

## Hawaii company offers solution to chronic pain

**Cardax Inc. is banking on its nature-identical anti-inflammatory dietary supplement**

By Dave Reardon

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David Watumull, president and CEO of Cardax Inc., holds a molecular model of the drug astaxanthin, an anti-inflammatory supplement, in his office at the Manoa Innovation Center. He and his eight employees took no salaries for the first half of this year.

Cardax Inc. CEO David Watumull plays tennis three times a week and takes large daily doses of natural astaxanthin as an anti-inflammatory to alleviate joint pain and stiffness that come from athletic activity or aging.

But sometime next year Watumull, 65, plans to switch to a synthetic nature-identical product that Cardax has been developing for nearly a decade that he says achieves a blood level of astaxanthin three times higher than competing products yet is safe enough to consume daily without side effects.

Watumull, who lives about three minutes from his office at the Manoa Innovation Center, said he and the company's eight other employees have put their heart and soul into this yet-unnamed anti-inflammatory product, which he expects to become commercially available as a dietary supplement in 2016. They took no salaries for the first half of this year and now are only receiving half their wages. But they all own shares in the publicly traded company, which trades at 16 cents a share, and are hoping the payoff will be worth the sacrifice.

"The science community is very well convinced that inflammation plays a causative role in most chronic diseases," he said in an interview. "Arthritis, cardiovascular disease, liver disease, diabetes and probably Alzheimer's and cognitive decline are all not just related to, but caused by chronic inflammation at the molecular level. And while there are many anti-inflammatories on the market today -- things like aspirin, Aleve, ibuprofen, Celebrex, prednisone, Tylenol -- none of them are safe enough to take every day. They all have significant side effects (such as internal bleeding and liver damage). What we think astaxanthin -- the compound we're working on -- can do is provide a medically meaningful anti-inflammatory effect safely every day."

### **Overwhelming potential**

Astaxanthin is normally produced in fresh water, such as ponds or streams, by microalgae. The streams empty into the ocean, where the astaxanthin is eaten by krill and other small crustaceans and taken up the food chain where it protects animals from strong inflammatory processes.

But Watumull is taking astaxanthin one step further with a synthetic nature-identical version that Cardax is developing in conjunction with partners BASF and Capsugel. He said Cardax's potential market is overwhelming.

"There are certainly hundreds, millions, maybe even a billion people or more who suffer from chronic inflammatory disease," Watumull said. "So if you could have something safe that could address that, I think that's the potential size of the market in terms of people. And if

you think of 50 cents or \$1 a day from that, you're looking at extremely large markets in the tens, if not hundreds, of billions of dollars at the retail level."

Besides having no side effects, Watumull said Cardax's product is purer than those of its competitors and thus would be less costly to produce.

"I need to take 120 milligrams today in order to get the amount of astaxanthin I think I need," he said. "It's a 12-milligram capsule, so I need to take 10 capsules. That's because there's maybe 8 to 10 percent astaxanthin in the capsule. Ours will have much more purity in it, so you'll be able to get more into your bloodstream from our product. We recently published a study on monkeys, which is the best (test) because they're primates, so they're closest to humans in absorption of these kinds of compounds like astaxanthin, and it demonstrated that our product was three times more bioavailable, meaning when you take it by mouth, how much (more) gets into your bloodstream than the microalgal products that are out there today. So if you have a 12-milligram capsule of ours and a 12-milligram capsule of a microalgal product, we would deliver three times as much to the bloodstream. So you'd have a lot fewer capsules than you'd have with the microalgal product."

Executives at Kona-based Cyanotech Corp., which produces the BioAstin product that Watumull currently takes and would compete with Cardax's new product, were unavailable Friday afternoon to comment on Watumull's claims.

Unlike a drug that needs to go through three phases of clinical trials, Cardax is taking a faster track to the market by going the dietary supplement route upon the advice of its U.S. Food and Drug Administration consultants. Watumull said Cardax already has done animal studies, including one with monkeys, and is finishing up manufacturing requirements.

"A dietary supplement company has a much less onerous set of processes to go through, and we should have a product on the market in 2016," he said. "We're much closer than most biotech companies are to commercialization. But it's not Phase 3 trials that we're doing that would result in FDA approval of a drug. We are going through the process that the FDA mandates for dietary supplements. That's called GRAS (Generally Recognized as Safe). You need to demonstrate that your product is safe in animals at very, very large doses, which can be translated into small doses in humans, and that your product is safe from a manufacturing perspective and is manufactured rigorously according to FDA standards. Those are the two processes that we're going through that we expect to finish up in 2016."

### **Global strategy**

Even though Cardax is taking the faster route to market, its costs have been mounting without revenue to offset expenses. The company's total deficit from inception in May 2006 through June of this year was \$51.6 million, according to company filings with the U.S. Securities and Exchange Commission. The company raised \$10.8 million last year when it

went public after taking over the shell of a dormant company, Koffee Korner. Cardax has been selling stock to raise additional capital and raised \$1.125 million during the first half of this year. Cardax said in its most recent SEC filing that the \$585,676 cash it had on hand at the end of the second quarter only would be sufficient to continue operations on a limited budget through Oct. 15.

Watumull said, though, that the probability of running out of cash before its product reaches the market is "quite low."

"We've been raising money, and we've been quite successful doing that," he said. "We think there's a very short time we have left to cover to get to commercialization, product sales and then profitability."

Cardax is partnering with German-based chemistry company BASF and Morristown, N.J.-based Capsugel, which creates mixtures that improve product performance.

"Our strategy would be to partner with other large companies that can help us build out this market, whether it's BASF in manufacturing, Capsugel in formulation or a large third-party marketer to help us market this on a global basis," Watumull said. "And of those large markets, Cardax certainly won't capture all of that, but we will capture a significant piece of that."

There are three major astaxanthin manufacturers that produce products through the cultivation of microalgae, according to Watumull. Besides Cyanotech, the others are Japanese-based Fuji Chemical Industries Co. and Israeli-based Algatechnologies Ltd.

"They all use the same or similar microalgal cultivation techniques," Watumull said. "The problem is that the amount of astaxanthin they can produce using these methods is quite limited -- maybe enough for a couple hundred thousand people in total if they were taking reasonable doses every day.

"The market, for example, for osteoarthritis globally is about 150 million people in the middle class, and obviously there are other diseases of equal size. So production capacity in the microalgal industry will frankly, at least in our judgment, never be sufficient for those large mass markets. And just like we saw in vitamin A, vitamin B, vitamin C, vitamin D and vitamin E, synthetic production of a nature-identical version of a compound will come to dominate the market. That's what we believe will happen with astaxanthin as well, led by us and our partners, BASF and Capsugel."