ACO formation is closely tied to the ongoing implementation of the Patient Protection and Affordable Care Act, it is likely they will be part of the health care financial landscape for decades to come.

Virtually all debates regarding ACO formation have centered around how to best bring hospitals and clinicians together and smooth out some of their historical frictions through the correct balance of payments, shared risks, incentives, and outcomes.

Clinical laboratories and hospital pathology departments can be particularly effective for providers both in the realms of cost control and patient satisfaction—two keys in the care and feeding of successful ACOs. But to date, there has been little discussion of how they might integrate themselves into this revamped payment environment.

Which begs a critical question: Is there room at the ACO table for labs? And if so, what kind of seat might be reserved for them?

Industry observers all agree laboratories and pathologists can play a key role in regulating some costs in an ACO structure, particularly in terms of some of the pricier procedures.

“The knowledge a pathologist has regarding molecular and genomic testing are among the values they can bring into an accountable care structure,” said Donald Karcher, M.D., a pathologist with the George Washington University health care system and chair of the College of American Pathologists’ ACO steering committee. Karcher noted that while the popularity of such tests has been growing in recent years, their costs—\$3,000 or more apiece—means oversight in their use can be valuable to an ACO.

***Is there room at the ACO table for labs? And if so, what kind of seat might be reserved for them?***

Developing specific protocols as to when blood transfusions are approved can also have a positive effect on an ACO’s bottom line, according to David Gross, director of the CAP’s policy roundtable. “Many (clinicians) don’t think of it in this way, but there are risks associated with blood transfusion, and they can drive up costs,” said Gross, who authored a case study earlier this year on the role pathologists can play in ACO formation and operation. Among the risks are antibody reactions that can lengthen hospital stays. Gross cited as an example the blood transfusion protocols used at the Accountable Care Alliance in Omaha, Neb., operated jointly by Methodist Health Systems and the Nebraska Medical Center.

“They introduced standards for transfusions in orthopedic surgery that reduced the cumulative cost of blood by 50 percent, saving hundreds of thousands of dollars a year,” Gross said.

### Controlling Test Utilization

However, within the bowels of an ACO itself, the answer of the role the labs play depends on whom you ask. Two ACOs—one nascent, another relatively mature—have been melding their laboratory and pathology services into an accountable care model in different ways.

David Scamurra, M.D., of Eastern Great Lakes Pathology in Kenmore, N.Y., has been working hard to install new protocols for an ACO operated by Catholic Medical Partners IPA in Buffalo, N.Y. The ACO is fairly new, operating for about a year. His primary focus at the moment is to reduce overall utilization in specific areas.

Currently, Scamurra has been working with the IPA's oncologists to reduce the use of what he refers to as "boutique tests" such as mammo-

prints and assays to determine chemotherapy resistance.

"There are a bunch of tests that are legitimate to do and have clinical impact, and there are others with no real literature yet to support their use," Scamurra said. He added that many oncologists order boutique tests because they either have read about them in a journal or encountered a sales representative for the testing company bearing both samples and persuasion.

Although CMP's pathologists can review such requests and recommend other forms of testing or protocols, they do not yet have the absolute power to overrule other

clinicians without specific medical backing for doing so. They may cite medical-legal concerns if the test or procedure is not performed—and can justify them if the guidelines haven't been established by committee.

"The pathologists can do a lot for setting standards for practices, but you need to have some sort of authority," Scamurra observed. "We can't force the issue and make the cost savings happen."

Scamurra believes that utilization of testing and transfusions may have to be accompanied by financial incentives. An arrangement that puts the laboratory or pathologists at risk of losing money would likely not work. "It would be an almost unfair shared risk," he said.

Karcher feigned shock when he heard that pathologists and other clinicians were potentially butting heads over utilization issues. "There is definitely going to be friction. It is predictable," he said.

Karcher strongly recommended that all ACOs form laboratory advisory or utilization committees to help codify guidelines. "It helps formalize the discussion where laboratorians are involved," he said. Karcher added that some states, such as Massachusetts, require the formation of such committees as part of state laws governing ACO operations.

Meanwhile, Scamurra has been trekking throughout the Buffalo area to meet with CMP's oncologists to obtain their buy-in on new protocols. Because of CMP's far-flung network, he is often meeting for the first time with clinicians he had only spoken to for years on the telephone.

***"The pathologists can do a lot for setting standards for practices, but you need to have some sort of authority. We can't force the issue and make the cost savings happen."***

***—David Scamurra, M.D.,  
Eastern Great Lakes Pathology***

### **An Integrated Approach**

As CMP moves forward with finding the proper role pathology and laboratory services play in its ACO, Geisinger Health, a large system that serves central and northeastern Pennsylvania, appears on firmer ground. It operates one of the most established and highly regarded ACOs in the nation, with participation in some ACO-related pilot projects dating back to 2005, and incentive payments to improve utilization date back more than a decade.

Partly as a result of having operated for so many years and being able to closely analyze utilization and outcomes data, Geisinger appears closer to more tightly integrating its laboratory services within its ACO operations.

“We don’t measure whether we can decrease laboratory costs per se. What we do is measure the effectiveness and cost of total patient care,” said Conrad Schuerch, M.D., Geisinger’s chairman of the laboratory medicine department. “The laboratory’s role is to streamline patient care and make it easier for both the physicians and patients.”

Geisinger has some advantages over CMP in how its medical staff operates. It uses an employed model, whereas CMP’s physicians are mostly contracted. About 80 percent of compensation is base salary, with another 20 percent based on performance incentives, according to Schuerch. Those incentives may be based on creating two or three new testing protocols a year, or establishing a fine needle aspirate clinic, rather than directly based on cost or utilization reduction.

A specific example is how the Geisinger’s lab and its pathologists implemented a test and dispensing protocol for patients who require anti-coagulants. Pathologists worked with pharmacists to create “coagulation clinics” wherein the prothrombin time (PT) and the partial thromboplastin time (PTT) tests and the related adjustment of drugs such as warfarin and cumadin were all conducted on-site in one session after the prescription was ordered. In the past, the patient had to return for the testing, often waiting days for a call to come back in.

“Because it’s convenient for the patient, the compliance for the testing protocol went from 35 percent to 80 percent,” Schuerch said.

About half of Geisinger’s pathologists receive their full incentive payments, while the others experience minor deductions, Schuerch noted. He added that other members of the medical staff know that certain excess behaviors are going to hurt their pay. “We don’t dictate what tests should be used,” he noted. “But we also have a rational payment system in place.”

That’s not to say that Geisinger hasn’t also picked out specific lab protocols whose utilization can be improved. Like CMP, it has been looking at blood conservation measures to cut down on unnecessary transfusions. It also has been closely scrutinizing expensive molecular tests focused on breast cancer and neurology. But at this stage of Geisinger’s ACO development, it is usually no more than a clinician or two who may be a utilization outlier, according to Schuerch.

“The target isn’t the bottom line in terms of lab tests. The target is the overall cost of health care,” he said. 

■ **INCYTE AND EASTSIDE PATHOLOGY TO MERGE**, *from page 1*

“The regional and national anatomic and clinical pathology landscape is so complex these days that collaboration and cooperation are critical to enhancing pathology services to all levels of health care providers,” said Peter Herreid, M.D., an Eastside dermatopathologist.

InCyte Chief Operating Officer Gary Gemar said marketing realities helped drive the merger.

“We have seen competition from a lot of specialty laboratories. They’re direct marketing to physicians, and it has really changed the marketplace,” Gemar said. “This is our entry into the western Washington market, and it will allow us to expand our subspecialty expertise.”

Altogether, the two labs have fellowship-trained pathologists in six subspecialties: gastrointestinal pathology, cytopathology, immunohistochemistry, dermatopathology, oral and maxillofacial pathology, and hematopathology.

Gemar also expects the merged labs to be much more efficient. For instance, it will be able to return some pricey but redundant testing equipment when it comes off lease, and increase and concentrate production in a single facility of tests such as HER2 for breast cancer patients.

“We’re going to be looking at expanding our molecular menu. This will allow us to set up more than one test on one run, and that’s where the economies come in,” he said. Although InCyte performs significantly more traditional tests such as surgicals and Pap smears than Eastside, both have almost identical volumes when it comes to more complex and expensive molecular testing.

Although InCyte is significantly larger than Eastside—25 pathologists versus 11—the management structures of both will remain intact. The merged labs will be governed by a corporate board consisting of nine directors, six from Incyte and three from Eastside.

There will be no layoffs, and the merged labs will actually increase its workforce about 4 percent in the coming months. Eastside has long outsourced its billing and financial services, and they will now be brought in-house, according to Gemar. Eight new positions related to those services will be created: five in Spokane and three in Bellevue.

Along with consolidating services in Washington state, Gemar said both labs will continue seeking business in other parts of the Northwest. InCyte currently has clients in Idaho, western Montana, and even Alaska. Eastside overlaps with InCyte in Idaho, but also has business in Oregon and Texas.

**Merger at a Glance**

**InCyte Pathology:** Founded 1957, 25 pathologists, 145 total employees

**Eastside Pathology:** Founded 1964, 11 pathologists, 61 total employees

**Annual revenue of combined laboratories:** \$50 million to \$60 million\* (\*estimated, companies would only disclose a range)

<b>Annual combined volume:</b>			
	<b>Combined</b>	<b>InCyte</b>	<b>Eastside</b>
<b>Surgical pathology:</b>	97,000	60,000	37,000
<b>Nongynecologic:</b>	12,000	8,000	4,000
<b>Paps:</b>	169,000	100,000	69,000
<b>Molecular:</b>	70,000	37,000	33,000

“We hope to expand into other states in the region,” Genmar said, adding that there would be a specific focus on building more clientele in Oregon.

Gemar added that the labs will be branded jointly, but that no specific decisions on logos or marketing materials have been made.

There is also a possibility of more consolidation down the line. “We believe that our practice model will be attractive to other pathology practices in the Northwest,” Herreid said. 

### Roper Acquires Sunquest for \$1.42 Billion

**R**oper Industries, a diversified industrial technology company based in Sarasota, Fla., has acquired privately held Sunquest Information Systems for \$1.42 billion, including \$25 million in cash tax benefits.

Headquartered in Tucson, Ariz., Sunquest provides a suite of clinical and anatomic laboratory software solutions that are used by more than 1,700 hospitals worldwide.

Roper expects the acquisition of Sunquest to be immediately cash accretive and to generate \$140 million or more of earnings before interest, taxes, depreciation, and amortization in 2013, excluding the impact of fair value accounting of Sunquest’s deferred revenue. Sunquest is owned by a group of investors resulting from a 2010 recapitalization, led by Huntsman Gay Global Capital, in partnership with Vista Equity Partners, which has owned the company since 2007.

“Sunquest meets all of Roper’s key acquisition criteria and is an ideal fit with both our medical and software platforms,” said Brian Jellison, chairman, president, and CEO of Roper. “The business is the market leader in software solutions for the critically important health care provider laboratory market. We expect Sunquest to benefit in all economic environments from very favorable market forces—an aging population, expansion of anatomic pathology, and the need for reduced health care costs and improved quality of care. Sunquest’s software and application engineering capabilities deliver an outstanding return on investment for their customers. The company has attractive cash return characteristics and generates recurring revenue through long-term customer relationships and very high retention rates.” 

### CombiMatrix Experiencing Record Growth

**C**ombiMatrix (Irvine, Calif.), a molecular diagnostics company performing DNA-based testing services for cancer and development disorders, reported in August that total revenues for the second quarter and first six months of 2012 increased to a record \$1.3 million and \$2.6 million, respectively, up 6 percent and 19 percent from the second quarter and first six months of 2011.

Revenues from the company’s core prenatal testing markets in the second quarter grew by 48 percent over the corresponding period in 2011 and grew by more than 77 percent in the first six months of the year over the prior-year period.

The company performed a total of 1,459 billable diagnostic tests for 116 customers in the second quarter of 2012, compared to 1,201 tests for 106 customers in the second quarter of 2011 and 1,377 tests for 105 customers in the first quarter of 2012.

Earlier this year, the company announced that it would direct resources to build on its success in the prenatal and pediatric markets, while in oncology it would focus almost exclusively on laboratory partnerships and de-emphasize direct oncology efforts. Prenatal testing revenue in the second quarter and first half of 2012 were \$422,000 and \$794,000, respectively, as compared to \$284,000 and \$449,000 in the 2011 periods.

Judd Jessup, president and CEO, noted that CombiMatrix is looking to capitalize on the upcoming publication of the National Institutes of Health-sponsored study that compares the use of microarray testing to standard chromosome karyotyping. "We believe the results of the study will be published in a top medical journal and that those data will usher in a steady shift among physicians towards making the microarray the standard of care for prenatal genetic testing," he said.

Jessup also pointed to new business that he said gives CombiMatrix solid commercial momentum into the second half, including laboratory and analytical support services associated with a clinical trial being conducted by Affymetrix.

"In addition, the company recently signed a contract with a large prenatal customer that expects to begin shipping samples immediately and anticipates an ongoing quantity of samples that alone could increase our prenatal run rate by 20 percent to 50 percent in the coming year," he said. "The combination of those two customers should make a measurable impact on test volume and revenues beginning in the third quarter." 

## Quintiles Acquires Expression Analysis

**Q**uintiles (Durham, N.C.) is expanding its personalized medicine capabilities with the recent acquisition of genetic testing firm Expression Analysis Inc., also based in Durham. Terms of the deal were not disclosed.

Founded in 2001 as a spinoff from Duke University Medical Center's Microarray Core Facility, Expression Analysis provides whole genome to focused set gene expression profiling and genotyping assays as well as DNA and RNA sequencings services, sequence enrichment technologies, and bioinformatics support. Through its CLIA-certified laboratory, the company serves clients in the pharmaceutical, biotechnology, academic, government, and nonprofit markets.

"This is the right move for our company and our employees," said Steve McPhail, president and CEO of Expression Analysis, in a statement. "Our mission perfectly fits Quintiles' strategy to use genomic data and advanced informatics to yield actionable insights and more effective personalized treatments."

McPhail will stay on as head of Expression Analysis. All 77 of the company's employees are expected to retain their positions following the integration, during which Expression Analysis will be rebranded as "EA, a Quintiles Company."

According to Quintiles, the acquisition is the latest in a series of deals "designed to help customers leverage the power of genomics to better understand diseases, develop diagnostic tools, and deliver safer, more effective therapies based on the genetic makeup of the disease and the patient." The company's recent purchases include a majority stake in Oxford Cancer Biomarkers and Advion BioServices, a bioanalytical laboratory. 

### New Test Approval Drives Revenue Growth at Psychemedics

**F**ood and Drug Administration (FDA) approval of five new drug tests is helping boost revenues at Psychemedics (Acton, Mass.), which reported a 10 percent increase in revenues in the second quarter, ended June 30.

Revenues for the quarter were \$6.9 million versus \$6.2 million for the same period last year. Net income for the quarter was \$1 million, or 19 cents per diluted share, versus \$1.1 million, or 21 cents per diluted share for the second quarter of 2011.

During the quarter, the FDA granted 510(k) clearance for five new assays for the detection of cocaine, opiates, PCP, methamphetamine, and marijuana using enzyme immunoassay analysis of head and body hair.

The newly developed immunoassays are uniquely designed to specifically meet and even exceed the standards of radioimmunoassay and represent a significant technological breakthrough, said Raymond Kubacki, chairman and CEO of Psychemedics. The company in January received a new patent covering a process that releases drugs trapped in hair without destroying the drugs.

"This patent is fundamental to hair analysis drug testing because if you can't get the drugs out of the hair, you cannot measure them," explained Kubacki. "By combining our new FDA-cleared immunoassays, which are equivalent in effectiveness and sensitivity to radioimmunoassay, with our new patented method of releasing the drugs from the hair, we continue to demonstrate our technological leadership and to offer truly proprietary technology that provides superior detection of drugs of abuse for many of our clients. That is what sets us apart."

Profits during the quarter were impacted by an increase in research and development spending, costs associated with the changeover to our new technology, and increased sales and marketing expenses. However, the company's pretax profit margin for the second quarter was still over 24 percent.

"We fully expect that these expenses, or investments, bode well for our long-term growth, despite the impact on the quarter," said Kubacki. "We continue to have a strong balance sheet with more than \$4.7 million in cash and cash equivalents as of June 30, 2012, and no long-term debt." 



# INDUSTRY BUZZ

## Is Illumina Losing the Next-Gen Battle?

It just might be, says Jon Groberg at Macquaries Equities Research, who has run the numbers on how Illumina's desktop next-generation sequencing machine is selling compared to Life Technologies Personal Genome Machine (PGM). Though sequencing users told Groberg that MiSeq is more accurate and easier to use than PGM, Life Technologies appears beating Illumina in sales.

Groberg estimates that Life has sold 1,300 PGMs to 700 units of Illumina's MiSeq. The difference, he says, comes down to price. PGM sells for about \$75,000 while the MiSeq costs about \$125,000.

Groberg sees three ways for Illumina to catch up: cut the price of its box, expand its sales efforts, or do nothing and hope that Life Technologies' Ion Torrent technology falters while MiSeq keeps improving.

"Illumina still remains the dominant player," writes Matthew Herper, a science blogger with *Forbes*. "But it's interesting how well Life's strategy of selling a lower-priced option has worked, keeping it in the game while other companies that make DNA sequencing gear, such as Pacific Biosciences and Complete Genomics, have struggled. The big question going forward is what will happen when the new sequencers from Oxford Nanopore reach the market, potentially further disrupting things, and whether either Life or Illumina has an advantage once these tests become used in the clinic."

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- InCyte Pathology 509-892-2700
- LabCorp 336-436-5274
- Life Technologies 800-955-6288
- Medtox 800-832-3244
- Myriad Genetics 801-584-3600
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- Roper Industries 941-556-2601
- Sunquest Information Systems  
520-570-2000

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