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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

Labs Facing a Shock to Molecular Diagnostic Pricing

This year has ushered in for laboratories a shift of pricing foundations beneath their very feet—both in general and at the molecular level.

The sector is already confronting a recent 2.95 percent cut in Medicare's clinical laboratory fee schedule, along with a 52 percent reduction in the technical component of CPT code 88305, the most commonly ordered surgical pathology code.

Then late last month, two Medicare administrative contractors (MACs) released initial gap-fill pricing for many of the 114 Tier 1 molecular tests, with pricing for many of the tests much lower than what labs had been receiving under the prior code stacking methodology.

The rates were released by Palmetto GBA, which has jurisdiction over California, Nevada, and Hawaii, and Cahaba GBA, which oversees Tennessee, Alabama, and Georgia. Some tests have seen double-digit rate cuts compared to code-stacking prices.

"If you have a lot of exposure to code stacking, it is not a positive," said Amanda Murphy, an analyst with the William Blair investment

Continued on page 6

PerkinElmer Reports Strong Profits for 2012

PerkinElmer reported strong profit and revenue growth for 2012 and expects to see greater expansion of its human health division—which includes laboratory services—during 2013.

The Waltham, Mass.-based PerkinElmer reported 2012 net income of $69.9 million on revenue of $2.1 billion. That compares to net income of $7.7 million on revenue of $1.9 billion for calendar 2011.

However, the company posted a $15.9 million loss on revenue of $572.9 million for the fourth quarter, ending Dec. 31. Much of the loss was related to charges involved with trademark names and pension plan adjustments.

"We are pleased with our strong finish to 2012, particularly in light of difficult year-over-year comparisons in the fourth quarter," said PerkinElmer Chief Executive Officer Robert Friel. "This performance caps another solid year of revenue growth and adjusted operating margin expansion."

Continued on page 2

■ **PerkinElmer Reports Strong Profits for 2012**, *from page 1*

Overall cash flow for 2012 was $153.6 million, compared to $234 million in 2011. It was dragged down by pension plan contributions, tax payments, what the company termed "incremental working capital," and additional royalty payments.

However, Friel was bullish on 2013. He noted the company's investments in China, particularly its purchase last year of that nation's blood testing giant Shanghai Haoyuan Biotech Co. Ltd., and in Eastern Europe. Offshore revenue now comprises nearly 30 percent of the companywide total—and it is expected to grow further—according to Friel. He also believes a collaboration with Verinata to distribute its noninvasive prenatal test will also create long-term benefits. "We believe incorporating Verinata . . . puts us in a leadership position in prenatal health," he said.

For 2013, the company projected revenue would grow in the mid-single-digits. And while profit margins are expected to be under pressure during the first part of the year, Friel believes they will grow significantly during the second half—the result of increased investments in research and development. G2

ARUP, Counsyl Enter Distribution Deal

ARUP Laboratories has entered into an agreement with a California company to significantly expand its offerings of genetic prescreening tests for prospective parents.

The deal between South San Francisco, Calif.-based Counsyl and the Salt Lake City-based ARUP will introduce scores of new tests on the latter's panel for inherited genetic disorders. Terms of the deal were not disclosed.

"We're energized about working with ARUP to make carrier screening a routine part of family planning across the country," said Ramji Srinivasan, Counsyl's chief executive officer.

Counsyl, which was founded by Stanford University students in 2007, offers low-cost screening for genetic diseases such as Tay-Sachs, Canavan, cystic fibrosis, and sickle-cell anemia. Its universal genetic test can screen parents for the risk of passing more than 100 genetic disorders on to their children. The saliva-based test costs about $350 per person. The company recommends usage of the tests for both parents planning a family with or without in vitro fertilization.

Counsyl's testing technology is a variant of the DNA testing offered by low-cost mail-order companies such as 23andMe, but tuned to focus on genetic diseases. Although such disorders are relatively rare, many children born with such disorders face significantly shorter life spans and often are mentally and physically limited.

The company's medical advisers include faculty members from Harvard University, Stanford University, and the Massachusetts Institute of Technology and

Jessica Jacobson, M.D., director of the special hematology laboratory at Bellevue Hospital in New York.

"We are pleased that the relationship with Counsyl now allows ARUP to offer testing for over 100 recessive genetic disorders to more than half of the nation's university, teaching, and children's hospitals," said Sherrie Perkins, M.D., ARUP's chief medical officer.

State-Funded Center for Personalized Medicine Growing Quickly

The Center for Personalized Medicine (CPM), a laboratory affiliate of the Roswell Park Cancer Institute in Buffalo, N.Y., has obtained $18.5 million in private funding since it received initial public seed funds two years ago.

The CPM had received $5.1 million in funding from the Western New York Regional Economic Development Council in 2011. Such councils were established as part of a public-private plan to rebuild the state's economy based on encouraging high-tech ventures.

"Through the regional council process, [Roswell Park] created a custom-tailored plan to take advantage of this opportunity."
—New York Gov. Andrew Cuomo

The CPM, which includes a CLIA-certified laboratory, has a staff of 21 employees, with plans to double that number in the coming months.

The lab uses a combination of high throughput and personal gene sequencers in the center, along with a dedicated 1,600-processor supercomputing cluster, to perform laboratory services.

"Through the regional council process, [Roswell Park] created a custom-tailored plan to take advantage of this opportunity, which will rebuild the regional economy," said New York Gov. Andrew Cuomo.

The lab received an additional $16 million from Roswell Park, as well as $2.5 million from the Buffalo-based health care IT firm Computer TaskGroup, and additional support from the University at Buffalo, IMMCO Diagnostics, and Western New York Urology Associates LLC.

The lab is developing a superficial bladder cancer detection test in conjunction with New York Urology Associates, officials said. It is the ninth-most common form of cancer in the United States and one of the costliest to treat.

"We now have the ability to do robust, 'next generation' gene sequencing on blood and tissue samples, with tremendous possibilities in terms of what we can learn diagnostically, prognostically, and therapeutically," said Candace Johnson, a Roswell Park deputy director and co-leader of three recently launched clinical research studies that rely on CPM resources.

"This is the future of medicine—across all diseases, not just oncology," Johnson added.

Are Quest and LabCorp Headed in the Same Direction? Growth Slowing at Two Largest National Labs

It's a tale of two national labs, but their numbers suggest similar rather than unique challenges.

Both Quest Diagnostics and LabCorp—the nation's number one and two laboratories in terms of revenue respectively—reported flat revenue for calendar 2012, decent earnings growth, and modest forecasts for 2013.

LabCorp announced its fourth-quarter and 2012 earnings on Feb. 8. Full-year net income was $584.8 million on revenues of $5.7 billion. That compares to net income of $533.1 million in 2011, a 9.9 percent increase. However, revenue was up only 2.3 percent, to $5.7 billion from $5.5 billion.

And LabCorp did not end the year on a high note: Fourth-quarter net income was $120.6 million, down 10 percent from the prior year's fourth-quarter net of $138.1 million. Revenues were virtually identical at $1.4 billion.

Quest's net income numbers were similar to LabCorp's: $555.7 million for calendar 2012, but on significantly larger revenue of $7.38 billion. In 2011, it netted $470.6 million on revenues of $7.39 billion, although legal settlements made up much of the difference in earnings for the two years.

The 2013 guidance for both companies was in the same range: Revenue growth of 2 percent to 3 percent for LabCorp, and virtually flat for Quest, which Kevin Ellich and Bradley D. Maiers, analysts with Piper Jaffray, called "disappointing." Earnings in 2013 are also expected to be relatively flat.

This is a far cry from the estimated 6 percent to 7 percent growth rate experienced by the two national labs in the mid-2000s.

	2010 Revenues	2010 Net Income	2011 Revenues	2011 Net Income	2012 Revenues	2012 Net Income
Quest Diagnostics	$7.37 billion	$757.0 million	$7.39 billion	$505.7 million	$7.38 billion	$592.1 million
LabCorp	$5 billion	$571.6 million	$5.54 billion	$533.1 million	$5.67 billion	$584.8 million

Is the Future Any Brighter?

The companies seem to be making the best of what is an environment slammed by recent deep Medicare cuts and anticipated financial strictures expected with the expansion of the Patient Protection and Affordable Care Act in 2014. Quest paid off more than $600 million in debt, while LabCorp nearly tripled cash on hand. Quest generated $1.2 billion in cash flow last year, a record. LabCorp generated just over $841 million—an impressive number, but the lowest in five years.

Quest is in the middle of an ambitious restructuring announced last fall that if successful will unify its sales team and generate $500 million a year in savings. LabCorp, with its significantly fatter net margins, is not going on any sort of new management diet, but instead will impart value to shareholders by announcing a new buyback of $1 billion of its stock.

It is also continuing to deploy its new Internet portal for providers, as well as Propel, a robotic platform expected to replace manual splitting and sorting in all of its major laboratory facilities.

"We see 2013 as a building year," Quest Chief Executive Officer Steve Rusckowski said as he announced earnings. He added that the company anticipated a 3 percent cut in Medicare reimbursements but that the company would see significant growth in 2013. LabCorp anticipates the Medicare cuts would lead to about a 3 percent to 4 percent hit on earnings.

"We see 2013 as a building year."
—Steve Rusckowski, CEO, Quest Diagnostics.

LabCorp CEO David King said the company will spend $200 million to $220 million in capital expenditures, primarily for facility consolidations and what King said during the earnings call was a "replacement of a major testing platform."

Analysts See Challenges

Analysts were not impressed, but neither are they forecasting apocalyptic doom.

"The labs face a number of challenges, in our view, including weak utilization driven by the macro environment, purchase of physician practices by hospitals, and insourcing of lab testing by physician practices," said William Blair & Co. analysts Amanda Murphy and Sylvia Chao.

"In addition, Medicare pricing pressures are well known . . . and private payer pricing pressure appears to be escalating." They projected 2013 revenue for LabCorp of $5.8 billion.

Quest also faces similar hurdles, note analysts. "While new management's organizational changes and strategies are starting to come together and should yield substantial cost savings over the next 24 months, reimbursement headwinds from Medicare and [managed care] payers will be very strong in [2013]," reported Darren Lehrich, a managing director with Deutsche Bank. He added that the near-term outlook for Quest "remains challenging."

It therefore could be a couple of years before growth for the two giants perks back up. And while they are both in the same boat, experiencing the same doldrums, most industry analysts believe they are financially strong enough to wait for the tailwinds to arrive.

■ **Labs Facing a Shock to Molecular Diagnostic Pricing**, *from page 1*

banking firm in Chicago. However, Murphy noted that the national labs will likely escape any major hits to their bottom lines due to the diversity of their business segments.

And there is also a wide variation in prices between the MACs. For example, Palmetto is permitting a payment of $605.24 for PTEN gene analysis (CPT code 81321), which tests a patient's genetic proclivity for several medical conditions. By contrast, Cahaba is permitting $123—less than a quarter of Palmetto's rate. Palmetto has released pricing for 78 tests to date.

CODE	TEST	PALMETTO	CAHABA
81200	Canavan	$93.90	$123.00
81215	BRCA1	$93.94	$50.00
81223	Full gene sequence	$1,554.56	$1,200.00
81243	Fragile X	$60.51	$123.00
81255	Hexa Gene	$93.90	$123.00
81263	LGH vari regional mutation	$259.93	$123.00
81270	Jak2 gene	$72.81	$90.00
81275	KRAS gene	$225.88	$235.00
81291	Mthfr gene	$92.92	$50.00
81321	PTEN gene analyis, full sequence	$605.24	$123.00
81324	PMP22 gene analysis, duplication/deletion	$486.16	$123.00
81325	Full sequence analysis	$297.24	$123.00
81332	Serpina1 gene	$70.20	$50.00
81342	Trg gene rearrangement analysis	$148.12	$205.00
81355	Vkorc1 gene	$83.19	$90.00
Source: Palmetto GBA, Cahaba GBA			

Although the deployment of these tests is not always commonplace, it has raised significant concerns among players in the western United States, where there is a large concentration of firms that focus on esoteric testing.

Chilling Effect on Personalized Medicine

The California Clinical Lab Association (CCLA)—one of the largest and most influential of the state-level trade groups—convened an emergency meeting of its trustees during the first week in February. It was decided at that meeting that its 58 member laboratories would lobby Congress for changes in the pricing process.

"It appears that [the Centers for Medicare and Medicaid Services] has required Palmetto to come up with pricing before sufficient understanding of the industry and the testing was obtained," said Michael Arnold, the CCLA's executive director. "It is really going to stop personalized medicine in its tracks."

One specific example Arnold cited is the CYP2D6 test (CPT code 81226), which tests enzyme levels. Arnold noted that it has a variety of testing applications for both cancer and cardiac patients. As a result, such a complex test had been highly priced, with a median price charged by labs of $510 and a high of $819. Palmetto

has priced it at $147.50; Cahaba at $50. "It does not take into consideration the different procedures involved," Arnold said.

Arnold added that the pricing recently released by Palmetto has led to layoffs within the laboratory industry. However, he declined to provide specifics.

Under Palmetto's molecular diagnostic services program (MolDx), launched in 2012, labs that bill for molecular tests in Medicare Jurisdiction 1 Part B region must register each assay, get a test code, and submit test information and supporting evidence in order to obtain coverage. Although Palmetto's MAC contract for Jurisdiction 1 was not renewed, company officials have said publicly that they have national aspirations for the MolDx program.

One particular lab that is affected by the Palmetto's coverage decisions is Berkeley HeartLab—five of its tests have been denied coverage by Palmetto—15 percent of its total offerings.

However, Berkeley is owned by Quest Diagnostics, the nation's largest laboratory. As a result of its size, Quest officials do not appear too fazed by the current denials.

"We estimate that molecular revenues are less than 5 percent of Quest Diagnostics' diagnostic information service revenues, and the current rate setting activity pertains only to the Medicare portion of these revenues," said Quest spokesperson Wendy Bost. She added that the company is in ongoing discussions with Palmetto regarding the rate setting.

A Palmetto official did not respond to a request for an interview.

Impact on National Labs Limited

Bost also mentioned a recently released report by William Quirk, an analyst with Piper Jaffray, who concluded that the changes in rates would "create some noise for the clinical labs and diagnostic product companies [but] the real impact is limited."

Murphy, the William Blair analyst, concurred that the national labs would not feel a great impact from the pricing changes or denials. "Quest is a pretty advanced organization," she said. "My guess is they have been working with all the local MACs regarding the tests."

In the meantime, Bost conceded that getting Palmetto to approve those five tests will take some time. However, she noted that several HIV and cancer tests now considered the standard of care "once encountered reimbursement and other market hurdles."

Agendia, an Amsterdam-based molecular diagnostics company that had its BluePrint cancer assay denied, was also undeterred.

"Agendia will soon submit several manuscripts which we aim to see published and that we believe could provide the clinical utility information to satisfy the Palmetto requirements so that we can get reimbursed for BluePrint in the latter half of the year," said company spokesperson Matthew Clawson.

And not every molecular lab of significant size will be affected by the changes. Redwood City, Calif.-based Genomic Health, which offers Oncotype DX molecular assays for breast and colon cancer, obtained its own codes.

INDUSTRY BUZZ

Sonic Launches Hospital Lab Initiative

Sonic Healthcare USA, based in Austin, Texas, is attempting to capitalize on a shift in the way health care systems manage their laboratory business, launching a new initiative intended to assist hospitals in reducing their lab costs.

Known as "Lab Synergy," the program has recruited Noel Maring as its new vice president of hospital affiliations. Maring was previously the longtime chief marketing officer for Spokane, Wash.-based PAML.

"As health systems move from a focus on inpatient care to systemic clinical integration that emphasizes value over volume, senior management teams are embracing new ways of evaluating and supporting their health system's service lines," said David W. Bryant, Sonic's chief executive officer. "Lab Synergy will provide health system executives with additional tools to cost-effectively manage their laboratories and enable local community hospitals to deliver quality patient care while successfully competing with large national labs that have historically encroached on their business."

According to Sonic spokesperson Nicole York, the company has ruled out acquiring hospital laboratories, which has been a more recent focus of national labs such as Quest Diagnostics.

"We would prefer to partner with health systems to maximize our respective strengths," York said.

Instead, Sonic will offer hospitals its access to economies of scale via equipment purchasing and the integration of inpatient and outpatient lab outreach through the installation of electronic medical record systems.

York noted that such agreements can staunch the annual 2 percent to 4 percent cost increases most hospitals are facing when operating their own labs. The Synergy program can also increase outreach lab revenues, according to York. The savings and additional cash flow can be deployed elsewhere within the health care organization, Sonic officials said.

Currently, Sonic has a Synergy-related agreement in place with 12 hospitals in Hawaii, which York said covers about 42 percent of that state's inpatient beds. It also has extensive management agreements in place with hospitals in Australia and the United Kingdom.

York declined to provide specifics on Synergy's pricing structure.

References

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California Clinical Lab Association
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