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HIGHLIGHTS

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Bio-Reference, Enzo Earnings Both Hit by Reimbursement Issues

The quarterly earnings of two midsize labs demonstrate the current up-and-down nature of the business.

While Elmwood, N.J.-based Bio-Reference Laboratories reported dramatic growth for its fourth fiscal quarter, ending Oct. 31, its earnings dropped. New York-based Enzo Biochem Inc. reported a dip in revenue and a continuing loss.

Bio-Reference, which provides clinical laboratory services in the Greater New York area, reported net income of $11.1 million on revenue of $192.2 million. That compares to third-quarter 2012 net income of $12.9 million on adjusted revenue of $163.5 million, a decrease of 14 percent and an increase of 18 percent, respectively.

Bio-Reference Chief Executive Officer Marc D. Grodman, M.D., attributed the dip in net income to continued reimbursement pressures from commercial payers; revenue from that segment dipped 4 percent compared to the fiscal fourth quarter of 2012.

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LabCorp, Quest Enter 2014 With Prospects Flat

If earnings and revenue guidance were the equivalent of topography maps, LabCorp and Quest Diagnostics would be stuck somewhere in the middle of the Great Plains.

The nation's two largest labs issued final earnings guidance for 2013 late last month, and LabCorp also offered a glimpse into 2014. The views from the corporate offices of both diagnostics giants remain mostly flat—with the end of the horizon yet to be sighted.

LabCorp's earnings guidance for 2013 was between $6.90 and $7.05 per share—a final number will be issued when its fourth-quarter and year-end numbers are issued on Feb. 7. It also said that revenue for the year would grow about 3.5 percent. That's essentially unchanged from the forecast it issued with third-quarter earnings last October.

However, the Burlington, N.C.-based company also issued its preliminary guidance for 2014. Revenue growth for the year is pegged at 2 percent. Earnings are predicted to be in the $6.50 per share range,

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"Over the past year . . . we identified a significant reduction in reimbursement, particularly from commercial payers," he said. Grodman added that the company was working on reducing costs but also noted that revenue from molecular and esoteric testing would drive future growth. The company reiterated its guidance that net income, revenues, and patient volumes would all grow 10 percent apiece during fiscal 2014.

For all of fiscal 2013, Bio-Reference reported net income of $45.8 million on revenue of $715.4 million. That compares to net income of $42.2 million on revenue of $614.3 million for fiscal 2012. Revenue was adjusted downward to $661.7 million due to recent changes made by the Financial Accounting Standards Board regarding the reporting of insurance claims revenue by health care entities.

Amanda Murphy, an analyst with William Blair & Co., believes that esoteric testing will comprise 67 percent of Bio-Reference's revenue by the fourth quarter of 2014. She maintained her market perform rating for the company.

Enzo Struggling

Meanwhile, numbers reported by Enzo Biochem for its first fiscal 2014 quarter are struggling to maintain the status quo.

The company reported a loss of $2.8 million on revenue of $24.1 million. That's improved from the $3.7 million net loss reported during the year-ago quarter, but revenue for that period was $25.6 million, meaning a 6 percent year-over-year drop. Revenue from each of its three business segments—clinical laboratory services, product sales, and royalty and license fee income—were down.

Company officials indicated that its operations are also being squeezed by reduced payments from insurers.

"We are faced with a new economic environment regarding health care. More people are being brought in under the health care umbrella, which will create greater demand. And at the same time, there is an intensive and relentless drive to reduce costs, which is reflected in lower reimbursement rates," said Barry W. Weiner, Enzo Biochem's chief financial officer, during a recent call to discuss earnings.

Weiner added that the company has cut expenses and improved collections with the intent of improving its bottom line in the coming quarters.

A recent report by Standard & Poor's on Enzo Biochem gave the company's stock a grade of C. However, its stock is up by about 7.5 percent over the past year, suggesting that investors currently have a positive outlook for the company.

Takeaway: Whether growing or struggling to grow, laboratories are being hit hard by reductions in reimbursements from payers.

Siemens, Pfizer Team Up on Companion Assays

Siemens' health care diagnostics division has struck a pact with pharmaceutical giant Pfizer to develop diagnostic tests that would complement its products.

The use of molecular and other esoteric tests to enable targeted medications or other forms of treatment has been gaining traction in the laboratory sector in

recent years. One prominent example is the use of a thrombosis panel to determine a patient's genetic predisposition toward blood clotting. The test can guide dosage for blood thinners and other drugs. A variety of molecular tests for cancer patients can also provide guidance for targeted forms of chemotherapy.

The companion diagnostics market for cancer alone is projected to grow at an 18 percent annual rate through the end of the decade, approaching nearly $6 billion in sales worldwide, according to data from Transparency Market Research.

"Companion diagnostics are an important enabler of targeted therapies for patients," said John Hubbard, a Pfizer senior vice president and head of the company's development operations. "This agreement with Siemens Healthcare Diagnostics is another example of Pfizer's commitment to develop new precision medicines to address unmet clinical needs."

Financial details of the deal, which was dubbed a "master collaboration agreement," were not disclosed.

Takeaway: Companion diagnostics are driving collaborations between industry giants. G2

Insight Genetics Launches New Laboratory

Insight Genetics, the Nashville, Tenn.-based molecular laboratory that focuses on oncology diagnostics, has launched a new laboratory to process assays.

The opening of the 2,750-square-foot Insight Molecular Labs was announced last month. Also based in Nashville, the CLIA-certified facility will offer a mixture of commonplace molecular tests such as KRAS, BRAF, and EGFR gene mutation analysis, as well as Insight's own proprietary products.

The company had been operating a smaller, non-CLIA-certified laboratory. The new facility was about a year in the making, according to company spokesperson Samantha Fiala, who noted that it was ramped up as business has developed.

The most significant test offered by Insight Genetics is the Insight ALK Screen, a qPCR test that assays fusions in the ALK gene. Such fusions tend to be responsive to kinase-inhibiting drugs. It also offers a more intensive variation of the test to determine a tumor's level of resistance to kinase-inhibiting drugs.

"The laboratory is a natural extension of Insight Genetics' work and will help us leverage our scientific expertise and specialized experience in resistance detection and monitoring to assist physicians in making therapy decisions and help identify patients for clinical trials," said Eric Dahlhauser, Insight Genetics's chief executive officer. "We look forward to the future of Insight Molecular Labs and the contributions it will make to enhancing drug development and patient care."

The new lab recently hired an associate director of business development to spur sales of tests, according to Fiala.

Projected test volumes for the new lab were not immediately available.

Takeaway: Molecular specialty labs such as Insight Genetics are continuing to ramp up their infrastructure to process their own proprietary tests. G2

The 2013 Laboratory M&A Market: Strong Yet Flat

The laboratory sector has been beset by reimbursement issues from both public and private payers that have led to flat revenues and a similar perspective for the short term. And while mergers and acquisitions are continuing at a brisk pace, they too have plateaued.

M&A activity in the lab sector was nearly the same in 2013 as it was in 2012. There were 23 deals consummated in the calendar year, compared to 25 in the prior year, according to data from Haverford Healthcare Advisors, a Paoli, Pa.-based health care advisory firm. Christopher Jahnle, a Haverford managing director, believes several more deals agreed to earlier in the year could be finalized this month.

However, Jahnle does not expect to see a spike in dealmaking in 2014 and beyond. "It's going to continue to be flat," he said. "I think we have reached a new normal of averaging two deals per month."

There were 33 lab deals consummated in 2011, but Jahnle said many of those were spurred by impending changes in tax law that motivated sellers to close deals in that calendar year.

This new normal of a relatively low volume of deals is primarily because of supply, not due to flagging demand. "It's definitely a seller's market, but demand is outstripping supply," Jahnle said. He added that the value of deals are up about 10 percent to 15 percent compared to 2010. "They're at historically high levels and are remaining there."

Pathology Labs Big Exception

The one exception to that pricing trend are pathology labs, which have been hit particularly hard by the more than 50 percent cut in reimbursement to the technical component of CPT code 88305.

"There aren't the . . . buyers lining up as in past years," Jahnle said. He added that the decline in demand for pathology labs has been exacerbated by other subspecialists building their own labs and continued uncertainty regarding reimbursement.

Dennis Weissman, president of Dennis Weissman and Associates and executive editor of G2 Intelligence, observed that if anatomic pathology laboratories are selling, they are likely at the bottom of the market. "You always have that handful of groups that feel if people are desperate, they can buy them out at well below market and see what happens after the dust clears," he said.

Nationals Under Pressure to Acquire

As for the national labs, Jahnle and other industry observers view acquisitions as a necessary way to boost organic growth and revenue that they have been unable to do otherwise over the past couple of years. Many of 2013's significant deals involved Quest, LabCorp, or other big players. LabCorp made six deals; Quest, three.

"They need to buy their volume," said Donna Hochberg, a vice president at Health Advances, a Weston, Mass.-based consulting firm that specializes in laboratory and product strategy including transaction support. She noted that labs are competing against hospitals purchasing medical practices, which is one way of keeping lab volume in-house.

"The more volume they can get, the better able they are to control costs and get their margins in a better place," Hochberg said.

Weissman concurred. "I don't see how they get their growth unless they find additional properties," he said.

CLINICAL LABORATORY TRANSACTIONS – 2013

	Date	Acquirer	Target	Target State	Purchase Price
1	Jan-13	Illumina	Verinata Health	CA	NA
2	Jan-13	Access Genetics	Oral DNA (sold by Quest)	TN	NA
3	Jan-13	Management (Selah Genomics)	Lab 21 Ltd.'s So. Carolina clinical lab operations	SC	NA
4	Jan-13	Ascend Clinical, LLC	PathCentral	CA	NA
5	Apr-13	Laboratory Corporation of America	Dignity Health's Outreach Clinical Lab Operations	AZ	NA
6	May-13	Quest Diagnostics	Dignity Health's Outreach Clinical Lab Operations	CA, NV	NA
7	May-13	Quest Diagnostics	Concentra's Advanced Toxicology Network	TN	NA
8	Jun-13	Laboratory Corporation of America	Laboratory Partners' MedLab Physician Office Business	OH, IN	10,700,000
9	Jul-13	BelHealth Investment Partners	General Genetics Corporation	NM	NA
10	Aug-13	Sterling Reference Laboratories	Norchem Drug Testing Laboratory	AZ	NA
11	Aug-13	Metamark Genetics Inc.	HealthTronics Laboratory Solutions Inc.	GA, PA	NA
12	Aug-13	Bio-Reference Laboratories	Hunter Laboratories	CA	NA
13	Aug-13	Gardiner -Smith Laboratories	ARUP-Animal Reference Pathology	UT	NA
14	Aug-13	Laboratory Corporation of America	Genesis Clinical Laboratory Outreach Business	IL	NA
15	Aug-13	Laboratory Corporation of America	Bendiner Schlesinger	NY	NA
16	Sep-13	Laboratory Corporation of America	John Muir Health Clinical Laboratory Outreach Services	CA	NA
17	Sep-13	Clinical Genomics Technologies Pty Ltd.	Quest Diagnostics	NJ	NA
18	Oct-13	Spectra Laboratories Inc.	Shiel Medical Laboratory Inc.	NY	NA
19	Oct-13	Quest Diagnostics	ConVerge Diagnostic Services LLC	MA	NA
20	Oct-13	Miraca Life Sciences	PLUS Diagnostics	CA	NA
21	Nov-13	Levine Leichtman Capital Partners	Genova Diagnostics	NC	NA
22	Nov-13	Laboratory Corporation of America	SEPA Labs	GA	NA
23	Nov-13	Viracor IBT Laboratories	Lab Operations of National Institute of Transplantation/NIT	CA	NA

Source: Haverford Healthcare Advisors

Lack of Pricing Data

The biggest deal—and also the only one with a publicly disclosed dollar amount—was LabCorp's acquisition of MedLab's physician office business from parent company Laboratory Partners for $10.7 million. The sale was spurred by financial issues faced by Laboratory Partners/Medlab, which filed for bankruptcy protection later in the year.

Although Jahnle indicated he had valuations for other transactions his company was involved with, he declined to disclose financial details.

Jahnle noted that this lack of price data was primarily because of an imbalance in size—Quest and LabCorp are so large compared to the companies they are acquiring that they are not reaching the regulatory threshold for disclosing the purchase price. Many of the other deals involve companies that are not publicly traded and have no legal obligation to disclose terms at all.

Hospital outreach business was also a significant generator of activity in 2013. Dignity Health, the large Catholic health care system, sold portions of its outreach business to both LabCorp and Quest last spring. LabCorp purchased Dignity's outreach operations in Arizona, while Quest purchased its outreach operations in California and Nevada. And in September, LabCorp purchased the outreach operations of John Muir Health, a two-hospital system east of San Francisco.

"We see that as many hospitals are facing challenges from a budget perspective they can avoid the capital expenditures of funding or expanding their outreach operations by selling them," Jahnle said. Sometimes, they can even go further. A deal that occurred in 2009 involving LabCorp's acquisition of Centrex Clinical Laboratories, which was operated by Faxton St. Luke's Healthcare in Utica, N.Y., was an acquisition of the system's entire lab operations, with the hospital lab employees becoming LabCorp employees. In turn, Faxton St. Luke's was able to negotiate discounts on its laboratory services.

More Outreach Deals Expected

Although there was no such turnkey deal consummated last year, Jahnle noted that the cost and operations inefficiencies in many hospital labs could spur such deals in the future. He, Hochberg, and Weissman expect to see more hospital-related transactions in 2014.

"I would expect there to be a number of health system and hospital labs that will be sold in 2014," Weissman said. He added that he has spoken to a number of hospital operators that are currently in active negotiations.

Hochberg was not as sanguine regarding the potential number of outreach deals.

"Hospitals that have really attractive outreach programs—there are not many targets left," she said. "That will keep the numbers down." She added that the management of some hospitals may also hesitate to take the plunge and sell some or all of their laboratory operations.

Takeaway: Although there is a strong market driving M&A in the laboratory sector, the dearth of desirable companies is likely to keep the number of transactions down for the foreseeable future. G2

■ **LabCorp, Quest Enter 2014 With Prospects Flat**, *from page 1*

suggesting its bottom line could shrink nearly 8 percent if its final 2013 earnings come in on the high side. More formal guidance will be issued in February, according to the company.

"We continue to operate in a very difficult environment," said LabCorp Chief Executive Officer Dave King. He added that LabCorp would continue to focus on cost cutting, improvement of its information technology initiatives, and strategic acquisitions.

Kevin Ellich and Bradley D. Maiers of Piper Jaffray called LabCorp's earnings guidance "disappointing" and said the lab industry "will continue to be pressured by weak organic volumes and reimbursement headwinds" this year.

The New Jersey-based Quest Diagnostics has yet to issue any guidance for 2014. But it finalized guidance for 2013, saying revenue would be 3.5 percent below its 2012 numbers, which was unchanged from prior guidance. Net income is expected to come in between $3.90 and $3.95 per share, which is on the higher end of previous guidance of $3.85 and $3.95 per share. However, the company will not issue 2014 guidance until it releases year-end 2013 earnings on Jan. 30, a week before LabCorp.

That Quest is hedging on issuing guidance raised some concern with some analysts.

"We are a little surprised that the company narrowed its FY13 EPS guidance with only a few weeks remaining in the year without providing FY14 guidance, which is the main point of contention with most investors," Ellich and Maiers observed. They maintained a neutral rating on Quest's stock, and lowered its 2014 revenue estimates to $7.12 billion from $7.16 billion, and dropped earnings estimates to $4.07 per share from $4.15 per share.

Takeaway: LabCorp and Quest Diagnostics continue to navigate a landscape of flat numbers for the foreseeable future.

23andMe Complies With FDA Order

23andMe has agreed to halt health-related genomic testing until the Food and Drug Administration (FDA) has given its explicit approval for such assays.

The Mountain View, Calif.-based lab is continuing to offer what it calls "ancestry testing" and raw genetic data without providing any specific interpretation. Its Web site explicitly requests visitors to acknowledge the change before they're allowed to place any orders.

The FDA ordered 23andMe last November to stop offering its $99 genomic analysis because it had not responded to questions the agency raised after it submitted its 510(k) form or clinically validated how the assay is being used. The FDA had ruled the test is a Class III medical device and requires prior approval.

Although 23andMe Chief Executive Officer Ann Wojcicki had complained on her company's official blog that the FDA's concerns were overblown, it complied with its order in early December.

Takeaway: 23andMe's business could be impacted for an indefinite period of time by withdrawing its personal genomic assay.

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INDUSTRY BUZZ

American Health Associates Likely to Purchase Laboratory Partners' Long-Term Care Business

Cincinnati-based Laboratory Partners, which filed for bankruptcy protection last fall, may be close to finding a buyer for its business that services the long-term care sector.

The company, which operates primarily under the name MedLab, announced in mid-December that it was in negotiations with Florida-based American Health Associates (AHA). Laboratory Partners Chief Executive Officer Bill Brandt indicated a deal was likely to be announced soon.

"Although I believe it's fair to say that negotiations are in a fairly advanced stage, I think it's also fair to say that the deal is all but certain to happen, and likely will have some type of closing toward the end of January," Brandt said in an e-mail.

Brandt is CEO of Development Specialists Inc., a Chicago-based firm that specializes in corporate workouts and turnarounds. It was retained by Laboratory Partners last year after it began encountering financial issues, and Brandt was placed in the executive suite not long after its top leadership departed last summer. Laboratory Partners had about $32 million in secured and unsecured debt when it filed for bankruptcy protection last Oct. 25. Although the filing was for a Chapter 11 reorganization, Brandt said at the time of the filing that the intent was to sell off the company's assets to other labs.

The biggest sticking point to a potential deal is that AHA was not licensed to conduct lab testing in all the states where MedLab does business, according to Brandt. He said this would likely require some transition period of a few months until AHA obtains proper licensure. He would not disclose what states were at issue. MedLab operates in eight states primarily in the Midwest, as well as the District of Columbia. Although AHA's focus is also on providing lab services to long-term care facilities, a large portion of its business is in the Southeast.

AHA Chief Executive Officer Debbie Martin did not return a phone call seeking comment.

Takeaway: Laboratory Partners' intent to sell itself off as part of its bankruptcy plan is continuing.

References

Development Specialists
312-263-4141

Dignity Health
415-438-5500

Haverford Healthcare Advisors
610-407-4024

Health Advances LLC
781-647-3435

Insight Genetics
615-255-8880

John Muir Health
925-941-2001

LabCorp
800-845-6167

Laboratory Partners/ MedLab
866-558-6749

Quest Diagnostics
800-222-0446

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