

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

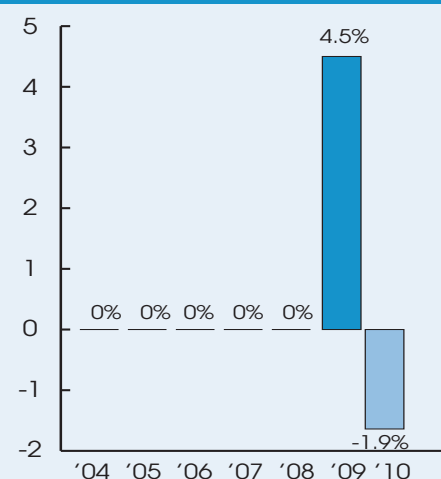
LAB MERGER & ACQUISITION TRENDS

Consolidation in the lab industry reached a record pace in 2006-2007. However, merger-and-acquisition activity slowed in 2008 and has been even slower so far this year. But some deals are still closing. In particular, Quest Diagnostics and LabCorp seem to be most interested in esoteric testing labs. For example, LabCorp is buying Monogram Biosciences (see below) and Quest recently acquired OralDNA Labs (see page 2). For a complete review of lab M&A trends, see pages 5-7.

PART B LAB FEES TO FALL 1.9%

Based on the latest inflation figures, the Medicare Part B Lab Fee Schedule will be cut by 1.9% effective Jan. 1, 2010. The Consumer Price Index for All Urban Consumers (CPI-U) has fallen 1.4% in the 12 months ended June, according to a report from the Bureau of Labor Statistics issued on July 15. The lab fee update approved by Congress from 2009 to 2013 is the CPI-U minus 0.5%. [It is 0.5% less than the full CPI-U because labs agreed to a small annual reduction in order to repeal competitive bidding.] In 2009, Part B lab fees were increased by 4.5% after a five-year freeze.

Annual Changes to Part B Lab Fee Schedule



Source: Laboratory Economics

LABCORP TO BUY MONOGRAM BIOSCIENCES FOR \$155 M

LabCorp (Burlington, NC) has agreed to acquire Monogram Biosciences (South San Francisco, CA) for \$4.55 per share in cash. The deal values Monogram at \$155 million, including an equity value of \$106.7 million plus the assumption of \$48.3 million in net debt. LabCorp's proposed purchase price represents a significant premium over Monogram's closing price of \$1.68 per share on June 22, the day before the acquisition was announced. The \$155 million price tag is equal to 2.5 times Monogram's revenue of \$62.2 million in 2008. This year, Monogram is expected to generate revenue of between \$66 million and \$70 million. Monogram lost \$11.7 million in 2008 versus a loss of \$23.5 million in 2007. Since its inception in 1995, Monogram has accumulated more than \$300 million of losses.

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LABCORP TO BUY MONOGRAM BIOSCIENCES (continued from page 1)

The acquisition of Monogram is expected to reduce LabCorp's earnings by approximately \$0.12 per share (~\$13 million) this year and be slightly accretive to 2010 earnings.

Monogram specializes in phenotypic and genotypic resistance testing for HIV patients. Its tests measure the impact of genetic mutations on HIV drug resistance. This information is used by physicians to optimize treatment options for patients.

In addition to these resistance tests, in 2007, Monogram initiated commercial sales of its Trofile Co-Receptor Tropism Assay. Trofile is a patient selection assay for the new HIV drug Selzentry (maraviroc) from Pfizer Inc. The list price for the Trofile test is \$1,960.

Monogram is also developing cancer tests. The company introduced its HERmark breast cancer test last summer. The \$3,300-plus HERmark test measures the level of HER2 protein, higher levels of which are produced in breast cancer patients.

All testing is performed at Monogram's CLIA-certified lab in South San Francisco. Monogram's largest clients, based on revenue for 2008, include Schering-Plough (13%), Quest Diagnostics (10%), LabCorp (7%) and Pfizer (3%).

William Young, chairman and chief executive of Monogram, is expected to remain with Monogram for a short transition period (90 days or less) in exchange for a \$50,000 retention bonus. As per his employment contract, Young will also receive a lump sum severance payment of \$673,650 immediately after the sale to LabCorp is completed. In addition, Young owns stock and options in Monogram worth \$524,000.

Monogram Biosciences at a Glance

	2008	2007	2006	2005
Revenue	\$62,193	\$43,229	\$47,958	\$48,252
Cash used in operations.....	-17,870	-18,616	-24,178	-13,750
Net loss	-11,663	-23,548	-38,703	-37,748
Earnings per share.....	-0.52	-1.07	-1.78	-1.83
Cash & securities	15,965	30,590	31,130	65,014
Total debt.....	38,766	43,766	31,450	1,041

Source: Monogram Biosciences

QUEST DIAGNOSTICS BUYS OralDNA LABS

Less than one year after being formed, OralDNA Labs (Brentwood, TN) has been sold to Quest Diagnostics. OralDNA was formed in August 2008 by its president and chief executive Brian Carr and had received financial backing from Oak Investment Partners.

The company operates a CLIA-certified lab that performs saliva-based DNA tests for dentists. The tests—MyPerioPath and MyPerioID PST—identify periodontal disease and susceptibility to the disease. OralDNA sells the test to dentists for between \$90 and \$100 per test. Dentists can mark up the tests for a profit in states where it's legal. The potential market for these tests has been estimated at \$1 billion per year (see *Laboratory Economics*, September 2008, pp. 1, 4).

The sale represents the third lab company that Carr, age 47, has formed and then sold. Carr founded Pathology Consultants of America in 1997 and sold it to AmeriPath in November 2000 for \$54 million. Carr then formed American Esoteric Labs in 2004 and sold it to Sonic Healthcare in January 2007 for \$180 million.

VIRACOR AND IBT LABS MERGE

ViraCor Laboratories (Lee’s Summit, KS) and IBT Laboratories (Lenexa,KS) merged effective July 1. The new company will process 400,000 patient samples and generate revenue of more than \$35 million per year.

The combined company will maintain the labs at ViraCor and IBT, which are located 22 miles apart near Kansas City. ViraCor president John Martin will serve as president of the as-yet-un-named new company. Martin says the companies merged more because of growth opportunities rather than cost savings. He says each company has experienced double-digit annual growth over the past few years and he expects that to accelerate.

ViraCor was founded in 2000 by Phillip “Flip” Short, who has stepped down from his role as chief executive and will serve on the new company’s board. ViraCor has a test menu of about 20 molecular diagnostics for infectious disease. Its primary clients are hospitals and physicians treating post-transplant patients and others with compromised immune systems. ViraCor operates a 32,000-square-foot lab and office in Lee’s Summit, Kansas, and has approximately 120 employees. Revenue grew by an estimated 30% to \$24-\$25 million in 2008.

IBT was founded by Jack Halsey, PhD, in 1983 and specializes in immunology and allergy testing (see *Laboratory Economics*, February 2009, pp. 1-2). Halsey will continue to work with the new company as a consultant. Maureen Loftus, former president of IBT, will be chief business officer

ViraCor-IBT Labs at a Glance

Executive chairman:.....	Laurence McCarthy, PhD
President:.....	John Martin
Chief business officer:	Maureen Loftus
Chief scientific officer:	Steven Kleiboeker, DVM, PhD
Annual revenue:.....	\$35-\$40 million
Annual patient samples:	400,000
Employees:.....	210
Source: <i>Laboratory Economics</i> from companies	

at the combined company. IBT has 26,000 square feet of lab and office space in Lenexa, Kansas, and about 90 employees. Last year, the company grew its revenue by nearly 20% to \$12 million.

Martin says the combination of ViraCor’s quantitative results (viral loads) and IBT’s cellular immunodiagnostics will provide clients with more comprehensive test results for

post-transplant patients. The combined company will have 22 sales reps with significant opportunities for cross selling, according to Martin.

The board of directors at the ViraCor-IBT will have six members, including three members from the equity investment firm Ampersand Ventures (Wellesley, MA). Ampersand had been majority owner of IBT and will maintain a stake in the combined company. Laurence McCarthy, PhD, a venture partner at Ampersand, will serve as executive chairman.

AIT LABS TRANSFERS OWNERSHIP TO EMPLOYEES

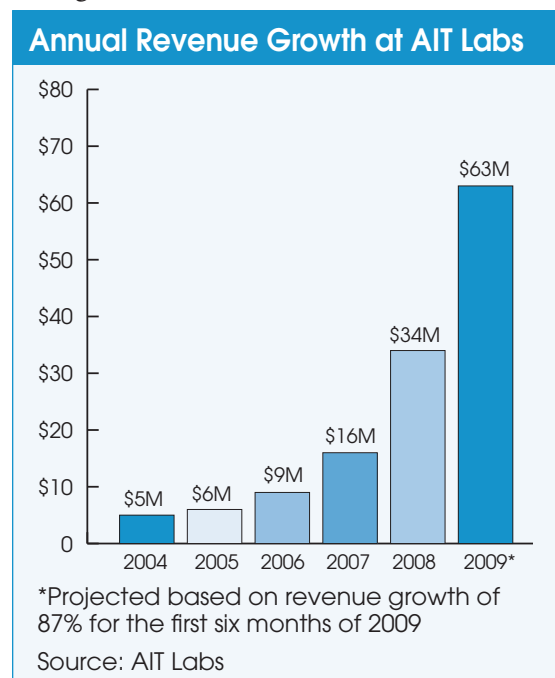
Michael Evans, PhD, age 65, founder and president of AIT Laboratories (Indianapolis, IN), has transferred ownership of his company to its 320 employees through an Employee Stock Ownership Plan (ESOP). AIT is an independent lab that specializes in pain management, forensics and clinical lab testing. The company generated revenue of \$34 million in 2008, more than double its \$16 million in 2007. Evans declined to reveal the price of the sale. He says he wasn't interested in taking the company public or selling to an outsider that might move or restructure the operation.

ESOPs essentially function as a retirement plan for employees. A fair market value was calculated for AIT Labs by the accounting firms BKD (Indianapolis, IN) and Moss Adams (Seattle, WA). Based on this price, an employee benefit trust then bought the company from Evans. Over time, company profits will be used to acquire shares from the trust. These shares will be distributed to employees based on their longevity and salaries.

AIT employees will not pay taxes on the shares they receive until they leave the company. When employees leave the company, they will receive their shares, which the ESOP will buy back at an appraised fair market value. The employee can then roll the amount over into a 401K to defer taxes even longer.

Evans says the ESOP will help the company thrive, even though it might provide him with less money than if he sold to a private investment firm or a commercial lab. "The employees deserve it...and it will motivate them to maintain standards and quality," he says. Evans says he plans to remain with the company as president and CEO.

In addition to the ESOP, Evans says AIT will continue its current profit sharing plan under which it pays out 25% of company net income to employees each year. In July, for example, AIT paid its employees a \$2 million profit-sharing bonus based on results for the first half of the year. The average lab worker earned an additional 40% of their first six months' salary. Evans says another



profit-sharing bonus is expected to be paid out at the end of the year. Other benefits include six weeks of paid maternity leave and free car washes.

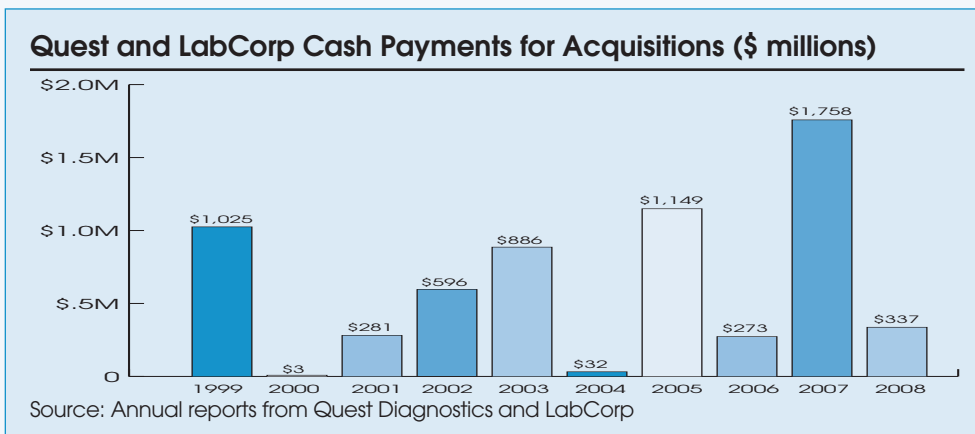
Evans founded AIT in 1990 at age 46, leaving his job as head of the toxicology department at Indiana University School of Medicine. "I put every cent I had into starting this lab," he says.

Today, the company operates a 60,000-square-foot lab/office in Indianapolis where it employs 220 people. AIT employs another 100 sales and technical staff across the country.

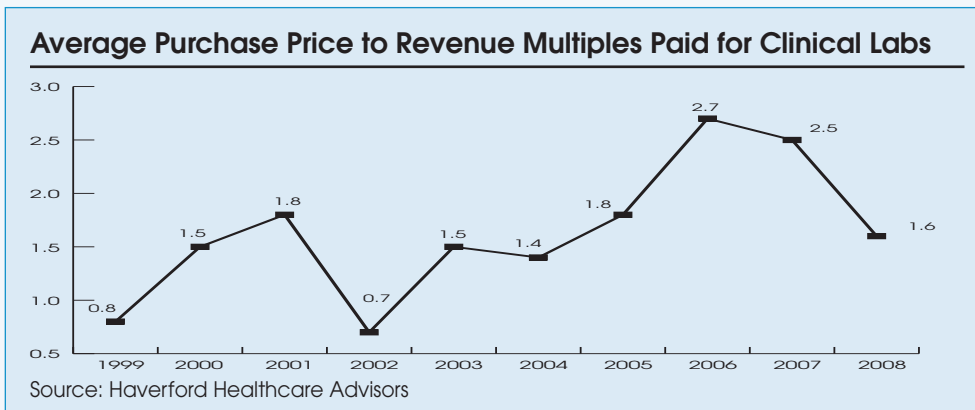
In addition to pain management, forensics and clinical lab testing, Evans says AIT is in the process of creating a pharmaceutical testing division—to be known as AIT Bioscience—that will perform lab testing for Phase I and II clinical drug trials.

M&A TRENDS: Lab Acquisition Expenditures Hit a High in 2007

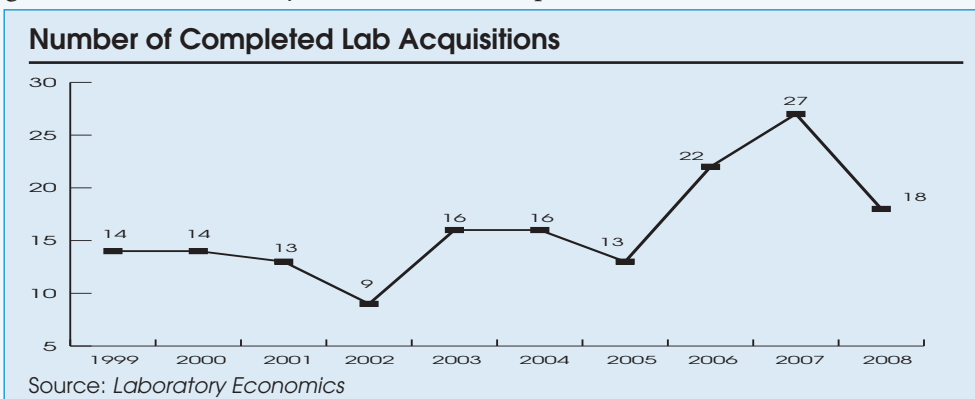
Over the past 10 years, Quest Diagnostics and LabCorp have spent a combined \$6.3 billion in cash to complete more than 50 lab acquisitions. Quest has spent \$4.2 billion and LabCorp has spent \$2.1 billion. The peak came in 2007 when Quest and LabCorp spent a combined \$1.8 billion, including Quest's \$1.2 billion (plus \$770 million in assumed debt) acquisition of AmeriPath.



Lab Valuations Peaked in 2006: In terms of lab valuations, the high-water mark came in 2006 when independent clinical labs sold for an average of 2.7 times their annual revenue, according to data from the healthcare consulting group Haverford Healthcare Advisors (Paoli, PA). Acquisition multiples for clinical labs declined to 2.5x in 2007, and then dropped to 1.6x in 2008.



Deal Volume Spiked in 2007: The number of completed lab acquisitions reached a peak of 27 deals in 2007. The most active buyers were Sonic Healthcare USA, which completed six deals; Aurora Diagnostics and Laboratory Partners each completed four deals in 2007.



Laboratory Acquisition Summary, 2007 - July 2009 (\$ millions)

DATE	BUYER	TARGET	PURCHASE PRICE*	ACQUIRED REVENUE	PRICE/REVENUE
Jan-07	Sonic Healthcare USA	American Esoteric Labs	180	100	1.8
Feb-07	Carilion Labs	Presbyterian Reference Lab	NA	NA	NA
Mar-07	Genova Diagnostics	AAL Reference Labs	NA	NA	NA
May-07	Sonic Healthcare USA	Mullins Laboratory	NA	15	NA
May-07	Quest Diagnostics	AmeriPath	2,000	760	2.6
Jun-07	Caris Diagnostics	Cohen Dermatopathology	NA	NA	NA
Jul-07	LabCorp	Home Healthcare Lab of America	NA	NA	NA
Jul-07	Sonic Healthcare USA	Sunrise Medical Labs	168	75	2.2
Jul-07	Laboratory Partners	Terre Haute Medical Lab	NA	NA	NA
Jul-07	Laboratory Partners	Kilbourne Medical Laboratory	NA	NA	NA
Sept-07	LabCorp	DSI Laboratories	76	23.5	3.2
Sept-07	United Dynacare Lab	Midwest Clinical Labs	NA	10	NA
Oct-07	Celera	Berkeley Heart Lab	195	85	2.3
Oct-07	LabCorp	PA Labs	NA	40	NA
Oct-07	Laboratory Partners	Medi-Lab	NA	10	NA
Oct-07	Thompson Street Capital	DCL Medical Labs	NA	20	NA
Nov-07	Aurora Diagnostics	Greensboro Pathology Associates	NA	NA	NA
Nov-07	Aurora Diagnostics	Mark & Kambour	NA	NA	NA
Nov-07	Sonic Healthcare USA	Consolidated Lab Services	NA	2.5	NA
Dec-07	Aurora Diagnostics	CHC Laboratories	NA	NA	NA
Dec-07	Aurora Diagnostics	Laboratory Medicine Consultants	NA	NA	NA
Dec-07	Carilion Labs	Innovative Pathology Services	NA	NA	NA
Dec-07	Inverness Medical	Redwood Toxicology Lab	99	44	2.3
Dec-07	Laboratory Partners	Clinical Health Labs	NA	8	NA
Dec-07	Perkin Elmer	Pediatrix Newborn Screening Lab	NA	15	NA
Dec-07	Sonic Healthcare USA	American Clinical Services	NA	13	NA
Dec-07	Sonic Healthcare USA	Woodbury Clinical Laboratory	NA	4	NA
Jan-08	Caris Diagnostics	Molecular Profiling Institute	40	NA	NA
Jan-08	LabCorp	Tandem Labs	NA	NA	NA
Mar-08	Aurora Diagnostics	Twin Cities Dermatopathology	NA	NA	NA
Mar-08	LabCorp	Acadiana Medical Labs	NA	10	NA
Apr-08	LabCorp	Albany Cytopath Labs	NA	5	NA
May-08	LabCorp	IDX Pathology	NA	10	NA
May-08	Manhattan Physicians Lab	Genatom Biomedical Lab	NA	10	NA
Jun-08	Rosetta Genomics	Parkway Clinical Labs	3	3	1.0
Aug-08	CellNetix	Northwest Pathology Services	NA	NA	NA
Aug-08	HealthTronics	UroPath	7.5	NA	NA
Aug-08	LabCorp	Stanford Outreach Lab	30	30	1.0
Sep-08	Sonic Healthcare	Clinical Labs of Hawaii	121	110	1.1
Sep-08	LabCorp	PathNet Esoteric Lab	NA	15	NA
Sep-08	LabPartners	Biotech Labs	NA	15	NA
Nov-08	Toxicology Holding Corp.	DrugScan	NA	NA	NA
Dec-08	CBLPath	Laboratory of Podiatric Pathology	NA	NA	NA
Dec-08	Quest Diagnostics	Pathway Diagnostics	NA	6	NA
Dec-08	American Path Partners	Unipath LLC	NA	25	NA
Jan-09	Ssurepath	Annapath Inc.	NA	NA	NA
Mar-09	American Path Partners	Eastern Carolina Pathology	NA	NA	NA
May-09	Quest Diagnostics	OralDNA Labs	NA	NA	NA
Jun-09	Sonic Healthcare	Axiom Laboratories (clinical lab only)	NA	NA	NA
Jul-09	LabCorp	Monogram Biosciences	155	62	2.5
Jul-09	Viracor/IBT merger	Viracor/IBT Laboratories	NA	35-40	NA
Jul-09	AIT ESOP	AIT Laboratories	NA	34	NA
Jul-09	Adeona Pharmaceuticals	HartLab LLC	300K	150K	2.0

NA=Not available; *Purchase price includes assumed debt

Source: *Laboratory Economics*

M&A UPDATE OF DEALS IN LIMBO

For every completed sale of a laboratory or a pathology group, there are probably five other deals that were started but never closed.

The two biggest buyers—Quest Diagnostics and LabCorp—have various motivations for acquiring labs, according to Kevin Hunter, president of the M&A advisory firm Hunter Consulting (Tampa, FL). He says some transactions are made to protect market share, or break into markets that have historically been difficult to penetrate. But in all acquisitions they are looking to build revenue and earnings to satisfy Wall Street expectations, he adds.

Meanwhile, Chris Jahnle from Haverford Healthcare Advisors, says there are a number of warning signals that would cause a strategic buyer to walk away from a deal. These include: 1) regulatory compliance issues; 2) unionized workforce; 3) concentration of business among too few key clients; 4) declining net revenue due to client loss or decrease in volume from existing clients; and 5) discovery by the buyer of a misrepresentation or lack of disclosure by the seller of any material facts.

Here's the status on a number of labs that were put up for sale in the past year:

Westcliff Medical Labs (Santa Ana, CA) is under pressure to pay off \$50 million in loans—primarily from GE Capital—and has been put up for sale (see *LE*, May 2009, pp. 1-2). *LE* hears that LabCorp had been negotiating a possible deal, but has backed away. In related news, Brian Urban recently resigned as chief executive of Westcliff.

PathGroup Inc. (Nashville, TN) hired Brentwood Capital Advisors to seek a potential buyer late last year (see *LE*, March 2009, pp. 1, 3). With annual revenue of nearly \$100 million, PathGroup is one of the largest pathology lab companies in the nation. The company is owned by its management and pathologists. In addition to Quest Diagnostics and LabCorp, potential buyers could include private equity firms such as General Atlantic (Greenwich, CT), Primus Capital (Cleveland, OH) and Cressey & Company (Chicago, IL).

St. John Hospital (Detroit, MI) put its lab outreach business (dba St. John Health Labs) up for sale last year (see *LE*, November 2008, pp. 1, 3). The business employs some 300 people and has collected revenue of roughly \$30-35 million per year. St. John collected bids from several labs in late 2008 and some negotiations took place. However, no deal was ever closed and St. John has apparently chosen to keep its lab business for now.

CBLPath (Ocala, FL) hired the investment bank Piper Jaffray to review the company's strategic options, including a potential sale, more than a year ago. But CBLPath has remained independent. The company is owned by current and former management and two private equity firms (Galen Partners and Prudent Capital). In fact, rather than sell, the company recently made two big expansion moves. In December, CBLPath acquired Dr. Harvey Lemont's Laboratory of Podiatric Pathology (see *LE*, December 2008, pp. 1, 3) and it opened a new lab in Manhattan in June (see *LE*, June 2009, p. 4).

Carilion Clinics (Roanoke, VA) had been in discussion with LabCorp during 2008 to sell Carilion Labs. But declining lab valuations has led Carilion Clinics to hold on to its lab subsidiary for now (see *LE*, April 2009, p. 8).

SONIC HEALTHCARE BUYS AXIOM LABS

Sonic Healthcare USA (Austin, TX) has acquired the clinical lab business of Axiom Laboratories (Tampa, FL). Axiom operates both radiology centers and a CLIA-certified lab. Axiom was formed by John McCoskrie and Fred Bergmann in 1995; its initial focus was radiology. The company currently operates six multi-modality radiology centers in the Tampa Bay area and one in Haiti. In 2006, Axiom expanded into lab business by acquiring a local lab. Sonic has acquired Axiom's CLIA-certified lab in Tampa, which has estimated revenue of \$10-\$15 million per year.

SIEDLICK LEAVES SUNRISE MEDICAL LABS

Larry Siedlick has resigned as chief executive of Sunrise Medical Labs (Hauppauge, NY). Siedlick says he now plans to focus on The Arx Group (also in Hauppauge, NY), which provides billing services to hospital lab outreach programs and independent labs. June Amoroso, formerly vice president of operations at Sunrise, has been promoted to chief executive.

Siedlick and Pat Lanza formed Sunrise in 1972. Sunrise was sold to Sonic Healthcare USA in July 2007 for \$168 million—a price that was, at the time, equal to 2.2x Sunrise's annual revenue of \$75 million. Following the acquisition, Lanza became director of government affairs for Sonic at its corporate office in Austin, Texas.

NEOGENOMICS TO GET \$615K IN GROWTH INCENTIVES

NeoGenomics (Fort Myers, FL) is getting \$615,000 from Lee County and the state of Florida in return for hiring 75 new employees over the next three years. The new workers will be in a variety of fields, including laboratory technologists, laboratory directors, pathologists and laboratory support personnel, said Helen Edenfield, NeoGenomics' director of support services, in a prepared statement.

In addition to its headquarters and laboratory in Fort Myers, NeoGenomics operates labs in Nashville, Tennessee, and Irvine, California. The company employs about 150 people in all, including 72 people in Florida.

The financial incentives that NeoGenomics will receive include a Qualified Tax Incentive from the state of Florida and Lee County worth \$300,000. In addition, the company has been approved for an incentive of \$315,000 from the Lee County Job Opportunity Program.

Last year, NeoGenomics reported a net loss of \$1.4 million versus a net loss of \$3.4 million in 2007; revenue increased by 74% to \$20 million.

NeoGenomics at a Glance

<i>Financials</i>	<i>2008</i>	<i>2007</i>	<i>2006</i>	<i>2005</i>
Revenue	\$20,015,319	\$11,504,725	\$6,476,000....	\$1,885,000
Requisitions.....	24,780	16,385	9,563.....	2,982
Average revenue/requisition	808	702	677	632
Net loss	-1,382,586	-3,380,172	-129,661	-997,160
Diluted E.P.S.....	-0.04	-0.11	0.00.....	-0.04

Source: NeoGenomics

WATER STREET INVESTS IN CONVERGE DIAGNOSTIC SERVICES

Water Street Healthcare Partners (Chicago, IL) has made an equity investment in ConVerge Diagnostic Services (Peabody, MA) for an undisclosed amount. ConVerge is a full-service anatomic pathology lab that operates under the brand name CytoDx and provides diagnostic and technical services to more than 225,000 patients per year. ConVerge was founded by Karl Proppe, MD, president; Harold Kisner, PhD, executive vice president; Jake Dougrey, executive vice president; and Brian DuChateau, PhD, lab director. This marks Water Street's second investment in a lab/pathology company. Water Street purchased Plus Diagnostics (Lakewood, NJ), formerly named Lakewood Pathology, in 2006 in a \$50 million transaction.

ADEONA BUYS HARTLAB

Adeona Pharmaceuticals (Ann Arbor, MI) has purchased HartLab LLC (Bolingbrook, IL), a CLIA-certified lab formed in 2006. Adeona paid \$201,000 in cash, issued 50,000 shares of Adeona stock and assumed \$79,000 in debt. Annual revenue at HartLab is currently between \$100,000 and \$200,000. Adeona plans to use HartLab as a platform for launching its proprietary copper toxicity and zinc deficiency blood tests for Alzheimer's disease. In connection with the closing of the deal, Adeona has signed a consulting agreement with Narayan Torke (former owner of HartLab) for a period of up to twelve months for a monthly consulting fee of \$4,000.

LABORATORY INDUSTRY MOVERS & SHAKERS

ARUP Laboratories (Salt Lake City, UT) has named **Sherrie Perkins, MD, PhD**, as chief medical officer (CMO) and director of laboratories, effective, July 1. Perkins will be taking over the responsibility from **Edward R. Ashwood, MD**, who will be transitioning into the role of president and chief executive officer. These changes will coincide with the announced retirement of ARUP founder and **CEO Carl Kjeldsberg, MD**.

Vicki DiFrancesco has resigned as the president of mergers and acquisitions at **Slone Partners** (Miami, FL). Francesco is now working independently as a lab consultant. The lab executive recruiting firm Slone Partners is quietly exiting the M&A business (see *LE*, October 2008, p. 8).

Mike Mosunic has been hired as chief operating officer for **Consultants for Pathology and Lab Medicine** (Los Angeles, CA). Mosunic was formerly chief operating officer at **Slone Partners**.

Signature Genomic Laboratories (Spokane, WA) has hired two new lab directors, **Marilyn Slovak, PhD**, and **J. Britt Ravnan, PhD**. Slovak joins Signature from the **City of Hope National Medical Center** (Duarte, CA), where she was director of cytogenetics and professor of pathology. Ravnan joins Signature from **Genzyme Genetics** in Santa Fe, New Mexico, where she was cytogenetics lab director for 11 years.

Richard J. Zarbo, MD, DMD, senior vice president for pathology and laboratory medicine at Henry Ford Health System (Detroit, MI), was elected president of the **United States and Canadian Academy of Pathology** at the group's recent annual meeting in San Diego.

FDA CLEARS GENETIC TEST FOR CELIAC DISEASE

A new saliva-based genetic test, My CeliacID, from Prometheus Labs (San Diego, CA) has been approved by the FDA. The test shows if a person has the genetic predisposition for celiac disease by detecting two genes—*HLA-DQ2* and *HLA-DQ8*—associated with the disease.

If you don't have the genes, you are highly unlikely to develop celiac disease in your lifetime. If you do have the genes, you may have celiac disease and you should consult a doctor.

Celiac is an immune-mediated disease triggered by the consumption of gluten, a protein found in grains like wheat, rye, and barley. Approximately 1 in every 100 Americans has celiac disease. Common celiac symptoms include bloating, diarrhea, anemia, infertility, recurrent miscarriage, short stature, weight loss and osteoporosis. Treating celiac disease mostly involves maintaining a gluten-free diet.

Prometheus is marketing the test directly to patients through the Internet. The company is charging \$329 for the test and accepting payment by Visa, Mastercard or American Express.

After payment has been received, Prometheus ships a sample collection kit for MyCeliacID via FedEx. Patients provide a saliva sample and send it to Prometheus' laboratory in San Diego. Prometheus sends the test results to the patient by e-mail in approximately seven business days.

Prometheus markets a combination of proprietary esoteric tests and pharmaceutical products for gastrointestinal diseases. In 2008, Prometheus's earnings rose to \$37.2 million from \$4.3 million in the same period a year earlier; revenue rose to \$278.1 million from \$220.9 million.

Prometheus' leading pharmaceutical product is Entocort EC capsules for Crohn's disease. The company's biggest selling lab test is its IBD Serology 7 (list price is \$445), which helps identify inflammatory bowel disease (IBD) and differentiates between ulcerative colitis and Crohn's disease.

Prometheus registered with the Securities & Exchange Commission for an initial public offering to raise as much as \$100 million in January 2008 (see *LE*, January 2008, p. 10), but the IPO has been delayed because of weak stock market conditions.

GENWAY GETS CLIA CERTIFICATE FOR NEW LAB

GenWay Biotech, Inc. (San Diego, CA), which manufactures and distributes antibodies and Antigens to IVD companies and laboratories, has become CLIA certified and received a California lab license. Joe Volans, MD, is lab director. GenWay plans to perform cancer testing at the new lab, including the DR-70 test from AMDL (Tustin, CA). DR-70 is an ELISA assay that has been cleared by the FDA for monitoring colorectal cancer. Other labs that currently offer the DR-70 test include Precision Diagnostic Laboratory (Garden Grove, CA). The test is marketed under the brand name Onko-Sure.

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PATHWAY GENOMICS RAISES VC FUNDS

Pathway Genomics (San Diego, CA) has raised an undisclosed amount of first-round funding. Backers include The Founders Fund, Edelson Technology Partners and Western Technology Investment.

Pathway operates a 10,000-square-foot CLIA-certified lab in San Diego. The company is marketing genotyping services directly to consumers. For example, its Health Test product sells for \$249 and checks for genetic risk for more than 90 conditions, including prostate, breast, lung and colorectal cancer, cardiovascular diseases, rheumatoid arthritis and type 1 & 2 diabetes.

The test is ordered online and Pathway mails a saliva specimen collection kit. The specimen is mailed back to Pathway using a prepaid Fed-Ex package. Results are e-mailed back to the patients in about eight weeks.

James Plante is Pathway's founder and chief executive; K. David Becker, PhD, is chief scientific officer.

Other companies marketing genetic tests to consumers via the Internet include Navigenics (Foster City, CA), which raised more than \$25 million from Kleiner Perkins Caufield & Byers, Sequoia Capital and Mohr Davidow Venture, and 23andMe (Mountain View, CA), which is backed by Genetech, Google and New Enterprise Associates.

SEC INVESTIGATING SEQUENOM TEST DATA PROBLEMS

On April 29, Sequenom Inc. (San Diego, CA) announced that its much-awaited prenatal Down syndrome test (SEQureDx Down) would be delayed due to the discovery of employee mishandling of research and development test data and results. The announcement caused Sequenom's stock to plunge 76% the day after the announcement. Now the company says the Securities and Exchange Commission (SEC) has initiated an investigation relating to the announcement. Sequenom says it will cooperate fully with the SEC in this matter.

Sequenom had planned commercial launch of the test in June through its newly-acquired CLIA-certified lab in Michigan (see *LE*, October 2008, p. 7).

Sequenom purchased the Center for Molecular Medicine (Grand Rapids, MI) from Spectrum Health and the Van Andel Research Institute in November 2008. Ninety percent of the purchase price was comprised of 187,794 shares of Sequenom's common stock (valued at \$3.6 million), with the remaining \$400,000 paid in cash. The lab was renamed the Sequenom Center for Molecular Medicine.

In conjunction with the acquisition, Sequenom received more than \$20 million in state employment and property tax breaks in exchange for promising a \$20 million investment and bringing 523 jobs to the area by 2013. Those promised jobs were related to a planned lab expansion to process the SEQureDx test. The lab currently has about 20 employees.

Sequenom recorded a net loss of \$44.2 million in 2008 versus a net loss of \$22 million in 2007; revenue was up 15% to \$47.1 million. Sequenom has accumulated losses of \$526 million since its inception in 1994.

LAB STOCKS UP 19% YEAR TO DATE

Lab stocks rose 4% in the four weeks ended July 13, and are up 19% so far this year. This compares with a 3% year-to-date loss for the S&P 500 Index and a 2% gain for the Nasdaq. The top-performing lab stocks are Neogenomics, up 130%; Clariant, up 112%, and Monogram Biosciences, up 75%. The worst declines have been recorded by Celera (owner of Berkeley Heart Lab), down 35%, and Enzo Biochem, down 22%. Meanwhile, Quest Diagnostics is up 5% and LabCorp is up 4%. Overall, eight lab stocks are up and five are down.

COMPANY (TICKER)	STOCK PRICE 12/31/08	STOCK PRICE 7/13/09	2009 PRICE GAIN	MARKET CAPITALIZATION (\$ MILLIONS)	EARNINGS PER SHARE (TTM)*	PRICE-TO-EARNINGS RATIO*
Bio-Reference (BRLI)	\$26.23	\$30.47	16%	\$421	1.24	24.6
Celera (CRA)	11.13	7.21	-35%	590	-1.16	NA
Clariant (CLRT)	1.63	3.45	112%	267	-0.15	NA
Enzo Biochem (ENZ)	4.89	3.80	-22%	142	-0.57	NA
Genomic Health (GHDX)	19.48	16.60	-15%	473	-0.50	NA
Genoptix (GXDX)	34.08	26.94	-21%	454	1.82	14.8
LabCorp (LH)	64.41	67.00	4%	7,256	4.66	14.4
Medtox Scientific (MTOX)	8.22	9.39	14%	80	0.51	18.4
Monogram Biosciences (MGRM)	2.60	4.54	75%	105	-0.96	NA
Myriad Genetics (MYGN)	31.59	24.94	-21%	2,382	1.48	16.9
Neogenomics (NGNM)	0.61	1.40	130%	46	-0.02	NA
Psychemedics (PMD)	6.46	6.73	4%	39	0.41	16.4
Quest Diagnostics (DGX)	51.91	54.68	5%	10,136	3.43	15.9
Totals & Averages			19%	22,391		

*Earnings per share and price-to-earnings ratios are based on figures for trailing 12 months Source: Bloomberg

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