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HIGHLIGHTS

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Lab Startup Focused on Consumer Subscription Model

Mately, a New York-based startup wants to remake STD laboratory testing with a unique subscription model, but appears to be facing stiff headwinds.

The company's business model is straightforward: Pay a $70 initiation fee and $30 a month to be tested for HIV. Pay more for testing of other STDs, such as syphilis. Kits and samples are sent through the mail, or via a participating pharmacy, with test results posted electronically and easily accessible via a mobile app, which can also share results with other Mately members.

The intended market are the millions of young urbanites who use online dating services, according to Mately founder and Chief Executive Officer Brandon Greenberg. He estimates the potential market includes 3 million LGBT individuals and 8 million in total.

"Mobile data speeds have increased significantly, and many people use these apps habitually," Greenberg said, adding that Mately would provide a matching lab service.

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PerkinElmer Continues to Make Global Transactions

In the space of 24 hours last month, PerkinElmer engaged in two deals that continued to demonstrate the growing globalization of the U.S. laboratory sector.

On April 25, the Massachusetts-based PerkinElmer sold its prenatal laboratory business to the Luxembourg-based conglomerate Eurofins Scientific. On April 26, it entered into an agreement to open up a joint research laboratory in Singapore.

A sales price for PerkinElmer Labs/NTD was not disclosed. That division had sales of $20 million last year, a little less than 1 percent of PerkinElmer's annual sales of $2.3 billion.

"Recent changes to U.S. healthcare reform continue to drive the consolidation of diagnostics testing toward broader service providers,"

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PerkinElmer Continues to Make Global Transactions, *from page 1*

said Prahlad Singh, president of PerkinElmer's diagnostics division, in a statement. "Eurofins, with its breadth of testing services and capabilities, is uniquely positioned to meet the expanding service needs of NTD's customers."

> *"Our collaboration with GIS brings together cutting-edge equipment and services along with insights from some of the world's leading cancer researchers."*
>
> — Brian Kim, president, life sciences and technology division, PerkinElmer

Eurofins has been particularly active in the U.S. market in recent months. Last year, it acquired Boston Heart Diagnostics for about $200 million. It also has purchased a majority stake in the Emory Genetics Laboratory. In addition to that transaction, PerkinElmer also entered into a development agreement with the Genome Institute of Singapore (GIS) to improve current technologies for analyzing cancer tumors and developing new treatment pathways. The two parties announced the opening of a joint research laboratory in Singapore to that end.

"Our collaboration with GIS brings together cutting-edge equipment and services along with insights from some of the world's leading cancer researchers," said Brian Kim, president of PerkinElmer's life sciences and technology division. "Combined with GIS's knowledge and experience, this partnership has the potential to unlock new doors in the future of applying precision medicine to cancer treatment." The financial terms of that deal were not disclosed.

In February, PerkinElmer opened up a new testing facility in Chennai, India, indicating the company has ambitious goals for the Asian market. In January, it acquired Swedish genomic laboratory firm Vanadis Diagnostics.

For PerkinElmer's first quarter ending April 3, it reported robust numbers. Net income was $47.5 million, up 17.6 percent from the $40.3 million reported for the first quarter of 2015. Revenue was also up 2.3 percent, from $526.9 million to $538.7 million. The company also bumped up its guidance for 2016 by 10 cents per share, from $2.75 to $2.85. That included 6 cents attributed to the strong first quarter and another 4 cents attributable to favorable foreign exchange rates.

Ross Muken, an analyst with Evercore ISI, attributed the growth and stronger forecast to "surprise" higher sales in its China market, where it performs a lot of food-related laboratory testing, a service in strong demand given that country's doubts about its food supply chain. He noted in a recent report that it was a turnaround from the company's more somber outlook issued during the fourth quarter.

"As such, we believe the quarter could serve as a clearing event for investors as a rosier macro outlook ... and the strong quarter will likely push aside any doubts in PerkinElmer's ability to hit fiscal year targets," he wrote.

Takeaway: PerkinElmer continues to make deals that demonstrate the globalization of U.S. laboratory companies.

Abbott Moves to Terminate Alere Acquisition

Abbott's move to acquire Alere is on the rocks. The $5.8 billion deal, announced in February, would have made Abbott the leader in the point-of-care diagnostics field, with about $7 billion in annual sales.

But the Illinois-based Abbott recently moved to terminate the deal, offering the Massachusetts-based Alere some $30 to $50 million to opt out. Alere said in a statement it has rejected the offer and wants to consummate the sale.

> *"Abbott informed Alere that it has serious concerns about, among other things, the accuracy of various representations, warranties and covenants made by Alere in the parties' merger agreement."*
>
> — Alere

Abbott's at-the-altar second thoughts stem in part from Alere's March disclosure that it had been subpoenaed by the Justice Department in relation to how it conducts business in overseas markets such as Africa, Asia and Latin America. Alere then announced it was delaying filing its 10-K annual statement for the 2015 calendar year—earnings it was to have released in late February.

"Abbott informed Alere that it has serious concerns about, among other things, the accuracy of various representations, warranties and covenants made by Alere in the parties' merger agreement," Alere said in a statement, adding that "Abbott has requested information from Alere about these and other matters, citing contractual rights to receive information under the merger agreement."

Alere had reported deteriorating sales for the third quarter of 2015 ending Sept. 30. It announced net income of $200,000 on revenue of $602 million. Last year it restated its 2014 earnings. For the third quarter of 2014, it reported a loss of $98.4 million on revenue of $645 million.

Abbott, which announced late last month the pending acquisition of medical device giant St. Jude Medical in a cash and stock deal worth $25 billion, has come under considerable pressure to make up its mind as to which target it wishes to pursue. Moody's Investors Service said consummating both deals would triple its debt, and that it would likely downgrade Abbott as a result.

"Abbott will be taking on two of the largest transactions in its history at the same time. Beyond high execution risk, this raises uncertainty about Abbott's longer-term M&A strategy once it deleverages," the credit ratings agency said in a recent report.

Should its acquisition by Abbott fall through, it would put Alere in a tough position. Along with the company's sales decline, its stock is also in a tailspin. Shares of Alere were trading below $40 a share, earlier this month, about a third lower than the $55 a share trading price it had as the Abbott acquisition was announced. Moreover, a variety of law firms have filed class action lawsuits on behalf of shareholders due to the issues swirling around Alere, or have announced that they intend to sue.

Takeaway: Alere's pending acquisition by Abbott appears to be headed toward a grim end. G2

Inside The Lab Industry

LabCorp, Quest Diagnostics Both Report Better-Than-Expected Quarterly Earnings

It wasn't that long ago when LabCorp and Quest Diagnostics were struggling to make their numbers. Now they're actually beating the expectations of Wall Street.

Both of the nation's largest laboratories reported better than expected earnings for the first quarter ending March 31, mostly demonstrating that a turnaround for the long-troubled laboratory sector has made a full-fledged arrival.

"We are off to a terrific start to the year, highlighted by robust organic revenue growth and double-digit adjusted (earnings) growth in the quarter."

— Dave King, CEO, LabCorp

The North Carolina-based LabCorp reported net income of $160.2 million on revenue of $2.3 billion. That compares to the first quarter of 2015 net income of $3.1 million on revenue of $1.8 billion. Given the nearly $140 million in restructuring charges LabCorp booked during the first quarter of 2015, operating income paints a more impressive picture: It was $301.9 million during the first quarter of 2016, compared to $132.4 million during the first quarter of last year. There was also $153.5 million in writeoffs during the first quarter of 2015 attributable to the acquisition of drug testing giant Covance.

Indeed, a considerable part of the year-over-year revenue growth is attributable to the Covance deal, which closed in mid-February of 2015. It contributed $703 million during the quarter, compared to $267.5 million during the first quarter of 2015, which excluded all revenue up to Feb. 18 of last year.

Nevertheless, revenue from Covance grew 12.3 percent compared to the first quarter of last year. LabCorp's diagnostics division contributed the other $1.6 billion, up 7 percent from a year ago.

The revenue growth was higher than the consensus of Wall Street analysts by $100 million, a 4.5 percent "beat" that is in the upper stratosphere for such outperformances. The Covance revenue contribution beat Wall Street consensus by nearly 7 percent.

Earnings per share, at $2.02, also beat the consensus of $1.95.

Quarterly Earnings

Company	1Q 2016 Net Income	1Q 2015 Net Income	1Q 2016 Revenue	1Q 2015 Revenue
LabCorp	$160.2 Million	$3.1 Million	$2.37 Billion	$1.79 Billion
Quest Diagnostics	$102 Million	$61 Million	$1.86 Billion	$1.84 Billion

Source: Company Reports

Inside The Lab Industry

"While some may argue that there were some temporal benefits on the lab side that elevated results in the quarter, ultimately we believe this result was more evident of performance we are likely to see throughout the year ... and should likely argue for continued multiple expansion/firming."

— Ross Muken, Analyst, Evercore ISI

"We are off to a terrific start to the year, highlighted by robust organic revenue growth and double-digit adjusted (earnings) growth in the quarter," said Dave King, LabCorp's chief executive officer, in a statement. "Broad-based demand for the services of LabCorp Diagnostics and Covance Drug Development is evidence of our customers' enthusiasm for our differentiated offering."

The robust numbers moved LabCorp to raise its guidance for the 2016 calendar year. Revenue guidance was changed to a forecast increase of 7.5 percent to 9.5 percent to an increase of 8.5 percent to 10.5 percent. The LabCorp diagnostics division is expected to experience revenue growth of 4 percent to 5.5 percent, up from 3.5 percent to 5.5 percent. The Covance division is expected to grow 6 percent to 9 percent, up from the prior guidance of 2 percent to 5 percent.

Earnings per share estimates were also raised from a range of $8.55 to $8.95, versus the prior $8.45 to $8.85. Earnings per share in 2015 was $7.91.

"While some may argue that there were some temporal benefits on the lab side that elevated results in the quarter, ultimately we believe this result was more evident of performance we are likely to see throughout the year ... and should likely argue for continued multiple expansion/firming," Evercore ISI analyst Ross Muken said in a report.

LabCorp is continuing to grow its operations through mergers and acquisitions and other new business growth. In a phone call with analysts, King said LabCorp had invested more than $100 million in so-called "tuck-in" deals—transactions small enough that they did not necessarily require a public announcement. It also has accumulated some $190 million in orders for the use of deidentified patient data, according to King. He also believes that revenue in the area of companion diagnostics will top $100 million by 2018.

The company did have one dark spot: Bad debt increased modestly, mostly as the result of what Chief Financial Officer Glenn Eisenberg said was "increased patient responsibility"— a reference to increased cost shifting by insurers.

Meanwhile, the New Jersey-based Quest Diagnostics also posted strong numbers, which, although not quite as earth-shattering as LabCorp's, suggest that it has greater headwinds than its now larger competitor in terms of growth.

The New Jersey-based Quest reported first quarter net income of $102 million on revenue of $1.86 billion. That compares to net income of $61 million on revenue of $1.84 billion.

Inside The Lab Industry

Although overall revenue grew only 1.3 percent year-over-year (3.6 percent on an equivalent basis), revenue for the diagnostics information division grew by 3.8 percent. Overall test volumes grew by 2.6 percent, boosted in part by some acquisitions.

"Bad debt expense is typically highest in the first quarter due to increased patient responsibility associated with high deductible plans."

— Mark Guinan, CFO, Quest

"We're off to a good start in 2016 with a solid performance in the first quarter," said Quest CEO Steve Rusckowski. "Our strategy to refocus on our Diagnostic Information Services business in line with our five-point strategy is largely complete. We are encouraged by the progress we're making and are on track to meet our commitments for the remainder of the year."

Like LabCorp, Quest also reported an increase in bad debt expense to 4.6 percent of revenue from 4.3 percent during the first quarter of 2015.

"Bad debt expense is typically highest in the first quarter due to increased patient responsibility associated with high deductible plans," Quest Chief Financial Officer Mark Guinan said in a call with analysts. "The drivers of the increase were a continued shift to greater patient responsibility, and a change in our business mix as our clinical trials and products businesses had lower bad debt rates."

Quest did not make revisions to its guidance. Revenue is forecast to increase between 1.5 percent and 2.5 percent for calendar 2016.

Nevertheless, the numbers posted by Quest for the quarter beat estimates of $1.84 billion for revenue, although earnings were in line with the consensus of Wall Street analysts.

"With respect to the guidance reiteration we find that unsurprising given the result and look for color on volume/pricing/mix expectations for the remainder of (the calendar year)," Muken said in a report.

The share prices of both companies diverged slightly.

Quest's stock price has stayed around $75 per share in trading on the New York Stock Exchange. LabCorp's moved up slightly, from around $125 a share to $126 a share. However, the share prices of both companies have been essentially flat over the past year, suggesting that there have not been too many surprises in the paths they are currently charting.

Takeaway: LabCorp and Quest Diagnostics, both of which were struggling to grow just a couple of years ago, have broken out of that slump in a dramatic fashion.

Lab Startup Focused on Consumer Subscription Model, *from page 1*

Testing would involve a relatively new dried blood strip technology developed by a laboratory in Texas. Test specimens would be sent to Texas, with a projected three- to four-day turnaround, according to Greenberg. Local pharmacies would also be used to collect buccal swabs for confirming the identity of individual users.

> *"I question, off hand, how many people will want—or see the need—to pay for a monthly subscription. That may be the ultimate stopping point when people read the fine print."*
>
> — Peter Francis, President, Clinical Laboratory Sales Training

Mately not only would enable ongoing STD testing, but allow easy transmission of test results to potential partners. The company has also proposed that a badge indicating a Mately membership could be integrated into an individual's online dating profiles.

According to the company website, there are 19 million new STDs diagnosed in the U.S. every year—10 times higher than the total arrived at by the Centers for Disease Control and Prevention, which claimed about 1.9 million in total in 2014, excluding HIV. However, rates of all STDs were on the rise, including a 15.1 percent increase in cases of syphilis.

Greenberg has experience in banking regulation and compliance investigations, but none in the laboratory or health care sectors. He said about $350,000 has been invested in the company to date, and the company is looking for additional investors, including venture capital.

Peter Francis, president of Clinical Laboratory Sales Training, a laboratory consulting firm in Maryland, said Mately's business model sounded intriguing, and may fill a need. But he also evinced some skepticism.

"I question, off hand, how many people will want—or see the need—to pay for a monthly subscription," Francis said. "That may be the ultimate stopping point when people read the fine print."

Mately has gotten some media attention, but not the kind typically sought by start-ups. It recently posted on its Facebook page a photo of Sesame Street characters Bert and Ernie peering at some pieces of paper. "See Ernie, you've got nothing to worry about, everything is positive!" the caption read.

The stunt drew media headlines—as well as a cease and desist letter from the Children's Television Workshop, which for some reason did not want its characters associated with STDs.

Mately spokesperson Alanna Astion said the intent was to be "light-hearted" and communicate how traditional test results printed on paper are confusing. Both she and Greenberg said they understood Sesame Street's point of view and no similar postings would occur.

Mately's crowdfunding campaign is currently making little headway. According to the website Indiegogo.com, it raised $3,859 in the days after its launch, and then stalled (its goal is $500,000).

Greenberg indicated there was no expectation of raising money from the crowdfunding campaign. "It's a nice story hook," he said.

Takeaway: Mately is trying to create a new business model for laboratory services, but appears a long way from success.

INDUSTRY BUZZ

ID Genomics Receives $3 Million NIH Grant to Develop Antibiotics Screening Test

Seattle-based startup laboratory ID Genomics has received a nearly $3 million federal grant to compile a database of antibiotic resistant bacteria.

The three-year grant from the National Institutes of Health (NIH) will be used to create a "barcode" test that would diagnose specific bacterial infections and suggest choices of antibiotics, all within a 30-minute time window.

"We are honored that the NIH believes so strongly in our research and the incredible opportunity it presents," said Evgeni Sokurenko, M.D. chief executive officer of ID Genomics and a professor of microbiology at the University of Washington.

The grant was given by NIH's Small Business Technology Transfer program.

The test being developed by ID Genomics is intended to address a growing issue in U.S. health care delivery: an increasing number of bacterial infections that are resistant to the current inventory of antibiotics. Up to 30 percent of current prescriptions for antibiotics fail to treat the infection due to resistance. This forces the patient to return for another round of a different medication. The delay in receiving the correct treatment can drag out the illness and potentially endanger the patient. Meanwhile, the multiple rounds of antibiotics drive up bacterial resistance to the drug even further.

According to data from the U.S. Centers for Disease Control and Prevention, antibiotic resistance costs the country's health care system $20 billion per year and adds 8 million patient days to hospital stays annually. The loss of productivity from patients with prolonged illnesses costs another $35 billion.

"Within the same bacterial species are individual 'crime families,' each of which has its own antibiotic resistance profile," Sokurenko said. "When doctors see a certain 'criminal' in the clinic, our technology will help them identify the associated antibiotic rap sheet and so choose the best treatment option."

ID Genomics has not said when such a test might become commercially available, or its potential retail price.

Takeaway: ID Genomics is receiving an enormous opportunity to develop a test that could help aid providers in the fight against bacterial resistance to antibiotic medications.

References

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