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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

WASHINGTON G-2 REPORTS

Lab Industry Follows Pharma Into Direct-To-Consumer Marketing

It's hard to believe that until recently, it was unheard of to see prescription drugs advertised in slick advertisements, encouraging viewers to ask their doctors if certain medications are right for them before lapsing into hurried lists of reported side effects. Then Digene took the cue of pharmaceutical companies and mounted a massive media campaign for its human papilloma virus (HPV) test, a move that was recently followed by Merck's campaign for Gardasil, its new vaccine that can prevent some types of cervical cancer. Now the clinical laboratory is getting into the act—almost.

Quest, LabCorp, and smaller players are working to build brand awareness and loyalty among physicians and consumers alike in burgeoning media campaigns that include radio, television, and the Web. It's no coincidence that this media blitz coincides with the industry turf wars that were the result of UnitedHealthcare's decision last fall to award a 10-year contract for laboratory services to LabCorp. At the same time, the branding of laboratory services has the potential to benefit the entire industry, particularly as the looming Medicare competitive bidding project threatens to promote the view of laboratory services as a commodity. For an in-depth look at the trend of laboratories marketing to consumers, see this month's *Inside the Laboratory Industry*, pp. 5-8.

Lab Execs Map Out Competitive Strategies

Senior executives from hospital laboratories and independent reference laboratories nationwide met in Phoenix in December to discuss strategies for competing in an environment where costs are squeezed, technology is changing, electronic medical records are rapidly gaining hold, and two giant national labs hold significant market share. The forum was LabCompete: Strategies for 2007, Washington G2 Reports' inaugural conference on how to compete and gain market share in the clinical laboratory industry of today—and of tomorrow.

Keynote speaker David Nichols, president of the Nichols Management Group (York Harbor, ME), stressed that small labs can compete with bigger players through product differentiation. "For example, Bio-Reference Laboratories has succeeded by focusing on correctional facilities and cutting-edge oncology treatments," he said. "There's plenty of room for high levels of personal service, but when managed care companies and the government look at you as a provider of health services, you need to have a concrete differentiation in addition to better service."

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Sonic Deviates From Offshore Strategy, Acquires Remaining 18% Of CPL

In December, Sonic Healthcare (Sonic; Sydney, Australia) announced that it would acquire American Esoteric Labs (AEL; Nashville, TN) for $180 million (see *LIR*, January, pp. 1-2). However, unlike their October acquisition of Cognoscenti Health Institute, which was purchased through what was thought to be Sonic's United States subsidiary, Clinical Pathology Laboratories (CPL), Sonic positioned the AEL acquisition as a purchase by Sonic, not CPL. Now the reason for that is clear. Upon completing the AEL acquisition in late January, Sonic announced that it would also acquire the remaining 18% of CPL, in which it purchased an 82% stake in October 2005. Sonic paid $82.7 million for the minority interests, which implies that the value of the businesses has appreciated by about 13% since the majority of CPL was acquired.

This represents a departure from Sonic's stated offshore strategy of acquiring a majority stake while leaving local management with a minority interest. At the time of the CPL acquisition, Sonic told *LIR* that it planned to acquire the minority stake progressively over a three-year period (2009 to 2012) to reach 100% ownership.

"In effect, [the AEL acquisition] flagged that the existing minority model was unsustainable," says Marcus Wilson, a healthcare equity research analyst at Macquarie in Australia. "We suspect Sonic is in advanced discussions with respect to a rapid succession of U.S. acquisitions and that the CPL minorities would be unlikely to assist in the funding of these deals." While this strategy could fuel rapid expansion, Wilson notes that it could also "entail higher downstream risk from the lesser alignment of U.S. management with Sonic shareholders."

Horizon/LabCorp Deal Ousts Bio-Reference

Horizon Blue Cross Blue Shield of New Jersey (Horizon; Newark, NJ) will terminate its longtime in-network provider relationship with Bio-Reference Laboratories (Elmwood Park, NJ) on March 31 of this year, according to a letter recently received by Bio-Reference. Two other New Jersey-based laboratories were also dropped from Horizon's panel of in-network providers. LabCorp and AtlantiCare Clinical Labs are now Horizon's only two in-network lab service providers.

As New Jersey's largest health insurer, Horizon provides coverage to more than 3.2 million people. Bio-Reference has been an authorized provider to Horizon for the past 20 years, and Horizon business accounted for about 5% of Bio-Reference's FY 2006 revenues, according to management.

Bio-Reference is not taking the news lightly. "The recent agreement by Horizon and LabCorp will essentially leave only one full-service clinical laboratory authorized to provide laboratory testing to Horizon subscribers," said Bio-Reference CEO Marc D. Grodman, M.D. "We have no intention of allowing this decision to be implemented without challenge. We have asked Horizon to rescind their decision; if they fail to do so, we will pursue all avenues of relief available to us."

RedPath Builds On A Convergence Of Technology

Mary Del Brady

Pittsburgh-based RedPath Integrated Pathology is hoping to fill an existing critical need by merging cutting-edge molecular technology tools with standard pathology practice, focusing first on cancer diagnostics. Founded in 2004 by Sydney Finkelstein, M.D., RedPath is built on a proprietary, patented Topographic Genotyping platform, a high throughput molecular profiling system.

"What we have is a breakthrough approach that helps to reduce diagnostic unknowns or missed diagnosis," says Mary Del Brady, president and CEO of RedPath and the former president of TissueInformatics (Pittsburgh, PA). "It's a molecular-based technology, and we integrate it with standard pathology practice, so what we end up doing is facilitating more definitive diagnoses where the standard practice could not."

Their highest volume test is for early pancreatic cancer diagnosis. "About 80% of the time, definitive pancreatic cancer diagnoses occur late-stage. Pancreatic cancer is also pretty aggressive," Brady tells *LIR*. "So obviously there was a real need to find a tool as a way to be able to enable earlier and more definitive diagnosis. We've experienced good market adoption on this indication around the country."

But RedPath's technology isn't limited to pancreatic cancer detection. Their system, known as PathFinderTG, can be used on a variety of tissue types, including solid tumors from standard formalin-fixed biopsy slides, cytology smears, and fine needle aspirated (FNA) solids and fluids. "We use our patented technology to manipulate and extract the DNA, amplify it, and then perform a mutational fingerprint on it," says Brady. A panel of between 15 and 20 markers is customized based on the organ system and application.

As a business model, Brady notes that RedPath operates as a commercial laboratory, providing diagnostic tools and support to pathologists and clinicians. They don't expect pathologists or surgeons to perform their jobs any differently. "We hope that we don't threaten the pathologists, that they can appreciate that this is a very powerful tool, which will help them do their jobs better and complement the skills of pathologists," says Brady. "We don't ask for all the cases—just the hard ones and where there is still some question left."

"We don't ask for all the cases—just the hard ones and where there is still some question left."

In 2007, RedPath expects to handle about 3,000 cases, double that of 2006. In September 2006, they raised $4 million in a Series A equity financing round led by NewSpring Capital (Philadelphia, PA) and joined by CID Capital of Columbus, Ohio, as well as other investors. They intend to use those funds to increase sales and marketing activities and scale-up operations. According to Brady, the company has experienced measured growth. "From an operations standpoint, we've been able to operate at a break-even level, but we need to resolve all the reimbursement issues so that we can do a total ramp-up of the sales effort," she says. "What we're doing this year is building marketing structure that will match what we're hearing from our target audience; we're building our information systems infrastructure that will be able to support a company in rapid growth. We really see a big gear-up in 2008 and beyond."

According to RedPath, their technology has been validated with a 95% accuracy rate, and over 150 peer-reviewed articles have been published about it. Brady doesn't feel they are limited to clinical diagnostics, either. "Our platform is really broad enough to be valuable in drug discovery, theranostics, and treatment effectiveness, so as we ramp up the service business, we also intend to explore the other markets as well. We are one of those small but growing group of companies that are really applying knowledge gained through the whole genomics revolution into everyday clinical practice."

RedPath Integrated Pathology At A Glance

President and Chief Executive Officer: Mary Del Brady
Founder and Chief Medical Officer: Sydney Finkelstein, M.D.
Revenue, 2006 (estimated): $5 million
Headquarters: Pittsburgh, PA
Employees: 18, expected to grow to 30 by year-end
Source: *LIR*

New Congress To Influence Critical Laboratory, Pathology Issues

Even before officially taking control of the 110th Congress, Democratic leaders promised to give priority to a broad range of healthcare issues, including coverage of an estimated 47 million uninsured Americans, expanded stem cell research, and changes to the Medicare prescription drug benefit program. At stake this year for clinical laboratories and pathologists are two particularly critical issues: competitive bidding and increased regulation of both "home brew" lab tests and a subgroup of complex molecular tests that the FDA calls In Vitro Diagnostic Multivariate Index Assays (IVDMIAs).

The Clinical Laboratory Coalition has been lobbying legislators and regulators on the controversial Medicare competitive bidding demonstration for independent lab services. Coalition members unanimously oppose the idea of applying competitive bidding to lab services, saying it treats the services as a commodity rather than a complex service.

Still awaiting final clearance from the Office of Management & Budget, the demo is now expected to launch in June, but this time frame might be further delayed to allow time for soliciting bids and selecting winning labs.

Lab groups expect a sympathetic ear on Capitol Hill to their concerns about competitive bidding. Both Reps. Charles Rangel (NY), head of the House Ways & Means Committee, and Pete Stark (CA), head of its health subcommittee, have said they think competitive bidding for lab services is a bad idea. What this might mean for the current CMS project is unclear. The leaders could use their oversight authority to revisit the issue or at least extend the rollout of the lab bidding demo while lab industry concerns are addressed.

On the issue of expanded controls on "home brew" tests and IVDMIAs, laboratory and pathology groups are keeping an eye on not only the FDA but also the office of Sen. Edward Kennedy (MA), who chairs the Health, Education, Pensions, & Benefits Committee. Kennedy's office continues to work on a draft bill to regulate home brew tests. A draft that surfaced last year would have defined virtually all home brews as class II devices, requiring labs to submit a 501(k) application for each test developed in-house. In other provisions, FDA review would proceed on a volume basis, rather than a risk basis, and tests in the lowest 20% of volume would be exempt from FDA review.

Cutting Out The Middle Man? Major Lab Players Target Patients In New Media Campaigns

When Digene advertised their new human papilloma virus (HPV) test on *Oprah*, it was big news. After all, this seemed to bypass physicians, who order the test, and appeal directly to consumers. Yet because there are physicians between the laboratory and the patient, it's probably not appropriate to call this type of advertising direct-to-consumer (DTC).

There does seem to be a trend, although possibly a short-lived one, of commercial laboratories targeting consumer-patients with marketing campaigns, especially print, radio, and online advertisements. Quest Diagnostics has hit the airwaves and Web with a campaign dubbed "My Lab is Quest" aimed at consumers. Similarly, LabCorp is executing a consumer-targeted campaign called "Choose LabCorp." These are not national, global campaigns, but targeted toward the east coast, including the New York metropolitan area, which has become a crucial battleground for customer awareness since LabCorp won the UnitedHealthcare contract from Quest. Another lab player in the same market, Sunrise Medical Laboratories (Hauppauge, NY), also has responded with radio advertisements.

"Anyone who's a player does not want Quest to be the only one to dominate the airwaves," says Larry Siedlick, CEO of Sunrise Medical Laboratories.

"I think there's a general trend in healthcare to do more of this type of advertising," Sunrise CEO Larry Siedlick tells *LIR*. "Quest initiated this on a larger scale, and I believe a number of lab ad campaigns are going to be in response to the Quest folks being out there. No one wants to leave. Anyone who's a player does not want Quest to be the only one to dominate the airwaves."

If It's Not DTC, What Is It?

Traditional direct-to-consumer advertising is when you advertise for a consumer to actually purchase a product or service. This is fairly rare in terms of medical devices and nearly nonexistent in laboratory services. Although there are some companies and products out there offering at-home drug testing, genetic testing, and a few others, typically laboratories in the United States don't work that way.

"Device and diagnostics aren't traditionally DTC advertisers," says Shelly Ducker, associated director of corporate communications for Digene. "Usually it's big pharma. For diagnostics and devices it's quite unusual. Digene was one of the first with its HPV test, and there have been a few devices like knee and hip replacement that have been targeted straight to consumers, but it's a little unusual."

Pam Sherry, senior vice president of corporate communications for LabCorp, is quick to point out that LabCorp's campaign is not direct-to-consumer.

"There's actually little in the lab industry that is handled that way. LabCorp's strategic plan does not have an element that is direct-to-consumer. That's not what we're focusing on. But, we're recognizing that sometimes you need to create awareness of what LabCorp is and what we do."

Siedlick concurs, emphasizing that their radio spots are branding, not DTC. "We're attempting to reinforce our brand in the marketplace where we're one of the dominant players. We're not specifically targeting a product or a service, like go to the store and buy one of these. It's brand awareness."

In the New York market, in particular, where LabCorp is opening numerous patient service centers and access points as a result of new business related to the UnitedHealthcare contract, creating an awareness of this greatly expanded presence may be critical. Despite being a laboratory service provider for the last 35 years, LabCorp felt that it was important to raise awareness of their presence among consumers in New York state and particularly in New York City. "When we move into certain markets—particularly the markets we have much greater access to because of our new agreement with UnitedHealthcare—we recognized that even in the northeast and in New York, that we really didn't have the visibility that we felt was important to have there," says Sherry. "We felt it was important for people to know that we were a very high-quality, innovative, convenient laboratory that is very familiar with this market and able to service people, and we needed to raise that visibility."

Tracking

One of the problems with a "branding" campaign is that it's difficult to track whether or not it's working. If you're selling a specific product—say Widget X—you can look at sales prior to the beginning of a campaign, then track how the sales have moved on a day-to-day basis as the campaign runs. To throw ads out into the airwaves for a laboratory or a laboratory test may be akin to drops in a bucket of water—only a significant period of time and long-term measurements will indicate if the ad campaign worked; and it may be difficult to determine exactly what aspect of your campaign did or did not work.

Siedlick notes that Sunrise Medical Labs doesn't have a specific measure in place to track the effectiveness of their ads. "Branding efforts, as we understand them, are a long-term proposition, so you have to be prepared to be in it for the long term to have an effect. We're fortunate that Sunrise is in a position to be able to take a long-term view. It's a campaign, not just a single ad."

Part of LabCorp's overall campaign is a small Web site, dubbed a microsite (www.chooselabcorp.com), whose primary focus isn't consumers, but physicians. It's also simple to track usage on the Internet. According to Sherry, "We recognized there would be a lot of interest on the part of physicians for signing up for LabCorp services, and this was one more way for them to do that."

In the case of radio ads, the radio stations are very aware of their audience and markets. "With radio ads you buy the market, and they know what their audience is and what the air times are," says Sherry. "We don't have anything set up to get direct feedback or a mechanism to know if people are really hearing the advertising, although we're hearing from people in that market that they've heard the ads."

Expenses

In the case of LabCorp, this advertising campaign was directly related to the UnitedHealthcare relationship. "We've talked about the implementation of the new UnitedHealthcare contract and the build-out and the opening of more patient service centers and more access points. It's an integrated program," says Sherry. "We have more access points, and we want people to know about it, and the way to do that is to communicate about it."

"In the markets where we've seen our advertising, we've seen a huge jump in tests that are done."

Siedlick notes as well that Sunrise's radio ads, which are a significant, but unspecified investment, are a new budget item. "It's not taking away from any of our existing budget."

Digene's campaign, including TV spots during *Oprah*, also involved a print campaign in women's and health magazines, as well as television spots in 14 markets nationwide. "It's a sizable marketing budget," Ducker tells *LIR*. "In the markets where we've seen our advertising, we've seen a huge jump in tests that are done. What we're seeing is that it takes an investment, especially with HPV—it motivates a conversation between patients and their physicians about HPV tests—and we're seeing that as volumes grow that we got twice the rate that we had in the non-advertising markets.

A Campaign

Sherry doesn't believe that this type of marketing is a trend. LabCorp isn't conducting a national campaign, but focusing on markets where they feel they need increased visibility. As Siedlick mentioned, Quest began their campaign in the New York and northeast areas, and regional competitors felt obliged to compete. "It's about heightened awareness as much as anything," says Sherry. "And we certainly don't need to do this in every market."

Ducker has been following this issue of direct-to-consumer marketing since 1997 when the FDA approved it for pharmaceutical companies. She notes that this type of branding in diagnostic and device companies can be a tricky proposition. "It's not a panacea for everything. You need to have the right product mix and the right messaging. You need to have owned the market in a particular way. One of the foibles people see in DTC is you invest millions in your campaign and you really just benefited your rival."

What is probably most important to understand about these campaigns is that it's not enough to simply focus on creating brand awareness in the

patient-consumer. Ultimately the guardian at the gate is the physician. If physicians aren't part of the campaign at some level, having patients requesting services of a particular laboratory are going to fall on deaf ears. Digene, for instance, preceded their print and TV campaigns with blast-fax campaigns to clinicians who frequently ordered Pap tests, providing information about the new HPV test and alerting them to the upcoming advertisements. "You want to make sure the doctor's offices are informed this is happening," says Ducker. "If you haven't informed your doctor's offices and you don't have the buy-in, then the consumer-patient campaign doesn't go anywhere. That's a big part of the foundation—before you target the consumer, you need to create a strong presence in the mind of the clinicians and have them be familiar with your product and inform them the campaign is starting."

Consumer-Directed Health Plans Breeding Savvier Patients

Consumer-directed health plans (CDHPs) economically incentivize their members to take a more active role in understanding, selecting, and shaping the healthcare services they receive, making them more likely to pay attention to media campaigns for everything from lab tests to drug plan options.

These plans are already creating more proactive, cost-savvy patients. According to a survey conducted last summer by the Kaiser Foundation (Menlo Park, CA), CDHP members are almost twice as likely as members of traditional plans to use the Internet to find lower prices for prescription drugs and other types of health services and to choose lower-cost options for a recommended test or treatment. Additionally, CDHP members are more than twice as likely as traditional plan members to negotiate with a health provider to get a lower price for services. And while the proportion of all CDHP members who are scouring the Internet for lower prices remains fairly low (10%-19%), it is likely to grow rapidly, as CDHPs become more widespread and better understood by members.

Reported Steps Taken to Reduce Costs

	*CDHP**	*Control*
Gone on the Internet to find a lower price for prescription drugs	19%	10%
Chosen a lower cost option for a recommended test or treatment	17	10
Negotiated with a health provider to get a lower price for services	14	6
Gone on the Internet to find a lower price for other types of health services	10	6

*Those belonging to consumer-directed health plan with an accompanying savings account.

Source: Kaiser Foundation National Survey of Enrollees in Consumer Directed Health Plans (2006)

John C. Goodman, president of the National Center for Policy Analysis (Dallas, TX), sees consumer-directed healthcare as a potential solution to two problems: how to choose between healthcare and other expenditures and how to allocate resources in an industry where normal market forces have been systematically suppressed. "If private spending on healthcare keeps up with public spending," notes Goodman, "the nation will devote approximately two-thirds of its income to healthcare by 2050—roughly equal to total consumption of all goods and services today. To avoid this disastrous scenario, someone must choose between healthcare and other uses of money." That someone is shaping up to be an increasingly better-informed consumer.

Philip Chen, M.D., Ph.D

COMPETITIVE STRATEGIES, *from page 1*

In the sessions that followed, a lineup of independent lab innovators continued with Nichols's theme by focusing on specific ways to compete and win. Networking emerged as one of the most powerful strategies that independent labs can use "to work smarter, not harder." Philip Chen, M.D., Ph.D., director of Cognoscenti Health Institute (Orlando, FL), and Rosalee Allan, senior vice president and COO of Pathology Associates Medical Laboratories (PAML; Spokane, WA), focused on competing through network innovation in outreach.

Chen, whose business was purchased by Sonic Healthcare-owned Clinical Pathology Laboratories last year, explained his entrepreneurial focus on "evidence-based laboratory medicine" as a way to differentiate his regional outreach laboratory. He went on to discuss Cognoscenti's use of outpatient laboratory utilization management, which he characterized as "adopting existing evidence," and of employer-based disease prevention and wellness programs, which he sees as a way to "generate new evidence."

Continuing with the theme of networking, Dennis Hodges provided valuable lessons from his tenure as manager of business development at Michigan Co-Tenancy Laboratory (MCL; Ann Arbor, MI). Through MCL, economically unrelated not-for-profit hospitals jointly own and use the assets of an Ann Arbor-based esoteric laboratory to reduce the cost of testing services through economies of scale.

Because MCL is a co-tenancy model, each user owns an undivided interest in the assets, Hodges explained. Testing done for each user/owner is considered to be done on that owner's share of the equipment, with that owner's share of the reagents, and by that owner's share of the staff. All billing for such testing is done by each owner under its own name.

Hodges also explained MCL's process of cost allocation. Each test performed in the co-tenancy laboratory is assigned a relative value unit (RVU), and at the end of each quarter, the total number of RVUs performed is divided by the same period's total costs to arrive at a cost per RVU. Each owner's total RVUs for the quarter is then calculated and multiplied by the cost per RVU, resulting in that user's allocated cost of testing.

Lab strategists were also impressed with Genova Diagnostics (Asheville, NC), a small specialty laboratory that operates largely outside of managed care. Genova offers customized esoteric testing, which patients pay for mostly out of pocket, creating enviable and sustainable profit margins and allowing Genova to offer cutting-edge tests. "The average revenue per patient is around $160," explained president and CEO Ted Hull. "Our profit on that is about 50%. We're still pretty small, so we have plenty of room to grow."

With a focus on noninvasive testing for digestive diseases, Genova partners with gastroenterologists and has two exclusive products. The first, pancreatic elastase 1 (PE1), tests for the only noninvasive marker that correlates with the secretin-pancreozymin test, which is regarded as the gold standard for assessment of exocrine pancreatic function. Genova also has an exclusive on testing for calprotectin,

which enables clinicians to distinguish between patients with inflammatory bowel disease (IBD) and irritable bowel syndrome (IBS), and to monitor therapy for IBD.

One of the most popular sessions featured Michael Snyder, a lab industry veteran who now leads Clinical Lab Business Solutions. Snyder provided conference participants with a valuable analysis of United Healthcare's recent industry-shaking contract with LabCorp, including its implications for those in attendance and the market as a whole.

The next LabCompete conference is planned for February 2008, at Loews Ventana Canyon Resort in Tucson, Arizona.

Spectrum To Use Thomson's MercuryMD Mobile EHR System

Spectrum Laboratory Network (Greensboro, NC) will deploy MercuryMD, an electronic health record (EHR) platform of Thomson Healthcare, across its affiliated network of hospitals in North Carolina and Tennessee. MercuryMD, which the company terms a "mobile health record," will enable the more than 20,000 doctors in Spectrum's network to have immediate access to laboratory results and patient information anywhere via a smartphone or PDA. This service will also be available to all independent physicians and physician groups within Spectrum's five-state market, which consists of the Carolinas, Tennessee, Georgia, and Virginia.

Spectrum provides laboratory services for three major health systems in North Carolina, including High Point Regional Health System and Moses Cone Health-System. In Tennessee, their network includes the four-hospital Wellmont Healthcare system. Spectrum processes more than 11,000 laboratory orders a day for inpatient and outpatient care.

According to Nate Headley, president and chief executive officer of Spectrum, "aggressive use of information technology is a fundamental strategy" in improving the quality of patient care, decreasing response times to lab results, and reducing costs and medical errors. "By untethering the doctor from the computer terminal, we are delivering our lab results to clinicians at the point of care—resulting in better, timelier, and more cost-effective clinical decisions," adds Headley.

Doctors can access the MercuryMD service by having it installed by Spectrum representatives on their smart phones or PDAs. All data is encrypted and password-protected to protect patient privacy.

United Will Cover Oncotype DX Testing

UnitedHealthCare (Minnetonka, MN), one of the nation's largest private payors, will now reimburse for Oncotype DX, Genomic Health's breast cancer test service. United's new policy establishes coverage across all of UnitedHealthcare's plans for women with early-stage breast cancer. Coverage is scheduled to become effective for claims for services performed after January 2 of this year. Oncotype DX quantifies the likelihood of breast cancer recurrence and predicts the likelihood of chemotherapy benefit for some early-stage breast cancer patients.

Lab Stocks Rose 29% In 2006; Genomic Health Was Best Performer

Eleven laboratory stocks rose an unweighted average of 29% last year versus respective gains of 14% and 10% for the S&P 500 Index and the Nasdaq. Overall, nine stocks rose in price and two fell.

Genomic Health (Redwood City, CA) was the best-performing lab stock in 2006, with an impressive gain of 104%, bringing the stock to $18.60 per share. The company has been racking up coverage arrangements for Oncotype DX, its flagship breast cancer testing service, with major payors such as UnitedHealthcare (see p. 10) and Aetna. The company is now focused on developing a test to predict the likelihood of colon cancer recurrence, a project they have just moved into full-scale clinical development. The colon cancer program is expected to build upon genes associated with prognosis in patients with stage II and III colon cancer treated with surgery.

Drug testing specialist **Medtox Scientific** (St. Paul, MN) soared 76% to end 2006 at $13.33 per share, and shares of **Myriad Genetics** (Salt Lake City, UT) gained 50% in 2006, reaching $31.30 per share at the end of the year.

Stock prices for the three publicly traded routine clinical lab companies—**LabCorp**, **Bio-Reference**, and **Quest Diagnostics**—were up by 36%, 20%, and 4%, respectively, reflecting LabCorp's industry coup: winning the UnitedHealthcare contract. United business accounted for approximately 7% of Quest's annual revenues.

The worst performing lab stock was DNA testing provider **Orchid Cellmark** (Princeton, NJ), which plummeted 59% to $3.10 per share in 2006.

Monogram Biosciences (South San Francisco, CA) was down 5%, ending the year at $1.78 per share. However, the company got a boost late in the year, when Pfizer announced its plan to establish a multinational Expanded Access Program for maraviroc, its HIV drug candidate. Monogram's co-receptor tropism assay, Trofile, was used for patient selection for maraviroc's clinical development program, and the two companies are collaborating to make the assay available for patient use on a global basis.

Lab Stock Review for 2006

Company (ticker)	*12/31/05 Price*	*12/31/06 Price*	*52-Week % Chg*	*P/E Ratio*	*Market Cap ($ millions)*
Genomic Health (GHDX)	$9.11	$18.60	104%	N/A	$551
Medtox (TOX)	7.58	13.33	76	24	100
Myriad Genetics (MYGN)	20.80	31.30	50	N/A	1.43B
Psychemedics (PMD)	13.43	19.25	43	21	95
LabCorp (LH)	53.85	73.47	36	24	9.05B
Clarient (CLRT)	1.30	1.72	32	N/A	98
Bio-Reference (BRLI)	18.81	22.49	20	27	309
Enzo Biochem (ENZ)	12.42	14.27	15	N/A	476
Quest Diagnostics (DGX)	51.02	52.90	4	19	10.22B
Monogram Biosciences (MGRM)	1.87	1.78	-5	N/A	224
Orchid Cellmark (ORCH)	7.60	3.10	-59	N/A	90
Unweighted average			29		

Source: *LIR*

INDUSTRY buzz

The FDA is coming closer to deciding the regulatory fate of complex genetic testing . . . On February 8, the FDA Office of In Vitro Diagnostic Evaluation and Safety (OIVD) will hold a public meeting on In Vitro Diagnostic Multivariate Index Assays (IVDMIAs) at the Hilton Washington, DC/Gaithersburg Hotel. During the public forum, the OIVD will hear from interested stakeholders, regarding the draft guidance issued late last year, which is intended to provide clarification on the FDA's approach to regulation of in vitro diagnostic multivariate index assays.

The Feb. 8 meeting will begin with a brief presentation by FDA on the draft guidance document, and presentations by the public will make up the remainder of the agenda. For more information see the Federal Register *notice:* www.fda.gov/OHRMS/DOCKETS/98fr/07-93.htm.

Issued in September of last year along with Q&A guidance on the FDA's rule governing analyte-specific reagents (ASRs), the draft guidance on IVDMIAs defines a subgroup of molecular tests as a new class of in vitro diagnostic devices. These assays, such as Genomic Health's Oncotype DX test, use complex mathematical formulas to interpret large amounts of gene and protein data to produce results that govern medical decision making.

The FDA believes that IVDMIAs should require clearance, and most of them will likely be subject to class II and III special controls. The draft guidance gives the example of a device intended as an indicator of a patient's risk of cancer recurrence, which may be a class II device, while the same device intended to predict which patients should receive chemotherapy might require premarket approval.

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Digene 301-944-7000
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