As obesity grows, Zafgen aims to fast-track treatment

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Cambridge's Zafgen [1] is starting the next phase of its obesity treatment trials this month, as it looks to fast-track the drug and get it to people "who are out of reach of other therapies," CEO Thomas Hughes said in an interview.

So far, the drug has been tested with patients over a four-week period, and patients have lost an average of one kilogram — 2.2 pounds — of bodyweight per week during the program. That's between two and five times what other drugs can offer, and the drug "works in every patient we see," Hughes said.

"There is almost no variation around the average. It doesn't matter if they're older or younger, heavier or lighter," he said. "We've seen every patient respond to the drug."

The Phase 2A trial will test the drug, which is given by injection twice a week, over a period of 12 weeks. The drug, Beloranib, works by targeting imbalances in fat metabolism, according to Zafgen. Those imbalances make it difficult for obese people to lose and keep off weight, Hughes said.

Zafgen is pushing for the drug to be fast-tracked for approval by the FDA due to the severity of the obesity problem in the U.S., he said. The Obesity Action Coalition estimates nearly 93 million Americans suffer from obesity, and that number is expected to reach 120 million within the next five years. And in 2006, treatment of obesity-related illnesses cost the nation an estimated $147 billion, about 9 percent of all U.S. medical spending, according to Obesity Journal.

A recent update to the Prescription Drug User Fee Act "will help us quite a bit," Hughes said. The update may allow the FDA to fast-track drugs for "special populations" — which could include people with severe obesity, he said.

If the FDA fast-tracks the drug, it will allow Zafgen to conduct smaller trials before filing for approval, and the company could file as soon as 2015, Hughes said. If the company has to go the traditional route, it may be 2017 by the time Zafgen can file, he said. The FDA decision would be expected to be made six to 18 months after the filing, he said.

Meanwhile, Zafgen is weighing whether to pursue acquisition by a pharmaceutical company or an initial public offering of stock. Acquisition would make sense in many ways for the company, due to the complexities of carrying the product through Phase 3 trials and registration with the FDA, Hughes said.

Still, "we hear that the public markets are really opening up and the climate for

going public is changing dramatically," he said. Within the next year or two, Zafgen may be ready for an IPO, Hughes said — following other Boston area biotechs that have recently gone public including Verastem, Tesaro and Merrimack Pharmaceuticals.

An IPO would require some beefing up, however. Zafgen operates as a virtual company, where only five people work full-time for the firm and the drug development work is outsourced. The company would need to add more financial staff before looking to go public, Hughes said.

Zafgen has raised $48 million in venture capital since its founding in 2005, from investors including Atlas Venture [2] and Third Rock Ventures. The company most recently raised a $33 million round [3] in July 2011.

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