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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

Congress Cuts Lab Fees by 2% Starting in 2013; TC Grandfather Protection Extended 4 Months

In an unexpected move decried by lab industry groups, Congress in mid-February passed legislation that would cut Medicare lab fees by $2.7 billion over 10 years to help pay for another short-term Medicare physician fee fix.

Starting in 2013, the change would cut lab payment rates by 2 percent under the Medicare clinical laboratory fee schedule. This is on top of any cut required by the schedule's update formula, as revised by the health care reform law.

"As [this 2 percent] reduction is applied after the update is calculated, the resulting 2013 update amount becomes the new reset base" for 2014 and subsequent years, according to a summary prepared by

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Genomic Health Reports Profitable Quarter, Plans Investment in New Genetics Subsidiary

Genomic Health (Redwood City, Calif.) reported a larger fourth-quarter profit in February and said it was launching a new genetics subsidiary.

Revenues for the fourth quarter were $53.4 million, a 13 percent increase over the same period in 2011. Income grew to $2.6 million, or 8 cents per share, from $1.7 million, or 6 cents per share. The company said it delivered 17,080 test results with its Oncotype DX test, up 13 percent from a year ago.

As was the case in the third quarter, the company benefited from a one-time polymerase chain reaction (PCR) royalty adjustment from Roche. In addition, the company benefited from some catch-up payments for its colon test by Medicare, which drove higher gross profit.

Management's guidance for 2012 includes total revenue of $230 million to $240 million (12 percent to 16 percent growth); net income of $5 million to $8 million (36 percent decline to 3 percent growth), excluding up to an $8 million loss in the new subsidiary; and total Oncotype DX volume of 75,000 to 77,000 (14 percent to 17 percent growth).

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■ **Genomic Health Reports Profitable Quarter**, *from page 1*

Although the company had begun to report a few quarters of operating profits, the formation of the new subsidiary could swing the company back to a net loss in 2012.

New Genetics Subsidiary

Company officials said they are in the process of establishing a wholly owned subsidiary that will focus on accelerating the integration of the human genome into medical practice with an emphasis on bioinformatics and clinical utility. The subsidiary is expected to be established by March 1 and provide its first commercial service in 2013. The new venture will be led by Randy Scott, who in his role as executive chairman for the past three years has focused on commercial applications of next-generation sequencing.

Scott will remain a Genomic Health board member, and Kim Popovits, president and chief executive officer, will assume the additional role of chairman of the board, effective March 1. In a related action, Julian Baker has been named as lead independent director.

Genomic Health plans to invest up to $20 million in the new subsidiary over the next two years. The new venture will focus on commercial applications of the human genome and plans to leverage the company's research and development as well as third-party R&D efforts.

"As the cost of sequencing continues to drop, new medical applications with the potential to impact millions of people are rapidly emerging," says Scott. "We are at a unique turning point in medicine and believe the investment we have made over the past several years in the development of a robust next-generation sequencing platform and the capabilities we have established in building a successful cancer genomic business make this the ideal time to expand into both common and rare genetic conditions and expect this new startup to be a significant long-term contributor of the company's growth."

Other Developments

The company has begun conversations with payers on reimbursement for Oncotype DX used in predicting local recurrence in patients with ductal carcinoma in situ (DCIS). Since this is a new use for the test, it's not clear how payers will treat it (i.e., as a new test or the same as Oncotype DX applicable to stage I patients). Management has reiterated the market opportunity for the test used for DCIS—there are about 45,000 newly diagnosed cases each year in the United States.

During the fourth quarter, the company secured Oncotype DX for colon cancer reimbursement for an additional 3.8 million covered lives in the United States. Genomic Health plans to continue to invest in the colon program in 2012, including ramping up sales reps, increasing covered lives, and conducting chemotherapy benefit studies for stage II and III patients. The company recently completed

gene identification studies to predict oxaliplatin benefit in colon cancer patients and plans to present results at conferences this year.

The company now covers more than 55 million covered lives internationally and has established distribution agreements in Hungary, Romania, and Peru. During the quarter, it received a recommendation from the British Columbia Breast Tumour Group that the Ministry of Health begin reimbursing for Oncotype DX for node-negative patients in British Columbia. Management suggested that international revenue was up 85 percent in 2011, making the international business contribute about 9 percent of product revenue. Going forward, the company expects international revenue to continue to grow faster than the core business.

Myriad Genetics' Second-Quarter Results Better Than Expected

Myriad Genetics (Salt Lake City) reported better-than-expected fiscal second-quarter 2012 results in February, marking the company's fifth quarter in a row of outperformance.

Revenue of $122.8 million (growth of 22 percent) beat analysts' consensus of $115.2 million. Earnings per share (EPS) of 33 cents also beat consensus estimates by 2 cents.

Molecular diagnostic testing revenue in the second fiscal quarter totaled $117.6 million, an increase of 17 percent compared to the prior-year period. This increase was driven by strong growth across all segments and products. Oncology revenue equaled $79.8 million, an increase of 15 percent over the second quarter of 2011. Women's health revenue totaled $37.9 million, an increase of 22 percent over the same period the prior year.

Revenue from the *BRACAnalysis* test, which represented 82.6 percent of total revenues in the second quarter, was $101.4 million, a 14 percent increase over the same period of 2011. Revenue from the COLARIS and COLARIS AP tests, which represented 8.9 percent of total revenue during the quarter, was $10.9 million, an increase of 56 percent. Myriad's remaining molecular diagnostic tests contributed $5.3 million to second-quarter revenue, an increase of 24 percent, accounting for 4.3 percent of total revenue.

Companion diagnostic service revenue in the second fiscal quarter equaled $5.2 million and represented 4.2 percent of total company revenue. There is no prior-year revenue, as the company acquired this business in May 2011.

Operating income was $45.5 million, an increase of 18 percent from the prior-year period. This included the impact of a 68 percent increase in research and development investment to support the company's existing molecular diagnostic tests and future product opportunities.

Net income for the second fiscal quarter was $28.3 million, an increase of 17 percent over the $24.2 million reported in the same period of 2011. The company

repurchased 927,709 shares of its common stock during the quarter under its previously announced stock repurchase program. The company ended the quarter with $428.3 million in cash, cash equivalents, and marketable investment securities.

Days sales outstanding for Myriad's accounts receivable improved to 32 days, compared with 37 days in the same period of the prior year. Bad-debt expense in the second fiscal quarter equaled 5.2 percent of revenue, compared with 4.2 percent in the same period of the prior year.

Total revenue for the first half of fiscal 2012 was $233.3 million, an increase of 21 percent over the $192.3 million reported for the first half of fiscal 2011. Operating income for the first half of the year was $86.9 million, an increase of 17 percent year-over-year. Net income for the first half of the fiscal year totaled $53.4 million, an increase of 14 percent year-over-year. In the first half of the year, diluted earnings per share increased 24 percent to 62 cents from 50 cents.

Outlook for 2012

Myriad has increased its expectations for fiscal year 2012 financial performance. Total revenue is now expected to be $465 million to $475 million, an increase from the previously announced expectation of $445 million to $465 million. This level of revenue is expected to result in fully diluted earnings per share of $1.24 to $1.28, up from the original guidance of $1.20 to $1.25.

Molecular diagnostic revenue is expected to range between $440 million and $450 million, and companion diagnostic service revenue continues to be expected to range between $24 million and $26 million.

Mayo Clinic Selects Complete Genomics To Provide Whole-Genome Sequencing

Complete Genomics (Mountain View, Calif.) has been selected by Mayo Clinic's Center for Individualized Medicine to provide outsourced whole-genome sequencing. Mayo Clinic researchers will now be able to employ Complete Genomics' sequencing services for some of its large-scale whole-genome sequencing projects.

The Center for Individualized Medicine operates a comprehensive sequencing laboratory in its own medical genome facility, but it determined that collaboration with Complete Genomics could supplement the services available to its community of medical researchers. Under terms of the agreement, Mayo Clinic can send genetic materials to the company for sequencing and analysis. Mayo will continue to operate and invest in its medical genome facility. Financial details of the agreement were not disclosed.

"Mayo Clinic, through the Center for Individualized Medicine, already has several high-impact genome- and epigenome-based studies under way in individualized care for our patients," said Gianrico Farrugia, M.D., director of the center. "Access to quality whole-genome sequencing services can only expedite our efforts to improve care for all of our patients with new individualized medicine tools and techniques."

LabCorp Fourth-Quarter Results Mixed; 2012 Guidance Soft

LabCorp (Burlington, N.C.) reported mixed results for the fourth quarter of 2011, with adjusted earnings per share (EPS) of $1.56 slightly above analyst's expectations, but revenues a little below the consensus estimate of $1.38 billion. Growth projections for 2012 also are lower than what analysts projected.

Revenues for the quarter were $1.366 billion, an increase of 5.5 percent over the fourth quarter of 2010. Testing volume, measured by requisitions, increased 1.2 percent, and revenue per requisition increased 4.2 percent.

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Net earnings were $135.4 million. Non-Generally Accepted Accounting Principles earnings per diluted share, excluding amortization, were $1.56 for the quarter, compared to $1.46 for the same period last year. Operating income was $247.4 million. Non-GAAP operating income excluding restructuring and other special charges recorded in the quarter was $258 million.

Operating cash flow for the quarter was $278.6 million. The balance of cash at the end of the quarter was $159.3 million, and there were $560 million of borrowings outstanding under the company's $1 billion revolving credit facility. During the quarter, the company repurchased approximately $172.1 million of stock, representing approximately 2.1 million shares. As of Dec. 31, 2011, approximately $84.4 million of repurchase authorization remained under the company's previously approved share repurchase plan.

Full-Year Results

Net earnings were $519.7 million and earnings per diluted share were $5.11 in 2011. Adjusted EPS excluding amortization were $6.37, compared to $5.98 for 2010. Results for 2011 include a full year of operations of Genzyme Genetics. Operating income was $948.4 million in 2011. Adjusted operating income was $1.06 billion, compared to $1.02 billion in 2010.

The company recorded restructuring and other special charges of $10.6 million during the fourth quarter of 2011. These charges include $6.3 million in net severance and other personnel costs, along with $1.7 million in net facility-related costs primarily associated with the integration of Orchid Cellmark and the continuing integration of Genzyme Genetics. The charges also include a $2.6 million write-off of an uncollectable receivable from a past installment sale of one of the company's lab operations. The company also recorded a net $2.8 million loss on the government-mandated divestiture of certain assets of Orchid Cellmark's government paternity business.

Revenues were $5.54 billion, an increase of 10.8 percent compared to 2010. Compared to the previous year, testing volume, measured by requisitions, increased 3.5 percent and revenue per requisition increased 7 percent.

Operating cash flow was $855.6 million and was reduced by $49.5 million as a result of the previously announced Hunter Labs settlement. During the year, the

company repurchased approximately $644 million of stock, representing about 7.4 million shares. The company announced that its board of directors has authorized a new stock repurchase program under which LabCorp may purchase up to an aggregate of an additional $500 million of its common stock.

Outlook for 2012

The company expects revenue growth of 2 percent to 3.5 percent, slightly less than consensus estimates of 4 percent. Adjusted EPS, excluding amortization, is expected to be in the range of $6.75 to $7.05. The company is projecting operating cash flow of $950 million and capital expenditures of about $155 million.

Based on this guidance, equity research firm William Blair is modeling revenue of $5.66 billion (growth of 2.2 percent) and EPS of $6.90 (growth of 8.9 percent) for 2012, down from its previous target of $5.69 billion (2.9 percent growth) and $6.95 (10.1 percent).

Analysts' Take

In a research note, William Blair says LabCorp's test volume and revenue per requisition, excluding Genzyme Genetics, were below consensus and the analyst's expectations, driven primarily by "tough volume comps relative to a year ago, as well as a mix shift toward lower-priced tests."

LabCorp reported a decelerating organic volume growth rate through 2011, notes William Blair. LabCorp's management remains conservative on volume trends for the coming year, which led to less top-line growth guidance than implied in consensus. "The company faced a difficult comp over fourth quarter 2010 (with organic growth up 3 percent)," notes William Blair. "LabCorp has also established a historical pattern of providing initially conservative guidance and exceeding expectations through the year."

The stock is trading at 13 times Blair's revised EPS estimate of $6.90 and at a free cash flow yield of 8.5 percent. Blair expects regulatory and reimbursement concern could drive volatility in the lab stocks through the course of 2012 but believes LabCorp is positioned to take advantage of positive fundamental trends in the lab in part fueled by LabCorp's balance sheet flexibility, which should drive earnings upside.

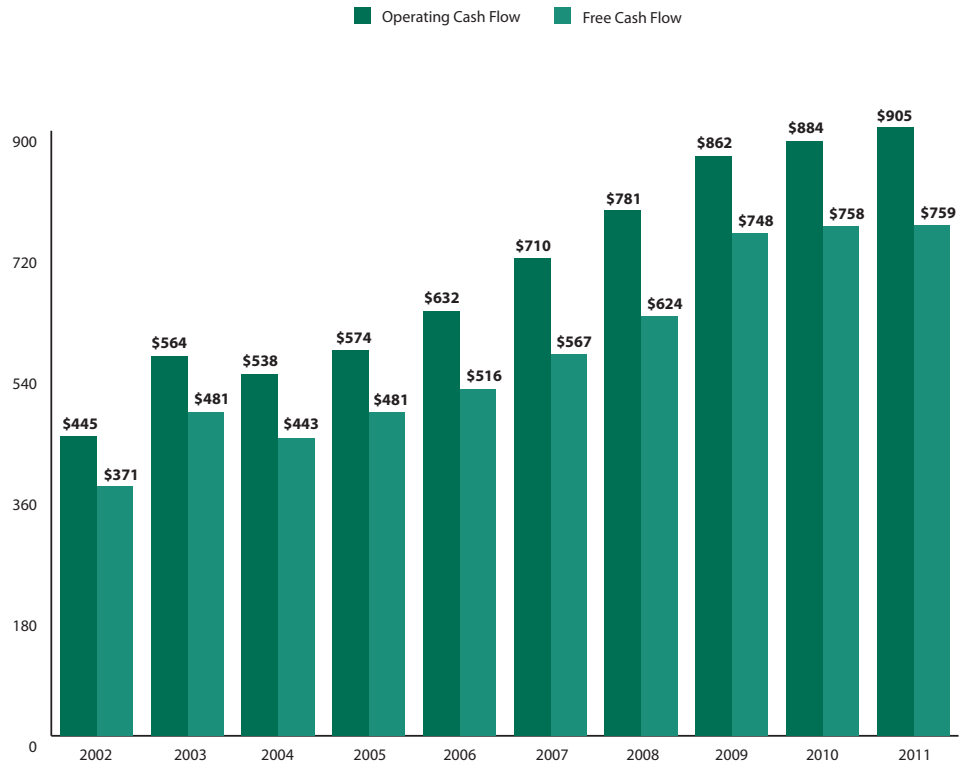
Though fourth-quarter results were mixed, Deutsche Bank (DB) maintains a positive outlook on the company. While EPS beat expectations and

LabCorp at a Glance *(in millions except earnings per share)*

	Three Months Ended Dec. 31		
	2011	2010	Change
Revenue	$1,366.10	$1,295.40	5.5%
Adjusted Operating Income	258.00	$252.40	2.2%
Adjusted EPS Excluding Amortization	1.56	1.46	6.8%
Operating Cash Flow	278.60	259.20	7.5%
Less: Capital Expenditures	(30.10)	(32.80)	-8.2%
Free Cash Flow	248.50	226.40	9.8%

Source: LabCorp

Cash Flow Growth Rate ($MM) 2002-2011



Source: LabCorp

margins demonstrated progress with regard to mergers and acquisitions integration, LabCorp's revenue growth was slightly below expectations.

"Importantly, management emphasized that its MCO [managed care organization] pricing was up sequentially (debunking the MCP pricing pressure argument) while management also noted that its volumes were stable sequentially (underscoring stability as opposed to deterioration in trend)," said DB in a research note.

Given the recent strength of the U.S. economy and labor market, DB believes there are upside risks to 2012 management's revenue growth outlook as demand picks up. However, the research company is revising its revenue growth forecast down from 4.3 percent to 3.5 percent. DB also is raising its price target to $100 from $94.

"We continue to believe [LabCorp] should be a core health care provider name for mid/large-cap investors looking for exposure to the space," writes DB. "Our investment case is underpinned by: (1) strong long-term secular growth dynamics in the U.S. diagnostics space; (2) strong market leadership and national scale as an organization; (3) robust cash flow and good long-term track record with regard to capital deployment; and (4) attractive valuation with a [free cash flow] yield of about 9 percent and [price to earnings of about 12.5x]."

■ **Congress Cuts Lab Fees by 2% Starting in 2013**, *from page 1*

staff of the House committees on Ways and Means and Energy and Commerce.

The physician fee fix—part of legislation that extends the payroll tax cut and unemployment benefits—cancels a 27.4 percent cut in Medicare physician fee schedule rates, slated to begin March 1, 2012, and freezes the rates at their current level through Dec. 31 of this year.

The lab fee cut is one of a series of offsets to pay for the fix through the rest of this year—$18 billion, according to the Congressional Budget Office (CBO). The offsets include spending reductions for other providers (among them, hospitals and nursing homes) and cuts in funding for prevention programs and other provisions under the health care reform law.

The pathology grandfather protection, set to expire Feb. 29, would get a four-month lease on life before it lapses as of June 30, 2012. The protection allows qualified independent clinical laboratories to bill Medicare directly, as opposed to billing the hospital, for the technical component of pathology services to hospital inpatients and outpatients.

According to the staff summary, "This four-month extension provides time for the labs and hospitals to establish payment arrangements. Expiration after a reasonable transition period addresses concerns that Medicare is paying twice for the same service, which causes beneficiaries to make an extra co-payment. Minimal CMS oversight of the policy has also made Medicare susceptible to making inappropriate payments. Further, the GAO has recommended that this policy expire." This provision would increase spending by less than $50 million over 10 years, according to CBO.

The American Clinical Laboratory Association (ACLA) blasted the cut to the lab fee schedule, saying that labs are being forced to bear a "vastly disproportionate share—13.5 percent—of the $20 billion needed to fix Medicare payments to doctors." Alan Mertz, ACLA president, also noted that the Patient Protection and Affordable Care Act already has reduced Medicare reimbursement for laboratory services by 19 percent over 10 years by reducing the annual consumer price index update and that the lab fee schedule has been frozen or reduced in nine of the last 10 years. G2

Medical Lab Company to Pay $6 Million To Settle Fraudulent Medicare Billing Charges

A Troy, Mich., laboratory company will pay a total of $6 million in cash and property to the U.S. government to resolve allegations that it fraudulently billed the Medicare program for tests (*United States v. Accela Medical LLC*, E.D. Mich., No. 2:10-cv-14627, 2/7/12).

U.S. Attorney Barbara McQuade said Coventry Diagnostics LLC and Western Slope Laboratory LLC were subsidiaries of Accela Medical LLC, a front company controlled by Thomas McCormick, a Troy, Mich., resident who had been barred from billing Medicare because of a previous health care fraud conviction. The

companies, the government alleged, fraudulently billed the Medicare program for lab tests, with McCormick and a co-conspirator splitting the profits of the fraud.

The fraud was detected by an analysis of billing records, which showed the labs were using a particular billing code more than any other Medicare provider in the nation, the Department of Justice (DOJ) said. Coventry and Western Slope allegedly performed the tests, which were billed using a Medicare provider number obtained by co-conspirator Charles B. Reinhardt of Tennessee, the government said.

When Medicare raised questions about the ownership and control of Accela, Reinhardt and McCormick submitted falsified documents to Medicare hiding the real ownership and control of the company, DOJ said. According to the government, the labs billed Medicare for about $900 worth of urine drug tests for virtually every patient referred to Accela by a physician, billing for 18 separate procedures for each patient to evaluate urine levels of opiates.

"This fraud was discovered by analyzing data to flag billing anomalies," McQuade said in a Feb. 7 statement. "Providers should be aware that law enforcement is scrutinizing billing records to identify providers who are stealing from taxpayers." G2

Bone Marrow Registry, Lab Company Settle Deceptive Practice Charges

A Massachusetts bone marrow registry and a medical laboratory company have agreed to pay $520,000 to settle charges that they used unfair and deceptive practices to sign up potential donors and then charged their insurers as much as $4,000 for DNA testing of mouth swabs (*Massachusetts v. Caitlin Raymond International Registry Inc.*, Mass. Super. Ct., No. 12-0421, consent judgment 2/2/12).

The two subsidiaries of UMass Memorial Health Care (UMMHC) in Worcester recruited donors at shopping malls and sporting events by using fashion models dressed as medical personnel, distributing free gifts, waiving deductibles and copayments for potential donors, and providing incentives for employees to sign up donors covered by health insurance, according to the complaint and consent judgment filed Feb. 2 in Suffolk County Superior Court.

The recruiting by Caitlin Raymond International Registry Inc. enabled UMass Memorial Health Ventures Inc. to increase the number of donor tests it performed from 7,000 in 2008 to more than 40,000 in 2010, according to the complaint filed by Massachusetts Attorney General Martha Coakley (D).

"No health care provider should be allowed to use gimmicks and free gifts to increase the volume of services covered by health plans for their own financial

gain," Coakley said in a Feb. 2 statement. The complaint alleged that the activity violated the Massachusetts Consumer Protection Act.

Under the settlement, the UMMHC system agreed not to charge health plans more than $175 over the next five years for donor testing and to pay full restitution to Massachusetts consumers for any out-of-pocket payments they previously made for donor testing.

"We accept full responsibility for the mistakes and errors in judgment that were made," said John G. O'Brien, president and chief executive officer of UMMHC. While agreeing to change its practices, the health provider said it "expressly denies" violation of any laws.

Under the settlement, the UMMHC system agreed not to charge health plans more than $175 over the next five years for donor testing and to pay full restitution to Massachusetts consumers for any out-of-pocket payments they previously made for donor testing.

The companies already have refunded close to $100,000 to consumers and "several times that amount" to reimburse health plans, according to Coakley. UMMHC cooperated with the attorney general's office and immediately halted the alleged unlawful practices once the investigation began, she said.

ALJ: Lab's Certificate Properly Revoked For Misrepresenting Test Volume

An administrative law judge (ALJ) for the Department of Health and Human Services Departmental Appeals Board Jan. 17 affirmed a Centers for Medicare and Medicaid Services ruling revoking a clinical lab's certificate for misrepresenting its annual testing volume and its authority to perform tests not covered by its certificate (*Huntington Beach Clinical Laboratory Inc. v. CMS*, Departmental Appeals Bd., Civil Remedies Div., Dec. No. CR2490, 1/17/12).

While the lab was only certified under the Clinical Laboratory Improvement Amendments of 1988 to perform urinalysis, endocrinology, and toxicology, it billed Medicare for 120,782 tests from February to June 2010, more than 14 times the 8,500 tests it said it would perform, 92 percent of which were outside its certificate.

Supposedly, just two individuals performed all the tests. Neither the lab nor its owner appealed the revocation, but lab director Howard Pfupajena, M.D., argued that he should not be sanctioned because he resigned from his position as director before the lab lost its certification.

ALJ Carolyn Cozad Hughes disagreed, finding the billing documents for the unauthorized testing showed that it occurred between February and June 2010, when Pfupajena admitted he was the director. The fact that he managed to tender a resignation letter a few weeks before CMS sent its first notice, on Sept. 3, 2010, does not make him less accountable for the rule violations that occurred on his watch, she said.

Lab Index Rises 8% in Last Four Weeks

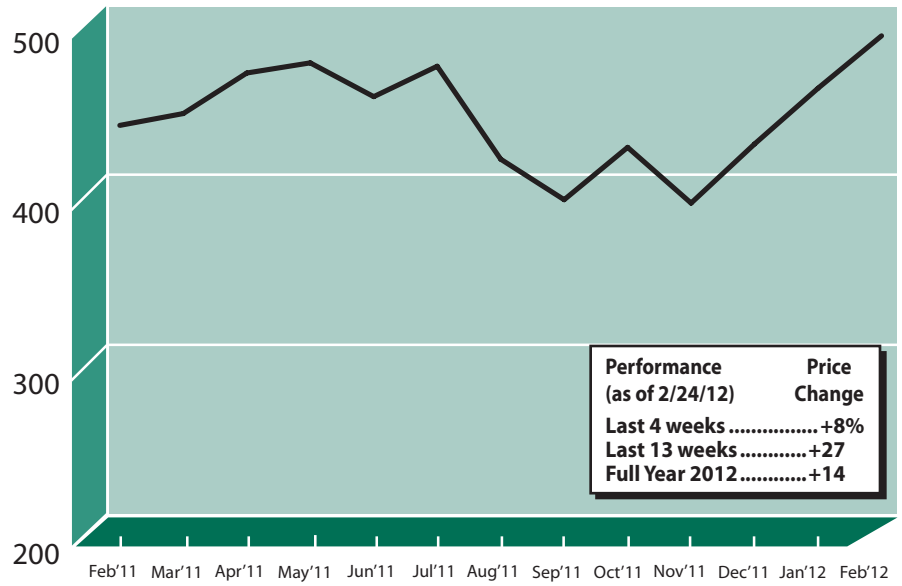
The G2 Intelligence Laboratory Stock Index climbed 8 percent in the four weeks ended Feb. 24, 2012, with seven stocks rising in price and two unchanged. Since the beginning of the year, the index has risen 14 percent. In comparison, the Nasdaq composite is up almost 14 percent, and the S&P 500 is up 9 percent.

Enzo Biochem (New York) climbed 22 percent to $2.86. The company recently announced that the New York State Department of Health has approved the company's use of the ColonSentry test for providing an assessment of a patient's risk of having colorectal cancer. The ColonSentry test was originally developed by GeneNews and requires only a small blood sample that can be collected during a routine blood draw. The test uses RNA contained in blood to measure the level of the expression of seven genes that serve as biomarkers for the disease. Enzo plans to begin offering the assay to its clientele in March 2012.

Shares of **Neogenomics** (Fort Myers, Fla.) rose 11 percent to $1.66. The company recently reported that revenue for the fourth quarter of 2011 was $12.9 million, a 47 percent increase over the same period the previous year. Test volume increased by 57 percent, and average revenue per test declined by 6 percent. Requisitions increased by 48 percent, and the average number of tests per case increased by 6 percent. For 2012, the company expects revenue of $54 million to $59 million and net income of 2 cents to 4 cents per share.

Psychemedics (Acton, Mass.) shares rose 2 percent to $9.91. The company reported that revenues for 2011 were $24.1 million, an increase of 20 percent over 2010. Net income for the year was $3.5 million, or 67 cents per share, an increase of 34 percent over the previous year. The company also announced an increase in the quarterly dividend to 15 cents per share. G2

G2 Laboratory Stock Index



Source: The G2 Laboratory Stock Index is tabulated weekly by Laboratory Industry Report *from the average percentage change of 9 laboratory testing service stocks.*

Percent Price Change, As of 2/24/2012

	Price	Percent Change
UP		
Bio-Reference	$20.29	11%
Enzo Biochem	2.86	22
Genomic Health	28.92	6
Medtox	16.81	1
Myriad Genetics	23.87	7
Psychemedics	9.91	2
Neogenomics	1.66	11
NO CHANGE		
LabCorp	89.08	NC
Quest	57.24	NC

INDUSTRY BUZZ

Quest Cuts Quarter of S.E.D. Staff

Quest Diagnostics (Madison, N.J.) is laying off a quarter of S.E.D. Medical Laboratories' 450-person staff over the next six months. Quest bought S.E.D. earlier this year. Most of the 125 layoffs are expected to occur at the lab's main office in Albuquerque, N.M.

"When we acquired S.E.D. Medical Laboratories in early January, we knew there were opportunities to drive efficiencies in the business, and as a result, we told employees that some initial job losses were to be expected," Quest said in a prepared statement. "It has taken six weeks to do a thorough analysis of the business, identify plans for the future, and develop the package of benefits that would enable us to treat impacted colleagues with fairness, dignity, and respect."

When the layoffs are completed, S.E.D. will have 325 employees working at 20 locations in the state. Quest officials said the decision to lay off employees was difficult, but that they are committed to making the process "as smooth and as dignified as possible." Affected employees are being offered competitive severance packages and outplacement services, as well as opportunities to relocate to one of Quest Diagnostics' other facilities nationally, said officials.

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References

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LabCorp
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Mayo Clinic
507-284-2511

Myriad Genetics
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Neogenomics
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Psychemedics
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Quest
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