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HIGHLIGHTS

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Neoteryx–A Less Ambitious Version of Theranos?

A California startup has launched a platform that can gather blood in tiny tubes for assays with all but no inconvenience for patients.

And it is not Theranos.

Unlike that troubled Silicon Valley laboratory, Neoteryx is not clashing with federal regulators over the efficacy of its platform, known as Mitra. The U.S. Food and Drug Administration has classified the platform as a class one medical device.

At the same time, the Torrance, Calif.-based Neoteryx has far less ambitious plans to remake the world of laboratory testing. Although the firm has been steadily hiring, it currently has only 20 employees.

"It is a way to collect and transport blood. We don't do any assays, and we don't have any claims of any testing and results," said Cathy Cordova, Neoteryx's senior marketing manager.

The company, which was founded in 2014, uses a pen-like device with a spongy tip that absorbs exactly 10 microliters of blood (blood is drawn through a commonly deployed lanced fingerstick).

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FDA Issues Informational Queries to Two Startup Labs

Although the laboratory sector is at loggerheads with the U.S. Food and Drug Administration (FDA) over the regulation of LDTs, that has not prevented the agency from warning two nascent players from marketing genomic tests without the proper approvals.

Last month, the FDA issued letters to Sure Genomics and Solopap International questioning whether the labs were marketing molecular tests without proper clearance from the regulator.

On February 16, the agency sent a letter to the Utah-based Sure Genomics, raising concerns about its $2,500 in-home SureDNA sequencing test.

In a statement, Sure said the process for its SureDNA assay "is similar to 23andMe or AncestryDNA—you sign up, receive a kit, spit in a tube and wait a few weeks. The difference is Sure Genomics prom-

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FDA Issues Informational Queries to Two Startup Labs, *from page 1*

ises full DNA analysis from more than 70,000 biomarkers and will update and add upon information every six weeks as new information becomes available."

Sure did not mention that 23andMe tangled with the FDA back in 2013, when the agency ordered it to stop marketing its direct-to-consumer genome test with interpretative data because it did not have the necessary approval to do so. Direct-to-consumer tests usually require FDA approval. The FDA raised a similar issue with Sure Genomics in its correspondence.

"The SureDNA test appears to meet the definition of a device as that term is defined in section 201 (h) of the Federal Food Drug and Cosmetic Act," the letter said. "We have conducted a review of our files, and have been unable to identify any FDA clearance number for the Sure DNA test." The agency asked Sure Genomics to provide a specific number.

The Nevada-based Solopap is selling through its website a $50 home test for pap smears and the presence of the human papilloma virus. Solopap charges an additional $90 to process the assay and issue test results to the consumer.

The FDA contacted Solopap the day after Sure Genomics. Its letter suggests there may be more leeway in the Solopap assay, which appears to be a more traditional assay as opposed to a molecular test. It may be either processed by its lab or by the buyer's own physician, according to information on the Solopap website.

The agency asked Solopap to provide a rationale if it does not believe the tests require FDA approval, and to furnish "a sample laboratory report which provides the test results to the medical practitioners."

The issue over smaller startup labs such as Sure and Solopap comes as the FDA appears poised to issue final regulations regarding the oversight of laboratory developed tests later this year. Its proposal has created fierce opposition in the laboratory sector, and the American Association of Clinical Chemistry issued a position paper this month in support of maintaining the current CLIA regulations for LDTs (see *Industry Buzz* on page 8).

Takeaway: The FDA has cracked down on two startup labs and their marketing practices prior to its issuance of final guidelines for the regulation of laboratory-developed tests. G2

Smaller Publicly-Traded Labs Report Mixed Results

The publicly-traded esoteric laboratories reported mixed results for the fourth quarter and the full calendar year of 2015.

The largest of those labs, Miami-based OPKO Health, Inc., which vastly increased its size with last year's acquisition of Bio-Reference Laboratories, broke into the black during the fourth quarter ending Dec. 31. It reported net income of $1.6 million on revenue of $276.2 million, of which $220 million was revenue from Bio-Reference operations. That compares to a loss of $53.5 million on revenue of $25.5 million for the fourth quarter of 2014.

For calendar 2015, OPKO reported a loss of $31.4 million on revenue of $491.7 million. For 2014, it reported a loss of $174.6 million on revenue of $91.1 million.

The company did not issue any guidance for 2016, but Executive Vice President Steven Rubin told analysts that the company had been granted a CPT code for its 4Kscore prostate cancer test, likely boosting the chances of it receiving steady reimbursement from payers. Company officials said they are seeking a price at about mid-point of the test's current $1,900 retail price.

"If we continue to trend a single marker companion diagnostic, oncologists—not to mention payers—will quickly become overwhelmed with the complexity around selecting the appropriate test for each patient."

— Michael Pellini, M.D., President and CEO, Foundation Medicine

By contrast, Cambridge, Mass.-based Foundation Medicine continued to operate in the red despite some fairly dramatic business growth. It reported a net loss of $19 million on revenue of $26.1 million for the fourth quarter. That compares to a net loss of $13.3 million on revenue of $18.7 million for the fourth quarter of 2015.

The company said it performed nearly 33,000 of its FoundationOne genomic cancer tests during 2015, up 36 percent from 2014.

For calendar 2015, Foundation reported a net loss of $89.6 million on revenue of $93.2 million, compared to its 2014 loss of $52.2 million on revenue of $61.1 million.

Foundation's 2016 guidance includes revenue projection in the range of $110 million to $120 million. However, expenses are projected in the range of $175 million to $185 million, suggesting another significant loss for the calendar year. It expects test volume of between 37,000 and 40,000.

Foundation President and Chief Executive Officer Michael Pellini, M.D., said the company would be working toward a streamlined companion diagnostic for its rapidly growing biopharmaceutical business. That segment generated $14.1 million in revenue during the fourth quarter.

"If we continue to trend a single marker companion diagnostic, oncologists—not to mention payers—will quickly become overwhelmed with the complexity around selecting the appropriate test for each patient," Pellini told analysts. "Our strategy is to eliminate the complexity and [remove] the guess work for physicians by working towards a universal companion diagnostic."

Fort Myers, Fla.-based NeoGenomics reported a $5.2 million loss for the fourth quarter on revenue of $27.3 million. That compares to net income of $1.3 million on revenue of $25 million for the fourth quarter of 2014.

For calendar 2015, NeoGenomics reported a loss of $5.6 million on revenue of $99.8 million. For 2014, it reported net income of $2.2 million on revenue of $87.1 million. Much of that loss was attributed to extra expenses due to its acquisition of Clarient, Inc., which closed on Dec. 30.

NeoGenomics' acquisition means a huge boost in business moving forward. The company's 2016 guidance includes revenue of $240 to $250 million, and improved profitability in every quarter of this year.

Takeaway: The smaller specialty laboratories are reporting growth but only mixed results regarding profitability. G2

Inside The Lab Industry

As Precision Medicine Initiative Evolves, Labs Play Just a Small Role—for Now

The Obama administration has redoubled its effort to encourage the use of precision medicine, although the role of laboratories in the initiative has mostly been limited to small-bore ambitions for now.

> *"There are few things in life as devastating as when a child is diagnosed with cancer. It's critically important to the achievement of our corporate mission that the robust genomics information we have amassed is freely and easily accessible to researchers and utilized as an important tool to address the significant unmet medical need in pediatric cancers."*
>
> — Michael Pellini, M.D., President and CEO, Foundation Medicine

On Dec. 18., legislation authorizing more than $200 million to fund the initiative was signed into law. On Feb. 25, the one-year anniversary of the precision medicine initiative announced by President Barack Obama, the White House announced a slew of specific new projects involving regulatory agencies, research hospitals and universities, and a sprinkling of commercial laboratories. Of that latter group, many are relatively new to the field and limited in what they may be able offer.

The most well-known laboratory involved in the initiatives was Cambridge, Mass.-based Foundation Medicine. It announced its intention to release its genomic dataset of pediatric cancers for researchers. The Obama administration said it would be the largest dataset in this area to be made publicly available.

"There are few things in life as devastating as when a child is diagnosed with cancer. It's critically important to the achievement of our corporate mission that the robust genomics information we have amassed is freely and easily accessible to researchers and utilized as an important tool to address the significant unmet medical need in pediatric cancers," said Foundation Medicine Chief Executive Officer Michael Pellini, M.D., in a statement.

Illumina, the San Diego-based company that primarily manufactures and distributes sequencing platforms, is involved in an initiative with the University of Chicago, Argonne National Laboratory, the Minority Coalition for Precision Medicine and The BioCollective to research the environments in which children are raised in conjunction with their microbiomes and whether it plays a role in their susceptibility to post-traumatic stress disorder.

One of the more intriguing projects that was announced involved Pairnomix, a Minnesota-based laboratory. It would be working with Harvard Medical School, the University of Utah, Boston Children's Hospital and Recursion Pharmaceuticals to create a system wherein patients with serious illnesses would be more rapidly matched with potential drug therapies through the use of tailored testing. Under this initiative, known as the Patient-Empowered Precision Medicine Alliance, Pairnomix would construct models of individual genetic mutations and perform "highly personalized" drug screenings.

Inside The Lab Industry

Pairnomix's participation in the initiative would appear to be a huge boost for the fledgling company, which was founded only last year. However, Pairnomix officials declined to provide any specifics regarding its role to *Laboratory Industry Report*.

"Through these efforts, we hope to help remove barriers to precision medicine for people of all backgrounds."
— Color Genomics

Color Genomics, another nascent laboratory, was involved in a third initiative, although it was relatively limited in scope. The Bay Area-based lab promised to double the number of free BRCA tests it offers through its Every Woman program, as well as double the number of cancer centers through which those tests are offered. Currently, Color offers the free testing in conjunction with cancer providers at the University of California San Francisco, the University of Pennsylvania, the University of Washington and the Morehouse College School of Medicine.

"Through these efforts, we hope to help remove barriers to precision medicine for people of all backgrounds," Color said in a statement. A company spokesperson did not respond to a query seeking further comment.

That labs have limited participating in the personalized medicine initiative at the moment may actually be following a logical path, according to Juergen Klenk, a principal with Deloitte Consulting, LLP, who is focused specifically on its precision medicine efforts.

"Where do you first light the fire to get this going?" Klenk said. "The challenge is to find and validate good biomarkers that will help provide good diagnostic insight. And that by and large depends on having more data available."

Indeed, many of the projects that were announced last month were focused on making data more available and easily shared by both providers and patients. The Washington, D.C.-based Advisory Board Company, for example, will create a standard application programming interface (API) for up to five pilot health care organizations that will allow them to communicate more efficiently with vendors and patients.

Allscripts, athenahealth, Cerner, drchrono, Epic and McKesson are also collaborating to create APIs that would allow individuals to contribute their data for research initiatives.

Acute care providers such as Hackensack University Medical Center, Carolinas Healthcare System, Intermountain Healthcare, Ochsner Health System, St. Joseph Health, the University of California health system, and Yale New Haven Health all announced they would make it easier for patients to access their data, as well as share it with researchers.

The White House also announced that the Office of the National Coordinator for Health IT and the National Institute of Standards and Technology would develop security frameworks for handling precision medicine data. And the U.S. De-

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partment of Health and Human Services Office for Civil Rights issued additional guidance on individuals' rights to access their health information under the Health Insurance Portability and Accountability Act (HIPAA). Specifically, the new HIPAA guidelines address the rights of individual patients to have copies of their health data sent to anyone they designate, including contributions for research.

The creation of such frameworks to regulate the sharing of genomic and related health care data is only the first step in creating regulatory guidelines that will allow laboratories to more widely participate in the precision medicine initiative, according to Dan Housman, chief technology officer of ConvergeHEALTH, a Deloitte affiliate.

"I can only imagine that they will be major players in high-volume sequencing, either through acquisitions or organic growth."

— Dan Housman, CTO, ConvergeHEALTH

"We don't yet have mature systems in place for handling the funding and approval of companion diagnostics that bring down the cost of medications for findings from genomics," he said. He believes those issues likely won't even be addressed until key regulations are in place to control personalized patient care—as well as guidelines for how providers should act on test results and inform patients—including findings that may or may not be incidental to treatment.

In the meantime, Housman believes that many labs are still ramping up their abilities to process large amounts of genomic data—another requirement that would be key to their participation in the precision medicine initiative on a larger scale.

Housman has worked with the Department of Veterans Affairs and the Department of Defense on the Million Veterans Project, an initiative to create a large research cohort for precision medicine. He noted that one of the biggest challenges has been finding enough labs with the capacity to process the data that would be gathered.

"Labs are still good for (crunching data) on traditional lab tests. But because genomic tests have a very specific profile, it will require data analytics on very high scale," he said.

However, Housman said that labs should be able to meet the challenge. He observed that there is a "deep bench" of startups that should be able to crunch genomic data on a large scale in the near-term. And both LabCorp and Quest Diagnostics have been working on their initiatives in precision medicine, he added.

"I can only imagine that they will be major players in high-volume sequencing, either through acquisitions or organic growth," he said.

Takeaway: The Obama Administration is continuing to press its initiative regarding precision medicine. However, the role that commercial laboratories are playing at the moment is small, although that will likely change as the initiative moves forward. G2

Neoteryx–A Less Ambitious Version of Theranos?, *from page 1*

The sample can be dried within two hours by air or accompanied by a dessicant and can be shipped without a courier and can be processed using common solvents.

The Mitra Microsampling Device is designed specifically for assays that require minimal amounts of blood. According to Cordova, Mitra can be used for ongoing care such as the monitoring of immunosuppressive reactions, as well as some assays that require small amounts of blood. Home testing for pediatric and geriatric patients are another target market, although Neoteryx is also targeting laboratories that performing testing on animals.

"Medical device companies and labs have consistently been seeking ways to make specimen collection easier and more convenient. We need to look no further than the marketing story of Theranos Labs."

— Peter Francis, President, Clinical Laboratory Sales Training

Cordova said Neoteryx has some laboratory clients, but declined to name them. She added that the platform is currently being tested by major health care providers such as the Mayo Clinic, Cedars-Sinai Medical Center, and Seattle Children's Hospital. It is also being tested by Exagen Diagnostics, a San Diego-area laboratory that focuses on autoimmune and neurologic assays.

She would not disclose the cost of drawing a sample, other than it is the equivalent of a dried blood card—$1 to $2—plus a premium.

Peter Francis, the president of Clinical Laboratory Sales Training, a Maryland-based consulting firm, said that competition has been intense regarding the more efficient collection of blood samples.

"Medical device companies and labs have consistently been seeking ways to make specimen collection easier and more convenient. We need to look no further than the marketing story of Theranos Labs," he said.

The primary difference between Neoteryx and Theranos is that the latter has developed an entire collection and testing platform and is conducting assays and processing on its own. And while Theranos has promised to conduct hundreds of tests using just a few drops of blood, the FDA has approved it for just a single test, an assay for a relatively rare form of herpes.

Francis does believe the Mitra platform has some promising applications, such as making point-of-care blood collection more convenient. However, he has raised concerns regarding home-based collections.

"The collection technique describe by Neoteryx requires special attention to several key aspects in order to obtain a good specimen," he said. "The average patient, especially (the) elderly, may not follow the explicit directions, creating frustration and eventual problems for the lab." Francis also raised concerns about whether home testing results would consistently wind up in electronic medical records.

Cordova conceded that some training is required to perform the blood draw accurately, although it is primarily isolated to making sure the tip of the collection device is now drawing the blood at a negative angle.

Takeaway: Neoteryx has introduced a laboratory microsampling device that is decidedly less ambitious than what has been marketed by Theranos. G2

INDUSTRY BUZZ

AACC Issues Position Paper on Regulation of Laboratory Developed Tests

Another industry trade group has chimed in on the issue of the U.S. Food and Drug Administration (FDA) regarding its intent to regulate laboratory developed tests (LDTs). The American Association of Clinical Chemistry (AACC) issued a position paper urging the FDA to give up its effort to regulate LDTs and instead strengthen the existing CLIA regulations. The FDA has proposed regulating LDTs in recent years, raising concerns that the complexity of the tests could put patients in danger if they are not properly interpreted. It has issued proposed guidelines for regulation over the objection of virtually all of the laboratory sector. In its position paper, the AACC made the following recommendations:

"Clinical labs have one of the lowest error rates in healthcare, showing that CLIA has done an excellent job of regulating labs so that clinicians get the quality test results they need to make critical decisions about patient treatment."

— Janet B. Kreizman, CEO, AACC

- LDTs should be defined as new or significantly modified tests for which the modification alters the clinical claims
- CLIA should be updated to require laboratories to demonstrate that LDTs are clinically valid for use in medical decisions
- The Centers for Medicare & Medicaid Services (CMS) should credential third-party organizations to review a laboratory's clinical validation data for LDTs
- CMS and deemed accrediting organizations should include on inspection teams individuals with expertise to evaluate LDTs

The AACC's position is similar to that of other trade groups in the laboratory space, including the American Clinical Laboratory Association. However, the AACC has gone the farthest in terms of articulating a specific alternative to the FDA regulating LDTs.

"Clinical labs have one of the lowest error rates in healthcare, showing that CLIA has done an excellent job of regulating labs so that clinicians get the quality test results they need to make critical decisions about patient treatment," said AACC Chief Executive Officer Janet B. Kreizman in a statement. "AACC urges Congress and CMS to update the already rigorous CLIA framework, as we firmly believe this is the most effective way to improve oversight of laboratory-developed tests while still fostering innovation and enabling labs to meet the changing needs of patients."

Takeaway: The AACC is joining the chorus of laboratory groups objecting to the regulation of laboratory developed tests by the FDA, but has issued an extensive alternative. G2

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