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LABORATORY INDUSTRY REPORT®

Jondavid Klipp, Managing Editor, labreporter@aol.com

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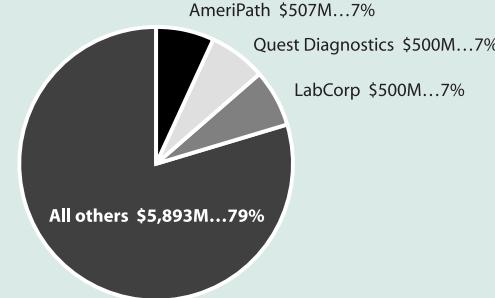
AmeriPath Has Survived, But Can It Thrive?

It's been almost 10 years since a group of healthcare executives and venture capitalists came together to form AmeriPath and began buying pathology groups across the nation. But while other physician practice management (PPM) companies have crashed and burned (e.g., MedPartners, Phycor, Phymatrix, etc), AmeriPath has endured.

Jeffrey Mossler, M.D., vice chairman at AmeriPath, says the company has survived because unlike most other physician specialties, the average pathologist has time in their day to do more cases. As a result, there is room for a management company to add value to a pathology practice through effective sales and marketing efforts and access to managed care contracts that will bring in extra work.

Nonetheless, AmeriPath faces a number of challenges. Although the company has acquired more than 60 pathology groups since 1996, it still only holds an estimated 7% of the total market and faces increasing competition from Quest Diagnostics and LabCorp. For an outline of six major challenges (many of which also affect local pathology groups) that AmeriPath now faces, see *Inside the Laboratory Industry*, pp. 5-9. ■

Anatomic Pathology & Cytology Market Share by Annual Net Revenue, 2004



Source: Washington G-2 Reports

Why Is Everyone Leaving Specialty Laboratories?

Senior executives at Specialty Laboratories (Valencia, CA) continue to jump ship. So far in 2005, four high-level executives have left the company, and two have had their positions terminated. People close to the situation tell *LIR* that Specialty's former execs have grown frustrated by the overbearing presence of founder Jim Peter, M.D., Ph.D., who has a controlling interest in the company and a seat on the board. Although Peter does not have an official role in the day-to-day operations, *LIR* is told that he has greatly increased his involvement with the company over the past year.

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■ WHY IS EVERYONE LEAVING SPECIALTY, from page 1

The latest exec to leave is Kevin Sayer, who has resigned as chief financial officer after just one year on the job. Specialty had entered into a retention agreement with Sayer on February 14 under which he got a bonus of \$150,000 if he continued his employment with the company through May 15, 2005. Sayer resigned effective May 16.

Mark Willig, senior vice president of sales and marketing, has also resigned. Specialty says that it's hired Vicki DiFrancesco as the company's new sales and marketing head. DiFrancesco has previously held top sales and marketing positions at

Specialty at a Glance (\$000)

	2004	2003	2002	2001
Revenue	\$134,803	\$119,653	\$140,150	\$175,169
Pretax income	-13,131	-9,250	-21,297	21,949
Net income	-12,950	-6,361	-13,385	13,079
Requisitions	3,002	2,486	2,869	3,033
Average revenue per req.....	44.90	48.13	48.84	57.75

Source: Specialty Laboratories

Quest Diagnostics and American Medical Laboratories. In her new position at Specialty, DiFrancesco will receive a base salary of \$235,000 and will also be eligible for an annual incentive bonus of up to 75% of her salary. In addition, pending approval by the company's board, DiFrancesco will be granted 160,000 stock options.

Executives that have had their positions at Specialty eliminated recently include Dan Angress, senior vice president of strategic business development, and Cynthia French, Ph.D., chief scientific officer.

Meanwhile, documents filed with the Securities & Exchange Commission reveal that Doug Harrington, M.D., was paid a lump sum of \$275,000 following his March 29, 2005, resignation as chief executive. Specialty's separation agreement also requires that Harrington receive severance payments totaling \$840,000 (equivalent to two years of his base salary), payable in bi-weekly installments.

Peter, age 71, founded Specialty in 1975 and grew it to be one of the largest reference labs in the country. In December 2000, Peter brought the company public, raising net proceeds of \$85 million from an IPO of 5.75 million shares sold at

\$16.00 per share. The stock quickly shot up and reached a high of \$47 in June 2001.

Recent Executive Departures at Specialty Laboratories

Name	Position	Date of resignation/ termination
Richard Belluzzo	chairman	February 2005
Doug Harrington, M.D.	chief executive	March 2005
Dan Angress	senior v.p., business development	April 2005
Cynthia French, Ph.D.	chief scientific officer	April 2005
Kevin Sayer	chief financial officer	May 2005
Mark Willig	senior v.p., sales & marketing	May 2005

Source: Specialty Laboratories

But a run in with California and federal regulators over lab staff licensing issues in 2002 caused Specialty to temporarily lose its CLIA certification and right to bill Medicare and Medicaid. Although these issues were resolved quickly, Specialty's stock price, annual revenue, and profitability have each not yet recovered to their 2001 levels.

The challenge facing the company today is the tremendous overcapacity and increased costs associated with its recent move to a gigantic new lab and office facility (198,000 square feet) in Valencia, California. To fill that excess capacity, Specialty has been aggressively cutting prices. Last year, the company's average price per accession was \$44.90, down 7% from \$48.13 in 2003, and down 22% since 2001. Specialty has also said that it's looking for acquisitions that can be folded into its new laboratory.

Note: Dr. Peter did not return a phone call from *LIR* seeking comment for this article. 

LabNet Quits Reference Testing Program

LabNet of Ohio (Columbus), a network of 23 hospital labs that covers southern Ohio, will officially terminate its shared-testing network on June 25, *LIR* has learned. An inside source tells *LIR* that a number of member hospitals have stopped referring their send-out tests to LabNet's primary in-network reference labs (Ohio State University Medical Center, Children's Hospital, and Mayo Medical Laboratories) and switched to one of the national reference labs to get lower pricing. As a result, LabNet has lost the volume needed to maintain its infrastructure.

LabNet was originally founded in 1996 by 13 hospitals, which each chipped in \$65,000 to get the venture off the ground. LabNet grew to include 18 hospital labs by early 2000 and reached 23 members in late 2004.

The initial goal of LabNet was to secure managed care contracts for lab services, but the network was unable to win any contracts, so it focused its efforts on building a system to direct members' reference testing orders to in-network labs. At its peak late last year, LabNet's three in-network labs were receiving a combined total of 11,000 send-out orders per month, and LabNet was considering opportunities to expand the network outside of Ohio (see *LIR*, November 2004, page 10).

Although LabNet will stop acting as a clearinghouse for send-out tests, the network will still continue to provide group purchasing services for lab equipment, reagents, and software systems, according to our source. 

Freeman Joins Kohlberg Kravis Roberts

Ken Freeman, age 54, who stepped down as the chief executive of Quest Diagnostics last year, has started the next chapter of his career. Freeman has joined the well-heeled investment firm Kohlberg Kravis Roberts & Co. (KKR-New York City) as managing director. In his new position, Freeman will work closely with KKR's healthcare team to find new investment opportunities.

Freeman left Quest in December, after ceding his chairman and CEO responsibilities to his former chief operating officer, Surya Mohapatra, Ph.D.

Note: Ken Freeman will be a keynote speaker at Washington G-2's Lab Institute conference in Washington, D.C., this October. The title of his presentation: *Taking a Hard Look at Healthcare & Labs: Business Opportunities & Challenges*. 



Sentara Opens New Molecular Diagnostics Laboratory

Sentara Healthcare (Norfolk, VA) has opened The Molecular Diagnostic Laboratory (MDL) in a renovated wing at Sentara Norfolk General Hospital. MDL cost \$1 million to renovate and equip, according to Suhail Nasim, M.D., medical director of the new laboratory. Among the instrument systems purchased were the Roche LightCycler and Cobas Amplicor analyzer, and the ABI 3100 automated capillary DNA sequencer and ABI 7000 sequence detection system.

The new lab has three employees, and professional services are being provided by Pathology Sciences Medical Group (Norfolk), which also serves Sentara's other labs. The initial test menu includes 11 molecular tests (see table), and Nasim expects to add CYP450 drug metabolism testing, strep A & B, bordatella pertussis, and cystic fibrosis genetic analysis within the next year.

Nasim says MDL will provide molecular testing services to the six hospitals in the Sentara Healthcare system and to local physician offices. Previously, Sentara had referred approximately \$500,000 worth of annual reference testing to the laboratory at Eastern Virginia Medical School (Norfolk), and additional work was sent to LabCorp and Quest Diagnostics.

Initial Test Menu at Sentara's Molecular Diagnostics Laboratory

HIV viral load	Chromosomal translocations in leukemia
HIV genotyping	T & B cell rearrangement
Hepatitis viral load	Factor V Leiden
Hepatitis genotyping	Prothrombin
Cytomegalovirus (CMV)	Microsatellite instability in colorectal cancer
Herpes	

Source: Sentara



Laughman Leaves Mayo For AmeriPath

After spending 30 years with the Mayo Clinic and its laboratory subsidiary, Keith Laughman has joined AmeriPath as president for esoteric services. His responsibility will be building up the company's Center for Advanced Diagnostics (Orlando, FL) and other esoteric testing services.

During his career with Mayo, he served as president of Mayo Collaborative Services for six years. He was also executive director of Mayo Medical Laboratories for nine years, administrator in the Mayo Foundation Department of Research, assistant professor at the Mayo Graduate School of Medicine, and research associate with the Mayo Biomechanics Laboratory.

Separately, AmeriPath says that Joseph Sonnier, M.D., has resigned as president of the company and is now managing director of the company's Dallas lab.



INSIDE THE LAB INDUSTRY

AmeriPath Faces Big Challenges



Jeffrey Mossler, M.D.

During 2004,
AmeriPath
processed and
diagnosed
approximately
four million tissue
biopsies and 1.5
million Pap tests.

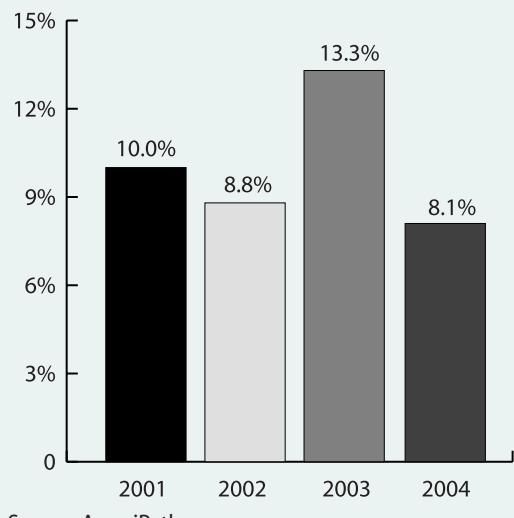
For an inside perspective on the challenges facing AmeriPath, *LIR* interviewed Jeffrey Mossler, M.D., age 52, vice chairman at AmeriPath. Prior to becoming vice chairman early last year, Mossler had served as chief medical officer. He joined AmeriPath in September 1997 when AmeriPath acquired his pathology laboratory CoLab, Inc. (Indianapolis, IN). For this article, *LIR* also relied on two recent investor conference calls (March 18 and May 12) led by AmeriPath's chairman and CEO, Donald Steen, 58, and its chief financial officer, David Redmond, 53, as well as the company's annual reports from 1996 to 2004. An outline of the six biggest challenges that *LIR* thinks AmeriPath now faces follows:

Challenge #1: Pathologist Turnover

The downfall of most PPM companies that have failed has been an inability to deliver true value to the physician groups they purchased. In the late 1990s, physicians were more than happy to sell their groups at fancy prices to MedPartners, Phycor, etc. But after a year or so, the good feeling physicians got from depositing a million bucks in the bank and getting thousands of shares of stock would begin to wear off. Then they'd start wondering what exactly it was that their PPM company was doing for them.

The answer was "not much," so physicians would start breaking off their management contracts or simply quit and move to another group. So far, AmeriPath has weathered the storm. Turnover hit a high in 2003 when approximately one out of every seven, or 13.3%, of AmeriPath's 400+ pathologists left the company. That year, AmeriPath was forced to sell two practices in Florida back to pathologists and terminated a management agreement with a group in Georgia. Another group in Michigan was sold back to its pathologists in early 2004.

Pathologist Turnover Rate at AmeriPath



But pathologist unrest at AmeriPath seems to have settled down. Last year, AmeriPath reduced its annual pathologist turnover rate to 8.1%. Not surprisingly, AmeriPath has had to increase pathologists' compensation. Many groups had sold their practices to AmeriPath at rich prices and accepted lower-than-average salaries in return (see *Challenge #5*).

But as each pathology group's five-year contract comes due, AmeriPath has been moving from salary-based compensation to a productivity-based structure in which pathologists incomes are tied to practice revenues and profits, says Mossler.

So far AmeriPath has moved about 35% to 40% of its 400+ pathologists to the productivity-based model. On average, AmeriPath now pays 30.6% of



its net revenue to pathologists for salaries, benefits, and malpractice insurance coverage.

In 2004, AmeriPath's 405 pathologists generated an average net revenue of \$1.25 million each, including roughly \$2.2 million for each of the company's some 75 dermatopathologists and about \$1 million each for its 430 other pathologists. Average compensation (i.e., salary, benefits, and malpractice insurance coverage) was \$383,271 per pathologist.

Mossler says that AmeriPath has survived, while other PPM companies have failed, because there is room to enhance production at pathology practices. He notes that many family practice physicians see upward of 50 or more patients per day. "A PPM company can't make them see 100 patients, they're already too busy. So there was very little a company like MedPartners could do to increase productivity," he says.

However, there is room to grow most pathology practices, according to Mossler. With effective sales and marketing efforts, Mossler says net revenue at the average pathology group can be doubled or tripled. AmeriPath can also add value to pathology groups by providing capital for investment in new systems so more molecular testing can be performed either at the company's esoteric testing centers—Center for Advanced Diagnostics (Orlando, FL) and other sites (Indianapolis, Dallas, and Denver)—or at local groups, according to Mossler.

He says AmeriPath has had its greatest success in building the outpatient revenue of its pathology groups. The inpatient side is more difficult to grow because AmeriPath does not have control of the pathology support staff (i.e., histotechs, transcribers, etc).

Last year, AmeriPath's overall net revenue grew by 4.6% to \$507.3 million, with the

outpatient business up 8% to 10% and the inpatient business flat. AmeriPath's esoteric testing business grew by more than 10% to approximately \$45 million in 2004.

Challenge #2: Increased Competition from Quest Diagnostics and LabCorp

It's no secret that Quest Diagnostics and LabCorp are each trying to build up their cancer testing businesses, and each has the economies of scale to compete aggressively for anatomic pathology work.

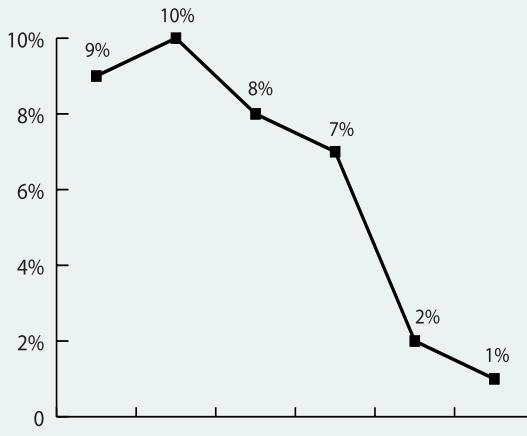
Quest reports that it generated approximately \$500 million from anatomic pathology services (including Pap testing) in 2004 versus \$475 million in 2003. Over the past few years, Quest has worked to internalize subcontracts with local pathology groups. In February 2003, for example, Quest opened a new 110,000-square-foot lab in Houston that consolidated three existing labs. Anatomic pathology and flow cytometry were among the new services it added in conjunction with the opening.

Quest is also striking exclusive deals to lock up new cancer testing technologies. For example, in 2004, Quest announced an agreement with Veridex LLC (Warren, NJ), a Johnson & Johnson company, to be the only national commercial reference lab to offer Veridex's CellSearch test. CellSearch measures the number of tumor cells circulating in the blood of patients with metastatic breast cancer, enabling physicians to individualize treatment.

LabCorp, which also generates some \$500 million per year from anatomic pathology services, has also increased its focus on cancer testing, largely by making big acquisitions (e.g., Dianon, US Labs, and Esoterix).

The expansion of cancer testing capabilities at Quest and LabCorp has reduced their

AmeriPath's Percentage of Revenue from the National Labs



Source: AmeriPath

need to send out work to local pathologists, including AmeriPath's groups. As a result, the percentage of revenue that AmeriPath derives from the national labs has declined from 10% in 2000 to only 1% in 2004.

Instead of being clients, the national labs are now competitors. Mossler says that anatomic pathology services run the risk of becoming perceived as a commodity as Quest and LabCorp get more and more involved in this market. So he says AmeriPath is seeking to expand in more specialized areas of pathology like hematopathology, gastrointestinal pathology, and dermatopathology. AmeriPath is also emphasizing the need for its pathologists to develop personal relationships with their physician clients, he adds.

Challenge #3: Increased Difficulty in Collecting Clinical Professional Component Fees

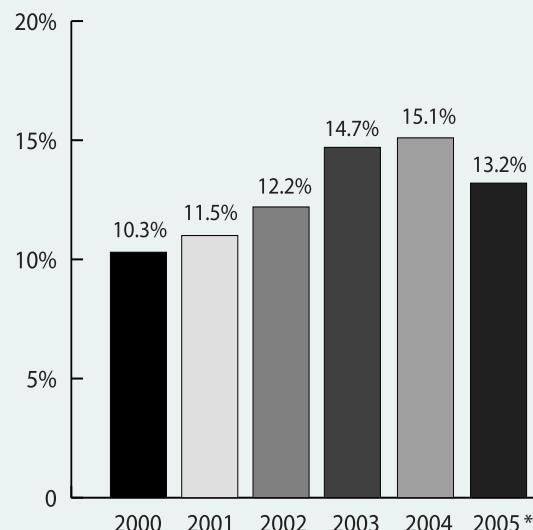
Last year, several large managed care companies, including UnitedHealth Group, unilaterally decided to stop paying pathologists for professional fees associated with serving as the medical director at clinical laboratories. Mossler says the

managed care companies gave no reason for their decision, they just stopped paying.

AmeriPath generated \$46 million, or 9% of its total revenue, from clinical professional component (CPC) fees in 2004. The increased difficulty in collecting these fees caused AmeriPath's overall bad-debt write-offs to rise to 15.1% last year, including bad debt of 23.8% for its inpatient services due to the lower recoverability of CPC fees.

Mossler says AmeriPath as well as the Texas Society of Pathologists are in active discussions with managed care companies concerning CPC fees, and he's hopeful that a compromise can be reached.

Bad-Debt Write-Offs at AmeriPath



*based on first-quarter 2005 reported results

Source: AmeriPath

Challenge #4: A Slowdown in Acquisitions

AmeriPath built its business by completing over 60 acquisitions of pathology groups and laboratories since 1996. The company's most feverish acquisition activity took place in 1998, when it bought 15 groups (adding a total of 93 pathologists) for total consideration of \$117 million, including \$55

million in cash, \$14 million of AmeriPath stock, and \$48 million of contingent notes dependent upon future performance.

Acquisitions helped AmeriPath grow from \$43 million of annual revenue and 81 pathologists in 1996 to \$507 million and 405 pathologists in 2004. But the company's acquisition activity and revenue growth have dramatically slowed over the past four years. Last year, for example, AmeriPath acquired only three pathology groups, while revenue growth was only 5%.

The largest deal completed last year was the purchase of Pathology Associates, P.C. (New Rochelle, NY) on December 1. Pathology Associates, a group of seven pathologists that operate an independent lab focused on dermatopathology located just north of New York City, generated roughly \$15 million of net revenue last year. AmeriPath paid a steep price of \$44 million for the group, including \$34 million in cash plus 1.7 million shares of AmeriPath stock valued at \$10 million.

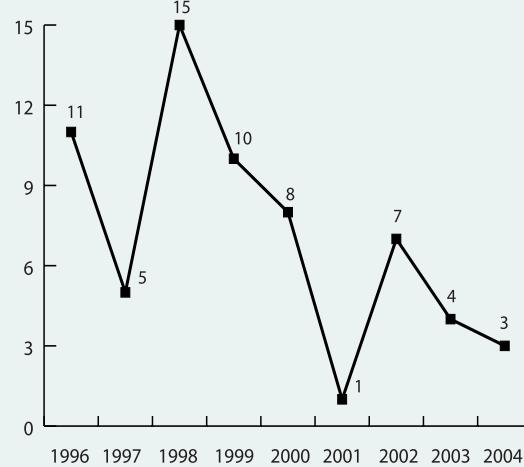
Steen said AmeriPath is now focusing its acquisition efforts on esoteric testing labs, rather than general anatomic pathology practices. But this could be difficult given that Quest Diagnostics, LabCorp, American Medical Labs, and at least half a dozen venture capital firms are also out there looking to buy esoteric labs.

Steen also said that AmeriPath has stopped using contingent notes as a form of acquisition currency. Prior to 2003, AmeriPath would typically pay nearly half of the acquisition price for a pathology group with contingent notes. Typically, the contingent notes were structured to provide for payments to selling pathologists upon the achievement of specified levels of operating income by the acquired operations over a three- to five-year period.

By using contingent notes, AmeriPath was able to reduce its immediate cash payout to acquired pathology groups. In addition, acquired pathologists accepted lower-than-normal compensation in exchange for the higher purchase prices that the contingent notes allowed AmeriPath to pay.

But ultimately the contingent notes had to be paid off, and they have now turned into a cash drain at AmeriPath. In the first three months of this year, AmeriPath paid out \$7.1 million to satisfy contingent notes issued in connection with previous acquisitions, and last year it paid \$14 million. In addition, AmeriPath has now had to begin adjusting its pathologist salaries back up to market rates (*see challenge #1*).

Number of Pathology Groups Acquired by AmeriPath



Source: L/R from AmeriPath financial statements

Challenge #5: Rising Medical Malpractice Costs

Skyrocketing medical malpractice insurance rates led AmeriPath to switch to a self-insurance, or captive, arrangement in June 2002. Under the company's self-insurance structure, it retains more risk for malpractice costs, including settlements and claims expense, than under its previous coverage.

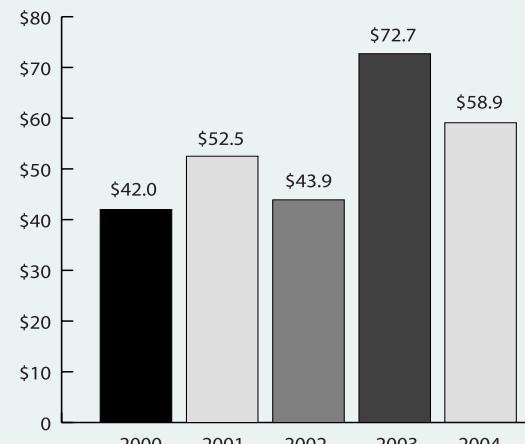
Despite the change in structure and added risk, AmeriPath's annual malpractice costs are rising at a near double-digit pace. The company's malpractice costs rose 9% to approximately \$13.5 million in 2004. And in the first quarter of 2005, AmeriPath reported malpractice costs of \$3.6 million, up 16% from \$3.1 million in the same period a year earlier.

Challenge #6: A Big Debt Burden

Last, but not least, AmeriPath has a high level of debt on its balance sheet, and the associated interest expense limits the company's ability to make investments in information technology, molecular diagnostics, acquisitions, etc. AmeriPath ended 2004 with long-term debt of \$497.9 million; interest expense for the year was \$44.8 million, and contingent note payments were \$14.1 million for a total debt expense of \$58.9 million.

That's a big burden, and it will play a big role in the strategic direction for AmeriPath in the next few years. The company was

Debt Expense* at AmeriPath (\$ millions)



* Includes interest expense plus contingent note payments
Source: AmeriPath

taken private by the investment firm Welsh Carson in an \$800 million transaction in March 2003. Undoubtedly, Quest Diagnostics and LabCorp have considered buying AmeriPath, but *LIR* thinks it's more likely that the company will return as a publicly traded company. The company could then use the funds raised by selling stock to reduce its debt level. 

AmeriPath at a Glance

Financials (\$ 000)	2004	2003	2002	2001	2000
Revenue	\$507,271	\$485,003	\$478,818	\$418,732	\$330,094
Cash from operations	54,038	68,899	69,109	48,027	31,953
Interest expense	44,797	35,649	4,016	16,350	15,376
Contingent note payments	14,079	37,033	39,856	36,101	26,645
Pretax income	2,875	10,616	75,761	40,751	27,160
Net income	1,514	5,395	44,641	23,352	11,488
Long-term debt	497,853	492,458	116,253	93,322	201,747
Cash/equivalents	20,980	23,536	964	3,208	2,418

Other Statistics (\$ 000)	2004	2003	2002	2001	2000
Number of pathologists	405	408	437	423	426
Net revenue per pathologist	\$1,253	\$1,189	\$1,096	\$990	\$775

Source: *LIR* from AmeriPath's financial statements

Mobile Pathology Venture Moving Forward



Ray Sukumar, M.D.

Last September, we highlighted a pathology group in Dover, Delaware (Doctors Pathology Services, P.A.) that has begun providing mobile pathology services to outpatient surgery centers from a CLIA-certified van outfitted with a cryostat, microscope, and other tools of the trade. DPS, which has four pathologists, also operates a traditional freestanding laboratory.

We recently spoke with DPS's founder and medical director, Ray Sukumar, M.D., to get an update on how things are going. Sukumar says DPS is currently operating one pathology lab van that performs intraoperative consultations in the parking lots of outpatient surgery centers six days per week. A second van is in the process of being customized and should be on the road by Labor Day, says Sukumar.

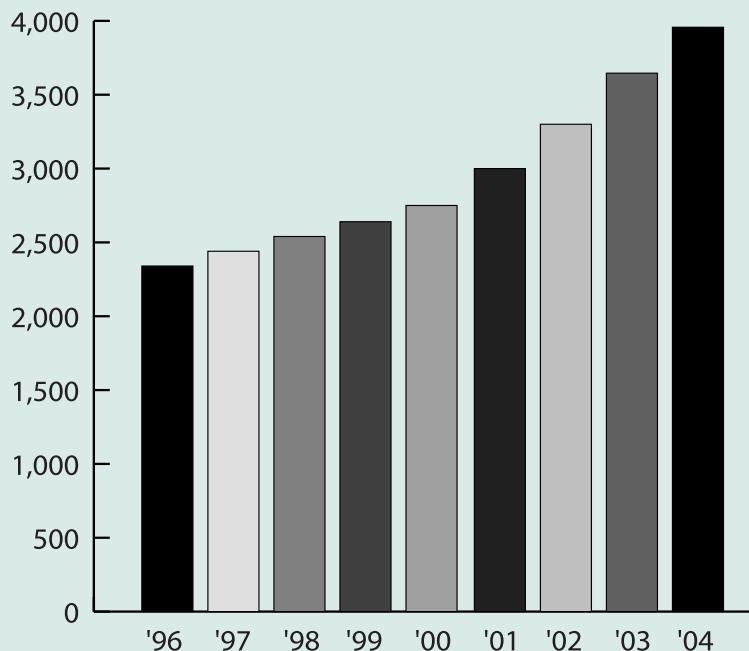
The second van will serve as a backup and handle expected new business from two new outpatient surgery centers that are opening up in New Castle County (north of Dover). There are several more outpatient surgery centers opening up in Washington, DC, and Philadelphia that could become potential clients as well, he says.

He's hired an attorney that specializes in franchise development and is now making plans to begin franchising his idea to other pathology groups. He calls his system the Mobile Intraoperative Consultation Service (or MIX Management

for short) and has filed trademarks and patents on the idea.

Separately, LIR observes that the number of outpatient surgery centers in the United States is growing rapidly—a trend that is hurting hospital-based pathology groups and helping independent labs and pathology groups. The number of freestanding outpatient surgery centers in the United States has grown more than 50% since 1996 to approximately 3,957 by February 2004, according to market research from Verispan's latest *Freestanding Outpatient Surgery Center Market Report*. The report estimates that the number of outpatient surgical cases performed in freestanding surgery centers increased 93% from 4.3 million in 1996 to 8.3 million in 2004.

Number of Freestanding Outpatient Surgery Centers in U.S.



Source: Verispan's *Freestanding Outpatient Surgery Center Market Report*

Lab Stocks Rise 5%; Psychedemics Up 14%

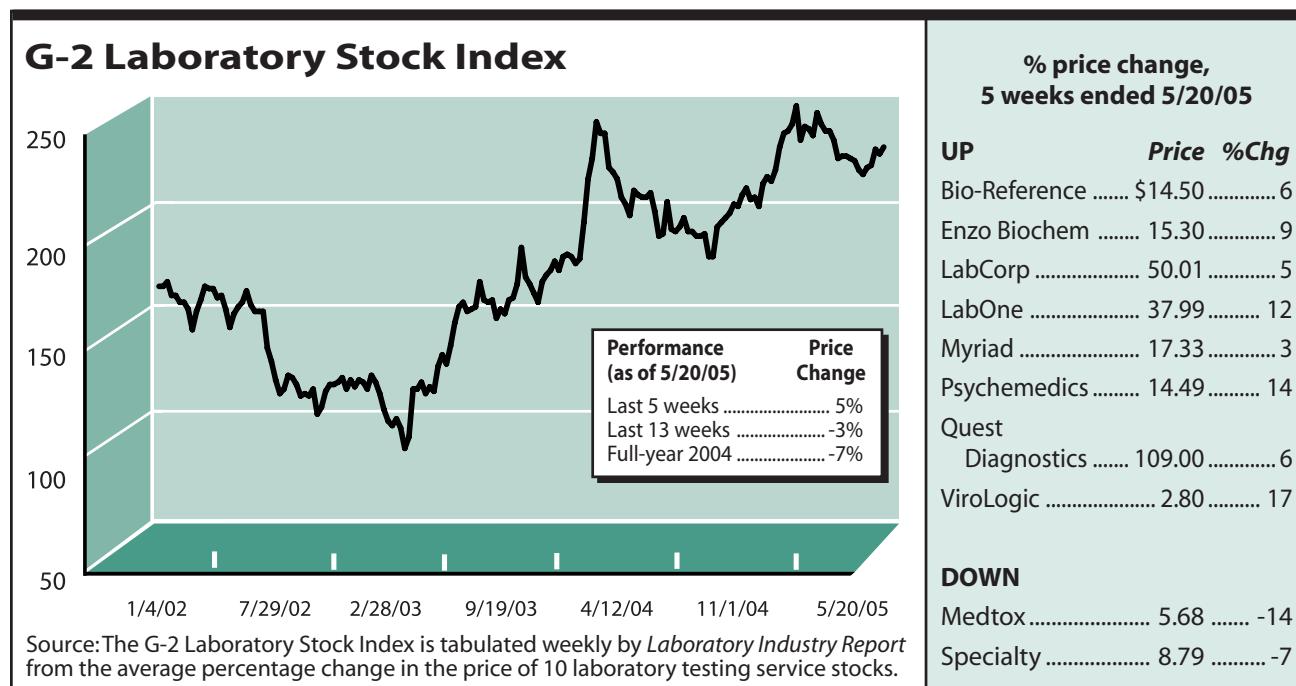
The G-2 Laboratory Stock Index rose 5% in the five weeks ended May 20, with eight stocks up in price and two down. So far this year, the G-2 index is down 7%, while the S&P 500 Index has fallen 2%, and the Nasdaq is down 6%.

The biggest gainer in the last five weeks was **ViroLogic** (South San Francisco, CA), which was up 17% to \$2.80 per share for a market value of \$341 million. ViroLogic, which performs phenotyping and genotyping HIV tests, recently presented clinical data demonstrating the ability of the company's eTag assays to accurately predict treatment response for patients with breast cancer who receive Herceptin. The presentation (abstract #553) took place at the 2005 American Society of Clinical Oncology Annual Meeting in Orlando, Florida in mid-May.

"Our data indicate that the eTag assays, which are directed to activated HER receptor family targets, may more accurately predict response in patients with breast cancer than current methods that look at gene amplification and protein levels of just HER2," said Sharat Singh, Ph.D., ViroLogic's chief technical officer for oncology, and co-author of the study. The company is planning to introduce an eTag panel focused on the EGFR/HER receptor family in 2006.

Psychedemics (Acton, MA) was up 14% to \$14.49 per share for a market value of \$74 million. Psychedemics, which performs drugs-of-abuse testing on hair samples, recently reported first-quarter revenue of \$5,337,750, up 28% compared to \$4,155,872 in the first quarter of 2004. Net income was \$948,140 or \$0.18 per share, up from \$452,988 or \$0.09 per share for the same period in 2004.

Meanwhile, **Quest Diagnostics** was up 6% to \$109 per share for a market cap of \$11 billion. Quest recently declared a two-for-one stock split effective June 20. LabCorp was up 5% to \$50.01 per share for a market cap of \$6.7 billion. ■





The nation's largest newborn screening labs include Mayo Medical Labs, Pediatrix Screening (Bridgeville, PA), Biochemical Genetics Laboratory at the University of Colorado, and Baylor Medical Center Institute of Metabolic Disease in Texas.

The movement to require all states to test newborns for a uniform list of childhood diseases is growing, and it could open up a major new testing market for laboratories. Currently, newborn screening requirements vary from state to state, with some testing for as few as three conditions and others for as many as 43.

But recently, a federal health task force—the U.S. Secretary's Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children—recommended expanding routine testing to 29 diseases for all states. The American Academy of Pediatrics and the March of Dimes support the recommendation. The Department of Health and Human Services has just completed a public comment period on the task-force report, but has not yet made a final decision on any recommendation to the states.

Annually, 4.1 million newborn babies are screened for congenital disorders in the United States, and 5,000 infants are diagnosed each year with a congenital disorder. But each year, more than 1,000 newborns go undetected for conditions that could have been identified through newborn screening because its administration is not uniform.

LIR estimates that the current lab testing market for newborn screening is roughly \$100 million (4.1 million newborns multiplied by an average of \$25 of lab testing), but this market could easily double if testing for 29 diseases becomes the norm. ■

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- Sentara Healthcare 800-736-8272
- Specialty Laboratories 661-799-6543
- ViroLogic 650-635-1100

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