

Stakely pilots a startup into statins

At first glance, Nagoya, Japan-based Kowa, which last month launched a statin, Livalo, in the US, looks to be running a somewhat counterintuitive play, expanding into a market in decline and starting with a category in decline—at least for branded pharmas.

Montgomery, AL-based Kowa Pharmaceuticals America, or KPA, is the nascent US arm of a giant Japanese conglomerate which has a hand in a wide range of products, from chemicals to reading lamps, high-end binoculars to A/V equipment. The firm was founded in 1894 (though its pharma division wasn't established until 1947), and it remains a privately owned, family-run, soup-to-nuts colossus of a company. In other words, typically Japanese.

Ben Stakely, president and CEO of KPA, on the other hand, couldn't be much more American. The bluff, big-voiced Alabamian has an entrepreneur's zeal and a "go west young man" kind of faith in the potential of his product.

It's not a bad argument, either. Livalo is aimed at the 75 million Americans with multiple types of cardiovascular disease, many of whom are using multiple drugs and don't tolerate lipids well. Livalo, metabolized through a novel pathway, offers them a workaround. The statin commands a healthy 13% share of the Japanese market for cholesterol-lowering drugs, with sales of \$399 million in that country alone. Eli Lilly & Co. saw enough promise in the drug to ink a co-promotion deal for the US, committing 500 reps to detail the drug to primary care docs and cardiologists alongside KPA's sales force of 250.

"We talked to a lot of companies and they were the best fit," said Stakely. "We're both very old companies, committed to the cardiovascular business and helping patients with cardiovascular disease."

Kowa's heritage may go back to the 19th century, but

"We'll be a cardiovascular-focused company, and we hope to be a major player in the cardiovascular arena"

Ben Stakely
*President and CEO,
Kowa Pharmaceuticals
America*

2009-2010
President and CEO, KPA

2001-2008
President, ProEthic Pharmaceuticals

1996-2006
Owner/operator, Pet Supplies Plus



KPA was founded by Stakely's neighbor, Carl Watley, as ProEthic Pharmaceuticals in 2002. Stakely was his first investor and shortly thereafter became president of the startup, which began with a sales force of five, one home office employee and a handful of OTC cough and cold products including Durahist, Duraphen and Duraflu (all since discontinued).

In 2007, the firm licensed its triglyceride-lowering drug, Lipofen, from Cipher, a Canadian company. That got the attention of Kowa, which was shopping for a small cardio-focused pharma to handle the US launch of Livalo. Kowa bought ProEthic in 2008, and Watley left in 2009.

KPA now has 320 employees, including its 250 reps detailing Lipofen and Livalo. Kowa also has an R&D operation in North Carolina and a research collaboration with Brigham and Women's Hospital in Boston.

Stakely is a serial entrepreneur. After a brief post-collegiate stint in the Marine Corps Reserves ("I needed discipline and they gave it to me") and selling real estate, he launched a frozen yogurt chain with his brother. It was called Ben and Harry's (this was the late '80s, and Ben and Jerry's was not yet a household name). They sold it in 1991 and Stakely sold orthopedic devices for DePuy before launching a pet supply store in 1996. He continued on as owner/operator of that business until 2006, juggling his responsibilities for ProEthic for several years.

You won't find too many pharma firms south of Research Triangle, but Montgomery suits Kowa fine, says Stakely, a native.

"We like being down here," he says, adding that he's found it easier than expected to draw talent from Philadelphia, Atlanta, Houston and St. Louis.

The firm works with New York's RCW Group and Philly's Vox Medica for advertising.

Going forward, Stakely seeks the company expanding its US portfolio of products.

"We'll have several other products on the market, either from Kowa internal development or licensing," he says. "We'll be a cardiovascular-focused company, and we hope to be a major player in the cardiovascular arena. Right now, we have a product in the largest category in the US. It's exciting."

—Matthew Arnold

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