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Bradford Siff,
CEO,
Biowave

No pain, big gain for Biowave’s electrode tool

By Dyke Hendrickson

The CEO of a Connecticut medical device company recently spent a weekend with an NFL team, but he wasn’t fitting players for knee braces or shoulder harnesses. Bradford Siff, who heads a young Norwalk company called Biowave Corp., administered hurry-up treatment for a player sidelined by pain.

“We used our tools and the player felt like he could go in again,” Siff said with some excitement. We’re very encouraged that our product has a future in college and pro sports, as well as medical offices where average patients seek treatment.” Siff is reluctant to identify the team he aided because his devices are not on the market. But he’s not abashed at discussing his promising company.

He says Biowave’s patented signal technology is similar to neuromodulation implants, but the procedure can be done less invasively in a doctor’s office. The tool is a single-use disposable percutaneous electrode array with 3,600 micro-needles. Company literature indicates these needles deliver a “pain-blocking” electronic field through the body into deep tissue.

“We’re very pleased with the testing so far,” said Siff, who earned a bachelor’s degree and two master’s degrees from Cornell University. “There’s more engineering work to be done, and then there is paperwork with the FDA. But we are getting closer to moving the product into medical offices.”

Biowave is focusing on a large financial opportunity. Industry statistics show that 80 million people suffer from chronic, acute or post-surgical pain. Close to 50 percent of doctor’s visits are related to discomfort. Biowave has developed a tool that will be offered to 7,000 specialists, many of whom are associated with pain clinics. And a version will be available for home use.

Market size is estimated to be over \$1 billion, a statistic that is based on potential applications including post-operative use in the hospital and the treatment of musculoskeletal pain conditions in orthopedic, sports medicine and pain clinics. It is too early to tell whether Biowave’s device will elevate the population’s comfort level, but the company has already developed one corporate believer. A large Japanese company in the medical device field has signed a letter of intent for a strategic partnership with Biowave. The Japanese company did so after executing due diligence testing earlier this year.

The Japanese company took the product into the clinic and reportedly found that 80 percent of patients responded positively to the Biowave treatment. The results replicated clinical data obtained in our studies at Cornell (hospital) and other locations, Siff said. The Japanese company reportedly has forked over \$700,000 in licensing fees to date, and is negotiating a marketing and manufacturing deal that could be worth as much as \$12 million to Biowave.

Biowave is planning to commercialize two separate products: DeepTreat for physicians and Home-Treat for patients to use after visits to the medical center. Company officials report that the reimbursement range for DeepTreat will be \$125 to \$320 per treatment. Reimbursement for the home device will be about \$400 per device. Cost of the Biowave systems has not been finalized.

Like players on the NFL team that Biowave recently assisted, Siff is intent on reaching the goal line. He is hoping to win FDA approval of his 510(k) application this summer. (Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers to notify the FDA, at least 90 days in advance, of their intent to market a medical device. It allows FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories.) And company officials are seeking \$5 to \$7 million to enhance its patented prototypes.

If Biowave’s game plan is properly executed, the product could be in pain clinics by Q2 of 2005. Such optimistic dates for rollout assume that the FDA will not sack the company for a major loss. But based on his recent NFL experience, Siff is not even considering the possibility. “We were able to get that player back into the game,” he said. “Biowave made a difference that day, and it will in the future.”