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## Big gains without pains

### Norwalk firm predicts \$1 billion sales from pain-killing device

By HAROLD F. COBIN

Passing an electrical current through the body with two specific frequencies can relieve pain and may accelerate healing, says an engineer who conceived the idea and wants U.S. Food and Drug Administration approval to market a device that emits such a signal. A 20-minute treatment on patients with chronic lower back pain gave an 80 percent reduction in pain, says Bradford E. Siff, describing the results of a clinical study using a prototype of his device. But "what was most interesting to the pain physicians is that pain relief lasted at least 24 hours post-treatment," Siff says. "At 24 hours, the patient still recorded a 65 percent reduction in pain."

Siff, 42, President and Chief Executive Officer of Biowave Corp. in Norwalk, says the device works by passing an electric current carrying two frequencies between opposing metallic pads on the skin that creates a low-frequency electric field within deep tissue. Research has shown that low-frequency electrical signals can relieve pain, and devices that create such signals, called TENS, short for transcutaneous electric nerve stimulation, have been marketed since the late 1960s. But because such devices only pass signals horizontally between adjacent pads on the skin, the signals don't reach deep tissue.

High-frequency signals, such as radio waves, transmit through the body easily, but don't affect tissue, while low-frequency signals, which can affect tissue, are blocked by skin. Siff says clinical studies have shown the high-frequency signals his device passes through the body interact to create low frequencies in deep tissue, blocking nerves from carrying pain messages to the brain.

"There's no other device we've seen that with a similar treatment provides such a long period of residual relief," says Siff, noting that it has no side effects, such as those that occur with the opiate-derived drugs often prescribed for persons with chronic pain. Siff has degrees from Cornell University in mechanical engineering and business administration, and a background in software development as well as technology mergers and acquisitions.

He developed his theory for pain relief while working for a startup company that had a unique pain-blocking technology for dentists. It created anesthesia electronically without numbness, but was "very klugey," and required dentists to completely change their practice habits. More interested in developing methods of pain relief for other parts of the body, and with a theory how to do so, Siff returned to Cornell's Engineering School and was introduced to John Carter, whom he described as a "brilliant research scientist," with a doctorate in electrical engineering who performs cardiology research.

"I explained my concepts to John, and John invented the technology we have today," says Siff. Together, they hold five patents on the process. Siff disclosed publicly for the first time that devices sold to doctors will use an adhesive pad with 2,000 percuta-



Bradford E. Siff, President and CEO of Biowave Corp. on Knight Street, holding a working prototype of the pain relief device he is developing.

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neous micro-needles, or spikes, on its surface that penetrate the outer two layers of skin. The home version will use "noninvasive" pads without needles.

The device works effectively with either pad, however, the percutaneous ones facilitate the delivery of the signal into even deeper tissue and require only half the amount of energy, Siff says. The percutaneous pads are single-use disposables, so from a company business-model standpoint, it's very attractive. Additionally, because the percutaneous pads break the skin, a physical therapist may not use them; they must be applied under a doctor's supervision. The device could be sold to physicians for up to about \$5,000, or be given away, "because we really make all of the money on the disposables, and those might go for \$50 a treatment," he says.

With the National Institutes of Health estimating \$100 billion is spent each year in the United States for pain management, Siff expects Biowave to sell about \$850 million a year in disposable electrodes to physicians. In addition, it expects to generate another \$350 million by selling pads to the home market.

Siff initially raised \$2.5 million from individual and institutional investors to develop the device and produce 15 working prototypes for clinical studies. Separately, a major Japanese company in the medical device field, has paid Biowave over \$700,000 in licensing fees to date as part of a relationship that will provide the Japanese company with rights to develop and sell a device in Japan using Biowave's signal technology. Biowave will solicit up to an additional \$10 million from Venture Capitalists to finish development of the physician and home prescription versions of the device, obtain regulatory approval, complete additional clinical studies, subcontract the manufacturing of the devices and create distribution channel relationships. We hope to launch in late 2005, Siff says.

Siff is talking with several U.S. companies about the device, but says the real interest in it will occur when Biowave generates \$15 million to \$25 million in revenue and captures the attention of the big players in the orthopedic and pain markets. The "typical exit strategy" for a startup medical-device company is to go public or be sold. "Only a very small percentage go public," says Siff.