RIVAL AND BOTOX TO GO CHEEK TO CHEEK

By BERNARD J. WOLFSON / ORANGE COUNTY REGISTER

Newport Beach-based company aims for a piece of the self-pay medicine market.

Botox, move over.

The world-famous anti-aging drug could be getting some local competition from a Newport Beach equity investment firm that is moving heavily into aesthetic medicine, including the acquisition last October of marketing rights for a potential rival to Allergan's trademark neurotoxin.

But alas, there is a wrinkle: The company, Strathspey Crown Holdings, does not have the U.S. Food and Drug Administration's approval for the new drug, which is manufactured by Daewoong Pharmaceutical Co. of South Korea and goes by the name Evosyal in this country. The nod from the FDA is not likely to come until later this decade, assuming it is approved at all.

That does not seem to worry Robert Grant, founder, CEO and chairman of Strathspey. He believes clinical tests will ultimately show the substance is a viable alternative to Botox in the market for more youthful faces.

In the meantime, Grant's company – actually, a wholly owned subsidiary of it known as Alphaeon – has a suite of other products ready to sell this year as it launches into what it calls the “self-pay” sector of medicine, where it hopes to blaze the trail.

Alphaeon, which bills itself as a “lifestyle” health care company, has made numerous acquisitions in recent months that will enable it to market a whole range of goods to dermatologists, plastic surgeons and ophthalmologists. It hopes ultimately to move into orthopedics and fertility as well. One thing that sets apart Alphaeon is that it will sell items only that are not covered by Medicare, the government insurance program for elderly people, or by private insurers, who generally follow Medicare's lead.
That means it is catering to a relatively wealthy minority of Americans who can afford to pay out of their own pockets. An article touting Alphaeon, published on Strathspey’s website, notes that it is “based in Newport Beach, the heart of California's Orange County, which consistently ranks among areas with the highest housing prices in the country.”

A short film produced by the company tells potential consumers “you are amazing” and exhorts them to “see better” and “dance better.” Alphaeon plans to start running ads in a similar vein – on the Internet and on TV – by midyear.

$20 BILLION MARKET

Grant said the total U.S. market for self-pay lifestyle medicine is about $20 billion and could rise to $30 billion by 2016. According to the American Society for Aesthetic Plastic Surgery, Americans spent nearly $11 billion on cosmetic procedures in 2012. That included plastic surgery and various nonsurgical procedures including injections, skin rejuvenation and laser treatment for hair removal and varicose veins. It did not include eye treatments, a market that is of interest to Alphaeon.

Physician investors – more than 100 of them – own a significant share of the company. They are the ones who decide which products to acquire or develop, based on their clinical practices.

The company and many of its investors are acutely aware that the Affordable Care Act, also known as Obamacare, is likely to accentuate downward pressure on payments to doctors, and they hope to offset those losses by increasing the portion of their business not subject to insurance claims.

“We want doctors to be able to augment their self-pay revenue,” Grant said. “We want them to be more successful, so we’ve built a system to help them be successful in their practice.”

That system will ultimately enable participating doctors to “opt out of Medicare and other insurance programs,” Grant said in an interview published on the company website late last year.

An important pillar of Alphaeon’s business strategy is to create a self-contained platform for referrals, patient monitoring and practice management. The plan is to run ads that refer consumers to the company’s website, where they can read about possible treatments to produce the physical improvements they desire and be referred to board-certified physicians who offer those treatments.
MATCHING PATIENTS, TREATMENTS

Doctors will then be able to educate their prospective patients about what to expect, including “before” and “after” pictures through Alphaeon's “Touch MD” software, which the company recently launched. Another software product, Engage MD – to be unveiled in the second quarter – will provide a system for tracking patients and managing appointments. Enhance MD, to be rolled out in the third quarter, will enable physicians to gather information on patient satisfaction, manage their inventory and analyze their return on investment.

Doctors can earn a more visible spot on the website – and thus more patient referrals – by accumulating points for information and ideas they post on Alphaeon's “Shout MD,” which Grant described as Facebook for physicians.

He said the traffic on Shout MD has generated valuable ideas that already have led to company decisions on product development, including a deal to acquire U.S. marketing rights for the German-made Schwind laser system, which is used in vision correction procedures, including Lasik. It still requires FDA approval to be sold in this country.

John Gross, an Alphaeon investor who practices plastic surgery in Pasadena, said the collaboration between physicians and industry in the pursuit of new products and services is one of the factors that attracted him to the company. The ability to do that is “significantly limited” when the government is involved, he said.

Some consumer advocates, not to mention regulators, would look askance at a business that is largely owned by physicians who stand to gain financially by prescribing the company's products to their patients.

‘TROUBLESOME’

“It's troublesome when doctors have a financial interest in what they're prescribing,” said Anthony Wright, executive director of Health Access, a statewide health care consumer advocacy group. “It undermines the trust of consumers, who want to know that the prescription of treatments or medicines is not impacted by financial interests.”

In an August interview with PharmaExec.com, Grant said that his company's business model afforded it freedom from regulatory strictures by “never taking a dollar from the government.” In particular, the federal Stark Law prohibits physicians from referring patients for medical services in which the doctors or their immediate family members have a financial interest. But it is specific to Medicare and Medicaid.
Obamacare's Physician Payment Sunshine Act requires medical manufacturers who participate in federal government health programs to disclose any payments they make to doctors or hospitals. Alphaeon's spokeswoman, Jenna Mons, said although the company is not subject to the act, “we actually require any physician who is an investor to disclose that to all patients. We go above and beyond what is required.”

As of the New Year, Alphaeon is cranking it into high gear. It will start selling a series of moisturizing and re-hydrating agents whose distribution license it acquired last August from Swiss manufacturer Teoxane Laboratories. It will also begin distribution of a device called the HD Analyzer, which can provide an early warning of cataracts by examining light scatter in the eyes.

**TAKING ON BOTOX**

But the most titillating tidbit, at least in these parts, is Alphaeon's longer-term play to wrest at least a small piece of business away from Irvine-based giant Allergan. Lending an element of intrigue to the nascent competition is the fact that Grant spent four years as president of Allergan's medical division, where he played a major role in the commercial success of Botox and Juvederm, a well-known dermal filler.

In its deal with Teoxane, Alphaeon also acquired marketing rights to Teosyal, a wrinkle filler that could one day do battle with Juvederm. It does not yet have FDA approval, though it is already being sold in Europe.

For Allergan, less than two miles to the northeast, Evosyal is little more than an abstraction.

“In our world, to get a product approved, you're probably talking about a five- to six-year period,” said the company's CEO, David Pyott. “And that would be for a company of our scale. This is a long way away, and not necessarily inevitable either.”

Grant is hopeful but cautious.

“Allergan is big,” he said. “I think Evosyal will prove to be efficacious and long-lasting. But I wouldn't comment on competing with Allergan until we see actual data from the clinical trials.”