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Firm Carves New Model in Biotech Research

BioServe Sells DNA Samples to Scientists

By Anita Huslin
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Modular desks and office chairs sit in the waiting room, pallets of unpacked supplies are stacked in a receiving bay where condensation drips from a cluster of cryogenic tanks. The walls and shelves of the chief executive's office are barren, except for a collection of framed diplomas.

The half-dressed appearance of BioServe's Beltsville offices reflects a recent shift in the biotech firm's business model. For years since its founding nearly two decades ago, BioServe did contract work -- extraction and analysis of genetic material -- for research agencies, including the National Institutes of Health.

But with the consumer and scientific worlds becoming increasingly interested in pharmacogenomics -- personalized medical treatment of patients based on their genetic makeup -- BioServe's founder Rama Modali thought it was time for a change.

"We'd been doing what we had for 18 years and I hadn't taken the company where I wanted to," he recalled. "I had to think about it and say maybe I'm not doing it right."

So in the first week of May, he spent \$2 million to acquire an extensive repository of biological samples, hire a new chief executive and launch projects that are rapidly transforming the privately held firm.

The new acquisition -- more than 600,000 samples of human DNA, tissue and blood products with data on the donors' medical histories -- immediately gave BioServe a sought-after commodity among researchers: high-quality material that can cut research times in half and provide a wealth of information to scientists looking for markers of diseases, and ultimately, cures.

Xin Li Wang, a cardiovascular researcher at Baylor College of Medicine, in June bought 750 samples from BioServe to use as controls in his research aimed at finding genetic causes of diseases of the aorta. It cost him \$20 per sample, a discount because BioServe will collaborate on the analysis and be involved with publishing any papers on the findings, Wang said.

Collecting samples and doing medical histories of 750 people who are disease free, Wang said, "is time consuming . . . if you put down a monetary value on two years of [research] costs, it's probably not that big. But if you talk about delays in data analysis and publication [of findings], it's huge."

BioServe's new chief executive, Kevin Krenitsky, was already familiar with the repository's potential. He had previously served as head of genomics at the firm that sold BioServe the repository, [SeraCare Life Sciences](#), which was in bankruptcy protection at the time of the sale. Krenitsky, who had already left SeraCare, served as a consultant to BioServe on the transaction.

Within a month of Krenitsky's arrival, BioServe began announcing a string of deals. In May, it launched a

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collaboration with a South Korean firm to develop new tests for various infectious diseases in India. In June, it announced that it had become the exclusive DNA testing provider for Suracell, a former SeraCare client, which sells vitamins and supplements matched to a patient's DNA profile.

And earlier this month, the company announced a partnership with Florida-based DNAPrint Genomics to analyze the repository's samples and add genetic histories to them. That boosted the value of BioServe's library, Krenitsky said, by giving researchers a way to track ancestral patterns among patients with various diseases. The collection would also help researchers identify new markers for diseases and candidates for clinical drug trials.

While all of this work is aimed at cracking the genetic codes of diseases, the industry so far has managed to produce more competition than dramatic results. And some of those efforts have stirred controversy.

Last year, the Government Accountability Office investigated four companies that sold genetic tests directly to consumers, including Suracell, which markets its kits through spas, physicians and online for individuals to identify genes that may contribute to obesity.

The test results purchased by GAO investigators, the agency said, "mislead consumers by making predictions that are medically unproven and so ambiguous that they do not provide meaningful information to consumers." Suracell executives did not return calls last week seeking comment.

At a Senate Special Committee on Aging hearing last year, SuraCell founder Kristopher King defended his company's work. The "program is designed for informed clients," he said in prepared remarks, and "is recommended for consumers with the oversight of a licensed physician, genetic counselor or health care practitioner."

Though BioServe is the exclusive testing laboratory for Suracell, Krenitsky said it provides the results only to physicians, who are responsible for how they are used.

Among researchers, the lack of high-quality specimens has become a growing problem, particularly as the number of clinical trials and epidemiology studies has grown, said Jim Vaught, deputy director of the National Cancer Institute's office of biorepositories and biospecimen research.

So has concern about the ethics and methodology of companies in the field, he said. Earlier this year, the National Cancer Institute began holding forums aimed at developing "best practices" for the collection, storage and use of bio-specimens.

Next month, BioServe plans to launch the latest in a series of new diagnostic products -- specimens that contain variations that could help researchers identify the genetic calling card of breast cancer.

"I do have a lot of ideas how to market DNA [tests] in addition to doing our own research," Modali said, and the ones the company has employed are paying off. So far, he said, Bioserve's revenues have increased 150 percent this year.

Staff researcher Richard Drezen contributed to this report.

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