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HIGHLIGHTS

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LabCorp Snaps Up a Momentarily Distressed Sequenom

LabCorp has entered into another big deal, coming to terms to acquire neonatal specialty lab Sequenom for $371 million.

The transaction, which will be consummated through a special firm created by LabCorp to handle the deal, includes a cash offer for $302 million and an assumption of $69 million in debt.

The San Diego-based Sequenom is best known for its MaterniT prenatal genomic test, but the company has been hit hard in recent years due to increased competition in the space. It reported revenue of $128.3 million in 2015, down more than 15 percent from the $151.6 million in 2014. Its stock had sunk from about $4.50 per share in the spring of 2015 to about 85 cents just prior to the deal being announced.

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LabCorp, Quest Post Big Earnings Growth through First Half of Year

LabCorp and Quest Diagnostics reported significant jumps in profitability during the second quarter of 2016 and throughout the first half of the year.

North Carolina-based LabCorp, the larger of the two entities, reported net income of $198.5 million on revenue of $2.43 billion for the quarter ending June 30. That compares to a net of $170.1 million on revenue of $2.2 billion for the second quarter of 2015. Earnings per share were $2.31, which beat estimates by a penny.

LabCorp's diagnostics division saw revenue grow 5.4 percent, to $1.66 billion. Test volumes grew 2.1 percent. Covance performed even better, up 12.2 percent to $722.4 million.

Organic growth of business was an impressive 6.4 percent compared to a year ago, across both the LabCorp and Covance books of business.

The company repaid $339 million worth of debt during the quarter, Chief Financial Officer Glenn Eisenberg told analysts during a conference call, although the company still has $6.1 billion in debt.

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LabCorp, Quest Post Big Earnings Growth through First Half of Year, *from page 1*

As a result of the strong results, LabCorp increased its calendar 2016 guidance. It now forecasts revenue growth of 9.5 percent to 10.5 percent, up from the previous guidance of 7.5 percent to 9.5 percent. It narrowed its earnings guidance on the low end, but did not increase it.

Deborah Keller, Chief Executive Officer of the Covance drug development division, told analysts that the merger between the two companies has paid significant dividends. "Clients have really been able to see and understand the value proposition of the combined companies. We are differentiated, and they see that," she said. "Since we've made the announcement, we've recorded over $200 million in clinical orders, where the LabCorp data actually played a key role in the win."

"We had another good quarter of earnings growth and a solid first half."

— Steve Rusckowski, CEO, Quest

For the first half of 2016, the company reported net income of $359 million on revenue of $4.7 billion. LabCorp had net income of $173.5 million on revenue of $4 billion.

LabCorp CEO Dave King told analysts that the company was well-positioned to take advantage of a bundled payment initiative for cardiac care recently announced by the Centers for Medicare & Medicaid Services. "In the inpatient setting, I continue to believe that these types of bundled structures will encourage hospitals to look at how they can reduce the costs of the components of the bundle, and on the laboratory and the diagnostics side, that obviously puts us in a very strong competitive position," he said.

Meanwhile, New Jersey-based Quest Diagnostics also posted a healthy second quarter, even though growth was flat. It reported net income of $209 million on revenue of $1.9 billion, compared to net income of $129 million on revenue of $1.93 billion for the year-ago quarter. The company said revenue was flat primarily due to divestitures so it could focus on diagnostic information services. Quest reaped $34 million in after-tax profit for the sale of its Focus Diagnostics division during the quarter. Earnings per share were $1.34, which beat estimates by two cents.

"We had another good quarter of earnings growth and a solid first half," said Quest CEO Steve Rusckowski. "We've refocused our business on diagnostic information services, and without clinical trials or diagnostic products businesses, reported revenues decreased 1 percent, but we grew equivalent revenues more than 2 percent in the quarter. Our expanding hospital relationships, including the CLP acquisition and Barnabas Health (outreach) agreement, have been key contributors to growth this year, and our latest agreement with HCA's HealthONE system will help continue the momentum."

In a call with analysts, Rusckowski said that drug monitoring services also continued to be a strong area of growth for the company. Revenue from Quest's diagnostic information services revenues grew 2.2 percent, while test volumes grew 1.9 percent compared to the year-ago quarter. For the first six months of 2016, Quest reported net income of $324 million on revenue of $3.8 billion, compared to net income of $199 million on revenue of $3.8 billion for the first half of 2015.

Quest adjusted its revenue guidance downward, to a range of $7.47 to $7.54 billion from $7.52 billion to $7.59 billion. Its forecast for earnings per share remained unchanged at $5.02 to $5.17 per share.

Takeaway: LabCorp and Quest Diagnostics continue to post healthy profits, although the latter is not in a growth mode.

Quest Launches Free iPad-Based Cognitive Evaluation Test

Quest Diagnostics has introduced a product that is a departure from the typical laboratory test but is expected to assist physicians in providing more precise delivery of health care services.

> *"Studies show that cognition plays a huge role in how patients take care of all the management of their health. That is why effective digital tools for the assessment of patients at risk for dementia are essential for an ACO."*
>
> — Harry Jacob, M.D., CMO, Primary PartnerCare

Known as CogniSense, it allows the administration of a five-minute test on patients suspected of having cognitive issues. It is based on the Memory Orientation Assessment Test, which includes questions pertaining to the patient's ability to recall words and objects and time and place.

The intent of the test, according to Quest, is to speed up such evaluations and eliminate demographic biases in applying such tests. Research has suggested that the educational level of the patient being evaluated can be an obstacle toward obtaining accurate results.

"CogniSense serves a pressing need for tools to improve the evaluation of neurological disorders such as dementia, particularly in the primary care setting," said Quest spokesperson Wendy Bost. "(It) aligns with our larger business strategy to provide diagnostic information services that serve unmet clinical needs." She added that the company collects revenue from a per-patient evaluation fee.

In addition to creating more business for Quest, such a test could be used to make a business case for the overall health improvement of those patients who undergo the CogniSense exam.

"Studies show that cognition plays a huge role in how patients take care of all the management of their health," said Harry Jacob, M.D., chief medical officer for Primary PartnerCare, an accountable care organization in New York State that piloted CogniSense on more than 200 patients. "That is why effective digital tools for the assessment of patients at risk for dementia are essential for an ACO."

CogniSense is a free Apple download for the iPad. However, sharing test results appears to require participating in Care360, Quest's electronic healthcare records system, which in some instances charges a monthly fee. Bost noted that Care360 can interface with hundreds of other electronic medical records systems.

Quest said it was developing a variety of tests for the more efficient diagnosis and treatment of dementia.

Takeaway: Quest's CogniSense application appears to be a new approach to future business development.

Inside The Lab Industry

Despite Changes in Final PAMA Rule, Many Hospital Labs May Still Not Be Reporting

When the Centers for Medicare & Medicaid Services announced in mid-June the final rules governing the Protecting the Access to Medicare Act (PAMA), it drew praise from several groups that had lobbied for major changes, including rules that allowed more hospital labs to participate in reporting levels of payer reimbursement.

One of the biggest of those changes CMS made to the final PAMA rule was the relaxing of reporting guidelines as they relate to hospital-based laboratories.

But sector executives and observers question just how many hospital labs will actually be able to participate in PAMA reporting. Some have raised concern that a dearth of hospital lab reporting could negatively impact future Medicare reimbursements to all labs, with some anticipating cuts in the coming years that could be well into double-digit percentages.

PAMA is essentially serving as a reset for the reimbursement formula the federal government uses to make payments under the Clinical Laboratory Fee Schedule.

The feds believe the Medicare program may be overpaying laboratories for services compared to commercial insurers, which have ratcheted down their rates through hard bargaining in recent years. As a result, PAMA requires labs to gather their commercial billing data and submit it to CMS for review and as the basis for future rate-setting. All labs that billed Medicare for $12,500 or more during the first half of this year would be affected.

Under the rules, labs have to submit payer data for the first half of this year to CMS by the end of the first quarter of 2017. CMS's payment recalculations would then begin in 2018, a year later than originally proposed.

Labs are obviously not paid at uniform rates, but the differences can be significant. Hospital-based laboratories, for example, can be paid at much higher rates than standalone labs. Their inclusion on a large scale would therefore be economically advantageous for the sector as a whole.

One of the biggest of those changes CMS made to the final PAMA rule was the relaxing of reporting guidelines as they relate to hospital-based laboratories. Under the proposed rule, CMS had said a qualifying hospital laboratory would not only be an independent Medicare entity, but have a taxpayer identification number and a national provider identifier number, or NPI.

Instead, CMS relented, dropping the TIN requirement but keeping the NPI prerequisite. It also moved back the reimbursement changes from 2017 to 2018.

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"It's great CMS made the change because that will open it up for hospital lab outreach programs," said Jane Pine Wood, a Massachusetts-based member of the healthcare law practice of McDonald Hopkins, although she wished the participation would have included all hospitals that performed any lab work.

"We are pleased that CMS will delay the program start date and include data from hospital-based labs in setting payment rates," said American Hospital Association Executive Vice President Tom Nickels in a statement. "Including hospital-based labs will better reflect market trends and lead to more appropriate reimbursement."

"Everyone with whom I have spoken has said they do not plan to participate in the PAMA data collection process because their hospital laboratory does not meet the definition of an applicable lab."

— Barry Portugal, president, Health Care Development Services

But whether or not many hospital labs actually have their own NPIs is a matter of speculation. In perhaps what is a reflection of the data gap the CMS is seeking to close through PAMA, no one appears to know how many hospital labs actually have their own NPI.

"We know there are more hospital labs that have their own NPI than TIN," said Alan Mertz, president of the American Clinical Laboratory Association, which had supported the change in the PAMA final rules to help include hospital laboratories. "We don't know how many hospital labs have their own NPI, but we also know a lot of them don't. It's not as easily discoverable."

Mertz noted that ACLA's own membership includes only a handful of significant hospital-based labs.

Wood also was uncertain of how many hospital labs have NPIs. "There are some hospitals with separate NPIs for their outreach programs, but many do not have one," she said.

Stan Schofield, president of NorDx, the laboratory network for MaineHealth and vice president and managing principal for the Compass Group, a trade federation that represents hospital-based labs, actually believes few hospital labs will participate in reporting data.

"The way [the PAMA rules] have been engineered, most big hospital labs are going to be excluded," he said.

Barry Portugal, president of Health Care Development Services, a Florida-based consulting firm, said he has contacted operators of many hospital-based labs. Most are not participating in PAMA, he noted.

"Everyone with whom I have spoken has said they do not plan to participate in the PAMA data collection process because their hospital laboratory does not meet the definition of an applicable lab," Portugal said.

Inside The Lab Industry

Portugal added that there are exceptions. Those are primarily hospital-owned labs located outside of the hospital, and where the lab performs inpatient, outpatient, and outreach testing. But he believes there are no more than 100 in operation nationwide.

Schofield concurred. "The criteria for reporting does not loop them in unless there [are] really sizable numbers to loop them in," he observed. Wood and Mertz noted that this may spur a surge of NPI-seeking.

"There may be more and more of them to decide and quickly get an NPI number so they can report, because generally everyone is going to be better off with more hospitals reporting," Wood said.

"It's my view that the impact of a very few hospital-affiliated labs participating in PAMA data collection will be minuscule at the end of the day."

— Barry Portugal, president, Health Care Development Services

While Mertz agreed that hospital labs could obtain their own NPI to participate in reporting, he said it was too late to do so for the 2016 reporting period. The next reporting period is in 2019, he added.

Another issue raised by Portugal is more esoteric. For those off-premise labs that do qualify, he said the average pricing for PAMA purposes "would be far less than typical outpatient pricing because a large portion of the lab testing performed at these facilities is billed back to their hospital parents at 'intra-hospital' prices which are a fraction of a hospital's typical outpatient fees."

Mertz did not believe such situations would be widespread, while Wood said she was unaware of the issue.

But with many hospital labs seemingly cut out of the loop, Schofield believes it will present a "worse-case scenario" for reimbursement cuts.

"If a hospital lab is billing at $10 a test and they're facing a 10 percent cut, that's $9. But if the actual base under PAMA is going to $7, then it's going to be cut to $6.30. The point is, they'll be looking at 30 percent-plus cuts."

Schofield pointed to aggressive cuts by Anthem and other big payers in recent years as the likeliest influencers of rates set under PAMA. In New Hampshire, for example, Anthem cut reimbursement to 66 percent below Medicare rates, he added.

Portugal believes that while on the face of it the changes to the PAMA final rules seemed beneficial to labs, he's skeptical for now.

"It's my view that the impact of a very few hospital-affiliated labs participating in PAMA data collection will be minuscule at the end of the day," he said. "CMS will get what they originally wanted—to pay out far less money for Medicare Clinical Laboratory Fee Schedule testing."

Takeaway: Although CMS has relaxed its PAMA reporting rules to include more hospital-based laboratories, it remains to be seen just what percentage will be able to participate in that first reporting period.

LabCorp Snaps Up a Momentarily Distressed Sequenom, *from page 1*

Ross Muken, an analyst with Evercore CSI, said that Sequenom had been challenged by a limited test menu and an inability to scale rapidly. He added that the deal with LabCorp should allow it to offer a much wider array of tests related to women's health care.

"Anyone who reviews the Sequenom balance sheet can see that this was a distressed sale. The company previously chose to capitalize the company using convertible debt instead of equity. Now the more cash they burned, the harder the prospects were for a shareholder-friendly recapitalization. Selling the company was not a surprise," said Marty Chilberg, an analyst with Seeking Alpha, in a recent report.

> *"I find it remarkable that Sequenom couldn't have timed their acquisition acceptance any worse."*
>
> — Marty Chilberg, analyst, Seeking Alpha

The purchase price—roughly a 180 percent premium over its stock price—drove shares back into the $2.30 range.

"This is exactly the kind of strategic acquisition that LabCorp seeks: Sequenom was the first laboratory to offer a clinically validated NIPT test and has performed more than 500,000 tests to date. Sequenom's proven best-in-class technology and strong research complement LabCorp's extensive women's health offering, providing patients and physicians with one source for the most complete range of testing options in women's health, including NIPT and reproductive genetics," said LabCorp CEO Dave King in a statement. "Sequenom expands LabCorp's geographic reach both domestically and internationally, offering services through licensing and commercial partnerships with an emphasis on the European Union and Asia Pacific. The addition of Sequenom to the LabCorp family meets our stated financial criteria, and creates a market leader in NIPT, women's health and reproductive genetics."

Muken said the deal likely canceled any potential LabCorp stock buybacks that "shareholders have been clamoring for" but "on a long-term basis if LabCorp is able to execute on repositioning the Sequenom asset the returns will likely be far superior to buybacks." He observed that the deal should be accretive to LabCorp's bottom line during the first year after the transaction closes "and be a significant contributor to growth over time."

But questions remain about the timing of the deal. Chilberg noted that Sequenom had begun turning around its fortunes during the second quarter ending June 30. Revenue was up a modest 4 percent from the second quarter of 2015, but gross margin had increased from 39 percent to 53 percent. That suggested to him that the company's leadership chose to sell prematurely.

"I find it remarkable that Sequenom couldn't have timed their acquisition acceptance any worse. The market had no opportunity to react to this quarter or updated guidance moving into the last half of 2016. The final chapter in this story, if no other bidder appears at the 11th hour, is a largely unsatisfactory one," Chilberg wrote.

At least two law firms said they were investigating a potential breach of fiduciary duty by the Sequenom board of directors.

Takeaway: LabCorp has pulled off another large deal that will allow it to expand its women's health menu, but the timing may have been questionable for Sequenom.

INDUSTRY BUZZ

Zalgen Obtains Rights to Two Tests from Corgenix

Zalgen Labs, the Maryland-based specialty lab that focuses on diagnosing obscure but often deadly infectious diseases, has obtained the rights to two tests from Corgenix Medical Corp.

Zalgen obtained the rights to the ReEBOV Antigen Rapid Test, a fast diagnostic test for detecting the Ebola virus that has been authorized for emergency use by the U.S. Food and Drug Administration. It also acquired the rights to the ReLASV Antigen Rapid Test for Lassa fever.

Testing will occur at a new business development facility Zalgen has established at the University of Colorado Anschutz Medical Campus in Aurora, Colo.

Zalgen entered into a test development deal with the Maryland-based Corgenix in 2013, with a focus on what the two companies have termed "high-impact neglected infectious diseases."

Like Ebola, Lassa is a virus that can cause severe hemorrhagic illness. It is confined primarily to Western Africa and transmitted primarily through contact with rodents. Although a large number of those who contract the virus have no symptoms, it can cause deafness, or even maternal and fetal death in pregnant women who contract the virus during its third trimester. Lassa was initially discovered in the 1950s but has become more persistent in recent years. Rapid diagnosis has been challenging because its symptoms are similar to Ebola.

"We are excited to add these remarkable diagnostic products to Zalgen's business, and we look forward to adding them to our expanding global distribution network," said Zalgen Co-Founder Luis Branco in a statement. "Zalgen has been active in the research and development of these products since our inception, and our new development site in Colorado will serve as the Company's primary site for diagnostics, while our immunotherapeutics activities will remain centered in Maryland."

In addition to the transfer of the two tests, Zalgen also received a National Institute of Allergy and Infectious Diseases small business innovation research grant for the development of recombinant antigen diagnostics for filoviruses such as Ebola.

Takeaway: Zalgen is using its development deal with Corgenix to expand its testing menu and capabilities.

Clarification: An article in the July 21 edition of Laboratory Industry Report ("CMS's Proposed Gapfill Prices for Molecular Tests Would Lead to Big Reimbursement Cuts") included a price chart ("Total Costs For Certain Molecular Tests") that could have been construed as reflecting final as opposed to proposed prices. The chart contained prices proposed by the Centers for Medicare & Medicaid Services that have yet to be finalized.

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