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LABORATORY INDUSTRY REPORT™

Vol. 13, Iss. 23, December 5, 2013

HIGHLIGHTS

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FDA Orders 23andMe to Stop Marketing Personal Genomic Assay

The Food and Drug Administration (FDA) has ordered 23andMe, the California-based personal genomics laboratory, to stop marketing a direct-to-consumer test intended to provide a glimpse into an individual's future state of health.

In a warning letter issued on Nov. 22, the FDA concluded that 23andMe's $99 personal genomics service (PGS) test of a customer's saliva for a variety of genetic abnormalities is a class III medical device and requires FDA approval.

"Some of the uses for which PGS is intended are particularly concerning, such as assessments for BRCA-related genetic risk and drug responses (e.g., warfarin sensitivity, clopidogrel response, and 5-fluorouracil toxicity) because of the potential health consequences that could result from false positive or false negative assessments for high-risk indications such as these," Alberto Gutierrez, director of the FDA's Office of In Vitro Diagnostics, said in the letter to 23andMe Chief Executive Officer Ann Wojcicki. "For instance, if the BRCA-related

Continued on page 2

Final CMS PFS Rule Viewed as a Positive After HOPPS Cap Proposal Scrapped

Industry analysts are looking favorably on a decision by the Centers for Medicare and Medicaid Services (CMS) to scrap a proposal to cap payment for certain anatomic pathology (AP) services provided by independent labs at Hospital Outpatient Prospective Payment System (HOPPS) levels. That proposal would have resulted in reductions of up to 80 percent for some common AP services.

In the final Physician Fee Schedule rule for 2014, released late on Nov. 27, CMS said it is not finalizing that proposal and will consider more fully all comments received. The agency does expect to develop a revised proposal for using HOPPS and ambulatory surgical center rates in developing relative value units, which it will propose through further notice and comment rulemaking.

"We view this as a meaningful positive," wrote analyst Amanda Murphy with William Blair & Co. "Based on the proposed rule

Continued on page 7

FDA Orders 23andMe to Stop Marketing Personal Genomic Assay, *from page 1*

risk assessment for breast or ovarian cancer reports a false positive, it could lead a patient to undergo prophylactic surgery, chemo prevention, intensive screening, or other morbidity-inducing actions, while a false negative could result in a failure to recognize an actual risk that may exist."

The FDA order came just 11 days after the *New York Times* published a profile of the company in which Wojcicki predicted that 23andMe would have genotyped 1 million consumers through its PGS assay by the first quarter of next year. The company had performed about 475,000 genotypes as of earlier this month. Late last year, it had raised $50 million in financing to expand its business operations and research.

23andMe submitted 510(k) forms to the FDA last year notifying that it intended to market its test and that it was already similar to other products already available. However, Gutierrez indicated in his letter that the firm had failed to respond in a timely manner to questions the agency had after the 510(k) was submitted.

"Even after these many interactions with 23andMe, we still do not have any assurance that the firm has analytically or clinically validated the PGS for its intended uses, which have expanded from the uses that the firm identified in its submissions," Gutierrez observed. According to the letter, 23andMe says the test can pinpoint 254 specific diseases and conditions. As a result, the FDA considered 23andMe's current 510(k) to have been withdrawn.

The agency has given 23andMe 15 business days after it received the letter to produce a plan of corrective action, including a timetable for implementation. If it doesn't respond within this period without explanation, it could be subject to legal injunctions and monetary penalties, among other sanctions.

In a blog entry posted to the 23andMe Web site on Nov. 26, Wojcicki acknowledged the company is "behind schedule with our responses." However, she also suggested the FDA's concerns regarding the results it provides consumers are overblown.

"We stand behind the data that we return to customers—but we recognize that the FDA needs to be convinced of the quality of our data as well," Wojcicki wrote.

The company, whose investors include Google co-founder Sergey Brin, has not provided a timeline as to when it expects to reintroduce the test to consumers, and a spokesperson did not respond to a request seeking comment.

Takeaway: The growth of the personal health component of genomic testing may be slowed by regulatory bumps.

Veracyte's Revenue Grows, but So Do Losses

Veracyte, the South San Francisco, Calif.-based molecular laboratory, reported growing revenues for the third quarter, ending Sept. 30, but the company's losses continued to mount as well.

Revenue for the quarter was $5.6 million, up 74 percent from the $3.2 million reported for the third quarter of 2012. Veracyte's net loss was $6.3 million, up 28 percent from the $4.9 million loss reported during the year-ago quarter.

The company markets a single molecular-based test, the Afirma gene expression classifier, for patients suspected of having thyroid cancer. The assay uses a thyroid nodule fine needle aspiration to analyze the expression of 142 specific genes. In many instances, it allows patients to avoid diagnostic thyroid surgery in order to determine if a nodule is benign or malignant.

Since mid-2013, Veracyte has been able to obtain positive coverage determinations from Aetna, Humana, and SelectHealth, a commercial payer subsidiary of Intermountain Health Care in Utah. Its test is marketed and sold through a venture with Genzyme, a division of the pharmaceutical giant Sanofi.

"Our strong financial performance . . . reflects both growing physician adoption and increased payer coverage and reimbursement for our Afirma solution. The results demonstrate increasing recognition of the value our product delivers in helping patients avoid unnecessary surgeries, while reducing health care costs," said Veracyte Chief Executive Officer Bonnie H. Anderson.

For the first nine months of 2013, Veracyte's revenue was $15 million, compared to $7.2 million for the first nine months of 2012, an increase of 110 percent. Its net loss for the first three quarters of the year is $19.7 million, compared to $13.8 million for the same period last year.

The company finished its initial public offering in late October, raising $65 million through the issue of 5 million shares at $13 apiece. After dropping to about $11.50 a share during the first week in November, Veracyte's stock rose back close to its initial offering price after earnings were announced on Nov. 25.

Takeaway: Veracyte is another of the esoteric testing firms that is reporting rapid revenue growth but is nowhere near bottom-line profitability. G2

Theranos Expands Clinics Outside of California

Theranos Inc., the California-based firm that can perform laboratory tests with nearly microscopic samples of blood, has opened new retail sites in Arizona.

The two new sites are located within Walgreens pharmacy sites in Phoenix and Scottsdale, tripling the number operated by the two firms. Theranos opened its first location at a Walgreens near its Palo Alto headquarters in September, allowing customers to have draws performed on-site.

Although Theranos has announced a pact with the nation's largest pharmacy chain to operate sites, both companies have been closed-mouth about their specific plans for expansion. Theranos Chief Executive Officer Elizabeth Holmes noted that the company plans to have a testing site within five miles of every resident of Phoenix, a city of 1.5 million that sprawls over 518 square miles, larger in area than Los Angeles.

Theranos uses proprietary technology to perform laboratory tests using just a few drops of blood that can be drawn with minimal physical discomfort. It is aiming at a consumer market that includes children and adults who are leery of needles. Its retail testing rates are fixed at 50 percent below what Medicare reimburses for the tests.

Takeaway: Theranos is expanding in a way that suggests it will open many more locations in the near future. G2

Cancer Genetics Wants to Take the Biopsy Out of Oncology Diagnoses

Although growing fast, Cancer Genetics Inc. is currently about one-thousandth the size of LabCorp and Quest Diagnostics.

While it lacks the heft of those two leading national players, the New Jersey-based Cancer Genetics does have some things those much larger labs do not: a burgeoning joint venture with the Mayo Clinic and rapidly growing revenues.

Where Cancer Genetics heads next will rely primarily on its young chief executive officer and whether the medical community and patients believe its biopsy-avoiding line of oncology-related molecular tests are worthwhile investments.

The bulk of Cancer Genetics' revenue is currently generated from molecular tests that can assist in predicting the progression of patients with non-Hodgkins lymphoma, leukemia, and renal cancer. An affiliate operation known as Expand DX provides consulting services to community hospitals and cancer centers in order to compress the diagnosis-to-treatment times, a process that often takes six weeks or more for many cancer patients receiving treatments at smaller facilities. Cancer Genetics currently works with about 10 hospitals primarily in the East and Midwest to provide this service.

However, Cancer Genetics is also in the middle of ramping up a product that shows the promise of a blockbuster: a test focusing on four biomarkers that allow it to detect and predict the progression of human papillomavirus-related cervical cancer through a routine Pap smear exam. The test, known as the FHACT, recently received CLIA approval and was launched in the United States on Nov. 18.

According to Cancer Genetics Chief Executive Officer Panna Sharma, the typical diagnosis of cervical cancer occurs in stages: an abnormal Pap smear, with a follow-up colposcopy scheduled at a later date. According to Sharma, 80 percent of patients do not require further follow-ups. But among those that do, a biopsy is the next step.

"A lot of women don't want the biopsy," Sharma observed in a lengthy interview with *Laboratory Industry Report*. It's a combination of physical and psychological dread that's also common with men who have abnormal prostate exams. As a result, appropriate follow-up care does not always occur. And cervical biopsies themselves are inefficient, with just some 3,700 cases of squamous cervical carcinoma diagnosed from the 2.5 million biopsies that are performed in the United States every year.

Instead, the FHACT can be ordered from the original Pap smear test without a colposcopy or biopsy. Any positive test is also accompanied by the cancer's stage of its progression. The total turnaround time for FHACT is three to five days. Sharma indicated the test can be adapted for the quick detection

of head, neck, and anal cancers as well, noting that those conditions have chromosomal abnormalities similar to cervical cancer.

The company's other assays also have a similar benefit of eliminating follow-up visits and often exceedingly uncomfortable—and expensive—biopsy procedures.

For example, Cancer Genetics' test for renal cancer, which was developed jointly with the Cleveland Clinic and Memorial Sloan-Kettering Cancer Center, can be performed in conjunction with a needle aspiration. That replaces a nephrectomy, a partial removal of the suspect kidney that is undertaken about 18,000 times a year. It requires general anesthesia and hospitalization and can cost up to $15,000, according to Sharma. By comparison, the average revenue derived from a Cancer Genetics test is between $400 and $500. Cancer Genetics received a patent on its kidney cancer assay earlier this year.

"The big question is if there is a way to better place diagnoses into different risk classes up front."
—Panna Sharma, chief executive officer, Cancer Genetics

Meanwhile, Cancer Genetics' joint venture with the Mayo Clinic, known as OncoSpire Genomics, will focus on assays to address lung cancer, multiple myeloma, and follicular lymphoma. The latter disease, a type of non-Hodgkin's lymphoma, is particularly problematic when it comes to rapidly diagnosing whether it has transformed into the indolent form, where life expectancy is often less than a year.

"The big question is if there is a way to better place diagnoses into different risk classes up front," Sharma said.

Cost Savings Potential

The potential cost savings for such assays is apparently catching on in the medical community, although slowly. For the third quarter of 2013, Cancer Genetics' test volume was up 71 percent compared to the third quarter of 2012. However, the numbers themselves remain small: 2,920 tests performed during the quarter, compared to the 1,704 performed in the year-ago quarter. For the first nine months of 2013, the company performed 8,035 assays, compared to 4,937 for the first nine months of last year.

However, those numbers could rise quickly if the FHACT test catches on. Cancer Genetics is also in talks with accountable care organizations in New York, New Jersey, Iowa, and Texas about using its tests as a potential component toward cutting costs and improving health care delivery. Anywhere from 10 percent to 30 percent of oncology-related tests have to be done a second time because of errors—a huge cost Sharma said his company can help providers eliminate.

The 42-year-old Sharma took over the reins of Cancer Genetics in the spring of 2010 after a life sciences consulting firm he co-founded, TSG Partners, had been retained to counsel the company. Within a few months he was approached by John Pappajohn, an Iowa-based billionaire venture capitalist who owns a significant stake in Cancer Genetics, to take over as CEO.

Sharma, who immigrated from the Punjab region of India with his family when he was four years old, matriculated at Boston University at the age of 16 through a special program. He threw himself into the new job at Cancer Genetics, regularly working late hours seven days a week.

Late last month, Cancer Genetics' public offering was closed, raising a relatively modest $46 million. However, given it had less than $1 million in cash on hand in 2012, it now has far more resources to fuel growth. The company's sales staff of about 14 is expected to more than double in the next year.

Peter Francis, president of Clinical Laboratory Sales in Woodstock, Md., noted that while there is some competition for such assays among smaller esoteric labs, Cancer Genetics has brought to market some promising applications involving microarray-based comparative genomic hybridization, which is a relatively new technique for detecting copy number variations in solid tumors.

"The issue I see is reimbursement on those proprietary tests."
—Peter Francis, chief executive officer, Clinical Laboratory Sales

However, Cancer Genetics also faces challenges in terms of getting paid. "The issue I see is reimbursement on those proprietary tests," Francis noted. He added that the way Medicare reimburses for molecular testing on the final Physician Fee Schedule will likely foretell the future for many of the smaller esoteric labs, although the company itself currently derives less than 15 percent of its overall revenues from the Medicare program.

Francis also sees promise in the Expand DX program, which accounts for more than 40 percent of the company's revenue. "I interpret this as akin to what other national labs offer to help with the local hospital's outreach program by providing an avenue for local physicians to use Cancer Genetics through the hospital," he said. "However, hospital administration and their lab's administration must be keenly aware of the negotiated fees charged by CGI versus insurance reimbursement to ensure the hospital is not losing money."

Cancer Genetics reported a loss for the last quarter, compared to a modest profit a year ago. But Sharma called it "phantom net income" tied to liabilities with some derivative warrants the company issued.

In the meantime, he considers Cancer Genetics to have reached a new stage beyond developing products, and it will now be focused on selling them. Although he has cut back on the frantic hours from when he first took over the company, Sharma has morphed from being slightly less hands-on to spending more time soliciting input.

"Since I'm not a medical doctor and not a pathologist, I have to get people's input in terms of how [our] offerings will be viewed," he said. "I have to engage in dialogue and ask the right questions. I am not relying on my own perspective."

Takeaway: Cancer Genetics could be on the cusp of dramatic growth, but its long-term future has yet to be determined. G2

■ **Final CMS PFS Rule Viewed as a Positive After Cap Proposal Scrapped,** *from page 1*
published in mid-July, these caps would have resulted in meaningful cuts to 39 anatomic pathology services and could have had meaningful (and outsized) implications to reimbursement rates for a number of key anatomic pathology procedures, including [fluorescence in situ hybridization] testing . . . and flow cytometry."

CMS is moving forward with two other proposals: one to revise payment for codes under the Clinical Laboratory Fee Schedule due to "technological changes" and one to bundle payment for all clinical diagnostic laboratory tests (other than molecular pathology tests) performed on hospital outpatients into a single payment for primary hospital outpatient procedures.

The expanded bundling payment would apply for services that are provided on the same date of service as the primary service and ordered by the same practitioner who ordered the primary service. This will begin Jan. 1, 2014.

In a statement, the American Clinical Laboratory Association said it commends CMS for not finalizing the proposal to "slash Medicare payments for anatomic pathology services which diagnose breast, colon, prostate, skin, ovarian, leukemia, and other cancers."

"We view this as a meaningful positive."
—Amanda Murphy, William Blair & Co.

The College of American Pathologists (CAP) said it remains opposed to this policy and "will consult with coalition partners and Congressional supporters on both sides of the aisle on next steps to prevent future implementation of this or similar proposals that do not accurately account for the cost of delivering laboratory services."

Other Changes

As expected, the final rule included payment reductions for immunohistochemistry procedures, enhanced cytology services, and in situ hybridization services. It also included new restrictions on billing of 10 or more prostate biopsies and will require individuals who bill more than 10 to use a G code on the bill.

In addition, under the final rule, pathologists will be able to qualify for 2014 Physician Quality Reporting System incentives by reporting on the existing five measures by either claims or registry. However, CMS did not accept three new pathology measures proposed by CAP.

The final rule also modified cuts to Medicare physician payment slightly. Under the rule, physician payment would be cut by 20.1 percent instead of 24.4 percent beginning in January. However, this cut is unlikely to take effect as lawmakers are expected to intervene before the end of the year, as they have in years past.

Takeaway: CMS's decision not to cap Medicare payment for anatomic pathology tests at outpatient payment rates provides some relief for labs that were facing significant cuts for many of the services they provided.

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INDUSTRY BUZZ

NeoGenomics, Covance Enter Into Pact

NeoGenomics Laboratories has entered into an agreement with Covance Inc. to provide anatomic pathology and other specialty lab services to support the drug-oriented clinical trials the latter firm conducts in the United States and overseas.

The pact between the Florida-based NeoGenomics and the New Jersey-based Covance will be for the purpose of the latter firm's testing of drugs for oncology care.

NeoGenomics performs a variety of oncology-related molecular tests. Assays include gauging the potential progression of cancers such as melanoma, colorectal cancer, and precancerous conditions such as Barrett's esophagus. The company is also working on a biopsy-free prostate-cancer test it plans to introduce next year.

The deal will have Covance establish a laboratory on the premises of NeoGenomics' Fort Myers, Fla., headquarters, allowing it to access services such as histology, immunohistochemistry, and fluorescence in situ hybridization testing.

"The collaboration with NeoGenomics will offer our clients fully integrated anatomic pathology services from sample preparation, staining, and imaging to pathology interpretation by leading pathologists, in an end-to-end manner," said Paul Kirchgraber, M.D., vice president of laboratory operations and medical affairs for Covance's laboratory division. He added that the pact will lead to "improved turnaround times critical to oncology clinical trials."

The two companies will eventually introduce expanded testing services to Covance's laboratories in Europe and Asia.

"Our oncology-focused genetic and molecular testing services are a perfect complement to Covance's extensive laboratory services and will allow NeoGenomics to rapidly grow its clinical trials business," said Douglas VanOort, NeoGenomics' chief executive officer.

Terms of the deal were not disclosed, but it likely serves as an avenue for building revenues for NeoGenomics at a time when reimbursements from government and commercial payers are under constant pressure. Revenue per assay performed by NeoGenomics has dropped by more than 20 percent over the past three years, prompting the company to painstakingly examine its operations in order to cut out every unnecessary overhead cost.

Takeway: Alliances with drug-testing firms may be a new avenue of business expansion for laboratories whose bottom lines have come under pressure due to reimbursement cuts.

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College of American Pathologists
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LIR 12/13a

December 5, 2013 **www.G2Intelligence.com**

 Laboratory Industry Report (ISSN 2332-3884) is published by G2 Intelligence, 24 Railroad Street, Keene, NH 03431-3744 USA. Tel: 800-531-1026. Fax: +1-603-357-8111. Web site: www.G2Intelligence.com.

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