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T2 Biosystems Has Strong Diagnostic Tool in Fight Against Sepsis

A small laboratory company in Massachusetts is taking on one of the biggest killers in the hospital setting.

That would be sepsis, a bloodstream infection that typically evolves from lung, skin or urinary tract infections. Hospital stays for sepsis cases are about 75 percent longer than average, according to data from the Centers for Disease Control and Prevention. And while sepsis can be fought off with antibiotics, its mortality rate hovers around 50 percent.

One of the biggest obstacles to treating sepsis is identifying its presence rapidly, and that is the issue T2 Biosystems is trying to address. The company received approval from the U.S. Food and Drug Administration in September 2014 to market its test, called T2Candida, and its T2Dx platform.

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Quest Acquires Hartford HealthCare Outreach Business

Quest Diagnostics has made another dip into hospital laboratory outreach, acquiring those specific assets from Connecticut's largest health care system.

The New Jersey-based Quest announced the acquisition of the outreach business of Clinical Laboratory Partners (CLP) earlier this month. CLP is an affiliate of Hartford HealthCare, which operates five hospitals within Connecticut.

The deal is one of several Quest has made for hospital outreach operations in recent years, both in the eastern and western United States. The latest transaction will actually take advantage of a previous outreach deal it made in Massachusetts in 2013 involving University of Massachusetts Memorial Medical Center.

“Over the past decade, many health systems have expanded their outreach lab businesses to service physicians in their area. Now that pattern is shifting, as these same systems reconsider their outreach lab

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■ QUEST ACQUIRES HARTFORD HEALTHCARE OUTREACH BUSINESS, *from page 1*

strategies in light of reimbursement pressures and the growth of high-deductible plans, which place a greater share of cost on patients,” said Quest Chief Executive Officer Steve Rusckowski in a statement. “Top health systems that have developed a commercial outreach business, such as Hartford HealthCare, are increasingly entrusting the vital diagnostic information service to Quest because we have unique assets, such as clinical expertise and scale, which allow us to deliver great value.”

“Quest is well positioned to offer consistently excellent lab services to our customers with wider access and greater affordability.”

— Elliot Joseph,
CEO, Hartford HealthCare

As part of the deal, CLP will transition its laboratory testing services currently performed at its site in Newington, Conn. to Quest labs in three other Connecticut cities. Work will also be performed at Quest’s 200,000 square-foot regional lab in Marlborough, Mass., which it built to help accommodate volume from the University of Massachusetts acquisition. CLP and Quest will also collaborate on various population health and data analytics initiatives, although no specifics have yet been disclosed.

“Quest is well positioned to offer consistently excellent lab services to our customers with wider access and greater affordability,” said Hartford HealthCare CEO Elliot Joseph in a statement.

Michael Cherny, an analyst with Evercore ISI, said he expected Quest “to maintain this trend of acquiring hospital outreach labs, particularly if hospitals view these as less core once the PAMA regulations are fully enacted in 2017 (creating further potential pricing pressure on these labs). All-in DGX’s focus on driving 1 to 2 percent incremental growth through acquisitions remains on track.” However, he added that the limited upside from this volume of deals was not likely to budge his current “hold” rating on Quest stock.

The deal is expected to close by early 2016, subject to approval by various regulators. Financial terms were not disclosed.

Takeaway: Quest continues to expand and consolidate its stable of hospital outreach acquisitions. 

UCSF Launches Center to Focus on Genomic Medicine

The University of California at San Francisco is making a significant investment in the development of new forms of genomic laboratory testing, with an initial focus on brain infections and how they can be more quickly diagnosed in a clinical setting. Such diagnoses can save health care providers enormous amounts of money by avoiding long-term intensive care for many patients suffering meningitis and encephalitis, researchers say.

The opening of the UCSF Center for Next-Gen Precision Medicine Diagnostics was announced over the summer. It’s been funded with \$2.4 million in private foundation grants and \$1.2 million from the public-private California Initiative to Advance Precision Medicine.

“When people present with the meningitis encephalitis symptoms, what you want to do with any sort of diagnostic tests, hopefully you can change the choice of care they’re receiving.”

— Brent Fulton, Associate Director, UC Berkeley

The clinical/research portion of the center is being headed by Joseph DeRisi, the UCSF chair of biochemistry and biophysics, Charles Chiu, M.D., and Michael Wilson, M.D. The latter two published a high-profile study in the *New England Journal of Medicine* last year about genomic techniques they have developed to identify rare forms of encephalitis. Last year, they were able to identify within a couple of days one form of the infection that struck a Wisconsin teenager. He had initially been misdiagnosed with an autoimmune form of encephalitis, leading to the use of corticosteroids for treatment. That caused his brain to swell, forcing doctors to place him in a medically induced coma. UCSF researchers were able to diagnose a relatively rare Caribbean variant of the disease in about 90 minutes. He was treated with penicillin and recovered.

“From a health outcomes standpoint, encephalitis and meningitis are very serious diseases,” said DeRisi. Along with a mortality rate of around 6 percent, such infections often lead to weeks-long stays in hospital intensive care units and patients suffer serious permanent cognitive damage, requiring even more care.

Although there has been extensive research on vaccine development regarding brain infections, there has been less regarding their economic costs. However, the Centers for Disease Control and Prevention released a report last year tallying the economic costs for those stricken by the mosquito-borne West Nile Virus, which rarely leads to symptoms but can cause encephalitis or meningitis in some patients. The tally: An average \$25,117 for each patient hospitalized, and another \$22,628 per average for related medical costs over the next five years.

Pinpointing the cause of the brain inflammation as quickly as possible is the key to driving treatment. But about half of encephalitis and meningitis cases are never specifically diagnosed, leading to guessing games that in the case of the Wisconsin boy almost killed him.

“When people present with the meningitis encephalitis symptoms, what you want to do with any sort of diagnostic tests, hopefully you can change the choice of care they’re receiving,” said Brent Fulton, associate director of UC Berkeley’s Global Center for Health Economics and Policy Research. Fulton will be conducting research to quantify the cost of deploying genomic tests for brain infections and their overall outcomes. Fulton will be poring over brain infection claims data, as well as the costs for outpatient treatments and drugs. In many instances, Fulton suggested that the costs of side-effects from certain treatments and long-term care may well outstrip the actual costs of treating a patient in the hospital.

Other potential hurdles to deploying genomic tests for brain infections will also be examined by Fulton. “When you look at prescription drugs, if they’re approved by the Food and Drug Administration, Medicare covers them automatically,” Fulton said. Not so with genomic tests and the laboratory companies that have developed them. The latter often have to engage in dialogue for months, if not years, with Medicare fiscal intermediaries to obtain codes that guarantee their coverage by Medicare. That does not even include separate dialogues for coverage by private payers.

Takeaway: The UCSF Center for Next-Gen Precision Medicine Diagnostics will use genomic testing to try to alter the economics of treating brain infections. 

Inside The Lab Industry

Outlook for Medium-Size Labs Continues to Show Promise

The outlook for the mid-size and smaller publicly traded laboratories appears to be bright. Most reported gains in earnings or revenue, or significant capital infusions in the most recent quarter and continued to issue optimistic broadcasts regarding revenue and earnings growth moving forward.

"We believe that the Pfizer transaction ... and the acquisitions of EirGen and Bio-Reference Laboratories have had a positive impact on our financial operations and will provide significant revenue opportunities and an expanded commercial platform for us going forward."

— Phillip Frost, CEO, OPKO

OPKO Health

OPKO Health had the biggest bump up in revenue of all the reporting labs, although that was primarily due to its acquisition of Bio-Reference Laboratories, which closed on Aug. 21. For the third quarter ending Sept. 30, the company reported net income of \$128.2 million on revenue of \$143 million. That's starkly different from the third quarter of 2014, when it reported a loss of \$48.7 million on revenue of \$19.8 million.

In addition to the Bio-Reference deal, OPKO also entered into a biopharmaceutical development deal with Pfizer. "We believe that the Pfizer transaction ... and the acquisitions of EirGen and Bio-Reference Laboratories have had a positive impact on our

financial operations and will provide significant revenue opportunities and an expanded commercial platform for us going forward," said Phillip Frost, OPKO's chief executive officer.

Adam Logal, OPKO's chief financial officer, told analysts that the Bio-Reference deal will also allow it to enjoy about \$93 million in overall income tax benefit as it can use the deal to claim research and development credits to offset the company's historical losses.

For the first nine months of 2015, OPKO reported a net loss of \$33 million on revenue of \$215.5 million, compared to a net loss of \$121.2 million on revenue of \$65.6 million for the first nine months of 2014. The company obtained a \$175 million credit facility not long after the Bio-Reference deal closed. That and the \$212 million of cash on hand will allow it to better market existing tests and assist in the commercial launch of a new drug to treat hyperthyroidism.

The purchase of the much larger Bio-Reference by OPKO led to its stock being hit hard, and Wall Street apparently remains unconvinced of the synergies within the transaction. OPKO's stock, which was trading at nearly \$19 a share in June, is currently below \$11 per share. The company did not issue any guidance with its earnings report.

Inside The Lab Industry

Myriad Genetics

After getting hit hard on losing the patent to its BRCA test in 2013, Myriad Genetics is on the comeback. The company reported a 9 percent gain in revenue for its first fiscal 2016 quarter ending Sept. 30, to \$183.5 million from \$168.8 million during the first quarter of fiscal 2015. Net income was up 66 percent, to \$26.6 million from \$16 million. The Salt Lake City-based lab had previously battled shrinking revenue after the U.S. Supreme Court invalidated its patent, allowing many other labs to introduce competing tests at lower prices.

Myriad's hereditary cancer testing business represented \$157 million of its revenue, and growth was up 4 percent compared to a year ago. In a call with analysts, Myriad Chief Executive Officer Mark Capone said that the company was focused on increasing its market share for colon and endometrial cancer testing.

"In our view, Myriad's hereditary cancer business has proved to be more resilient than originally anticipated with the CDx assay helping offset other pressures," William Blair analyst Amanda Murphy said in a report.

"In the third quarter, we delivered the highest level of test growth in two years and nearly double-digit revenue growth in the U.S."

— Kim Popovits, CEO,
Genomic Health

The company stuck with its full fiscal year guidance of \$750 to \$770 million in revenue. That's up from the \$723.1 million in revenue it reported for fiscal 2015, but still down from fiscal 2014's revenue of \$778.2 million. Earnings are expected to rise about 10 to 15 percent.

Genomic Health

The Redwood City, Calif.-based Genomic Health reported modest growth for the third quarter, although its losses widened. It reported a loss of \$11.8 million on revenue of \$73.5 million, although \$6.2 million was attributable to a tax expense regarding some of the company's security holdings. That compares to the third quarter of 2014,

when it lost \$6.2 million on revenue of \$57.8 million. Revenue was up a total of 6 percent, while volume of the company's Oncotype DX prostate cancer assay was up 17 percent.

"In the third quarter, we delivered the highest level of test growth in two years and nearly double-digit revenue growth in the U.S.," said Genomic Health Chief Executive Officer Kim Popovits.

The company noted that it received Medicare approval for Oncotype DX in mid-October, and that is likely to drive significant revenue growth in subsequent quarters and move the company closer to profitability.

Foundation Health

The Cambridge, Mass.-based laboratory is still in late startup mode, and continues to post steep losses. However, revenue is growing quickly.

Inside The Lab Industry

For the third quarter of calendar 2015, Foundation reported a loss of \$20.6 million on revenue of \$25.4 million. That compares to a loss of \$13 million on revenue of \$16.4 million for the third quarter of 2014. Much of the 54 percent of the year-over-year revenue growth was attributable to its testing for the biopharmaceutical realm, including an ongoing relationship with drug giant Roche. Overall test volume was up 25 percent during the quarter, although the company is still performing fewer than 3,000 tests per month.

For the first nine months of the year, Foundation lost \$70.6 million on revenue of \$67.2 million. That compares to a loss of \$38.9 million on revenue of \$42.4 million for the first nine months of 2014. Foundation is forecasting revenue for all of calendar 2015 to be between \$85 million and \$95 million. Its 2014 total revenue was \$61.1 million and \$29 million for 2013.

“We experienced robust growth in our Afirma business, driven in part by increased private payer coverage, new in-network contracts, and test performance that is unmatched in its ability to help patients avoid unnecessary surgery”

— Bonnie Anderson, CEO,
Veracyte

Veracyte

The South San Francisco, Calif.-based Veracyte also reported a big uptick in its quarterly sales. It reported a net loss of \$8.9 million on revenue of \$12.3 million for the third quarter ending Sept. 30. That compares to a net loss of \$7.9 million on revenue of \$9.8 million for the third quarter of 2014.

Volume of Veracyte’s primary assay, the Afirma thyroid test, grew rapidly. It was up 46 percent compared to the year-ago quarter, buoyed in part by a recent recommendation by the American Thyroid Association that the Afirma can be used instead of surgery to rule out thyroid cancer in patients with indeterminate-sized nodules.

“We experienced robust growth in our Afirma business, driven in part by increased private payer coverage, new in-network contracts, and test performance that is unmatched in its ability to help patients avoid unnecessary surgery,” said Veracyte Chief Executive Officer Bonnie Anderson in a statement.

For the first nine months of 2015, Veracyte reported a net loss of \$25.7 million on revenue of \$35.5 million. That compares to a net loss of \$21.2 million on revenue of \$26 million for the first nine months of 2014. The company stuck with its full year guidance of \$48 million to \$53 million in revenue and test volume of 19,000 to 21,000. For calendar 2014, it reported revenue of \$38.2 million and performed slightly more than 14,000 tests.

Murphy noted in a recent report that given the cost savings associated with Afirma, “we continue to believe that the company has quite a bit of runway on the Afirma product.”

Takeaway: The medium-sized and smaller molecular laboratories are continuing to report healthy rates of growth in revenue, if not profit. 

■ T2 BIOSYSTEMS HAS STRONG DIAGNOSTIC TOOL IN FIGHT AGAINST SEPSIS, from page 1

The platform uses magnetic resonance imaging to analyze blood samples based on how water molecules react in the presence of magnetic fields. In the presence of *Candida*, the fungal virus that is among the leading causes of sepsis, the behavior of water in the blood samples is a tip-off. Blood samples are run through a worktop device that is about the size of a dormitory refrigerator. It can process up to seven samples simultaneously and test for five different forms of *Candida*. Test results are usually available within three to five hours.

Sandy Estrada, a Lee Memorial pharmacist with expertise in infectious diseases, said that use of the platform has cut the initiation of anti-fungal drug regimens from 40 hours to just six, and has eliminated use of the medication on sepsis patients who won't respond to such treatment.

Sepsis testing typically requires blood culturing, and if a case is fungal in nature it can take at least a couple of days to lead to a positive diagnosis. The mortality rate for candida-related sepsis cases is about 35 percent when it takes 48 hours or longer to make an accurate diagnosis. That drops to 11 percent if the diagnosis is made in less than 12 hours after a case is suspected.

A strong economic case can also be made for a quicker sepsis diagnosis. A rapid diagnosis cuts treatment costs by about \$30,000, a roughly 23 percent decrease, and reduces the average hospital and intensive care unit stay by about nine days, according to studies made on the subject.

That the platform costs \$150,000—not including the costs of supplies—is apparently not an obstacle for some larger health care systems, according to T2 Biosystems Chief Executive Officer John McDonough. “We are seeing cases where it is literally paying for itself in the first week of operation,” he said.

Although the T2 platform is considered a point-of-care diagnostic that required FDA approval, Medicare has shifted payments for most hospitals treating sepsis to a bundled payment tied to existing DRG codes. McDonough said that meant T2 would not have to go through a long process with Medicare fiscal intermediaries in order to obtain coverage.

At present, 19 of the largest 450 hospitals and health care systems in the U.S. have purchased the testing platform, according to McDonough, with nine occurring during the third quarter of this year.

Among them is the Lee Memorial Health System, which operates four hospitals in Florida. It has run 60 tests since it began using the platform two months ago, six of which tested positive for sepsis caused by candida.

Sandy Estrada, a Lee Memorial pharmacist with expertise in infectious diseases, said that use of the platform has cut the initiation of anti-fungal drug regimens from 40 hours to just six, and has eliminated use of the medication on sepsis patients who won't respond to such treatment.

“We've implemented this pathway and it's working,” Estrada said.

Takeaway: T2 Biosystems' sepsis testing platform could be a game-changer regarding one of the costliest maladies in the hospital setting. 

INDUSTRY BUZZ

FDA Releases Report Listing 20 Potentially Dangerous Lab Tests

In the ongoing battle over the regulation of laboratory developed tests (LDTs), the Food and Drug Administration on Nov. 16 issued a report detailing the potential risk of allowing some tests to go unregulated by the agency.

The FDA has proposed to regulate LDTs along the lines it does medical devices, with particular scrutiny to those assays it considers more likely to harm patients. The laboratory sector has asserted that CLIA regulations would suffice for most tests, and suggested that updates to CLIA would allay most of the FDA's concern.

In its report, the agency issued 20 different case studies of LDTs that while compliant with CLIA regulations, did not require approval of the FDA. A couple of the tests have been withdrawn or not brought to market, but most are currently available commercially.

According to the FDA report, they “illustrate, in the absence of compliance with FDA requirements, that these products may have caused or have caused actual harm to patients. In some cases, due to false-positive tests, patients were told they have conditions they do not really have, causing unnecessary distress and resulting in unneeded treatment. In other cases, the LDTs were prone to false-negative results, in which patients' life-threatening diseases went undetected. As a result, patients failed to receive effective treatments.”

Among the tests disputed by the FDA include assays to determine the risk for ovarian cancer; a test for whooping cough; tests to help guide treatment of patients with breast cancer, prostate cancer and melanoma; non-invasive prenatal testing; and vitamin D deficiency testing, among others.

The American Clinical Laboratory Association was immediately dismissive of the report.

“These so-called case studies are not representative of the thousands of LDTs utilized on a daily basis by providers to positively impact patient care,” the ACLA said in a statement.

Laboratory Industry Report will delve more deeply into the FDA report—along with responses from laboratories—in its next issue.

Takeaway: The Food and Drug Administration is ratcheting up pressure regarding the regulation of laboratory developed tests. 

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Laboratory Association**
202-637-9466

Food and Drug Administration
888-463-6332

Genomic Health
650-556-9300

Myriad Genetics
801-584-3600

NeoGenomics
239-768-0600

OPKO Health
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