Executive forecast

Interview by Dottie Dunham, Associate Editor

bioMérieux’s Philippe Sans translates challenges into delivery

Dottie Dunham: As one of the worldwide leaders in disease prevention, what global trends will influence bioMérieux’s strategy over the next five years? Based on these trends, what significant challenges will your company face, and have you begun to implement changes to meet the goals?

Philippe Sans: The relationship between diagnostics and therapeutics will be increasingly important over the next five years. Responding effectively to this new paradigm will require us to leverage the tremendous information opportunity presented by the diagnostic laboratory. This means delivering “actionable and timely” information to the clinician. These opportunities could be anywhere, from dynamic management of emerging pathogens or resistance patterns to creating new treatment pathways based on appropriate diagnostic results.

Advances in genomics and proteomics provide new insight into links between disease pathology and the patient as an individual. Based on this new approach, therapy will be directed more efficiently. There is huge pressure to provide innovation such as this.

The Mérieux family has always had the vision of “medicine without boundaries” and of the ongoing challenges posed by the emergence of new infectious diseases.

Economic concerns about the cost and a critical shortage of key technical personnel, however, make its implementation difficult, to say the least. First, it is important to provide cutting-edge technology packaged in formats that are easy to use, support, and manage. At the same time, our solutions must demonstrate substantial value well over their cost. This can only be accomplished by organizing the information generated by our products to maximize documented outcomes.

Dunham: With the acquisition of the diagnostic division of Organon Teknika in 2001, bioMérieux became one of the major groups in the field of in vitro diagnostics. Describe how this integration changed your product line, and tell us about products that are on the horizon.

Sans: From a product-line standpoint, this acquisition has first reinforced our core business — traditional microbiology — with the addition of BacT/ALERT, the state-of-the-art automated microbial-detection system. With the VITEK automated bacterial-identification and susceptibility-testing system and BacT/ALERT, bioMérieux is offering microbiology laboratories best-in-class performance from detection to identification to susceptibility/resistance. The recent launch of BacT/ALERT plastic blood-culture bottles adds an unmatched safety feature to the lab.

Additionally, this acquisition has given bioMérieux a wide portfolio of unique technology and intellectual properties for the nucleic acid diagnostics business. For instance, bioMérieux now owns the proprietary amplification system, nucleic acid sequence-based amplification (NASBA), and a proprietary extraction system, the Boom technology. In terms of products, we have a U.S. Food and Drug Administration (FDA)-approved quantitative HIV-1 assay, the NucliSens HIV-1 QT — one of the very few available on the U.S. market. We have just launched the NucliSens EasyQ Analyzer, a new-generation, real-time platform for molecular diagnostics. Other significant additions to our product portfolio have been in the hemostasis product line and HIV diagnostic testing.

With the Organon Teknika integration, we have realigned all of our research and development programs. From an integration standpoint, the main challenge has certainly been the realignment of our molecular strategy. We are now focusing our efforts on two complementary platforms — our NucliSens EasyQ system and the Cepheid GeneXpert, both platforms powered by our patented NASBA-amplification technology.

Dunham: As global diseases become more prevalent, does your company have a strategy to meet the mounting demands they pose?

Sans: The Mérieux family, which owns the majority of bioMérieux, has a long legacy of fighting infectious diseases. In the 70s, through its former vaccine company, Institut Mérieux, its contri-
bioMérieux has entered into an agreement with the American Red Cross Biomedical Services to supply its BacT/ALERT automated microbial-testing system to blood centers. How will this help U.S. blood centers standardize their bacterial-detection needs?

Sans: We are committed to providing solutions that enhance the safety of the blood supply — not only in the United States but worldwide. The BacT/ALERT provides blood banks with continuous, automated, quality-control testing of leukocyte-reduced apheresis platelets and leukocyte-reduced single-unit whole blood-derived platelet concentrates. When the American Association of Blood Banks recently issued new guidelines for limiting and detecting bacteria within all platelets, many blood banks chose the BacT/ALERT because of its sensitivity, continuous monitoring, and ease of use. The product detects a wide range of organisms typically found in platelets, even in very low levels, and its implementation offers one more means to limit and reduce the chance of bacterially contaminated platelets.

Dunham: Describe some of the cutting-edge products that bioMérieux has just released or will release in the coming months.

Sans: All of our customers have been converted from our old glass bottles to our recently introduced plastic blood-culture bottles. The first of their kind, the BacT/ALERT plastic blood-culture bottles are made from a unique multilayer plastic that is optically clear, autoclavable, maintains a vacuum, does not let CO₂ or O₂ in or out, does not break or shatter like glass, and — most importantly — does not interfere with microbial growth. In addition to the obvious safety advantages, the plastic bottles are lighter than their glass counterparts, reducing the cost of shipping and hazardous-waste disposal.

bioMérieux will be releasing a new clinical decision-support product called Stellara in 2004, targeting the clinicians who need to aggregate the data from the various microbiology instruments and present it in a concise format. Improved quality via reduced medication errors — and, thus, increased patient safety — is the goal of this new offer, adding further value to our suite of microbiology products.

With the NucliSens line, we are actively expanding the menu of analyte-specific reagents. Throughout 2004, bioMérieux will also offer enhancements to our Boom technology. The main improvement will be in the way of magnetic silica reagents that will provide labs with a convenient process for high-quality, total nucleic-acid isolation from clinical samples. This adaptation will also pave the way for upcoming modular automation.

We will release our premier assay for the exclusion of deep vein thrombosis (DVT) in 2004 under the new label, VIDAS D-Dimer Exclusion. In September [2003], the FDA issued clearance to market for an intended use that allows a physician to exclude a diagnosis of DVT based upon a clinical assessment model and VIDAS D-Dimer Exclusion results alone, without radiological imaging or ultrasonography. This greatly reduces the diagnostic costs incurred by the patient, as well as time in the emergency department, since the VIDAS D-Dimer Exclusion results are available in less than one hour. FDA clearance of an exclusion claim for pulmonary embolism is pending.

Dunham: What solutions has bioMérieux put in place to help the labs that face a personnel shortage?

Sans: In the area of identification and antibiotic-susceptibility testing, bioMérieux’s VITEK 2 automation may reduce labor requirements up to 50%. Both the advanced expert system and the VITEK expert system can automate results release and notification. Cross-training of valuable personnel can improve overall employee efficiency, which is another approach for handling personnel shortages. In the area of blood culture, scalability and ease of use are two key components of our solutions, which address the personnel shortage in the laboratory. Additionally, a third component would be the easily accomplished cross-training of the generalist.

Dunham: How does bioMérieux service its customer base via the Web?

Sans: bioMérieux uses its U.S. website to quickly and efficiently disseminate information to customers and potential customers. Website visitors can find general information about current products and notifications of new product releases or newly received FDA clearances. Our website also houses a wealth of technical information to support the performance and use of our products. Customers can download technical bulletins, material safety data sheets, package inserts, product specifications, and other useful information. We also provide interactive presentations, news bulletins, a schedule of important professional meetings, access to technical support, and contact information. Complementing the technical library are a number of interactive presentations with instrument demos; knowledge forum and symposium presentations from American Society for Microbiology meetings, and other technical presentations concerning microbiology, coagulation, immunoassay; nucleic acid diagnostics; and laboratory economics. The Web has facilitated communication; we can get more information to our customers faster and more efficiently. As laboratorians and other clinicians gain easier access to the Internet, it will become more important for us as a customer-communication tool. We have several upcoming products intricately linked to the Web that will facilitate the dissemination of results and data from the lab directly to the healthcare team.