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As New Products Arrive, Wound Care Sales Grow

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When [Kinetic Concepts](#) went public in February 2004, the company told investors that its best-selling products - a family of devices that promote wound healing - were reaching about 25 percent of the patients who could use them.

When Kinetic reported second-quarter earnings recently, it said the devices' share of the potential market was down to less than 20 percent.

What went wrong?

Nothing, actually. Kinetic has had strong results, but the overall market is growing faster than the company expected.

Kinetic, which is based in San Antonio and started out selling hospital beds, is benefiting from double-digit gains in sales of its line of vacuum-assisted wound healing devices. Thanks to those products, Kinetic's overall revenues are expected to exceed \$1.2 billion this year, up from \$993 million last year.

"It's the first blockbuster wound healer," said Dr. David G. Armstrong, professor of surgery at the Dr. William M. Scholl College of Podiatric Medicine in North Chicago, Ill.

Kinetic's share of the potential market is down because booming demand since the public offering have led Kinetic and its outside consultant to expand their estimate of the opportunity for sales. They now say that if everyone who could benefit from the devices received them, Kinetic would be selling or leasing the products for use on 1.4 million Americans annually, not 1 million as Kinetic previously forecast.

Wall Street is thinking along the same lines. Kinetic's shares closed yesterday at \$60.62 on the New York Stock Exchange, more than double the \$30 offering price last year. A number of analysts who follow the stock expect it to climb to more than \$75 in the next 12 to 18 months as annual sales of the devices climb to more than \$1 billion.

Kinetic was founded in 1976 by Dr. James Leininger, an emergency room doctor who is no longer involved with the company's operations but remains on its board and is its largest shareholder, holding just under 18 percent of the stock, according to filings with the Securities and Exchange Commission. A one-time agnostic who says he experienced a religious epiphany in 1979 as he struggled to keep the company afloat, Dr. Leininger is best known these days as a major financial supporter of Christian and conservative political groups.

Kinetic acquired most of the technology underlying its wound healing technology in 1994 from Wake Forest University and introduced its first commercial versions the next year. Known as VAC (for vacuum-assisted closure, and pronounced vack), the devices create a vacuuming effect above a wound dressing that is meant to stimulate tissue growth in the wound area while removing, to a limited extent, infectious microbes and fluids between the tissues that contribute to inflammation.

The VAC's consist of battery-powered control canisters that can be attached with tubes to a variety of specialized dressings placed over wounds, keeping the areas moist and sealing them to reduce the risk of infections. Kinetic makes different versions for wounds or burns on the skull, abdomen, hands and feet.

Kinetic's success in the large wound market is spotlighting growing interest in the broader field of wound healing, which currently generates revenues of \$10 billion to \$15 billion in the United States alone, depending on which products and services are included.

Startups and medical giants alike are responding to the demand for new products to cope with antibiotic-resistant bacteria and the growing incidence of diabetes, which frequently leads to chronic ulcers and wounds that become infected. Infection often leads to amputation.

"We don't have a full tool box," said Dr. David E. Allie, a surgeon at the Cardiovascular Institute of the South in Lafayette, La., and a specialist in circulatory problems and related severe ulceration. "People should use anything that gives a ray of hope."

Other recent products include [Smith & Nephew's](#) Acticoat dressings, which incorporate microscopic silver nanoparticles from Nucrust Pharmaceutical to enhance antimicrobial activity. Another newcomer is a device from Celleration that uses ultrasonic energy to spray a saline mist on wounds.

Smith & Nephew, a publicly traded British company, also makes skin patches derived from living cells. So does Organogenesis, a formerly public company based in Canton, Mass., that was taken private during a bankruptcy reorganization last year.

[Johnson & Johnson](#), meanwhile, makes Regranex, a wound care gel incorporating blood-cell derived proteins that promote the early stages of healing. Agennix, a startup that received \$22 million in venture capital funding this spring, has been testing a gel that features a protein derived from human milk to make the wound unfriendly to bacterial growth.

Then there is so-called superwater, a technology that is attracting attention from wound and burn specialists. The approach, which zaps a mixture of salt and water with electricity, is being developed by Oculus Innovative Sciences. The process, known as electrolysis, can produce well-known chlorine disinfectants, including basic bleach.

Oculus says that its multistep electrolysis process produces a minimally chlorinated water laden with free-floating electrically charged oxygen ions, which it calls Microcyn. The company says Microcyn has rapidly killed bacteria, spores and fungi in lab tests without harming plant or animal cells. The Food and Drug Administration recently approved Microcyn for use in disinfecting equipment but not for wound care.

Similar disinfectants have been available to health care workers for several years, but they have been too unstable to store. Oculus says Microcyn can remain on a shelf for a year or more and will be sold as a finished product.

Clinical trials are just beginning in the United States on Microcyn's healing potential. But doctors in Mexico, India and Italy have already reported intriguing results.

"If this works, it's big news," said Dr. Allie, who has agreed to join Occulus's clinical advisory board and plans to conduct clinical trials.

The trials will be small, but device companies have rarely been required to conduct extensive randomized patient trials to get regulatory clearance from the F.D.A. to sell their products. Although the F.D.A. approved the first VAC's in 1995, by last year no scientifically rigorous study demonstrating their healing benefits had yet been conducted, according to the Federal Agency for Healthcare Research and Quality, a research arm of the Department of Health and Human Services.

That criticism may be countered today in Orlando, Fla., at the annual scientific meeting of the American Podiatric Medical Association. Dr. Armstrong will be presenting evidence on what he described as the first VAC trial to meet generally accepted standards for scientific rigor.

He said he was barred from disclosing the results in advance of the presentation but said the data would support use of Kinetic's devices. If persuasive, the report could provide further stimulus to Kinetic's shares.