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Roche buys 'sample in, susceptibility out' technology

Roche has signed a definitive agreement to acquire Los Gatos, Calif.-based GeneWeave BioSciences, a privately held company focused on molecular clinical microbiology diagnostic solutions.

The acquisition provides Roche with GeneWeave's Smarticles technology, which quickly identifies multidrug-resistant organisms and assesses antimicrobial susceptibility directly from clinical samples without the need for traditional enrichment, culture, or sample preparation processes. GeneWeave's first system in development is the vivoDx, a fully automated, random-access system designed to meet the needs of laboratories addressing MDRO detection and antibiotic therapy guidance. The technology, marketed as enabling a "sample in, susceptibility out" testing paradigm, is being evaluated at multiple sites across the U.S.

"Part of the reason we went forward with this GeneWeave acquisition is that we recognize there's a good market opportunity out there, and a very clear medical need," says Paul Brown, PhD, head of Roche Molecular Diagnostics. "Our belief is that GeneWeave's technology is the best technology available to be able to do AST in a much more efficient, much quicker way than has been done in the past. We shared their vision for this technology as a game-changer."

Officials at Roche knew they needed a new approach to help tackle the MDRO problem, Dr. Brown tells CAP TODAY.

"To be very candid, we recognized that PCR, which is our expertise, would not allow us to get after antisusceptibility testing," he says. "It has limitations. We can rule antibiotics out, but that's not really what the physician wants looking forward. They're looking for rule-in, what's the bacteria for the patient and the antibiotic that would work. We knew PCR would not allow us to get down to that."

GeneWeave co-founder and chief marketing officer Jason Springs says company officials were excited by the prospect of becoming part of Roche because they "shared our vision for how Smarticles technology could address one of the largest health problems in the world, and they can deliver the global reach to make this happen."

"We believe Roche's position as the world leader in in vitro diagnostics and its strong commercial organization will allow us to accelerate our vision and realize the full potential of our Smarticles technology," Springs adds, while hinting the integration with Roche will aid future projects.

"We have discussed a number of future applications with Roche," he says. "They were happy to join us and accelerate us in that direction but we aren't at liberty to go into any specific details at this point in time."

Roche will pay GeneWeave shareholders \$190 million up front and as much as \$235 million for contingent product-related milestones. The transaction is subject to customary closing conditions and, once closed, GeneWeave will be integrated into Roche Molecular Diagnostics.

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Cerner partnership lands DOD EHR deal

A partnership among Leidos, Cerner, and Accenture Federal Services was awarded a \$4.3 billion contract to modernize the Department of Defense's electronic health records system. The contract asks the partnership to deliver an "off-the-shelf" EHR solution along with "integration activities and deployment across the Military Health System," the DOD said.

The initial contract is for two years, with two three-year option periods and a potential two-year award term that could bring the total deal to 10 years. The work is expected to be finished by 2025 and will replace about 50 legacy systems. The Cerner-led partnership beat out five other offers, including separate proposals from Allscripts and Epic.

"The trick . . . in getting a business system fielded isn't about the product you're buying, it's about the training, the preparation of your people, it's about minimizing the changes to the software that you're buying," Frank Kendall, undersecretary of defense for acquisition, technology, and logistics, said at a news conference. "We've done a lot of work to ensure that our users . . . are prepared to take on this product and use it."

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More than half of pathology trainees in 2012 were women

Pathology was among seven medical specialties in which women accounted for the majority of graduate medical education trainees in 2012, said a research letter published online. According to the diversity in GME study, pathology drew a larger share of Hispanic trainees but fewer black trainees than there were overall.

Researchers at Johns Hopkins University used publicly reported data to assess the representation of women and historically underrepresented minority groups in medicine (Deville C, et al. JAMA Intern Med. Published online Aug. 24, 2015. doi:10.1001/jamainternmed.2015.4324).

Of the 115,111 trainees in GME in the 20 largest residency training specialties, 46.1 percent were female, while in pathology women made up 54.6 percent of trainees. Obstetrics and gynecology attracted the largest share of women, 82.4 percent. The other five specialties in which women accounted for the majority of trainees were pediatrics, dermatology, internal medicine/pediatrics, family medicine, and psychiatry. Orthopedics drew the smallest share of women, 13.8 percent.

Of the 20 specialties examined, 7.5 percent of trainees were Hispanic and 5.8 percent were black. In pathology, 7.7 percent of trainees were Hispanic and 3.7 percent were black.

In 2012, 30.1 percent of the nearly 690,000 practicing physicians were female, 5.2 percent were Hispanic, and 3.8 percent were black. In medical schools, 48.3 percent of that year's 16,835 graduates were female, and 15.3 percent were underrepresented minorities.

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Front-end automation for multiplex genetic analysis

Agena Bioscience has introduced the Chip prep module to automate sample handling after PCR for the MassArray 96-well system. This enables laboratories to operate the MassArray system largely unattended for high-throughput, multiplex genetic analysis.

"Whether you are a lab manager, pathologist, or medical director, automation of the post-PCR workflow reduces labor and helps to improve the quality and consistency of genetic testing," Agena Bioscience CEO Peter Dansky said in a statement.

The Chip prep module is designed to minimize hands-on time and reduce the risk of cross-contamination associated with manual sample handling. It automates several processing steps, including dispensing and desalting samples onto the SpectroChip Array and subsequently loading these onto the MassArray analyzer. The module can process eight 96-pad SpectroChip Arrays in less than a day and includes onboard cooling and storage, which allow overnight processing and storage of two additional SpectroChip Arrays. The module is an add-on to the Mass-Array analyzer.

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Noridian OKs Prolaris for Medicare coverage

Noridian Healthcare Solutions has issued a final local coverage determination for Prolaris, Myriad Genetics' 46-gene RNA-expression prognostic test for assessing the aggressiveness of prostate cancer. Noridian is a Medicare administrative contractor for the western U.S.; its decision follows a final LCD from Palmetto GBA in January.

The final LCD takes effect Oct. 15 and provides Medicare coverage for prostate cancer patients defined as low risk and very low risk by the National Comprehensive Cancer Network. The Medicare coverage decision extends payment for testing to the approximately 60,000 U.S. patients diagnosed each year with localized prostate cancer who meet the criteria of a Gleason score of six or lower and serum PSA level of less than 10 ng/mL.

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