



Your Independent Source for Business & Financial News

LABORATORY

INDUSTRY REPORT™

Vol. 15, Iss. 13, July 2, 2015



HIGHLIGHTS

TOP OF THE NEWS

Quest Says Workplace Drug Use on the Rise 1

Cynvenio Raises Capital, Enters Into Pact With Cancer Patient Exchange Firm 1

Invitae Adopts Flat-Rate Price Policy for Patients, Contracted Entities 2

Illumina Enters Into Prenatal Testing Pact With Chinese Firm 3

INSIDE THE LAB INDUSTRY

Sonora Quest—In Command and Control in Arizona 4

INDUSTRY BUZZ

PathGroup Introduces Molecular Cancer Panels 8

www.G2Intelligence.com



Upcoming G2 Events

Lab Institute

October 14-16, 2015

Hyatt Regency Washington DC on Capitol Hill

www.labinstitute.com

Quest Says Workplace Drug Use on the Rise

For much of the past decade, the U.S. job market has been tough. It was placed into a tailspin by the Great Recession, with 750,000 positions being lost monthly at the start of 2009.

But things began stabilizing in the past couple of years. The nationwide unemployment rate dropped from 8 percent at the start of 2013 to below 6 percent at the start of this year—the lowest it’s been in seven years.

And Quest Diagnostics’ annual Drug Testing Index (DTI) may reflect less anxiety over keeping a job or finding another. The New Jersey-based national laboratory performs more than 9 million workplace-related urine, oral fluid and hair-based tests every year and distills and publishes the general findings.

Continued on page 7

Cynvenio Raises Capital, Enters Into Pact With Cancer Patient Exchange Firm

Cynvenio Biosystems has raised \$35.5 million in second-round private equity funding and has struck an agreement with another company to help place its patients into clinical trials.

The funding for the Westlake Village, Calif.-based Cynvenio came from several venture capital funds, but most notably from Livzon Pharmaceutical Group, Inc., a Chinese-based drug company, which is investing \$10 million. That money will be used to offer testing in China, although few details were available.

“This gives Cynvenio a firm foothold in the world’s largest market in terms of addressable patient populations,” said the company’s Chief Executive Officer, André de Fusco, in a statement.

Cynvenio specializes in what are known as “liquid biopsies”—blood draws for cancer detection and analysis. Its test, known as ClearID, is able to analyze germline DNA and DNA from circulating tumor cells and provide rapid test results and recommendations for treatment.

In addition, Cynvenio also announced it had come to terms with Cure Forward, a Cambridge, Mass.-based startup, for potential patient referrals.

Continued on page 2

■ CYNVENIO RAISES CAPITAL, ENTERS INTO PACT WITH CANCER PATIENT EXCHANGE FIRM, from page 1

Cure Forward, which calls itself a “patient activation” service, acts as a clearing-house of sorts for cancer patients, referring them to labs for personalized medicine tests, as well as potential clinical trials for treatment. A recent Harris Interactive survey of cancer patients concluded that only about 15 percent were aware that a clinical trial could be an option for care.

“We are excited to work with Cynvenio to open the doors of genomic medicine so that more patients can find insights and options that shape their care,” said Cure Forward Chief Executive Officer Martin Naley in a statement.

In an email response to questions from *Laboratory Industry Report*, Naley said Cure Forward had reached pacts with “a broad range of commercial and academic testing labs,” and that more such agreements would be announced in the coming months. Its patient referral platform is currently in beta testing and is expected to be fully operational in September.

The company expects initially to derive revenue from payments from companies that perform recruitments from clinical trials, according to Naley, although other revenue streams will be developed in the future, he added.

In addition to announcing the agreement with Cynvenio, Cure Forward also received \$15 million in first round funding from Apple Tree Partners, a Princeton, N.J.-based venture capital firm that focuses on pharmaceutical and biotech firms.

“Cure Forward addresses a profound need to connect patients with therapies tailored specifically to their disease. Empowering patients with this access will further accelerate the innovative research needed to advance toward cures and, most importantly, save lives,” said Aaron Kantoff, vice president of Apple Tree Partners and a member of the Cure Forward board of directors, in a statement.

Takeaway: Cure Forward could act as an information hub for cancer patients in need of personalized medicine and molecular testing. 

Invitae Adopts Flat-Rate Price Policy for Patients, Contracted Entities

Invitae is inviting cash-pay patients to its test menu with open arms. The San Francisco-based genomics laboratory has announced that it will charge cash-pay patients a flat rate of \$475 per test. Company officials have indicated the new policy is intended to open its panel to patients whose insurers are reluctant to cover assays.

“For years, many people and their families have not had the benefit of clearly indicated genetic testing due to unwillingness of third-party payers to pay the historically high cost,” said Robert Nussbaum, M.D., Invitae’s chief medical officer and chief of the genomic medicine division at the University of California at San Francisco, in a statement. “Now that the genetics market is becoming a generic market—and thanks to the ongoing innovations and cost reductions in sample preparation, sequencing and medical interpretation—we are beginning to see the benefits translated into affordable testing for patients.”

There have been a variety of economic pressures on the laboratory sector to keep prices down for genomic tests. They include the 2013 U.S. Supreme Court decision that prohibited labs from holding a patent on a single gene. That opened up the BRCA testing market to many laboratories, quickly driving down the price of that assay. But a combination of new federal regulations making it easier for patients to order tests directly from laboratories and a slow-moving and often rancorous process over how much Medicare would pay for such tests have likely contributed to the trend, although in Invitae's case, cash-paying individual patients still have to obtain a test authorization from a physician.

There are also follow-up tests that patients can take advantage of—such as determining whether they possess high-risk genes after testing negative for BRCA—that their insurers may be unwilling to cover, Invitae said in a statement.

Invitae has also initiated flat rate test pricing for its contracted institutional customers, charging \$975 per test. Non-contracted payers and providers will be charged a flat rate of \$1,500.

Takeaway: The genomic testing sector may be turning to cash pay patients to overcome short-term reimbursement uncertainties. 

ILLUMINA ENTERS INTO PRENATAL TESTING PACT WITH CHINESE FIRM

Illumina has entered into a collaboration with a Chinese company to bring molecular reproductive health testing to the world's most populous country.

The pact between the San Diego-based Illumina and Beijing-based Annoroad will lead to the development of prenatal DNA tests in China. Illumina will provide next-generation sequencing testing platforms and reagents, while Annoroad will provide nucleic acid extraction, library preparation, and data analysis software. Financial details of the agreement were not disclosed.

“Non-invasive prenatal testing is used widely in the reproductive health arena, and we hope to promote it as a standard practice in hospitals,” said Junbin Liang, Annoroad's founder and chief executive officer, in a statement. “Cooperation between our two companies will provide additional high-quality diagnostic solutions in the field of reproductive health.” The pact is one of many recently announced between U.S. laboratories and Chinese companies. “Particularly in China, healthcare providers are working hard to promote the clinical application of genomic technology. Evidently, non-invasive prenatal testing has now gained wide popularity in the reproductive health space,” stock research firm Zacks recently wrote about the Illumina-Annoroad pact. “We believe the aforementioned collaboration will help Illumina, which in itself is one of the leading sequencing companies globally, capture a larger share of this multi-billion dollar market, going forward.” It maintained a strong buy rating for Illumina stock, which has been up about 20 percent over the past year.

Takeaway: Illumina is one of many laboratory firms creating deals to enter the Chinese market. 

Inside The Lab Industry

Sonora Quest—In Command and Control in Arizona

When Dave Dexter got the call from Kenneth Freeman in 1999 to take over Sonora Quest, the joint venture laboratory in Arizona, it was a Hail Mary pass. The venture had lost money every month for the 27 it had been in operation. Freeman was looking for someone to save it from being shut down.

The weather from Dexter's office window at Quest Diagnostics in Portland, Ore. seemed fitting for the grim scenario. It was raining—the 87th consecutive day with rain. When Dexter—then in charge of Quest's Northwest operations—flew down to Phoenix, it was sunny and 82 degrees.

Sonora Quest performs about 45 million tests a year—far, far more than any other lab in Arizona—and has annual revenue crowding \$300 million.

“I was feeling kind of weak that day,” Dexter recalled. “But I thought, ‘I could get used to this.’”

Freeman left as Quest Diagnostics' CEO more than a decade ago. Dexter hasn't budged from Arizona. His longevity may have something to do with his second month at the helm of Sonora Quest Laboratories. During his first month, the venture lost \$1.3 million, hemmed in by business contracts with global caps.

If Dexter was still feeling weak, he hid it very well. “I blew every single one of those contracts up,” he said, and held payers to new pacts with leakage clauses.

The next month, Sonora Quest eked out a \$13,000 profit.

Sixteen years later, the Tempe-based Sonora Quest is the dominant laboratory in the Grand Canyon State. It's a joint venture between Quest Diagnostics and Banner Health, Arizona's biggest hospital system with 16 inpatient facilities statewide and 13 others in Alaska, California, Colorado, Nevada and Nebraska. Sonora Quest has about 2,600 employees. Banner is involved in a dozen accountable care organizations statewide, and Sonora Quest has been along for the ride, making it one of the nation's most deeply immersed labs in ACOs.

Dexter juggles a variety of titles and duties. He is not only Sonora Quest's president and chief executive officer, but also heads Laboratory Sciences of Arizona LLC, a wholly-owned non-profit subsidiary that manages Banner's hospital labs. And he also has a title with Quest, serving as the lab giant's general manager of joint ventures in Arizona.

Sonora Quest performs about 45 million tests a year—far, far more than any other lab in Arizona—and has annual revenue crowding \$300 million. Revenue and test volumes have been growing slowly but steadily in recent years—about 3 to 4 percent, according to Dexter. It has also found a new niche in prescription drug management. According to Dexter, it went from zero assays just a couple of years

Inside The Lab Industry

ago to nearly 400,000 tests a year, mostly from the state's Medicaid program, and potential new contracts are likely to make that grow further.

Sonora Quest has won several awards over the years for being among the best places to work in Arizona.

Banner's merger with the University of Arizona Health Network just a few months ago will also grow Sonora Quest substantially. The deal includes two hospitals, a cancer center and five pathology groups with more than two dozen pathologists. The hospital lab business is being integrated into Laboratory Sciences, while Sonora Quest will manage the hospital outreach volume. According to Dexter, it will add about 8 million in annual testing volume to the venture.

Dennis Weissman, a Washington, D.C.-based laboratory industry consultant, attributed a lot of Dexter's success to his management style.

"The way he works with personnel and staff, really is one of the big differentiators," Weissman said. Sonora Quest has won several awards over the years for being among the best places to work in Arizona.

According to Dexter, the primary goal is not to work 24 hours a day. "It is not how many hits you get, but how many runs you score," he said. Instead, Sonora Quest focuses on being highly engaged with employees—which Dexter believes leads to satisfied customers—and keeping a focus on ethics. He noted that the company has walked away from business if there has been an integrity issue.

For senior managers, Dexter asks that they give their best 9 hours in a workday. "That means if you want to go to your kids' little league baseball game, you can," he said, adding that the precise business plans and roadmaps Sonora Quest formulates every year makes the performance expectations quite clear.

Dexter also requires himself and senior management to lead a major charitable event each year and sit on the board of a philanthropic organization. Sonora Quest provides resources to 36 different charitable organizations, and the executive leadership provides business acumen. "It's a nice intertwining with what we do," Dexter said.

Last year, G2 Intelligence recognized Dexter with its Laboratory Public Service National Leadership Award for Business Creativity and Innovation. Weissman, who founded G2 Intelligence and was a consultant for the organization until last year, said the award was given for his ability to create a cohesive organization.

Theranos—threat or pretender?

Yet for the first time since its first couple of difficult years in the 1990s, Sonora Quest is facing a potential challenge to its business.

Theranos, the often closed-mouth Silicon Valley-based lab created a decade ago by Stanford University dropout Elizabeth Holmes, has decided to make Arizona

Inside The Lab Industry

its first place to challenge the diagnostic world's old guard. It operates 41 centers in Arizona at Walgreens sites where patients can undergo lab tests.

But Theranos didn't enter Arizona with just its fingers crossed. The company lobbied to change state law so that any lab test offered in the state could be marketed directly to consumers.

"Arizona's law can and should serve as a model for the nation for direct access testing," Holmes said at the bill's signing last April. "Every state should have a law like Arizona's because it demonstrates how it is possible to help health care providers engage with patients in preventative care, save money for the government and individuals, protect physicians and health care providers from liabilities that can hinder preventive care, and strengthen an individual's basic right to information about themselves."

The law goes into effect the day before Independence Day. Theranos has been taking out full-page ads in the *Arizona Republic* to publish its prices, which are 50 percent below Medicare rates. The most expensive test on the menu is a hepatitis C genotyping at \$117.96. A hemoglobin test can be had for less than \$2.

"Because of Sonora Quest's involvement with the largest health care system in the state, for the foreseeable future I don't see Theranos driving consumers in the hundreds of thousands from Quest. It's not the same market as an established health system laboratory. It's a much different process."

— Dennis Weissman

Theranos' cowboy-like incursion into Arizona has not gone without Sonora Quest's notice. It had previously offered 50 tests directly to consumers. Beginning on July 5, that number will double to 100, and prices will also be posted at Sonora Quest's draw centers, Dexter said. But that is about as far as the market adjustments will go.

"We're not competing with Theranos, and we're not competing with them on price," he said, adding that Sonora Quest believes that having access to a primary care or other physician in the testing process is critical for the appropriate interpretation of results.

Whether Theranos becomes a major force in Arizona still remains to be seen. Dexter noted that Theranos hired 80 phlebotomists statewide to service its draw centers in Walgreens, but that they have not appeared to be overworked.

Weissman also believes that Theranos will have a tough go of it. "Because of Sonora Quest's involvement with the largest health care system in the state, for the foreseeable future I don't see Theranos driving consumers in the hundreds of thousands from Quest. It's not the same market as an established health system laboratory. It's a much different process."

Takeaway: Sonora Quest is likely to remain Arizona's dominant laboratory—and do so on its own terms. 

■ QUEST SAYS WORKPLACE DRUG USE ON THE RISE, from page 1

According to the DTI, the volume of American workers testing positive for the use of such drugs as marijuana, cocaine and methamphetamine grew 9.3 percent between 2013 and 2014. However, the percentage of those testing positive for such drugs remains quite low, rising to 4.7 percent from 4.3 percent of the total population. And for the most part, only tiny percentages of workers tested positive for illegal drugs that are also considered highly dangerous.

"In the past, we have noted increases in prescription drug positivity rates, but now it seems illicit drug use may be on the rise, according to our data."

— Barry Sample, M.D.

Moreover, the positive test rate has plummeted since Quest began keeping records in the 1980s. In 1988, the overall positive test rate for urine-based testing was 13.6 percent; it was 3.9 percent in 2014. However, that was up from 3.7 percent in 2013, the first time the overall percentage has ever risen.

Nevertheless, there were some troubling trends. Heroin positives have doubled between 2011 and 2014, although they still only comprise about 0.03 percent of all testing. Quest officials have suggested that some doctors may have shifted their prescribing of prescription painkillers over to opiates that would lead to a positive reading, but they remain concerned.

"In the past, we have noted increases in prescription drug positivity rates, but now it seems illicit drug use may be on the rise, according to our data," Barry Sample, M.D., director of science and technology for Quest's employer solutions division, said in a statement. "These findings are especially concerning because they suggest that the recent focus on illicit marijuana use may be too narrow, and that other dangerous drugs are potentially making a comeback."

Quest officials did not respond to email and telephone requests seeking comment.

Additionally, marijuana positives increased 14.3 percent between 2013 and last year, rising to 2.4 percent from 2.1 percent. In workplaces where drug use could constitute a safety hazard, the number of positives grew by 6 percent, although the overall rates are still well under 1 percent of all employees tested. Marijuana was the biggest gainer among all the drugs being screened, but whether it remains illicit is up for debate.

Marijuana is currently legal for recreational use in Colorado and Washington, and for medical use in 23 states plus the District of Columbia. It will become legal for recreational use in Oregon this month and likely other states in the future, but there are few workplace protections in place for employees who use it for either purpose. The percentage of employees who tested positive for marijuana in Washington and Colorado is slightly higher than the nationwide average.

Meanwhile, cocaine use also rose significantly, up 9.1 percent between 2013 and 2014. However, that meant an overall bump of positive tests from 0.22 percent to 0.24 percent.

Methamphetamines, which have plagued many rural parts of America, also saw an uptick in positive tests, up 7.2 percent year-over-year. Overall, just over 1 percent of employees tested positive for methamphetamine use, up from 0.97 percent in 2013.

Takeaway: The improved economy and laxer laws may be driving up illicit drug use test results. 

INDUSTRY BUZZ

PathGroup Introduces Molecular Cancer Panels

PathGroup, the Tennessee-based pathology practice, has introduced a genomic profiling panel for community-based oncologists.

Known as SmartGenomics, it includes panels for in-depth testing for lung, colon, brain and thyroid cancers, as well as for melanoma/GIST.

“Genes that are relevant at diagnosis of lung cancer are not the same as those of melanoma or colon adenocarcinoma,” said Pranil K. Chandra, PathGroup’s medical director of molecular pathology services in a statement. “PathGroup has profiled thousands of patients and we have found that the addition of diagnostic testing at biopsy via SmartGenomics and gold-standard technologies are true advances to our customers and ultimately our patients. Integrating genomic profiling into patient management and therapy selection is the future of clinical oncology practice and cancer pharmaceutical development.”

PathGroup has about 90 pathologists, making it one of the largest such practices in the United States. Company officials said it developed the tests to improve care options for the oncologists it contracts with. “When considering the likelihood of recurrence in many cancers, having a baseline of the most commonly altered pathways for each tumor allows us to determine what changes have occurred since initial diagnosis,” said Jeffrey F. Patton, M.D., chief executive officer of Tennessee Oncology, a PathGroup client.

The tests are not being marketed directly to patients. Instead, PathGroup “is actively promoting and educating clinicians such as medical and radiation oncologists, surgeons and hospital pathologists as to the benefit of testing their patients through all stages of cancer both at initial diagnosis and relapsed/refractory disease,” according to company spokesperson Jessica Mollmann.

Pricing for the tests on the panel was not available. “There are multiple test methodologies and technologies that may or may not be performed based on the patient’s history,” Mollmann explained.

Payer coverage for PathGroup testing has been a bit of an issue. According to Mollmann, “payer coverage is currently inconsistent and ranges from blanket non-coverage policies for Next-Generation Sequencing panel testing to payers requiring prior authorization.”

Takeaway: PathGroup is trying to expand its reach and market share with oncology-based genomic testing. 

References

Cure Forward

650-463-4052

Cynvenio

805-777-0017

Illumina

858-202-4500

Invitae

415-374-7782

PathGroup

615-221-4455

Quest Diagnostics

973-520-2700

Sonora Quest Laboratories

602-685-5000

Theranos

650-838-9292

Dennis Weissman and Associates

202-320-2640

Note the change of address effective immediately.

© 2015 Plain Language Media, LLC, 15 Shaw Street, New London, CT, 06320, 1-888-729-2315

To subscribe or renew LIR, call now: 1-888-729-2315

(AAB and NILA members qualify for a special discount. Offer code: LIRN1)

Online: www.G2Intelligence.com

Email: customerservice@plainlanguagemedia.com

Mail to: Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320

Fax: 1-888-729-2315

Multi-User/Multi-Location Pricing? Please contact Randy Cochran by email at Randy@PlainLanguageMedia.com or by phone at 201-747-3737.

Notice: It is a violation of federal copyright law to reproduce all or part of this publication or its contents by any means. The Copyright Act imposes liability of up to \$150,000 per issue for such infringement. Information concerning illicit duplication will be gratefully received. To ensure compliance with all copyright regulations or to acquire a license for multi-subscriber distribution within a company or for permission to republish, please contact G2 Intelligence's corporate licensing department at Randy@PlainLanguageMedia.com or by phone at 201-747-3737. Reporting on commercial products herein is to inform readers only and does not constitute an endorsement. *Laboratory Industry Report* (ISSN 1060-5118) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320. Phone: 1-888-729-2315. Fax: 1-855-649-1623. Web site: www.G2Intelligence.com.

Kelly A. Briganti, JD, Editorial Director; Barbara Manning Grimm, Managing Editor; Ron Shinkman, Editor; Stephanie Murg, Managing Director; Kim Punter, Director of Conferences & Events; Randy Cochran, Corporate Licensing Manager; Jim Pearmain, General Manager; Pete Stowe, Managing Partner; Mark T. Ziebarth, Publisher.
Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 1-888-729-2315.