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HIGHLIGHTS

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Through Deals and an Executive Revamp, Aurora Diagnostics Strains Toward the Black

Debt-laden Aurora Diagnostics has all but revamped its executive ranks and engaged in several deals in the past few months that has refocused the Florida-based laboratory on pathology and dermopathology services.

In little more than five months, Aurora has appointed a new chief operating officer (the promotion of Bruce Walton, the former vice president of operations, was the only internal move); a chief medical officer (Alan D, Pierce, M.D., a Florida-based pathologist); a chief information officer (Anthony Bobos, former chief technology officer for a Wisconsin blood bank and laboratory); a vice president of hospital operations; and a vice president of revenue management.

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CAP to Palmetto on Staining LCD: Withdraw It Completely

The College of American Pathologists has waded into the immunohistochemical staining issue, asking Medicare fiscal intermediary Palmetto GBA to drop its draft local coverage determination (LCD) for regulating the practice.

The request comes after CAP had all but asked for an LCD in lieu of an educational letter Palmetto had posted on its website last year regarding staining guidelines for some gastric cases. Palmetto withdrew the letter after CAP said it was acting in an arbitrary manner. The lobbying organization also filed a letter of complaint with Centers for Medicare & Medicaid Services Director Marilyn Tavenner on the matter.

Palmetto had decided to scrutinize special and immunohistochemistry staining practices because some pathologists had been ordering as many as a dozen such stains for a single gastric case, suggesting the process was being abused. Medicare pays between $12.12 to $97.67 per stain, depending on the region of the country the work is being performed in and other circumstances.

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CAP to Palmetto on Staining LCD: Withdraw It Completely, *from page 1*

Although lengthy, Palmetto's draft LCD is quite specific about when staining should be used and not used. In its draft LCD, which covers not only staining for gastric but breast, lung, gynecologic, skin, and soft tissue samples, among others, Palmetto suggested that stains for many breast and lung cancer cases are not necessary, and that special gastric stains can be performed only when medical necessity is established in the patient records (about 20 percent of the time, Palmetto concluded).

Nevertheless, a Christmas Eve letter from CAP President Gene Herbek, M.D. to Palmetto Medical Director Elaine Jeter, M.D., asked that the organization hold off on its LCD. The correspondence was part of the 45-day public comment period that began in November and ended on Christmas Day.

"The (draft) LCD uses highly selective and partial literature citation, takes references out of context, overlooks fine points, misrepresents the opinions of national organizations, and is contrary to generally accepted guidelines," Herbek wrote. CAP's specific comment on the entire LCD suggested that Palmetto did not even substantiate overutilization.

Moreover, CAP claimed there was a lack of clinical consensus in some of its conclusions, such as the 20 percent threshold for gastric staining. "This utilization threshold is arbitrary and not supported by evidence or consensus of the pathology community," Herbek wrote, adding that Palmetto appeared to make its conclusion based on a single 2006 study.

As a result, the LCD would interfere with a pathologist's ability to make conclusions on staining based on medical necessity alone, CAP argued.

Palmetto is expected to analyze the public comments on its draft LCD and issue revisions later this year.

Takeaway: The College of American Pathologists is continuing to exert pressure regarding the outcome of how special stains are regulated and paid for.

LabCorp, PerkinElmer Introduce Two New Pediatric Tests

LabCorp and PerkinElmer have released two dramatically different tests that are both intended to address challenges in diagnosing pediatric patients with potentially life-threatening conditions.

The North Carolina-based LabCorp had released a test that is expected to provide a more accurate diagnosis of the Enterovirus D68, which is commonly known as EV-D68. The test, which was released last month, was introduced after an outbreak of EV-D68 in the U.S. in 2014 that was far larger than normal. The outbreak season for the virus is in the summer and autumn months.

The U.S. Centers for Disease Control and Prevention reported that the numbers of persons infected with EV-D68 last year exceeded 1,100 — "far higher" than

any year going back at least to 1987, the agency said. A typical year includes just a handful of reported cases. As a result, the agency issued treatment protocols for EV-D68 patients.

Although adults can be infected with EV-D68 and have so few symptoms they may not be aware they are ill, the virus can be brutal on children and teenagers, particularly those with existing respiratory conditions such as asthma or wheezing, and may require hospitalization. At least 13 deaths last year were linked to the virus, the CDC reported.

LabCorp's assay is known as a "reflex" test in that it will be conducted in multiple stages depending on the initial findings. The test initially determines the presence or absence of enteroviral RNA in a respiratory sample. If that's positive, it will then "reflex" to an EV-D68-specific PCR test to determine the virus' specific strain.

"Understanding the underlying cause of this severe illness allows the clinician to manage symptoms appropriately through protocols like those issued by (the Centers for Disease Control and Prevention), which may also help reduce further transmission of the virus," said Mark Brecher, M.D., LabCorp's chief medical officer.

PerkinElmer released another assay that tests for another potentially deadly condition in children: Severe Combined Immunodeficiency (SCID), or what is popularly known as "bubble boy disease." The condition occurs in about one in every 58,000 births, and essentially brings the newborn into the world without an active immune system. The Massachusetts-based PerkinElmer had previously sold the test, known as EnLite, in Europe, but recently received regulatory approval to sell it in both the United States and Canada.

Most undiagnosed sufferers of SCID would rapidly succumb to infections not noticed in an infant with a normal immune system. In the past, the few survivors of SCID were confined to carefully controlled sterile environments. More recently, the condition can be treated with the transplantation of stem cells from family members or other donors, although a rapid diagnosis of the condition tends to lead to better outcomes.

PerkinElmer officials said the test focuses on a particular DNA structure that is the primary marker for SCID. The test can be used in conjunction with other typical screenings of newborns.

"Earlier detection and diagnosis of SCID can result in cost-savings and benefits, due to the fact that earlier-diagnosed infants with SCID require less-intensive clinical care for a shorter period of time," said Fred Lorey, a PerkinElmer consultant specializing in newborn screening services.

Neither LabCorp nor PerkinElmer released prices for the new tests.

Takeaway: LabCorp and PerkinElmer have introduced esoteric tests that can better improve care for pediatric patients with specific conditions. G2

Inside The Lab Industry

Venture Capital and Laboratories: A Lingering Question Mark

Despite the vastness of the health care industry, the laboratory sector is one business branch with minimal leverage. Despite its ubiquity — what patient hasn't undergone a lab test? — it still only counts for about 2 percent of total health care spend.

As a result, the lack of leverage has exposed the lab to payment cuts other segments have not had to experience. And it has also made it a little less attractive for firms with deep pockets to wade into the market. One of the most notable illustrations of this was the $250 million Warburg Pincus invested in Regional Diagnostic Laboratories to acquire properties. Primarily because of the business climate, the company has not executed a single deal to date. The company's website says it is being redesigned.

"We are pleased with the success of this capital raise. It will provide the funds necessary to propel our commercial transition."

— James LaFrance, CEO, Vermillion

There are some signs that may be changing. At the close of 2014 and early into this month, there were four significant infusions of capital into esoteric labs. None of the deals were particularly large on their own, but it may be indicating a loosening up of venture capital going into the lab market.

However, there are some provisos: The recent capitalizations were mostly to already existing labs that offer products, as opposed to startup firms. And in some of the instances the labs took the private equity money in lieu of making public stock offerings.

The biggest deal of the three involved California-based CardioDx, which develops tests focused on detecting cardiac anomalies. It raised $35 million from the Canadian investment firm Alberta Investment Management Corporation, or AIMCo. The proceeds will be used to better promote its primary test, the Corus CAD, which helps detect coronary artery disease. The company recently performed its 100,000th test, but given the pathology of heart disease in the United States, has barely penetrated its potential market. It had previously raised $21 million earlier in the year from a variety of funders.

The investments apparently took CardioDx onto a different course. Less than a week after receiving the funding, the company withdrew its plan to make an initial public offering that would have raised as much as $92 million. According to its December 23 filing with the Securities and Exchange Commission, "the terms currently obtainable in the public marketplace are not sufficiently attractive to the registrant to warrant proceeding with the public offering."

A spokesperson for CardioDx did not respond to a request seeking comment.

Inside The Lab Industry

The second-largest transaction was the only one that included a startup firm. Sera Prognostics, a Salt Lake City-based lab, raised $20 million in second-round financing to develop prenatal tests for conditions such as pre-term births and pre-eclampsia. European-based Chione, Ltd. led the round. Previous investors such as Investors Domain Associates, InterWest Partners and Catalyst Health Ventures, also participated.

Sera is currently conducting clinical trials involving more than 5,500 patients.

Vermillion, an Austin, Texas-based laboratory that focuses on women's health and gynecologic diseases, closed a $10.5 million investment from a couple of funds, Oracle Investment Management, Birchview Fund LLC and several of the company's directors. The proceeds will be used for working capital and general purposes.

Unlike CardioDx, Vermillion is publicly-traded, and it is struggling. For the third quarter ending September 30, it reported a loss of $5.6 million on revenue of $323,000. In the year-ago quarter, it lost $2.3 million on revenue of $330,000. The buy-in also includes an option to purchase another $8.3 million in equity.

"We are pleased with the success of this capital raise. It will provide the funds necessary to propel our commercial transition," said Vermillion Chief Executive Officer James LaFrance in a statement. Simultaneously, the company suspended its at-the-market offering of additional stock. A Vermillion spokesperson did not respond to a request seeking comment.

10 Major Capital Investments In Laboratory Ventures (2014-15)

Company	Date	$ Raised
Proteus Digital Health	$120 Million	Undisclosed
Precision Therapeutics	$60 Million	HealthCare Royalty Partners
CardioDx	$56 Million	AIMCo., Artiman Ventures LP, Asset Management Ventures, Longitude Capital Management
Integrated Diagnostics*	$31.7 Million	Baird Capital, InterWest Partners
Guardant Health	$31.5 Million	Khosla Ventures, Sequoia Capital, Pejman Mar Ventures
Acutus Medical	$26.2 Million	Undisclosed
Sera Prognostics**	$20 Million	Chione, Ltd., Investors Domain Associates, InterWest Partners, Catalyst Health Ventures
Daktari Diagnostics	$13 Million	Global Healthcare Innovation Fund, Norwich Ventures, Partners Innovation Fund
Vermillion	$10.5 Million	Oracle Investment Management, Birchview Fund LLC
Interleukin Genetics	$10 Million*	New Enterprise Associates, Bay City Capital

* Included debt financing ** Announced in 2015 Sources: MoneyTree Report, FierceDiagnostics

The third lab that received funding, Massachusetts-based Interleukin Genetics, raised $5 million from New Enterprise Associates and Bay City Capital. The company also secured $5 million in debt financing from Horizon Technology Finance Corporation. Interleukin intends to use the proceeds to continue promoting its oral health assays. An official with New Enterprise Associates did not respond to a request seeking comment.

Inside The Lab Industry

"There are a number of solid private companies with launched Dx products that have consumed (more than) $100 million in equity capital: CardioDx, XDx, Tethys, Crescendo, to name a few. These will need to be very large exits to generate a venture return."

— Bruce Booth, Managing Partner, Atlas Venture

For the third quarter of 2014, the most recent data available, there were only eight deals consummated, according to the MoneyTree Report, a list of such transactions compiled by PricewaterhouseCoopers and the National Venture Capital Association. They ranged in size from the $21 million CardioDx raised to just around $1 million.

However, the second quarter of 2014 was a different story. The sector (which also included medical devices for categorization purposes) reached $649 million, up 8 percent from the second quarter of 2013. Deals included Proteus Digital Health raising $120 million from a variety of individual investors, and Integrated Diagnostics, which raised nearly $32 million.

Overall, biotech and medical devices are among of the hottest areas of venture capital — according to the MoneyTree Report, the two areas combined represented 18 percent of all the money that flowed into companies through the first nine months of 2014.

However, published reports say that many firms are still skittish about investing in diagnostics companies. That's primarily because of uncertainty in reimbursement — think the sequester — the huge cut in the technical component of CPT 88305 for pathology services and the ongoing decision-making among both governmental and private payers as to how molecular diagnostics will be reimbursed.

Specialty niche laboratories have been attracting equity funding, and I think I would tell you that this is likely not a growing trend across all lab businesses," said William Brandt, chief executive officer of Development Specialists, Inc., a Chicago-based turnaround firm that has extensive experience in the lab sector. "Such money as is still out there for investments in laboratory endeavors is flowing to these niche candidates versus being invested in the larger general laboratory businesses.

Bruce Booth, a partner in Atlas Venture, remarked on his blog that "venture-backed diagnostics have been a painful sub-sector to invest in." Among the reasons: Diagnostics are no less risky than the pharmaceutical sector, which requires a product that actually delivers and regulatory approval. Meanwhile, the exit point for diagnostics is usually commercialization — a viable product.

"There are a number of solid private companies with launched Dx products that have consumed (more than) $100 million in equity capital: CardioDx, XDx, Tethys, Crescendo, to name a few. These will need to be very large exits to generate a venture return." Whether any of the venture capital firms have a big exit this year — or head for the exits instead — remains to be seen.

Takeaway: The prognosis for venture capital into lab ventures continues to be unclear.

Aurora Diagnostics Strains Toward the Black, *from page 1*

Aurora, which has about 130 pathologists and 21 testing sites, also engaged in five deals in the last six months after a couple of years of all but staying on the M&A sidelines. Four of those deals were acquisitions of regional pathology laboratories in Georgia, Arizona, Virginia, and Massachusetts.

The most recent transaction, announced on Jan. 5, was the sale of Aurora's blood testing lab in Greensboro, N.C., to Dominion Diagnostics in Rhode Island. The terms of the transaction were not disclosed.

"We are pleased to complete this transaction, which allows us to focus our efforts and resources on our core business of anatomic pathology," said Aurora Chief Executive Officer Daniel D. Crowley in a statement.

Aurora officials declined comment for this article, as the company is currently in a "dark period" mandated by the U.S. Securities and Exchange Commission. Although Aurora stock is not publicly traded, its debt is, according to spokesperson Bill Halldin. The company expects to announce quarterly and year-end earnings in the near-term, Halldin added.

Aurora's recent SEC filings show it is struggling to reach profitability and significant growth. It noted in its filings that it's been hit hard by recent reductions in both Medicare and commercial reimbursement for pathology services.

For the third quarter ending Sept. 30, 2014, it reported a loss of $7.3 million on revenue of $63 million. In the third quarter of 2013, Aurora reported a loss of $3.5 million on revenue of $62.1 million. For the first nine months of 2014, Aurora reported a loss of $16.8 million on revenue of $180.9 million. During the first nine months of 2013, Aurora reported a loss of $16.3 million on revenue of $186.1 million.

Aurora had significantly improved its cash on hand with $22.1 million at the end of the third quarter, compared to little more than $1 million during the same time in 2013. That's primarily due to Aurora obtaining $220 million through a new credit facility last summer, including a $30 million revolving credit line.

It used the bulk of the proceeds, $145.6 million, to retire its prior credit facility, and another $9.7 million to fund an acquisition, most likely Arizona Dermopathology, based on the timeline mentioned in the filing (Sept. 30) and the day the deal was announced (Oct. 1).

Its most recent SEC filing indicated that the credit line provided Aurora its current working capital, and also explained the relative flurry of transactions in recent months.

"In order to access the amounts available under its revolving credit facility, the company must meet the financial tests and ratios contained in its senior secured credit facility," the filing said. "The company's management currently expects to meet these financial tests and ratios at least through the end of 2014. The company may undertake acquisitions which it believes would add to earnings and performance with respect to the credit facility covenants."

Takeaway: Aurora Diagnostics appears determined to refocus its clinical mission in order to help pay down its debt.

INDUSTRY BUZZ

Ambry Offers New Genetic Tests for Serious Heart Conditions

Ambry Genetics, the Aliso Viejo, Calif.-based esoteric laboratory, has released a new panel of tests that focus specifically on detecting life-threatening cardiac conditions.

The tests focus on inherited cardiomyopathy, a weakened heart muscle, and arrhythmias, irregular heartbeats. Either can lead to sudden cardiac arrest, among other conditions, and are often asymptomatic until the moment the person's heart stops.

The tests identify genes associated with such conditions – particularly MYBPC3 and MYH7 – and provide analysis regarding a patient's specific risk profile.

"Variants of unknown significance are a major concern with cardiovascular genetic testing ... this greatly reduces the number of uncertainties families may receive," said Ambry Cardiology Product Manager Melissa Dempsey.

The assays are offered as tiered products within an overall 84-gene cardiovascular panel marketed as CardioNext. It also includes Ambry's existing test for markers signifying a risk for aortic aneurysms or dissections; Marfan syndrome (a connective tissue disorder that can lead to an enlarged aorta); Ehlers-Danlos syndrome (weakened blood vessels); familial hypercholesterolemia (high levels of LDL cholesterol); hereditary hemorrhagic telangiectasia (spontaneous internal bleeding); and transthyretin amyloidosis (abnormally high cardiac protein deposits). Any of these conditions can lead to a debilitated heart and circulatory system that can catastrophically fail without warning.

The assays can be performed with samples of blood, saliva, DNA, or cultured cells. The turnaround time is between six to eight weeks.

The new tests represent an expansion of Ambry's focus, which has primarily been on cancer-related genetic testing. It introduced a breast cancer genetic test not long after the U.S. Supreme Court invalidated patent claims to single genes in 2013.

"We are very pleased to offer updated testing for these inherited cardiac conditions that impact so many people, young and old," said Brigette Tippin Davis, Ambry's technical laboratory director. "Tiered panels offer clinicians cost-effective, timely options that focus on specific phenotypes – all with the goal of giving families a rapid and meaningful diagnosis."

Takeaway: Ambry is expanding its product line to include tests for more conditions that can lead to sudden death if untreated.

References

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