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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

WASHINGTON G-2 REPORTS

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Time Ticking as Physician Fee Cut Freeze Expires on March 1; Congress's Next Move Remains Unclear

As the freeze on the update to Medicare physician payments is set to end on March 1, it's unclear at press time how Congress will address the issue when it reconvenes the week of Feb. 22 after a week-long recess. Medicare reimbursement to doctors is scheduled to be reduced 21 percent under the Sustainable Growth Rate (SGR) formula on March 1.

Congress earlier this year blocked the cut scheduled for Jan. 1, 2010, under the SGR formula and froze physician fees at their 2009 levels through Feb. 28.

But a draft Senate Finance Committee jobs bill unveiled earlier this month included a provision to extend the freeze for seven more months, through Sept. 30. However, majority leader Harry Reid (D-Nev.) decided to strip it of all provisions not focused on jobs, including the physician fee freeze and other Medicare provisions, including payments to hospitals, managed care plans, and ambulance services, reports Washington G-2 Reports' *National Intelligence Report*.

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Carilion-Spectrum Merger to Shake Up Lab Industry's Duopolistic Stronghold in Mid-Atlantic and Southern Regions

The recent merger of Roanoke, Va.-based Carilion Labs and Greensboro, N.C.-based Spectrum Laboratory Network is set to disrupt the current competitive environment in the Mid-Atlantic and Southern regions, as well as intensify the already compressed pricing environment, say industry insiders.

"Instead of the consistency and predictability of the previous duopoly environment in this industry dominated by LabCorp and Quest, we now have a new competitor on the scene who, with several additional acquisitions, could approach $500 million in revenue," explained Dave Nichols, president and founder of Nichols Management Group (York Harbor, Maine), a consulting firm that recently worked on behalf of Predictive Biosciences on its acquisition of OncoDiagnostic Laboratory. "The last time that the lab industry saw four significant competitors, including Sonic, the price compression in the industry was at its greatest point.

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CARILION-SPECTRUM MERGER, *from page 1*

This is when we saw 25 cents to 30 cents per member per month capitation, exclusive of any anatomic or esoteric carve outs." Nichols also noted that LabCorp (Burlington, N.C.) is by far the industry's lowest cost producer and is likely to weather this challenging pricing climate better than the other lab leaders, particular Sonic Healthcare U.S.A. and Carilion-Spectrum.

The Carilion-Spectrum merger will create a still-to-be-named company that will service 37 hospitals and 14,000 physicians in eight states. The new entity is slated to have over 2,600 employees and annual revenues are slated for at least $300 million. The CEO will be David Weavil, the former CEO of Valencia, Calif.-based Specialty Labs, which was owned by Quest Diagnostics (Madison, N.J.). Carilion Clinic will own 33 percent of the new company. In November of last year, Spectrum was sold by the New York City-based private equity firm Apax Partners to another New York firm, Welsh, Carson, Anderson, & Stowe, for a reported $230 million.

This recent merger underscores the value of creating a robust outreach business for health system sellers, but it remains to be seen whether the desired private equity exit value will be achieved this time around, said Nichols. "The merger of Spectrum and Carilion appears to be fully valued. Therefore, in the parlance of the private equity professionals, will Welsh, Carson, Anderson & Stowe achieve a four, six, or eight 'bagger' or will they be left holding the bag?"

Merger Challenges Create Opportunities

"The newly merged lab company may be a formidable competitor but will undergo a lot of change first," predicts Kathy Murphy, Ph.D., president of Chi Solutions Inc. (Ann Arbor, Mich.), a health care consulting firm. Chi is currently owned by Carilion but is in the process of being acquired by Chi management (Kathy Murphy and Earl Buck, Chi's vice president). Murphy explains that the merged lab will develop a new vision, values, and culture. Spectrum is a private equity-backed lab and Carilion is a hospital-owned lab.

The distinct cultures of each operation will present some synergistic challenges. Carilion will have to adapt to a more financially driven culture. In addition, the newly merged company will be focused internally over the next 12 to 18 months—combining operations and gaining financial synergies. There will be an opportunity for labs in this region to strengthen their competitive position through expanding and strengthening their client base. "This is not to be underestimated," said Murphy. "We have seen instances where a laboratory has lost as much as 50 percent of the business in the first year post acquisition if it's not done well. Local labs can take advantage of this turmoil and capture new market share."

In Other M&A News

- Sonic Healthcare (Sydney, Australia) has acquired Antwerp, Belgium-based Medhold Group for approximately U.S.$316 million (EU232 million), representing an earnings before interest, taxes, depreciation and amortization (EBITDA) multiple of 8.4x before synergies. Medhold has over 300 employees and operates a core lab in Antwerp, as well as four regional labs in Brussels and northern Belgium.
- Medco Health Solutions (Franklin Lakes, N.J.) has acquired DNA Direct (San Francisco), which provides guidance and decision support for genetic testing to patients, providers, payers, and employees. Medco plans to integrate DNA Direct's services with its own portfolio of personalized medicine capabilities, which include a pipeline of pharmacogenetic research, testing programs for drugs like tamoxifen and warfarin, and warnings on over 50 drug-gene interactions that are used by the company's specialist pharmacists. Founded in 2005, DNA Direct's laboratory partners include LabCorp, ViroMed Laboratories, and Myriad Genetics.

■ **PHYSICIAN FEE CUT FREEZE EXPIRES ON MARCH 1**, *from page 1*

Reid's move left lawmakers scrambling to find a legislative vehicle to delay the cut before it is implemented and extend other Medicare provisions.

If Congress fails to act before March 1, it could try to enact a fee fix in a Medicare extenders bill in early March and have it be retroactive to March 1, so no cut would take effect. The Centers for Medicare and Medicaid Services (CMS) also can legally hold claims for up to 15 days, which gives lawmakers some maneuvering room.

The House has approved a fundamental change to the Medicare physician payment system, repealing the SGR system and establishing a new update formula based on growth in the gross domestic product. The Senate reform bill makes no SGR changes but does block the 21 percent cut and grants a 0.5 percent increase for 2010 at a paid-for cost of an estimated $10.9 billion.

The American Medical Association, pathology groups, and other physician organizations, along with the AARP, the seniors' lobby, continue to urge lawmakers to repeal the SGR system, which has triggered ever-deeper cuts over the past decade and is poised to force even more in coming years. But the price tag is looming as a major stumbling block.

LabCorp's Q409 Revenues Up 3.4% to $1.16 Billion; Economy Still Challenges Volume Growth in 2010

The nation's second largest testing provider ended 2009 in strong fashion, with fourth-quarter revenues up 3.4 percent to $1.16 billion, and full-year revenues climbing 4 percent to $4.69 billion. This is solid growth for LabCorp (Burlington, N.C.), particularly compared to fourth-quarter and full-year results from the industry leader, Quest Diagnostics (Madison, N.J.)—which reported fourth-quarter revenue growth of 2.7 percent to $1.8 billion and full-year revenue growth of 2.8 percent to $7.5 billion.

But economy-related issues continue to drag volume growth this quarter, an issue likely to continue this year, said company officials in the most recent earnings call. Volume increased by only 0.7 percent. Declines in drugs-of-abuse testing reduced volume by 0.4 percent, termination of two government contracts in the second quarter reduced this quarter's volumes by 1.5 percent, and weather reduced volume by 0.3 percent.

"Job losses, leading to declines in the number of commercially insured lives, fewer physician visits, and the timing of COBRA and severance expirations had a negative impact on our fourth-quarter volumes," said LabCorp CEO David P. King, who added that managed care organizations are reporting declines in membership. Cigna's membership (Nashville, Tenn.) is down 5.5 percent, UnitedHealthcare (Minneapolis, Minn.) is down 6.5 percent, WellPoint (Wilmington, Del.) is down 3.8 percent, and Humana (Louisville, KY) is down 5.8 percent. "Forty-four percent of our revenue comes from managed care and four of our

largest payers have [faced] significantly negative [membership issues] throughout this year, therefore we have to expect that this will have an impact on overall volumes." In comparison, Quest's volume growth was 2.3 percent in the fourth quarter.

On the positive side, esoteric testing continues to drive revenue, with these volumes up 6.8 percent for the quarter and 9 percent full year. The company is also keeping a tight hold on its bad debt and days sales outstanding (DSO) rates. At the end of December, DSO was at 44, down four days compared to the third quarter and seven days year over year. Bad debt is stable at 5.3 percent (for comparison to Quest's DSO and bad-debt rates, please read the latest benchmarking analysis on p. 9).

The unprecedented snow storms in February are expected to drag down volumes in the first quarter of 2010, said LabCorp Chairman and CEO David P. King. Weather negatively affected fourth-quarter 2009 volumes by 0.3 percent and is expected to have a more significant impact in the first quarter of 2010.

Growth for 2010

The company also released guidance projections for this year. Revenues are expected to grow between 2.5 percent and 4.5 percent, which will be helped with some pricing escalators scheduled to go into effect this year. One analyst recently estimated that LabCorp received a 7 percent hike in their UnitedHealthcare contract (*LIR*, Dec. 2009, p. 1). Priorities for this year include revenue growth with a focus on esoteric and enhanced information technology (IT) platforms. IT improvements will focus on online services to improve patient and physician experiences, including online scheduling and analytic tools. Free cash flow in 2010 is expected to be invested in strategic acquisitions and licensing and partnership agreements, like the agreement just announced with CancerGuide (*see box below*).

But volume growth will continue to be a challenge, warned King. "We expect volume growth to remain challenging throughout the year, given the headwinds from contract losses and the economic environment," he said. "However, our pricing outlook is positive, despite the 1.9 percent reduction in the Medicare clinical lab fee schedule. We will receive price increases from several large payers in 2010."

CancerGuide Diagnostics Announces LabCorp Deal, Secures $10.5 Million in Private Financing Agreement

Durham, N.C.-based CancerGuide Diagnostics has entered the molecular oncology testing arena, having reportedly recently received $2 million of a $10.5 million round of private financing. In addition, the company has also signed a multiyear collaboration and license agreement with LabCorp (Burlington, N.C.). CancerGuide's CEO is Myla Lai-Goldman, the former chief science officer and chief medical officer at LabCorp.

Under the agreement with the nation's second-largest laboratory testing provider, CancerGuide will collaborate with LabCorp on the development and commercialization of molecular oncology assays.

In addition to this collaborative agreement, LabCorp is also participating in the financing as an equity investor. The financing was coled by Hatteras Venture Partners and Intersouth Partners, both of which are based in Durham.

Managing Risk in Lab Sales and Marketing: Nine Rules to Sell By

Health care providers, including laboratories and pathologists, face restrictions on their sales and marketing practices that many other professionals do not have to contend with. Violation of key laws can result in substantial financial penalties, warns Hope Foster, an attorney with Mintz Levin (Washington, D.C.).

At Washington G-2 Reports' Lab Sales and Marketing Conference, held in Chandler, Ariz., in December, Foster shared nine rules for managing legal risk while engaging in effective sales and marketing.

Rule 1: Tell the Truth

Understand exactly what a test can do and sell only that to clients, Foster advises. Don't mislead, don't misrepresent what the test can do, don't exaggerate test characteristics or capabilities, and don't urge doctors to order assays to test for conditions for which the test has not been proven to be effective.

Rule 2: Don't Sell Off-Label or Beyond Validated Results

If using a kit cleared by the Food and Drug Administration (FDA), only sell to the labeled indications. If using a non-FDA-cleared kit, only sell in conformance with the validated results. Keep up with FDA pronouncements about tests.

Rule 3: Disclose, Disclose, Disclose

If a test stops performing in accordance with claims, stop making the claims. Disclose what is happening, select appropriate methods for making such disclosure, and keep the information flowing and current.

When marketing a multicomponent package of tests, be sure to disclose the contents and the CPT codes that will be used to bill for each component. Also, disclose the reimbursement amounts that Medicare will pay for each component and the total that Medicare will pay for the entire package. If the doctor pays for this package of tests himself, make sure that he understands that Medicare may pay more and make it easy for him to know how much more.

Make sure the doctor knows the alternative tests that may be ordered and their prices, make it easy for the doctor to decide what is medically necessary for his patients, and enable the doctor to understand the economic consequences of his test-ordering decisions.

Rule 4: Don't Buy or Pay for Referrals

Paying for referrals of government work is a felony, and paying for referrals of any testing is unlawful in many states. This is a broad rule, so providers should use extreme caution. Paying for referrals can be interpreted to include any of the following: cash, trips, lavish meals, tickets and other types of entertainment, golf games and golf balls, professional courtesy, free goods and services, equipment at less than fair market value, gifts, certain types of discounts, rebates, prebates, up-front payments, signing bonuses, and anything of value.

But it's not just payments linked to referrals that can get labs into legal trouble. Under Stark regulations, there is an annual limit of approximately $360 for financial nonmonetary/cash equivalent that you can allocate per physician per year, explained another attorney, Jane Pine Wood of McDonald Hopkins (Dennis, Mass.). This includes taking a pathologist out for dinner or bringing the staff pizza for lunch

to go over new or changed service offerings. Wood has heard of some cases of labs or pathology practices being asked to write a check to cover a holiday party or other event, which is a violation.

"Another problem is when a lab gives a physician a gift certificate, because these are prohibited, as they are treated like cash," she said. "Having lunch or dinner with physician clients to discuss offerings is fine, but you have to keep track and log the money spent per physician over the course of the year."

Rule 5: Don't Pay Others to Recommend or Arrange for Referrals
This is a very broad ban. Paying others to arrange for referrals is a felony under the anti-kickback law. "I am defending numerous cases right now that fall under this category," says Foster. "This can be hard to defend. You need to be careful when you think about who you're paying and what you're paying for."

Rule 6: Obtain Legal Advice When Contemplating Paying for Leads
This could also implicate the anti-kickback law, so use caution. "This is a very sensitive area," warns Foster. "You need to structure this very carefully if you are thinking about it." In some cases, purchasing leads from brokers can be legal if there is no correlation between the purchase and the success of the leads—in other words, if it's a passive transaction. However, if payment is somehow tied to the success of the leads, this becomes more complicated. "I'm not saying you can't do it, but you should definitely obtain legal advice before you do," she says. "You want to establish protections for yourself and for the person you're buying the list from."

Rule 7: Avoid Sales Techniques That Emphasize How Much Doctors Can Earn
There is nothing illegal about this, but it can easily be misunderstood by the government and viewed as a potential inducement. Suspicions are raised when a salesperson underestimates quality and service and overemphasizes economic benefit to the test referrer. If you do plan to use these techniques, it's best to consult with an attorney to ensure that you are protected legally.

Rule 8: Avoid Using Physician Practices to Induce or Get Referrals of Government-Reimbursed Tests
Many of the LabScam cases of the 1990s were tied to allegations of illegal inducements, notes Foster. Project LabScam was the first systematic nationwide enforcement project targeting medical laboratories. A number of major laboratories paid millions of dollars to settle allegations that they unbundled clinical laboratory tests, billed for tests not performed, inserted false diagnosis codes to obtain payment, paid kickbacks to physicians for patient referrals, and billed for tests that were medically unnecessary.

In December 1999, the Health and Human Services Office of Inspector General (OIG) issued Advisory Opinion 99-13 that specifically addresses the issue of offering discounted laboratory services to physicians. In the 1999 opinion, the OIG said that offering substantial discounts to referring physicians may violate the Medicare prohibition against giving kickbacks in exchange for referrals. In the opinion, the OIG says that price reductions offered to physicians that are not offered to Medicare or Medicaid raise issues under federal law.

This issue of discounts is also implicated in an ongoing investigation in California. The state alleges that seven clinical laboratories have charged the state Medicaid program up to six times more for tests compared to other clients over the past 15 years. The state attorney general alleges that the labs provided deep discounts to physicians in exchange for referral of their government business.

Rule 9: Use Care with Requisition Forms, Test Directories, and Custom Profiles

Beware of inappropriate unbundling of laboratory tests, advises Foster, noting that the OIG said in its work plan for 2010 that it is looking closely at this practice. "They're not just looking at the new stuff, they're looking at the old stuff, too," she says.

Don't steer test ordering through requisition form design. Disclose test offerings and price and offer choice. In addition, be sure that test ordering and listing tools are designed for clarity.

Failure to follow these rules can result in severe penalties, warns Foster. These penalties can include civil monetary penalties of between $5,500 and $11,000 per false claim, criminal fines, and imprisonment. A substantial number of federal enforcement actions have stemmed from sales and marketing activities, she says, noting that individuals—as well as employers—can be held accountable.

Other Sales and Marketing Landmines

In addition to these legal issues, lab sales and marketing personnel can also get into trouble when it comes to electronic medical record (EMR) donations, according to Wood. There are numerous legal requirements when it comes to the donating EMRs in a way that is not conditional on referrals. "This is the real crux of the difficulty, because the only reason any GI or urology or dermatology group would request the donation and the only reason that the pathology testing provider would provide the EMR is to secure the work," she said. However, she added, it's a violation to have a contract link the EMR donation to services provided.

Another issue that Wood has noticed cropping up recently involves what labs can provide physician clients for free in order to collect specimens. There is language in the preamble to the Stark II regulations that indicates a lab can provide low-cost items that are used solely for collection purposes, such as test tubes and urine collection cups, that are used to transport the specimen to the lab. If there are other items used for the underlying procedure that the physician is billing for, such as biopsy snares and needles, labs cannot provide these without a charge.

But some labs are providing devices such as prep kits and endometrial brushes for free to patients, indicating that it provides them with a better specimen. These are clearly questionable, especially in the case of the endometrial brush, which is not "low cost."

"I have had some recent conversations with the OIG office regarding the need for more bright-line advice in terms of what can be provided," said Wood. "From a legal perspective, it's unclear how a pathology lab can provide a prep kit that includes the drape for the patient, the alcohol swab, and wipes to clean the area, when it has nothing to do with the service. But clinicians want these items and labs are under pressure to provide these without charge."

Bostwick Shutters AIPL after Only Six Months; Announces Tenn. Closure

Citing economic pressures, anatomic pathology (AP) testing provider Bostwick Laboratories (Richmond, Va.) has shut down its Washington, D.C., metro-based American International Pathology Laboratories (AIPL) only six months after its launch, according to a company memo from CEO and chief medical officer David Bostwick, M.D., recently obtained by *LIR*. The company has also shut down its histology lab in Tennessee, following the departure of its medical director, Michael Choi, M.D., to Bostwick's New York facility. In addition, clinical pathology testing services at the company's Arizona and New York locations have been consolidated with the Richmond location due to operational issues and disappointing marginal revenues. Calls and e-mails requesting comments from Bostwick officials were not returned by press time.

One industry analyst contacted by LIR said that these developments are likely a result of pursuing too many growth opportunities at once. The AIPL closure and other consolidation moves are likely recognition that this growth is simply not sustainable, he explained.

Before its closure on Feb. 12, AIPL was located in a 30,000-square-foot facility in Silver Spring, Md., and was slated to be staffed by 25 civilian pathologists formerly with the Armed Forces Institute of Pathology (AFIP) at the Walter Reed Army Medical Center in Washington, D.C. The AFIP closed last fall, under the Base Realignment and Closure (BRAC) command by the Department of Defense.

The memo also indicated that the company is grappling with billing issues, relating to delays in getting reimbursed by Virginia Medicare and Aetna. Errors on the part of Virginia Medicare have resulted in a two-month delay, while policy changes from Aetna have resulted in a three-month delay. While the memo said that both of these are currently being resolved, the delays have impacted Bostwick's cash flow.

Too Much Growth?

The shutdown is a serious financial blow to Bostwick, as a significant investment was needed to get the lab up and running. This investment involved the acquisition of American International Biotechnology Services (AIBioTech) in November 2009, which included the purchase of two labs, CBI Services and Fairfax Identity Laboratories (FIL). CBI Services was set to become a division of AIPL, while FIL was to remain a separate operation. In October, the company's vice president of marketing, Brent Sower, declined to comment on the specific investment amount, but said that a full laboratory would be set up with full immunohistochemical capabilities and virtual pathology technology. "With the personnel and technology we are bringing on, it's clear that this is a big investment for us, but we think it's something that's going to be very successful," he told *LIR* at the time.

One industry analyst contacted by *LIR* said that these developments are likely a result of pursuing too many growth opportunities at once. The AIPL closure and other consolidation moves are likely recognition that this growth is simply not sustainable, he explained.

Myriad Genetics Emerges as Early Leader in G-2's Preliminary FY09 Benchmarking Analysis

While not all the publicly traded labs' full-year 2009 results are in and 10-Ks have been filed, some early analysis of productivity data reveals that Salt Lake City specialty testing provider Myriad Genetics is showing big gains in two benchmarking measures: revenue per full-time employee (FTE) and pretax income per employee (see Table). It's important to note a number of top-performing labs, including Genoptix (San Diego) and Orchid Cellmark (Princeton, N.J.), had not released results before *LIR* went to print. Benchmarking analysis including these labs' results will be featured in the next issue of *LIR*.

But among those labs tracked by G-2 Reports that have released full-year 2009 results, Myriad is the leader in revenue per FTE at $375,719, an increase of almost 67 percent compared to the previous year. Following Myriad in this measure is Genzyme Genetics/Diagnostics (Cambridge, Mass.) at $315,105, an increase of 13 percent compared to 2008. Rounding out this top three is Bio-Reference Laboratories (Elmwood Park, N.J.) at $214,488, an improvement of 6 percent over 2008.

The second measure, pretax income per FTE is also led by Myriad at $156,962, an increase of over 100 percent compared to the previous year. The national labs follow Myriad in this category. LabCorp's pretax income per FTE is $31,593, an increase of 13 percent over 2008, while Quest is at $28,556, an increase of 16 percent.

Preliminary Full-Year 2009 Financial Benchmarks

	Full-Year Revenue (in millions)	Full-Time Employees	Revenue/ Employee	Comparison to FY08	Pretax Income (millions)	Pretax Income /Employee	Comparison to FY08
Quest	$7,455.2	43,000	$173,377	2%	$1,227.90	28,556	16%
LabCorp	4,694.7	28,000	167,668	4	884.60	31,593	13
Bio-Reference	362.7	1,691	214,488	6	38.60	22,827	27
Enzo Clinical Labs	39.6	300	132,000	-17	(7.30)	(24,333)	-424
Genzyme Genetics/Diagnostics	538.2	1,708	315,105	13	n/a	n/a	
MedTox Scientific	84.1	582	144,502	-2	2.00	3,436	-77
Myriad Genetics	326.5	869	375,719	68.6	136.40	156,962	109

Note: Myriad Genetics fiscal year ended June 30; Enzo Clinical Labs fiscal year ended July 31. These are preliminary data and do not include industry leaders such as Genoptix, Orchid Cellmark, and Psychemedics. Full results will be featured in the April 2010 issue of *LIR*.
Source: Washington G-2 Reports, company filings, William Blair & Co. research notes.

DSO, Bad Debt Holding Steady

Of course, the one measure of interest to Wall Street is how the labs are managing their days sales outstanding (DSO) and bad-debt expense amidst the persistence of economic uncertainty (*see table*). Quest is leading in DSO rates; its DSO has held steady at 43 all year, down from 44 at the end of 2008. LabCorp has made

	DSO					Current Bad-Debt Expense (%)				
	2008	Q1 2009	Q209	Q309	Q409	2008	Q1 2009	Q209	Q309	Q409
Quest	44	43	43	43	43	4.3	4.5	4.4	4.4	3.9
LabCorp	51	52	50	48	44	6.2	5.32	5.3	5.3	5.3
Bio-Reference	107	115	104	95	95	13.3	14.5	13.9	14.2	14.2

significant improvement throughout the year, down to 44 compared to 51 at the end of 2008. Bio-Reference has also improved its DSO—down to 95 compared to 107 at the end of 2008.

Quest also is leading in bad-debt expense rates, down 3.9 percent compared to 4.3 percent in 2008. LabCorp has also improved in this measure, down to 5.3 percent compared to 6.2 percent at the end of last year. Bio-Reference's bad debt has climbed to 14.2 percent, compared to 13.3 percent at the end of 2008.

Baylor Health Care Launches Joint Venture with US Oncology

Dallas-based Baylor Health Care will team up with Houston-based cancer care and research company US Oncology to launch a molecular diagnostic laboratory. The joint venture, temporarily named NewCo, will start in a 172,000 square-foot facility in Lewisville, Texas, which is north of Dallas. The company reportedly plans on hiring 200 staff this year and as many as 900 over the next five years. The focus of NewCo will be pharmacogenomic testing and treatment.

The new company's CEO is reportedly Keith Laughman, formerly president of AmeriPath's esoteric services division, as well as former president of Mayo Collaborative Services (Rochester, Minn.).

Oral Arguments Heard in Gene Patents Lawsuit

Both sides in the landmark lawsuit challenging the patenting of human genes have asked a federal court to rule in their favor without a trial during oral arguments at a Feb. 2 hearing in New York City, reports Washington G-2 Reports' *National Intelligence Report*. This marks the first time that a challenge to gene patenting has been heard in federal court.

At issue are patents granted to Myriad Genetics (Salt Lake City) and the University of Utah Research Foundation for BRCA1 and BRCA2 genes, which are indicators of hereditary disposition to breast and ovarian cancer. The core of the case is whether the patent claims cover "products of nature" and "laws of nature" and are therefore invalid. The lawsuit was filed in May 2009 by the American Civil Liberties Union (ACLU) on behalf of an estimated 150,000 researchers, physicians, laboratory professionals, and patients.

Myriad said a decision to invalidate the patents would "lead to the invalidity of thousands of biotechnology patents, and effectively unravel the foundation of the entire biotechnology industry. Numerous therapeutic drugs and diagnostic tests in development would be jeopardized."

The core of the case is whether the patent claims cover "products of nature" and "laws of nature" and are therefore invalid.

A decision is expected in the next few months, the ACLU said. It is likely to be appealed to a court in Washington, D.C., that specializes in patent law, according to legal sources following the case.

Lab Index Continues Winter Slump; Down 10% Over Last Five Weeks

The 13 publicly traded labs tracked by G-2 Reports' Laboratory Stock Index continue to struggle in early 2010. Over the past five weeks, the index is down 10 percent, and down 4 percent over the past 13 weeks for the week ended Feb. 19, 2010. The Nasdaq and S&P 500 are also down over 2 percent each. The S&P is down 2.3 percent, while the Nasdaq is down 2.8 percent.

Those that did post increases over the past four weeks for the week ended Feb. 19 only made slight gains. Leading the gainers is **Medtox Scientific** (St. Paul, Minn.), which is up 8 percent to $8.95 for a market cap of $74.53 million. Following is **Enzo Biochem** (New York City), up 5 percent to $5.34 per share for a market cap of $199.89 million.

Rounding out this group are two labs tied for third, both up 2 percent each. **Bio-Reference Laboratories** (Elmwood Park, N.J.) is up to $39.82 per share for a market cap of $547.81 million and LabCorp (Burlington, N.C.) is up to $73.98 per share for a market cap for $7.94 billion.

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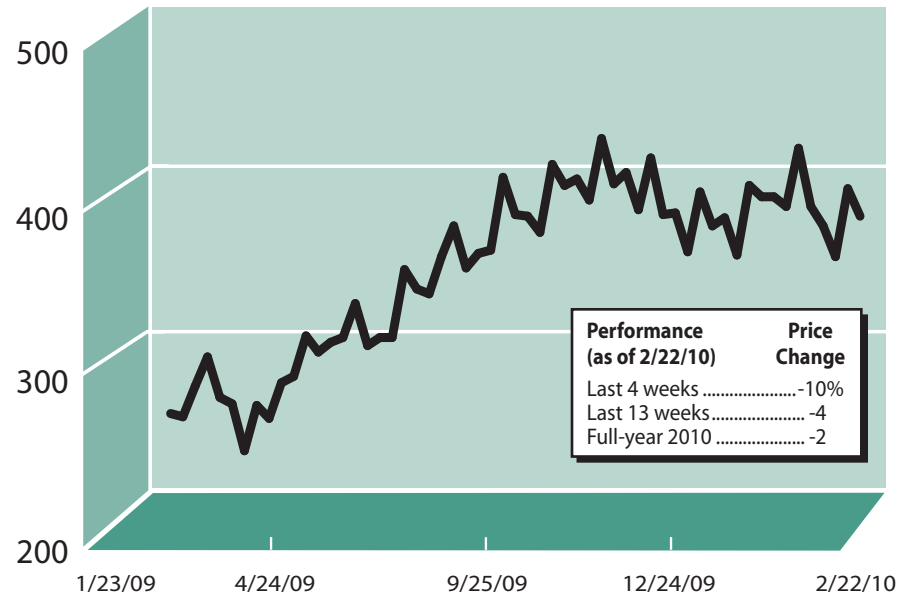
The list of top three labs posting losses over the past four weeks for the week ended Feb. 19 is lead by **Clarient** (Aliso Viejo, Calif.), down 16 percent to $2.13 per share for a market cap of $164.7 million.

Following is **Orchid Cellmark** (Princeton, N.J.), down 9 percent to $1.53 per share for a market cap of $48.41 million. **Psychemedics** (Acton, Mass.) is also down 5 percent to $7.59 per share for a market cap of $39.45 million.

G-2 Laboratory Stock Index



Source: The G-2 Laboratory Stock Index is tabulated weekly by *Laboratory Industry Report* from the average percentage change in the price of 13 laboratory testing service stocks.

Top Gains and Losses Over Past Four Weeks
Percent price change, week ended 2/19/10

	Percent Change	*Price*
UP		
Medtox	8%	$8.95
Enzo	5	5.34
Bio-Reference	2	39.82
LabCorp	2	73.98
DOWN		
Clarient	16	2.13
Orchid	9	1.53
Psychemedics	5	7.59

INDUSTRY buzz

MedPAC Considers Removing Some Lab Tests from In-Office Ancillary Services Exception

The Medicare Payment Advisory Commission (MedPAC) is considering three options for addressing problems resulting from in the in-office ancillary services exception to the Stark law, including excluding certain services from the exception (such as diagnostic tests that are not usually provided at the same time as the office visit).

In-office ancillary services are growing at a rapid pace, and the increased utilization may require narrowing the exception for such services under the physician self-referral law, as well as altering the payment system, the head of MedPAC said at a public meeting Jan. 15.

"Over the last several years, there's been an increase in imaging, lab tests, and physical therapy provided in physician offices," Ariel Winter, a senior analyst with MedPAC, said at the meeting. Winter provided three options for controlling the escalation of in-office ancillary services: excluding certain services from the in-office exception, creating new payment tools to reduce the incentive for using such services, and establishing a prior-authorization system for physicians who are self-referring for advanced imaging.

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Genoptix 760-268-6200
Genzyme 617-252-7500
LabCorp 800-334-5161
Medtox Scientific 800-832-3244
McDonald Hopkins 216-348-5400
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