



# LABORATORY



# ECONOMICS

*Competitive Market Analysis For Laboratory Management Decision Makers*

## FLORIDA LABS MAY BE NEXT TARGET FOR MEDICAID PRICING LAWSUIT

Quest Diagnostics has paid \$241 million to settle a lawsuit that alleged it overcharged Medi-Cal for lab services. And LabCorp recently announced an agreement in principal to pay \$49.5 million to resolve the California lawsuit. Seven other labs—Health Line Clinical Labs, Westcliff Medical Labs, Physicians Immunodiagnostic Lab, Primex Clinical Labs, Stanford Medical Labs, Whitefield Medical Lab and Seaciff Diagnostics—have also reached final or tentative settlement agreements.

But legal disputes focused on lab test pricing for Medicaid programs are far from over. In fact, California whistleblower Chris Riedel and his law firm Cotchett, Pitre & McCarthy may have already filed similar lawsuits in other states with *qui tam* provisions and “lowest charge” rules for Medicaid. Florida fits both of these qualifications, and *Laboratory Economics* believes it is likely to be the next legal battleground. *Continued on pages 3-4.*

## NO NEW REGS FOR IN-OFFICE LABS PROPOSED FOR 2012

The Centers for Medicare and Medicaid Services’ Part B physician fee schedule proposal for next year includes no new rules for in-office pathology labs. In fact, in-office pathology labs were not mentioned at all in the agency’s 621-page document released on July 1. This means that urology, gastroenterology and dermatology groups will continue to build in-office histology labs to capture pathology technical and professional fees. This trend is hurting all pathology labs, including the national labs, hospital-based labs and local pathology groups. *Continued on page 5.*

## BOSTWICK LABS GETS \$43 MILLION LOAN

Bostwick Laboratories (Richmond, VA) has closed on a \$43 million senior secured loan from Healthcare Finance Group LLC (New York City). The loan is part of a restructuring underway at Bostwick Labs after a decade of rapid growth and expansion. *Continued on page 5.*

## LIPOSCIENCE FILES FOR \$86 MILLION IPO

LipoScience Inc. (Raleigh, NC) has filed plans to sell up to \$86.25 million worth of shares in an initial public offering (IPO). The company wants the money to expand marketing of its NMR LipoProfile, a blood test that measures the level of bad cholesterol to check for heart disease risk. The IPO will be managed by Barclays Bank, UBS Investment Bank and Piper Jaffray. *Continued on page 2.*

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**LIPOSCIENCE FILES FOR \$86 MILLION IPO** (*cont'd from page 1*)

LipoScience first filed IPO plans in early 2002, but withdrew them after failing to attract enough demand from Wall Street. Investor interest waned after LipoScience lost its biggest client, Quest Diagnostics, in late 2002 and the company's revenue dipped.

But LipoScience has rebounded. The company has recorded average annual revenue growth of 13% between 2006 and 2010. Over the same time frame, the number of NMR LipoProfile tests ordered increased by approximately 30% per year to reach 1.1 million tests in 2010.

In the three months ended March 31, 2011, LipoScience recorded a net loss of \$745,000 versus a net profit of \$28,000 in the same period a year earlier; revenue increased by 12.5% to \$10.5 million.

The overall number of NMR LipoProfile tests increased by 31.6% to 327,000 tests for the three months ended March 31, 2011, while the average selling price decreased 9.8% to \$29.40. Medicare reimburses the test under CPT code 83704 at a national cap of \$44.40.

LipoScience's biggest customer is now LabCorp, which accounted for 32% of the company's revenue in the first quarter of 2011. Its second-largest customer is Health Diagnostics Laboratory (Richmond, VA), which accounts for 15% of revenue.

LipoScience performs its NMR LipoProfile exclusively at its CLIA-certified lab in Raleigh, North Carolina. The test measures the number of low density lipoprotein, or LDL, particles for use in managing cardiovascular disease risk.

Among LipoScience's competitors are Berkeley HeartLab (San Francisco, CA), now part of Quest Diagnostics, as well as Atherotech (Birmingham, AL) and SpectraCell Laboratories (Houston, TX).

LipoScience has 160 employees, including 64 sales and marketing employees focused on 23 states.

LipoScience plans to use proceeds from the IPO to expand its salesforce. In addition, the company is developing an automated analyzer, the Vantera system, to decentralize NMR LipoProfile testing to other labs. The company anticipates submitting a 510(k) to the FDA by the end of 2011, with a goal of making Vantera commercially available in 2012.

Founder and chief scientific officer James Otvos, 63, has an 8.6% stake in LipoScience. Chief executive Richard Brajer, 50, owns 6.2%. The private equity firm Three Arch Capital (Portola Valley, CA) holds a 19% stake.

**LipoScience at a Glance (\$'000)**

|                      | <b>2010</b> | <b>2009</b> | <b>2008</b> | <b>2007</b> | <b>2006</b> | <b>4-Year<br/>CAGR</b> |
|----------------------|-------------|-------------|-------------|-------------|-------------|------------------------|
| Revenue              | \$39,368    | \$34,713    | \$28,954    | \$24,758    | \$24,305    | 12.8%                  |
| Pretax income        | 4,296       | 260         | -3,634      | -5,492      | -6,103      | NA                     |
| Net income           | 920         | -782        | -4,674      | -6,532      | -6,530      | NA                     |
| Total debt           | 1,200       | 3,000       | 2,000       | 187         | 2,642       | -17.9%                 |
| Cash & securities    | 11,058      | 12,045      | 9,889       | 10,179      | 14,942      | -7.3%                  |
| Shareholder's equity | -40,632     | -44,385     | -43,990     | -39,542     | -33,267     | NA                     |

Source: LipoScience

## FLORIDA LABS MAY BE NEXT TARGET *(cont'd from page 1)*

The Medi-Cal lawsuit settlements total roughly \$300 million, including \$241 million from Quest, \$49.5 million from a pending LabCorp settlement and \$5.3 million from Westcliff Medical Labs (now owned by LabCorp). As whistleblower, Chris Riedel's share of the settlements will come in at more than \$75 million, including \$70 million from his share of the Quest settlement.

In addition to California, Riedel and his law firm Cotchett, Pitre & McCarthy have filed "lowest charge" lawsuits in six other states: Florida, Georgia, Massachusetts, Michigan, Nevada and Virginia.

Some people in the lab industry view Riedel as a crusader out to rehabilitate the pricing practices of the national labs. "Quest got what they deserved—I'm sorry it wasn't a bigger settlement," says a hospital outreach lab director from northern California. Others see Riedel as an opportunist. "He never made a lot of money operating labs, but he's made a lot suing them," says an independent lab executive from southern California.

Irrespective of your opinion on Riedel, more "lowest charge" Medicaid lawsuits are coming. Although Quest Diagnostics vehemently denied it violated California's "lowest charge" rule, it did pay a huge settlement and LabCorp is expected to do the same.

"The Medi-Cal lawsuit has set a precedent. ... All the heavy lifting has been done for the next state that wants to pursue a similar lawsuit," notes an independent lab executive from California.

The question is which state's attorney general's office, if any, will be the first to announce that they have joined one of Riedel's lawsuits? *Laboratory Economics* believes it will be Florida because:

### MEDICAID IS A BUDGET BUSTER

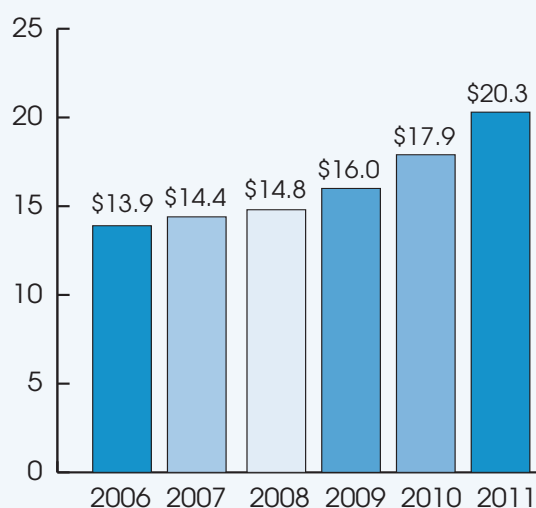
Medicaid has grown to the point that it now eats up nearly one-third of Florida's overall budget, costing the state \$20 billion per year. Medicaid expenditures have increased by an average of 8% per year in the five years ended June 30, 2011. Florida covers three million Medicaid recipients making it the fourth largest state after California, New York and Texas.

### DEEP-POCKET TARGETS

Quest Diagnostics and LabCorp are the two biggest lab companies in Florida, as well as the nation. Any potential "lowest charge" lawsuit will target their deep pockets. The Florida Medicaid program spends an estimated \$75 million per year on independent lab services, with the majority going to Quest and LabCorp.

Florida Medicaid's estimated \$75 million per year of spending on independent lab services makes it the biggest state among the six states where lawsuits have been filed. Obviously, Riedel and his lawyers want to put their resources on the states that would offer the highest potential reward.

Growth in Florida Medicaid Spending  
(\$ billions)



Source: Florida Agency for Health Care Administration

A key question is: Which other labs in Florida might be named in a “lowest charge” lawsuit? Several defendants in California’s Medi-Cal lawsuit were small independent labs. One reason California picked these small labs was so that it didn’t look like the state was only targeting the national labs.

### States with “Lowest Charge” Medicaid Lawsuits

| State         | Lowest Charge Rule | Whistleblower Provision | Medicaid Recipients | Independent Lab Expenditures* |
|---------------|--------------------|-------------------------|---------------------|-------------------------------|
| California    | Yes                | Yes                     | 7.7M                | \$200M                        |
| Florida       | Yes                | Yes                     | 3.0M                | 75M                           |
| Michigan      | Yes                | Yes                     | 2.0M                | 50M                           |
| Georgia       | Yes                | Yes                     | 1.7M                | 40M                           |
| Massachusetts | Yes                | Yes                     | 1.2M                | 30M                           |
| Virginia      | Yes                | Yes                     | 0.8M                | 20M                           |
| Nevada        | Yes                | Yes                     | 0.3M                | 7M                            |

\*Estimated annual Medicaid expenditures on independent labs

Source: *Laboratory Economics*

### LOWEST CHARGE RULE

The Florida Medicaid Provider General Handbook states: “The provider’s charges for services billed to Medicaid must not exceed the provider’s lowest charge to any other third-party source for the same or equivalent medical and allied care, goods, or services provided to individuals who are not Medicaid recipients.”

Florida’s Medicaid program has a clinical lab fee schedule that is set at slightly below 70% of Medicare Part B lab fees (*see table below*). However, both the Medicare and Medicaid lab fee schedules are meant to serve as an upper limit to what labs can charge for tests, rather than set the standard for how much to bill.

### Medicare vs. Florida Medicaid Lab Reimbursement for 12 Key Codes

| CPT Code                     | National Medicare Fee Schedule | Florida Medicaid Fee Schedule | Difference  |
|------------------------------|--------------------------------|-------------------------------|-------------|
| 85025 (CBC)                  | \$10.94                        | \$8.00                        | -27%        |
| 84443 (TSH)                  | \$23.64                        | \$17.50                       | -26%        |
| 80053 (metabolic panel)      | \$14.87                        | \$10.00                       | -33%        |
| 80061 (lipid panel)          | \$18.85                        | \$9.50                        | -50%        |
| 83970 (parathormone)         | \$58.08                        | \$40.50                       | -30%        |
| 83036 (A1C)                  | \$13.66                        | \$9.50                        | -30%        |
| 82306 (vitamin D)            | \$41.66                        | \$30.00                       | -28%        |
| 85610 (prothrombin time)     | \$5.53                         | \$3.50                        | -37%        |
| 84153 (PSA)                  | \$25.89                        | \$21.50                       | -17%        |
| 80048 (metabolic panel)      | \$11.91                        | \$8.00                        | -33%        |
| 80069 (renal function panel) | \$12.22                        | \$8.00                        | -35%        |
| 80051 (electrolyte panel)    | \$9.87                         | \$6.50                        | -34%        |
| <b>Average</b>               |                                |                               | <b>-32%</b> |

Source: CMS and Florida Agency for Health Care Administration

**NO NEW REGS FOR IN-OFFICE LABS** (*cont'd from page 1*)

The proposed rule is the first step in an annual process intended to update Medicare Part B payment policies and rates. The comment period on the proposed rule is open for 60 days. CMS is scheduled to issue a final rule by November 1 that will apply to calendar-year 2012.

The American Society for Clinical Pathology and the College of American Pathologists have been vigorously lobbying for changes that would restrict or outlaw in-office pathology labs. They argue that profiting on patient referrals distorts medical decisions and leads to overutilization.

In the meantime, specialty groups continue to build on-site histology labs.

Recent examples include:

- ❑ **The Center for Digestive and Liver Health** (Savannah, GA), which includes eight gastroenterologists.
- ❑ **The Urology Center** (New Haven, CT), which has six urologists.
- ❑ **Fort Wayne Dermatology Consultants** (Fort Wayne, IN), which has seven dermatologists.

“We are disappointed that CMS chose not to address the in-office lab issue and will continue to address the issue in our comments to the agency,” says JoAnne Glisson, senior vice president at the American Clinical Laboratory Association.

**BOSTWICK LABS GETS \$43 MILLION LOAN** (*cont'd from page 1*)

The \$43 million loan is comprised of a \$20 million revolving line of credit, a \$15 million senior secured term loan and a second senior secured term loan for \$8 million. The purpose of the financing was to refinance certain components of the company’s existing capital structure, including a revolving line of credit, term loans and an interest rate swap, according to a press statement from Bostwick Labs.

Gregory Geisz, Bostwick’s vice president of finance, stated that, “The continued growth of our company requires a lender that understands our current and future needs for capital, the health-care regulatory environment and the surrounding issues that accompany the growth we expect.”

Meanwhile, Bostwick Labs is consolidating its operations and has put several of its lab buildings up for sale, including buildings in Tempe, Arizona; Nashville, Tennessee; and Long Island, New York. Unfortunately these lab facilities were all purchased at the height of the real estate boom in 2007 and 2008. It’s unlikely that the company will be able to sell these properties for anything near its original purchase prices.

**Buildings for Sale by Bostwick Labs**

| <i>Location</i>       | <i>Purchase Date</i> | <i>Purchase Price</i> | <i>Square Feet</i> | <i>Asking Price</i> |
|-----------------------|----------------------|-----------------------|--------------------|---------------------|
| Tempe, AZ .....       | August 2007 .....    | \$9.45 M.....         | 75,000.....        | \$9.45 M            |
| Nashville, TN .....   | January 2008 .....   | \$2.10 M.....         | 41,128.....        | \$2.75 M            |
| Long Island, NY ..... | March 2007 .....     | \$14.80 M.....        | 74,000.....        | \$14.8 M            |
| Total .....           |                      | \$26.35 M.....        | 190,128.....       | \$27.0 M            |

Source: Laboratory Economics from broker listings

## SOLSTAS BUYS THREE MORE LABS

Solstas Lab Partners (Greensboro, NC), the for-profit lab company that was formed last year by the merger of Carilion Clinic's lab business and the larger Spectrum Laboratory Network, has acquired three North Carolina lab companies: Select Diagnostics, NextWave Diagnostics and Wilmington Pathology Lab. With these acquisitions, Solstas now employs about 3,500 and has estimated annual revenue of nearly \$400 million.

Here are the highlights for the three acquisitions, all completed in June and July:

- ❑ **Select Diagnostics** (Greensboro, NC) was founded in 2001 by its president Ernie Knesel. Select operates two large labs in Greensboro and Raleigh, North Carolina, and a smaller lab in Lexington, Virginia. Select also manages an in-office pathology lab for Alliance Urology Specialists, a urology practice with 12 doctors based in Greensboro. Select has approximately 130 employees and estimated annual revenue of more than \$15 million.
- ❑ **NextWave Diagnostic Laboratories** (Wilmington, NC) is a clinical lab formed by several principals at Wilmington Pathology Associates. NextWave has estimated annual revenue of more than \$5 million.
- ❑ **Wilmington Pathology Laboratory** (Wilmington, NC) is the technical lab that provides service to Wilmington Pathology Associates. The WPL acquisition comes with a long-term deal to provide exclusive services to the seven-pathologist WPA group, which remains independent.

## FOOD GIANT NESTLE TO BUY PROMETHEUS LABS

Nestlé Health Science, a new subsidiary of Switzerland's Nestlé S.A., has agreed to acquire Prometheus Laboratories (San Diego, CA). This peculiar deal is expected to close this month. Financial terms have not been disclosed, but Zurich-based analyst Jean-Philippe of Bank Vontobel estimates that Nestlé is paying between \$567 million and \$1.1 billion.

Prometheus, which sells specialty drugs and lab testing services focused on gastrointestinal diseases, reported net income of \$48.2 million on revenue of \$519 million in 2010.

However, Prometheus's revenue is expected to nose dive to \$250 million in 2012. That's because its distribution agreement with AstraZeneca to sell EntoCort EC will expire at the end of this year. Sales of EntoCort EC, a prescription drug used to treat Crohn's disease, currently account for 61% of Prometheus's overall revenue.

Nestlé, with over \$100 billion in annual revenue, is the world's number one food company. Its best-known brands include Carnation instant milks, DiGiorno frozen pizza, Gerber baby food, Fancy Feast and Purina pet foods, Nescafe coffee, Poland Spring bottled water, Toll House cookies, and Butterfinger and Nestlé Crunch candy bars.

Nestlé formed Nestlé Health Science in January 2011 with the goal of linking food and pharmaceuticals to create nutritional products to treat chronic health conditions such as diabetes, obesity and cardiovascular disease.

"This acquisition is a strategic move into gastrointestinal diagnostics. Prometheus's leading-edge diagnostics and highly experienced medical sales representatives together constitute a robust

platform for Nestlé Health Science to accelerate its current and future healthcare business. It will enable new personalized healthcare solutions based on diagnostics, pharma and nutrition,” according to Luis Cantarell, president of Nestlé Health Science.

Laboratory testing accounts for about 20% of Prometheus’s total revenue. The company’s highest revenue generating test is its IBD Serology 7. This panel of tests, which has not been cleared by FDA, helps identify inflammatory bowel disease (IBD) and differentiates between ulcerative colitis and Crohn’s disease. IBD Serology 7 incorporates seven tests, including three patented biomarkers and a proprietary pattern-recognition algorithm. Prometheus performs this test at its CLIA-certified lab in San Diego and bills by stacking two CPT codes (CPT 83520 x 5 and CPT 88347 x 2) for a list price of \$445.

Prometheus markets its pharmaceutical products and lab tests directly to gastroenterologists through a sales force of more than 100 reps.

Prometheus was founded in 1995 with equity funding from DLJ Merchant Banking Partners, Split Rock Partners, Sprout Group, Apax Partners, Pamlico Capital (formerly Wachovia Capital Partners) and Brentwood Venture Capital. Prometheus had filed for an IPO in December 2007 (see *LE*, January 2008, p. 10), but was never able to complete the deal.

### Prometheus Laboratories at a Glance (\$000)

|                 | 2010      | 2009      | 2008      | 2007      | 2006      | 4-Year<br>CAGR |
|-----------------|-----------|-----------|-----------|-----------|-----------|----------------|
| Total Revenue   | \$518,972 | \$341,503 | \$278,058 | \$220,940 | \$187,411 | 29.0%          |
| Pharmaceuticals | 434,655   | 256,777   | 195,985   | 143,655   | 119,150   | 38.2%          |
| Lab testing     | 81,291    | 84,422    | 82,073    | 77,285    | 68,261    | 4.5%           |
| Other revenue   | 3,026     | 304       | 0         | 0         | 0         | NA             |
| Pretax income   | 86,735    | 58,034    | 60,265    | 26,611    | 54,513    | 12.3%          |
| Net income      | 48,215    | 32,092    | 37,225    | 4,318     | 32,239    | 10.6%          |

Source: Prometheus Laboratories

## US CLINICAL LABS ACQUIRES GEORGIA LAB

**U**S Clinical Laboratories (Houston, TX) has purchased Vidalia Lab Services (Vidalia, GA) for an undisclosed sum. VLS specializes in lab testing for nursing homes in southern Georgia. VLS president and founder Riley McDonald will remain as president and will manage an expansion throughout Georgia and into new customer markets, such as hospitals, according to Rod Proto, chief executive of US Clinical Labs.

US Clinical Labs was formed in 2009 by Proto and chief operating officer J.R. Meszaros. The two founders also provided the start-up capital.

VLS is the second acquisition for US Clinical Labs. The company acquired Elite Clinical Labs (Houston, TX) in July 2010.

US Clinical Labs now has a total of 50 employees and estimated annual revenue of about \$5 million.



## AGENDIA PULLS IPO CITING WEAK MARKET CONDITIONS

Dutch company Agendia Inc., which markets the proprietary breast cancer test MammaPrint, has canceled a planned initial public offering because of weak stock market conditions. The company had hoped to raise approximately 75 million euros (US \$107 million) and list its shares on the Euronext stock exchange in Amsterdam.

Agendia had planned to spend the IPO proceeds on expanding its sales and marketing in the United States, as well as to complete clinical validation and begin commercialization of ColoPrint, its new colon cancer recurrence test.

Last year, Agendia reported a net loss of 16.1 million euros (US \$23.1 million) on revenue of 4.7 million euros (US \$6.7 million). The company has incurred aggregate losses of more than 50 million euros (US \$72 million) since being founded in 2003 as a spin-off of the Netherlands Cancer Institute.

Without the IPO, Agendia will need to find alternative sources of capital to fund its business.

To date, Agendia's primary source of liquidity has been private equity investors. The company has raised 75 million euros (US \$107 million) over the past eight years. Its major shareholders include Van Herk (29% stake), ING Corporate Investments (16%), Gilde Healthcare (14%) and founding management team members.

Agendia's lead product, MammaPrint, is used to assess whether a breast cancer patient will need hormonal therapy, chemotherapy and other therapies. The test analyzes 70 genes to separate early-stage patients into high and low risk groups, so that unnecessary forms of treatment can be avoided. MammaPrint, which has a list price of \$4,250, is currently the only molecular diagnostic test for breast cancer approved by the FDA. The test is performed at Agendia's CLIA-certified labs in Irvine, California and Amsterdam, The Netherlands.

Agendia's main competitor is Genomic Health (Redwood City, CA), which markets the OncotypeDx 21-gene breast cancer recurrence test at a list price of \$3,975. Although OncotypeDx lacks FDA clearance, its market share dwarfs MammaPrint.

Genomic Health reported net income of \$4.3 million from revenue of \$178.1 million in 2010.

### Agendia vs. Genomic Health

|                       | <i>Agendia Inc.</i>                               | <i>Genomic Health</i>                          |
|-----------------------|---|--|
| Primary test product  | MammaPrint 70-gene assay                          | OncotypeDx 21-gene Recurrence Score            |
| Test list price       | \$4,250   | \$3,975  |
| Type of tissue sample | Fresh/frozen                                      | FFPE   |
| Technology            | DNA microarrays                                   | Q-RT-PCR                                       |
| CLIA-certified lab    | Yes   | Yes  |
| FDA clearance         | Yes   | No   |
| Indication            | Stage I-II disease, tumor size 5cm, node-negative | Stage I-II disease, ER-positive, node-negative |
| Availability          | US/Europe   | US/Europe                                      |
| # Sales reps          | 39  | 150  |
| Revenue 2010          | \$6.7M  | \$178.1M                                       |
| Net income            | -\$23.1M  | \$4.3M   |

Source: *Laboratory Economics* from Agendia and Genomic Health

## MEDICARE SPENDING ON MOLECULAR DX UP 37% PER YEAR

Medicare Part B carrier spending on 21 molecular diagnostic codes (CPT 83890-83914) grew by an average annual rate of 37% between 2006 and 2009, according to an analysis of claims data by *Laboratory Economics*. In comparison, Medicare Part B carrier spending on routine clinical lab tests grew by 9.2% during the same time period (see *LE*, March 2011, pages 1, 9).

The 21 molecular diagnostic codes have become controversial because they are used in “code stacking.” This billing process involves using a series of CPT codes to describe a molecular test that does not have a specific designated code. But code stacking makes it difficult for payers to know exactly what is being tested and what they are reimbursing.

The American Medical Association is in the process of developing new CPT codes for molecular diagnostic testing with the goal of eliminating code stacking by the end of 2013.

However, despite the rapid growth in spending on CPT codes 83890-83914, Part B carrier spending on these codes totaled only \$64.4 million in 2009.

### MEDICARE PART B CARRIER SPENDING ON MOLECULAR DIAGNOSTICS

| CPT Code | Short Descriptor             | 2009 Payment | 2006 Payment | 3-Year CAGR* |
|----------|------------------------------|--------------|--------------|--------------|
| 83890    | Molecule isolate             | \$124,669    | \$80,648     | 15.6%        |
| 83891    | Molecule isolate nucleic     | \$1,309,872  | \$492,823    | 38.5%        |
| 83892    | Molecular diagnostics        | \$2,152,883  | \$929,436    | 32.3%        |
| 83893    | Molecule dot/slot/blot       | \$265,334    | \$183,235    | 13.1%        |
| 83894    | Molecule gel electrophor     | \$338,010    | \$270,743    | 7.7%         |
| 83896    | Molecular diagnostics        | \$5,549,915  | \$2,882,247  | 24.4%        |
| 83897    | Molecule nucleic transfer    | \$3,624      | \$4,210      | -4.9%        |
| 83898    | Molecule nucleic ampli, each | \$19,718,989 | \$8,160,297  | 34.2%        |
| 83900    | Nuclear antigen antibody     | \$1,633,173  | \$532,599    | 45.3%        |
| 83901    | Immunoassay, tumor qual      | \$2,694,435  | \$595,890    | 65.4%        |
| 83902    | Molecular diagnostics        | \$859,254    | \$293,921    | 43.0%        |
| 83903    | Molecule mutation scan       | \$3,710,930  | \$1,869,290  | 25.7%        |
| 83904    | Molecule mutation identify   | \$13,735,544 | \$6,766,397  | 26.6%        |
| 83905    | Molecule mutation identify   | \$10,480     | \$12,541     | -5.8%        |
| 83906    | Molecule mutation identify   | \$1,022      | \$2,313      | -23.8%       |
| 83907    | Lyse cells for nucleic ext   | \$393,597    | \$18,029     | 179.5%       |
| 83908    | Nucleic acid, signal ampli   | \$705,222    | \$237,991    | 43.6%        |
| 83909    | Nucleic acid, high resolute  | \$6,974,337  | \$281,851    | 191.4%       |
| 83912    | Genetic examination          | \$2,259,433  | \$1,105,438  | 26.9%        |
| 83913    | Molecular, rna stabilization | \$192,377    | NA           | NA           |
| 83914    | Mutation ident ola/sbce/aspe | \$1,775,775  | \$293,479    | 82.2%        |
|          | <b>Total, 21 Test Codes</b>  | \$64,408,875 | \$25,013,375 | 37.1%        |

\*CAGR=compound annual growth rate

Note: The BESS files include data for outpatient laboratory services billed by independent labs, physician offices, a limited number of hospital outpatient labs, and any other provider whose claims are processed by Medicare Part B carriers. It does not include claims processed and paid by Medicare Part A intermediaries to facilities such as hospitals and nursing homes.

Source: *Laboratory Economics* from CMS's Part B Extract and Summary System (BESS), 2006-2009; CPT codes © American Medical Association.

## MORE COST CUTS AT QUEST DIAGNOSTICS AS PROFITS DROP

Quest Diagnostics has announced a cost-cutting initiative to take \$500 million out of its cost structure over the next three years. The latest plan follows a similar \$500 million cost-cutting plan that Quest undertook between 2007 and 2009.

The new round of cost cutting comes as Quest reported net income of \$109.3 million for the six months ended June 30, 2011, down sharply from \$357.1 million in the same period last year. Profit was decreased by Quest's recent Medi-Cal settlement payment of \$241 million. Revenue was up 1.2% to \$3.725 billion. However, revenue was down slightly after adjusting for the acquisitions of Athena Diagnostics and Celera Corp.

On July 20 conference call with analysts and investors, chief executive Surya Mohapatra, PhD, said Quest's anatomic pathology business continues to be hurt by physician in-sourcing of histology labs, especially at dermatology groups. Separately, Mohapatra noted that neither he nor the company's board of directors has given a notice of non-renewal for his employment contract which runs through December 31, 2011.

### Quest Diagnostics Mid-Year 2011 Financial Summary (\$ Millions)

|                               | First-Half 2011 | First-Half 2010 | % Chg |
|-------------------------------|-----------------|-----------------|-------|
| Revenue                       | \$3,724.8       | \$3,680.2       | 1.2   |
| Pretax income                 | 280.8           | 606.4           | -53.7 |
| Net income                    | 109.3           | 357.1           | -69.4 |
| Diluted EPS                   | 0.68            | 1.96            | -65.3 |
| Requisition volume            | 73.8            | 73.1            | 1.0   |
| Overall price per req.        | 46.12           | 46.12           | 0.0   |
| Days sales outstanding (DSOs) | 54              | 42              | 31.0  |
| Bad-Debt %                    | 3.9%            | 4.0%            | -2.5  |

Source: Quest Diagnostics  
(requisition volumes and prices are estimated by *Laboratory Economics*)

## LABCORP AT MID-YEAR: PROFITS DOWN; REVENUE UP 14%

LabCorp (Burlington, NC) reported net income of \$250 million for the six months ended June 30, 2011, down 12.7% from \$286.4 million in the same period last year; revenue was up 14% to \$2.772 billion. Revenue growth was an estimated 2% after adjusting for the numerous acquisitions made over the past year, including Genzyme Genetics, FirstSource Laboratory, DCL Medical Labs and Westcliff Medical Labs. For full-year 2011, LabCorp expects revenue growth of about 10.5% (including the benefit of acquisitions).

On July 20 conference call with analysts and investors, chief executive Dave King noted that the insourcing of histology labs at some specialty groups [urology and gastroenterology] was leveling off; however, other specialties [dermatology] had begun "exploring" insourcing.

### LabCorp Mid-Year 2011 Financial Summary (\$ Millions)

|                               | First-Half 2011 | First-Half 2010 | % Chg |
|-------------------------------|-----------------|-----------------|-------|
| Revenue                       | \$2,771.7       | \$2,432.0       | 14.0  |
| Pretax income                 | 421.0           | 483.1           | -12.9 |
| Net income                    | 250.0           | 286.4           | -12.7 |
| Diluted EPS                   | 2.44            | 2.70            | -9.6  |
| Requisition Volume            | 62.2            | 59.0            | 5.4   |
| Overall price per req         | 44.59           | 41.21           | 8.2   |
| Days sales outstanding (DSOs) | 46              | 45              | 2.2   |
| Bad-Debt %                    | 4.7%            | 4.9%            | -4.1  |

Source: LabCorp

## MAYO PARTNERS WITH CHINESE LAB KINDSTAR

Mayo Clinic (Rochester, MN) has signed a multiyear agreement with Wuhan Kindstar Globalgene Technology Inc. (Kindstar) to provide advanced esoteric testing services. Kindstar operates labs in Wuhan, Beijing, and Shanghai.

The Chinese government does not allow lab specimens to leave their country, so Mayo sees its service as more knowledge-based. “Kindstar has an excellent and highly schooled workforce,” says Franklin Cockerill, MD, president and chief executive at Mayo Medical Labs. “The partnership was especially attractive to us because of similarities we share with Kindstar.” Mayo Clinic is a physician-run organization. Shiang Huang, MD, founder and chief executive of Kindstar, is a physician who actively practices at Wuhan Union Hospital.

Kindstar, which has a test menu of 750 tests, provides reference testing services to about 2,000 hospital clients across China. Mayo’s test menu includes more than 2,700 tests. It will help Kindstar’s expand its menu in highly specialized categories. “We could easily be transferring hundreds of tests,” says David Herbert, chief administrative officer of Mayo Medical Labs. He says Mayo will build on Kindstar’s existing expertise in China and “leap frog quickly” as opposed to trying to build their own presence from the ground up.

Mayo will be paid for its services by Kindstar through a combination of royalties and equity in the company.

Kindstar recently raised \$11 million from a Series B financing. Lead investors were WI Harper Group, Baird Capital Partners Asia, Morningside Ventures and Mayo Clinic. Morningside was the exclusive investor in Kindstar’s Series A raise in 2008.

The Mayo-Kindstar deal follows similar recent partnerships, including the collaborations between University of Pittsburgh Medical Center and KingMed Diagnostics, and Ronald Reagan UCLA Medical Center and Second Affiliated Hospital Zhejiang University (see *LE*, June 2011, pp. 1, 6).

## MEDICARE REIMBURSEMENT SET TO INCREASE BY 0.65%

The Medicare Part B lab fee schedule will rise by approximately 0.65% next year, according to the latest inflation figures released by the Bureau of Labor Statistics. Under the new health-care reform law, Part B lab reimbursement changes are based on the consumer price index for urban consumers (CPI-U) minus a productivity adjustment and a fixed cut of 1.75%.

For the purposes of the Part B fee schedule, the CPI-U is based on 12 months ended June 30 of the year preceding the new update. The CPI-U applicable to 2012 is 3.6%. This will be reduced by a productivity adjustment that is currently estimated at 1.2%. The update will then be cut by a fixed 1.75%. Add it all together and the Part B fee schedule is set to rise by approximately 0.65% effective January 1, 2012.

The 0.65% increase in Part B lab reimbursement for 2012 will follow the 1.75% cut that became effective at the start of this year and the 1.9% cut for 2010.

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## LAB STOCKS UP 12% YEAR TO DATE

Eleven lab stocks have risen by an unweighted average of 12% so far this year through July 15. The combined market capitalization for the group is currently \$23.2 billion. In comparison, the S&P 500 Index and the Nasdaq are each up 5%. The top-performing lab stock so far this year is CombiMatrix, up 53%, followed by Genomic Health, up 28%. Meanwhile, the stock price of LabCorp is up 9% and Quest is up 8%.

| Company (ticker)         | Stock Price<br>12/31/10 | Stock Price<br>7/15/11 | 2011<br>Price<br>Gain | Market<br>Capitalization<br>(\$ millions) | Earnings<br>Past<br>12 Months | Price-to-<br>Earnings<br>Ratio |
|--------------------------|-------------------------|------------------------|-----------------------|---|-------------------------------|--------------------------------|
| Bio-Reference (BRLI)     | \$22.18                 | \$21.10                | -5%                   | \$562                                     | \$1.16                        | 18.2                           |
| CombiMatrix (CBMX)       | 2.15                    | 3.29                   | 53%                   | 35  | -1.02                         | NA                             |
| Celera (CRA)*            | 6.30                    | 8.00                   | 27%                   | 662                                       | -0.23                         | NA                             |
| Enzo Biochem (ENZ)       | 5.28                    | 4.28                   | -19%                  | 165                                       | -0.35                         | NA                             |
| Genomic Health (GHDX)    | 21.39                   | 27.37                  | 28%                   | 801                                       | 0.20                          | 136.9                          |
| LabCorp (LH)             | 87.92                   | 95.73                  | 9%                    | 9,592                                     | 5.66                          | 16.9                           |
| Medtox Scientific (MTOX) | 13.10                   | 14.75                  | 13%                   | 132                                       | 0.47                          | 31.4                           |
| Myriad Genetics (MYGN)   | 22.84                   | 23.56                  | 3%                    | 2,020                                     | 1.20                          | 19.6                           |
| Neogenomics (NGNM)       | 1.30                    | 1.40                   | 8%                    | 60  | -0.10                         | NA                             |
| Psychemedics (PMD)       | 8.20                    | 8.97                   | 9%                    | 47  | 0.57                          | 15.7                           |
| Quest Diagnostics (DGX)  | 53.97                   | 58.06                  | 8%                    | 9,136                                     | 2.85                          | 20.4                           |
| Averages                 |                         |                        | 12%                   | \$23,212                                  |                               | 37.0                           |

\*Celera was acquired by Quest Diagnostics on May 10, 2011 for \$8 per share.

Source: Bloomberg

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