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LABORATORY INDUSTRY REPORT®

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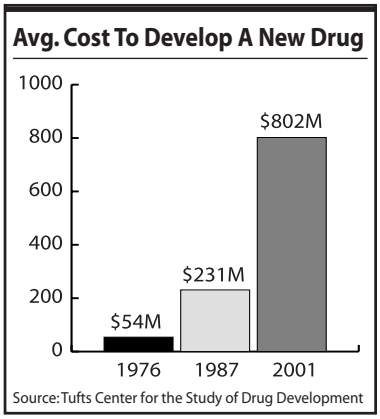
HIGHLIGHTS

WASHINGTON G-2 REPORTS

Clinical Trials May Offer Labs New Business Prospects

Discovery and development of a new prescription drug is a lengthy, complex process that is becoming increasingly expensive. Tufts Center for the Study of Drug Development (Boston, MA) estimates that the current average cost to develop an approved drug is $802 million, more than three times the estimated $231 million cost in 1987. The Center also estimates that it takes 10-15 years on average to bring a new drug to market. Joseph A. DiMasi, PhD, director of economic analysis at the Center, attributes much of the increase in time and cost to rising clinical trial expenses.

As a result, pharmaceutical and biotech companies rely more and more on independent drug development service companies and laboratories to help speed new drugs through clinical trials. According to research firm Frost & Sullivan (San Antonio, TX), the pharmaceutical and biotech industries spent approximately $50.6 billion on global R&D in 2001, of which approximately $9.8 billion was outsourced. A good portion of this sum was spent on laboratory testing needed to determine the safety and efficacy of new drugs.



For those laboratories able to meet the exacting demands of pharmaceutical and biotech companies, the clinical trials market offers a lucrative business opportunity. For a market overview and leading company profiles, see *Inside The Laboratory Industry*, pp. 5-7.

Aurora Health Care To Launch Genetic Testing Program

Aurora Health Care (Milwaukee, WI), a health system with 12 acute-care hospitals and 100 clinics, is launching a large-scale program to identify patients in eastern Wisconsin who are at-risk for deep vein thrombosis (DVT), or blood-clotting in the veins of the legs, using genetic tests for the Factor II and Factor V Leiden mutations. All testing will be performed at ACL Laboratories' esoteric testing center at Advocate Lutheran General Hospital (Park Ridge, IL). ACL Laboratories is the entity that manages the combined lab operations of Advocate Health Care (Chicago, IL) and Aurora Health Care.

Continued on p. 2

AURORA, *from page 1*

Aurora's new DVT program represents an emerging trend in the practice of medicine from reactive to predictive patient care that identifies the probability or onset of disease at the earliest possible stage using gene-based testing

DVT is the third most common cardiovascular disease in the United States. Aurora expects the program to reduce costly and potentially deadly surgical complications, thereby increasing overall patient safety and improving patient outcomes.

The initial phase of the program make use of clinical data management software made by PointOne Systems LLC (Wauwatosa, WI), a private for-profit company that is partly owned by Aurora. PointOne's software programs will be used to identify from among Aurora's 72,000 cardiovascular patients, those who are at risk of DVT. After this initial screening, Aurora physicians will then determine which patients would benefit from genetic testing and individualized patient care plans.

The genetic testing (with patient consent) for the gene variations, Factor II and Factor V, will be performed by equipment contributed to the program by Third Wave Technologies (Madison, WI). Patients with either of these gene variations have a seven-fold increased risk of DVT; those with both factors are at an 80-fold increased risk. Testing will be overseen by Jan Nowak, MD, PhD, medical director for the ACL Esoteric Testing Center at Advocate Lutheran General.

Test results will be combined with clinical data using PointOne software to create summary reports for Aurora physicians. Nick Turkal, MD, Aurora's senior clinical vice president for academic and medical affairs, says the data will be used by physicians to: 1) assess the risk of blood clots developing after surgery; 2) help determine which patients will receive the most benefit from anti-clotting medication; 3) allow clinicians to choose the best dosage of medication; and 4) allow clinicians to educate individuals who are at increased risk for blood clots, and their families.

Jay Schamberg, MD, general manager for ACL Laboratories, tells *Laboratory Industry Report (LIR)* says that Aurora, PointOne, and Third Wave are all contributing funds to the collaborative program to cover any costs that are not reimbursed by Medicare or third-party payers.

Cheryl Vance, former vice president, Illinois operations at ACL and vice president of Advocate Laboratories at Advocate Health Care, recently resigned to take a senior lab management position at Provena Health (Frankfort, IL)

Schamberg says that the program highlights a key advantage that hospital-affiliated labs have over commercial labs—namely the ability to integrate inpatient and physician office clinical data with laboratory test results to create comprehensive treatment plans. Schamberg says that, if successful, the program could be replicated for other disease states like neoplastic disease and other forms of cancer.

Separately, Schamberg says that ACL continues to make progress toward integrating the lab information systems of Aurora and Advocate Health Care. ACL was formed in May 2000 when Advocate and Aurora signed a contract to combine their laboratory operations under a single management team in an effort to reduce costs and build outreach. ACL currently includes 22 hospital labs with core labs at West Allis Memorial Hospital (West Allis, WI) and Advocate Lutheran General. ACL has a combined annual operating budget of $160 million, with 1,800 FTEs and 16 million billable tests annually.

Schamberg says one long-term goal is to provide outreach to all of the approximately 5,500 physicians in Wisconsin and Illinois that have admitting privileges to one or more of the 22 hospitals that are part of Aurora or Advocate.

Marketing A Must For Community-Based Pathology Practices

Competitive pressures in the anatomic pathology business are shaking up the once tranquil world of community-based pathology practices, says Mick Raich, president of Vachette Business Services (Palmyra, MI), a pathology practice management firm. "In the past, all the groups in a town had a given territory and there were non-verbal agreements on the boundaries. This has changed."

In 2001, AmeriPath added 21 people to its sales & marketing staff to reach a total of 84 employees

Raich says the emergence of national pathology companies like AmeriPath (Riviera Beach, FL) and Dianon (Stratford, CT) have introduced new competitive stress on pathology groups. For example, AmeriPath, with annual revenue of more than $400 million, employs 84 salespeople. Dianon, with annual revenue of about $200 million, employs some 110 sales and marketing employees.

The typical hospital-based pathology group generates about 60% of its revenue from physician office clients, Raich points out. This large chunk of business is open to competition. In particular, the national pathology companies are focusing on winning business from dermatology practices, he notes. Within the past three years, for example, AmeriPath has developed its own training center, The Ackerman Academy of Dermatopathology (New York City), and now employs a total of 50 board-certified dermatopathologists.

Simple economics are behind the national companies' interest in dermatopathology, according to Raich. The average dermatologist refers some $60,000 to $75,000 in annual pathology work (on a collected basis), he says. "These are very valuable customers and losing just one can be devastating to a pathology group." In this regard, Raich strongly advises pathology groups to add a dermatopathologist to their practices.

In addition, Raich notes that Medicare reimbursement for anatomic pathology has risen dramatically over the past three years. For example, global reimbursement for CPT 88305 (surgical biopsy), the most commonly billed code for anatomic pathology, has risen from $65 in 1999 to $93.40 in 2002 (unadjusted for geographic practice differences). This represents a 44% increase.

The Centers for Medicare & Medicaid Services has proposed changes to the Medicare physician fee schedule that would cut this reimbursement to $83.06 for 2003 (*LIR, July '02, p. 1*). Even if this cut is finalized, the cumulative increases for CPT 88305 over the past few years remain substantial, he stresses.

Quest and LabCorp are each seeking to expand their anatomic pathology businesses

"The major labs had always considered anatomic pathology a loss leader, but not anymore," declares Louis Wright Jr., MD, chairman of Pathology Service Associates (Florence, SC), which provides billing and marketing services to approximately 70 pathology groups (with about 350 pathologists) across the country. Wright notes that since Quest acquired American Medical Laboratories, (Chantilly, VA), it has stepped up its pathology marketing efforts throughout the mid-Atlantic region.

Quest, which employs 200 pathologists and currently generates some $400 million annually from pathology, has publicly stated its intention to hire more specialty pathologists and build its overall anatomic pathology business.

Services Offered By National Labs

- ❑ Referrals to nationally known experts (especially in dermatopathology)
- ❑ Discounted prices and client or doctor office billing arrangements
- ❑ Combined AP CP services
- ❑ 24 hour TAT
- ❑ Color pathology reports
- ❑ Internet-based ordering and results
- ❑ Face-to-face sales and customer services

Source: Vachette Business Services

Laboratory Corp. of America (Burlington, NC) is also trying to expand its AP business. Raich says that in Midwest markets (Indiana, Illinois, Michigan, etc.) he has seen Quest and LabCorp competing for AP work from physician offices by discounting their services below Medicare rates.

The national labs are also competing by offering extra service like 24-hour turnaround, color pathology reports, and Internet-based ordering and results reporting, notes Raich. "The major lab companies do not see marketing as an outlandish expense. They see it as a necessity. It is typical for some companies to spend 10%-15% of their revenue on marketing."

Raich advises pathology groups to get a better handle on their referral sources by having their billing or software vendor provide them with a monthly referring physician report. A basic report should include cases per month, average charge per case, actual charges, payments, adjustments and collection percentage for each referring physician, he says.

Sample Monthly Report For Monitoring Referral Sources

Physician	*Cases per Month*	*Avg. Per case*	*Charges per month*	*Collections per month*	*Collection percentage*
Dr. Smith	10	$200	$2000	$1000	50%
Dr. Jones	50	$200	$1000	$600	60%
Dr. White	10	$100	$1000	$300	30%
Dr. Brown	20	$200	$4000	$2000	50%

Source: Vachette Business Services

Volume changes in monthly physician reports help pathologists identify when they may be losing a customer, Wright says. "If volume from a particular client drops, then it's time to visit that physician, so any potential concerns or problems from that client can be corrected."

Raich and Wright agree that nearly every pathology group should have a professional salesperson (either full-time or contracted) in the field, meeting regularly with existing clients and building new relationships. Too often, pathology groups treat sales and marketing as an unnecessary expense and delegate these responsibilities to a medical technologist or courier rather than hire a professional salesperson.

Raich sums it up this way: "Just as managed care contracts moved across the nation and redefined the market, so will the commercialization of anatomic pathology services. Practices must make a decision to stand and defend their referral sources or sit by and watch another segment of their practice be sectioned off."

Opportunity For Labs In $1 Billion+ Clinical Trials Testing Business

Clinical trials testing for pharmaceutical and biotech clients is a lucrative market that pays substantially more for testing services than the routine market. While labs earn an average of roughly $12 per billable test for traditional patient testing, average revenue for non-esoteric tests performed under clinical trials contracts is generally several times higher (i.e., $24 to $48 per test), executives at several clinical trials testing companies tell *Laboratory Industry Report* (LIR). On top of this, pharmaceutical and biotech companies also pay additional fees for project management services provided by clinical trials testing labs as well as test kit assembly and shipment to physician offices.

The value of laboratory testing to drug developers becomes evident when one considers that, on average, roughly 85% of the data on new drug applications submitted to the U.S. Food and Drug Administration is lab test results.

Based on interviews with executives at six leading clinical trials testing labs, LIR estimates that pharmaceutical and biotech companies outsourced $1 billion to $1.5 billion of lab testing services last year. Executives tell LIR that this market is growing by roughly 5% to 10% annually and they say that growth could accelerate given that there are more drugs in clinical development today than ever before.

Key Steps In The Clinical Trials Process For A New Drug

Pre-Clinical Phase:	Effects of new drug are tested on animals.
Phase I Clinical Trials:	Drug is tested on 20 to 80 healthy or ill human volunteers to determine metabolic actions, study side effects, and observe effectiveness.
Phase II Clinical Trials:	Drug is tested on several hundred human subjects to evaluate effectiveness in treating patients with the disease
Phase III:	Several thousand human subjects are tested to evaluate benefit/risk ratio of drug and determine most effective use
New Drug Application:	Pharmaceutical company submits data to FDA. Review may take two years for approval. Pharma company may then market drug.
Phase IV Clinical Trial:	Additional information about long-term use of drug, new uses, and optimal dosages are determined.

Source: *LIR* from ACM Medical laboratory

In a nutshell, a clinical trials testing lab oversees the collection and analysis of lab data for various stages of the clinical trial of a drug candidate. If the trial is international, the lab must go to great lengths to ensure that the data are consistent. The average clinical trials lab testing contract is 20 months in duration, according to research from analysts at UBS Warburg (New York City).

Although pharmaceutical and biotech companies outsource testing to labs for every stage of the clinical trial process (pre-clinical and phases I-IV), the highest volume of lab testing is performed at phase III. At phase III, the effectiveness and safety of a drug is tested over time on several thousand subjects using hematology, chemistry, and urinalysis tests.

For an overview of nine of the leading companies providing clinical trials lab services, see pp. 6-7.

Covance Inc. (Princeton, NJ) is the largest provider of lab testing services in the clinical trials testing market. In 2001, the company generated an estimated $250 million to $300 million from lab services. The company's largest lab facility is located Indianapolis, IN. Covance also operates labs in Switzerland and Singapore. Covance also has a new pharmacogenomics capability through a joint venture with Variagenics (Cambridge, MA). The joint venture is focused on developing assays to test the genetic differences in the way that drugs are metabolized.

Quest Diagnostics (Teterboro, NJ) is the second largest clinical trials lab services company. Quest's clinical trials division generates some $100 million in annual revenue and has 450 employees, according to Joy Nassif, vice president of clinical trials. Quest owns laboratories dedicated to clinical trials in Van Nuys, CA and Heston, England. In addition, through alliances, Quest operates clinical trials labs in South Africa and Australia, with another scheduled to open in Singapore by year's end.

Nassif says Quest is most deeply involved with clinical trials for oncology, AIDS, and diabetes drug candidates. Other growing areas include testing for weight loss, smoking cessation, and pain management drugs.

In addition, she notes that logistics expertise and data management are keys to winning clinical trials lab services contracts. She believes that as drug therapies become more personalized through advances in genetics, clinical trial service companies that operate esoteric labs (i.e., Quest' Nichols Institute) will have an advantage.

Quintiles Transnational (Durham, NC) generates some $50 million per year in revenue from clinical trials lab testing. The company owns clinical trials labs in Smyrna, GA, Europe, South Africa, and Singapore, but the company subcontracts a significant portion of its testing to other labs. Quintiles also offers a broad range of other services to the drug industry, including marketing services to help pharma companies commercialize their drugs. Companywide revenue totaled $1.6 billion in 2001.

Laboratory Corp. of America (Burlington, NC) is making a concerted effort to expand its clinical trials business, according to Scott Neilson, senior vice president of clinical trials. LabCorp is primarily known for its clinical trials work in infectious disease testing (i.e., HIV and HCV), but has broadened its capabilities and now performs clinical trials tests for drugs being developed for central nervous system, cardiovascular disease, and rheumatology disorders.

LabCorp performs its highest volume of clinical trials testing at its major lab in Raritan, NJ and does esoteric tests at its Center for Molecular Biology & Pathology (Research Triangle Park, NC) and National Genetics Institute (Los Angeles, CA). In addition, LabCorp owns a clinical trials lab in Belgium that specializes in lipid testing.

Neilson believes that more and more clinical trials testing will move away from contract research organizations like Covance and Quintiles toward clinical laboratory companies like LabCorp over the long term. He says that national laboratories have several advantages including wide patient service center networks that reduce distribution costs. In addition, he believes that clinical laboratories have a greater technological expertise in the area of esoteric testing that companies like Covance and Quintiles may never be able to match.

MDS Inc. (Toronto, Canada) operates clinical trials labs services through its MDS Pharma Services division, which operates

labs in Toronto; Paris, France, Hamburg, Germany; and Beijing, China. MDS Pharma Services, which provides other drug development services in addition to lab testing, generated total revenue of $430 million Canadian dollars (US $277 million) in the fiscal year ended Oct. 31, 2001.

ACM Medical Laboratory (Rochester, NY), a for-profit regional reference lab owned by Unity Health System (Rochester), operates a dedicated clinical trials laboratory with 31 employees. ACM entered the clinical trials business in 1998 and is currently performing tests for trials associated with new drugs for diabetes, insomnia, osteoporosis, arthritis, breast cancer, prostate cancer, and other diseases, according to Marie Levin, vice president and chief operating officer for clinical trials at ACM.

Levin says that while clinical trials testing can be lucrative, pharmaceutical customers are extremely demanding. She estimates that a routine lab seeking to enter the business would need to invest a minimum of $1 million (primarily in data management systems) to get a clinical trial business up and running. They [pharma companies] want triple A quality and dedication and are willing to pay for it," says Levin.

Note: Ms. Levin will be a speaker at Washington G-2's upcoming Lab Institute 2002 (Oct. 23-26 in Arlington, VA). Her presentation is entitled "*How Labs Can Successfully Enter The Clinical Trials Business*."

ARUP Laboratories (Salt Lake City, UT) formed its clinical trials testing division in 1996. The unit now accounts for approximately 10% of ARUP's overall revenue of about $160 million per year, according to Richard Etter, PhD, vice president of new business ventures. He says that ARUP is focused on providing esoteric testing for clinical trials. "Pharma companies are not out there collecting bids for the type of work we do. It's a word of mouth industry. You build your reputation one project at a time," says Etter.

Esoterix (Austin, TX) generated approximately 20% of its total revenue of $68 million in 2001 from clinical trials testing, according to Jim McClintic, president. Annual clinical trials growth at Esoterix has averaged about 30% over the past three years, says McClintic. He says the company recently invested $10 million to build a new 32,000 square foot lab dedicated to clinical trials in East Windsor, NJ and to double the size of its clinical trials lab in The Netherlands to 25,000 square feet. Esoterix specializes in specialty testing in endocrinology and coagulation for the clinical trials market.

Medtox (St. Paul, MN) entered the clinical trials business ten years ago by providing services to generic drug makers. Mike Bunkers, national sales manager for Medtox, says the process of bringing a generic drug to market is much simpler than for new brand name drugs and involves clinical trials that prove the generic is equivalent to the existing brand name product. He says Medtox has used generic drug market as a stepping stone to winning clinical trials lab services contracts with pharma companies for new drugs. "This market requires experience and time to build relationships," notes Bunkers.

Laboratory Responsibilities In Clinical Trials

- ❑ Making kits and test request form
- ❑ Shipping kits to/from physician sites
- ❑ Receiving and processing specimens
- ❑ Testing specimens
- ❑ Reporting results to physician and drug company
- ❑ Storing specimens as requested (up to 15 years)
- ❑ Data management

Source: ACM Clinical Laboratories

Quest To Market Test Services In CVS Drugstores

Quest Diagnostics (Teterboro, NJ) has begun marketing a limited menu of its laboratory testing services directly to consumers at CVS drugstores in Tampa Bay, FL (10 stores) and Columbus, OH (71 stores). If these pilot programs are successful, Quest says the service could be rolled out to other CVS drugstores. CVS Corp. (Woonsocket, RI) is the nation's largest drugstore chain with a total of 4,175 stores located primarily in the eastern U.S.

Under the program, consumers can choose one of 12 "QuesTest" order cards from display racks at CVS drugstores. Each card represents a test or test panel. Payment is made at the drugstore; health insurance is not accepted. Consumers then take their validated card to a Quest patient service center to get their sample taken. CVS gets a fee for each patient who buys a QuesTest card at its stores.

Customers get their test results directly from Quest via mail and the Internet. Critical results are flagged and forwarded to physicians with whom Quest has contracted. These doctors call patients and advise them to contact their physician.

Among the 12 tests that Quest is offering at the drugstores are: a cholesterol panel that costs consumers $40, a woman's health profile (includes tests for anemia, diabetes, cholesterol, thyroid, urinalysis, etc.) priced at $115, and a food allergy panel (includes allergy tests for milk, soybean, peanut, clam, shrimp, etc.) priced at $150.

The agreement with CVS follows a similar deal that Quest signed with US Wellness Inc. (Gaithersburg, MD) earlier this year (*LIR, May '02, p. 9*). US Wellness is in the process of opening "wellness centers" at 40 Giant Food Supermarkets (Landover, MD) in Maryland and Virginia. The centers offer consumers the opportunity to purchase laboratory tests which will be performed by Quest.

Meanwhile, a spokeswoman for Quest tells *LIR* that the company has scaled back the number of QuestDirect retail lab sites that it directly owns and operates to six centers in Colorado and Kansas. About a year ago, Quest had opened more than 23 retail sites (including adapted patient service centers) in five states (*LIR, July '01, p. 1*). Quest says its operation of retail lab sites remains in the "proof of concept" phase.

Costco To Offer Cardiovascular Screenings To Customers

Costco Wholesale Corp. (Issaquah, WA) will begin offering direct-to-consumer cardiovascular screenings at several of its West Coast stores, beginning in October. The program will be managed by OnSite Wellness Medical Associates Inc. (Torrance, CA) and will utilize the CVProfilor DO-2020 System made by Hypertension Diagnostics (Eagan, MN).

Greg Guettler, president of Hypertension Diagnostics, tells *LIR* that if the test market is successful, the program will be offered at Costco stores nationwide. Costco is the nation's largest wholesale club operator in the U.S. with more than

350 stores and 18 million members. The price to consumers for the screenings has not yet been determined.

The CVProfilor test involves placing a blood pressure cuff around a patient's left upper arm and a non-invasive sensor on the right wrist. The five-minute test measures arterial elasticity. Patients who show reduced arterial elasticity are at increased risk of cardiovascular disease.

Guettler says approximately 100 physicians currently use the CVProfilor for office-based screenings. Reimbursement from insurance companies typically averages about $100 per test.

FTC To Investigate Healthcare Mergers

The Federal Trade Commission plans to step up its review of completed hospital mergers and physician groups to make sure they had not joined forces simply to fix prices, the *New York Times* reported Aug. 9. Timothy Muris, chairman of the FTC, told the *Times* that the Commission has increased its spending on antitrust efforts in healthcare by 50%. If it finds evidence that healthcare mergers raised prices without benefiting patients, the FTC could move to dissolve the mergers through administrative hearings, the *Times* reports.

A staffer at the FTC tells *LIR* that the heightened interest in merger and acquisition activity covers all of healthcare, including laboratory services. This comes as no surprise to Quest Diagnostics (Teterboro, NJ), which continues to work on answering questions from the FTC about its planned merger with Unilab Corp. (Tarzana, CA). For the latest news on this transaction, see p. 12.

The increased scrutiny appears motivated by concerns about rapidly rising healthcare costs. Carl Mercurio, president of the managed care research firm, Corporate Research Group (New Rochelle, NY), notes that managed care premiums are set to go up 15.5% in 2003, after a 15% hike in 2002 and an 11.5% rise in 2001. The rate hikes are being driven by reimbursement pressure from hospitals, pharmaceutical companies, physicians and laboratories, according to Mercurio.

For example, Tenet Healthcare (Santa Barbara, CA), the nation's second-largest for-profit hospital chain, recently reported that its net collected revenue per inpatient admission increased 12.9% to $9,259 for the fiscal year ended May 31, 2002. Tenet, which operates 116 hospitals in 17 states, attributed the increase to "a shift in the company's business mix to higher-acuity services and continuing strong reimbursement trends." And HCA (Nashville, TN), the nation's largest for-profit hospital chain with 175 hospitals, reports that its collected revenue per admission rose 8.5% in the six months ended June 30, 2002.

Big Labs' Price Per Accession

	2Q02	2Q01	% Chg
Quest	$33.49	$32.67	+2.5
LabCorp	31.88	30.56	+4.3
Unilab	27.94	26.81	+4.2

Source: U.S. Bancorp Piper Jaffray

Among laboratory companies, U.S. Bancorp Piper Jaffray estimates that Quest's average price per accession in the second quarter was $33.49, up 2.5% from $32.67 a year earlier; LabCorp's was $31.88, up 4.3%; and Unilab's was $27.94, up 4.2%

Tenet CEO To Get $2.9 Million Pension

Despite increasing public scrutiny of lavish executive pay packages and growing concern over rising healthcare costs, Tenet Healthcare has a adopted a plan that will roughly double its annual retirement payments to its chief executive, Jeffry Barbakow.

A recent filing with the Securities & Exchange Commission shows that Tenet plans to credit Barbakow, 58, with 20 years of service in 2004 even though he will have worked only 11 years at the company. By accelerating Barbakow's service, Tenet will enable its CEO to collect annual retirement payments of $2.9 million, rather than the approximately $1.4 million he would have received based on actual years served.

Tenet has already been criticized by some investors and healthcare officials for paying Barbakow significantly more than other hospital executives. Last year, for example, he got a salary of $1.204 million, a bonus of $4.178 million, plus other compensation of $249,571, including personal use of a Tenet corporate jet valued at $66,962. Finally, he got 1.5 million stock options valued at $26.4 million. Tenet did not return a call seeking comment.

Abbott Recalls 1.5 Million Gonorrhea Test Kits

Abbott Laboratories (Abbott Park, IL) is recalling 1.5 million gonorrhea tests sold worldwide because they might give false negative results, the U.S. Food and Drug Administration announced on August 30. Abbott distributed the kits to hundreds of hospitals and independent laboratories, 80 percent of them in the United States, from Jan. 11 to June 24.

Abbott spokesman Don Braakman says Abbott voluntarily recalled the tests July 18 after learning through routine testing that certain tests did not meet specifications. Additional testing showed that the kits had lost some of their sensitivity to the gonorrhea bacteria, so a positive result might not be shown for patients with low amounts of the bacteria in their system. Braakman says that all customers had been contacted and offered a refund. The company has since produced new gonorrhea test kits now available for sale.

The FDA says it made its own announcement regarding the Abbott recall because of the of the dangers associated with false negatives for gonorrhea, a sexually transmitted disease that can worsen if left untreated. "We want to make sure laboratories that have purchased these tests, physicians who ordered these tests, and people tested for gonorrhea since January receive this information so they can act on its," stated Larry Spears, acting deputy director the FDA's Office of Compliance, in a press release.

The recalled sets are: 84073M400, 84075M400, 84142M300, 84146M300, 85487M200, 87007M400, 87103M400, 87243M100, 87377M200, 87899M200, 87905M200, 88097M300, 88105M300, 88107M300, 88439M200 and 88439M201.

Lab Stocks Rise 5% In Latest Four Weeks

Stock prices for the 14 companies in the G-2 Laboratory Index increased an unweighted average of 5% in the four weeks ended August 30, 2002, with seven stocks up in price, two unchanged, and five down. So far this year, lab stocks have fallen 22%, while the S&P 500 is down 20% and the Nasdaq is down 33%.

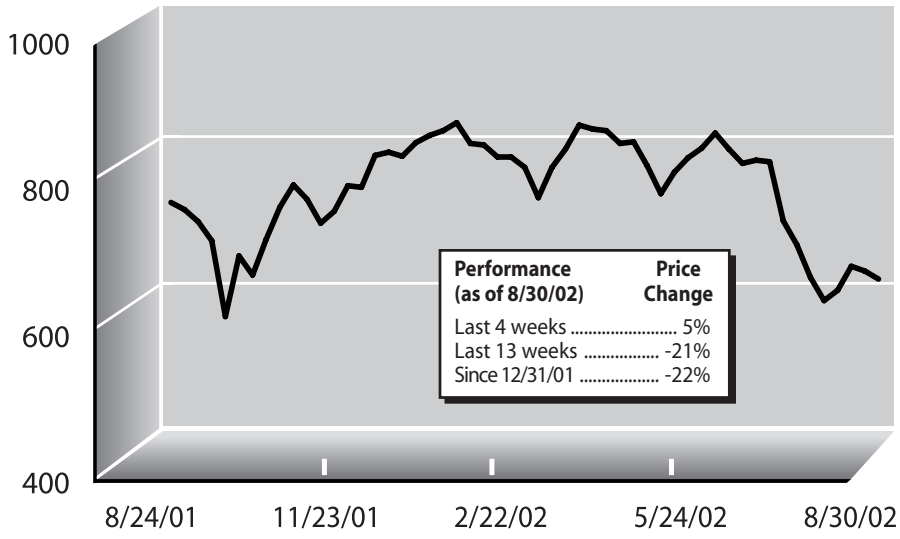
Bio-Reference Laboratories (Elmwood Park, NJ) rose 28% to $8.02 per share for a market cap of approximately $93 million. The company recently promoted Maria Pedemonte-Coira, MD, to the position of vice president and chief medical officer, expanding her prior position as medical director. Pedemonte will continue to directly oversee GenPath, the company's cancer laboratory and direct the expansion of Bio-Reference's esoteric testing menu.

Specialty Laboratories (Santa Monica, CA) was up 22% to $9 per share for a market cap of $197 million. The shares, which had reached a low of $6.15 in June, continue to rebound on news that the company has resolved its CLIA compliance issues *(LIR, August '02, p. 4)*.

Myriad Genetics (Salt Lake City, UT) was down 21% to $17.17 per share for a market cap of $408 million. The company recently reported a net loss of $6.848 million for the three months ended June 30, 2002 vs. a net loss of $2.187 million in the same period last year; total revenue was up 30% to $14.112 million (including $7.681 million from genetic testing and $6.432 million from drug development efforts).

PharmChem (Haltom City, TX) was down 17% to $0.55 for a market cap of only $3 million. The company recently reported a net loss of $208,000 for the three months ended June 30, 2002 vs. a net loss of $5.557 million in the same period a year earlier; revenue was down 11% to $8.066 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 14 laboratory testing service stocks.

Avg. % Price Change, 4 weeks ended 8/30/02

Up	Price	%Chg
AmeriPath	16.45	9
Bio-Reference	8.02	28
Dianon	40.01	13
LabCorp	31.45	2
MDS	15.75	16
Specialty	9.00	22
Unilab	19.17	8
Unchanged		
LabOne	20.90	0
Medtox	8.01	0
Down		
Enzo Biochem	12.74	-4
Impath	12.30	-6
Myriad	17.17	-21
PharmChem	0.55	-17
Quest	56.05	-1

INDUSTRY buzz

FTC may require divestitures before allowing close of Quest/Unilab merger. Informed sources in California, tell *LIR* that the U.S. Federal Trade Commission may make laboratory facility divestitures in northern California a requirement before allowing Quest Diagnostics' planned acquisition of Unilab to proceed. In northern California, Quest owns a major lab facility in Dublin (just east of San Francisco), while Unilab operates major labs in Sacramento and San Jose.

Quest would not comment on the above speculation and *LIR* has been unable to pinpoint exactly which facility(s) may be required to be sold. However, sources tell LIR that Quest is eager to get the deal completed and willing to divest a northern-California facility.

The most likely potential buyer would be LabCorp, which had initially made a bid to acquire all of Unilab that was topped by Quest. A handful of small independent labs in California could also emerge as a buyer.

A spokeswoman for LabCorp would not comment on the Quest/Unilab situation. However, in related news, *LIR* has learned that LabCorp has closed on the purchase of Immunodiagnostic Laboratories Inc. (IDL—San Leandro, CA), a small independent lab formerly owned by Edward Winger, MD, IDL, which is focused on infectious disease testing, operates eight patient services centers throughout the San Francisco area.

References in this issue

Abbott Labs 847-937-6100
ACM Medical Laboratory 585-247-3500
ARUP 801-584-5157
Aurora Health Care 414-647-3000
Covance 609-452-4440
Esoterix 512-225-1100
Hypertension Diagnostics 651-687-9999
LabCorp 336-584-5171
Pathology Service Associates 843-664-4300
Quest Diagnostics 201-393-5000
Quintiles Transnational 919-998-2000
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