

Q&A with Gila Therapeutics Inc. Co-founder, Chairman and CEO, Dr. Thomas Vasicek, PhD, on developing a Novel Topical Lingual Application for Treating Obesity based on Satiety Hormones that Naturally make the Patient Feel Full after Eating



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“We at Gila are developing a revolutionary treatment that promises to be safe, economical and effective for obesity, the devastating epidemic sweeping the globe.”
- Dr. Thomas Vasicek, PhD

CEOCFO: *Dr. Vasicek, what is the focus at Gila Therapeutics, Inc. today?*

Dr. Vasicek: We are developing a novel treatment for obesity involving topical lingual application of satiety hormones that naturally make us feel full after we eat. These hormones are normally secreted by our intestines after food begins leaving the stomach; we will provide them before you eat with the expectation that we can help you feel full sooner, eat less and lose weight.

CEOCFO: *What has been the history of a concept like this? What have you figured out to potentially have it work?*

Dr. Vasicek: Back in the 1990s, we at Millennium Pharmaceuticals, and others, were looking for the genes that encode these hormones and their receptors as potential therapeutic targets. Ten years ago at Medtronic we explored the delivery of satiety hormones with drug infusion pumps. The hypothesis was that we might be able to create effective therapies for obesity by boosting the body's natural weight control mechanisms. We used insulin pumps, which are ideal for delivering the correct dose at the optimal time. The concept worked well, with the pumps programmed to deliver the hormones before meals.

Unfortunately, we at Medtronic and others at some of the major pharmas found, when you deliver these hormones systemically and raise the blood levels, many people become nauseated. This effect is now widely known with drugs related to the satiety hormone GLP 1, such as Saxenda and Victoza, which are injectables for obesity and diabetes, respectively. About forty percent of people who use these therapies experience nausea and about ten percent drop out because of vomiting. Therefore, in 2008 we gave up the effort, and those at the major pharmas also stopped their development efforts.

CEOFCO: *What is the approach from Gila today?*

Dr. Vasicek: Our novel approach involves topical lingual application of the satiety hormone PYY to the tongue where we believe it binds to receptors that signal directly to the brain's satiety centers. This pathway was recently discovered by our cofounders Drs. Andres Acosta, MD, PhD and Sergei Zolotukhin, PhD, at the University of Florida; Dr. Acosta is now a physician scientist in the Gastroenterology Obesity Clinic at Mayo in Rochester, Minnesota.

We had long known that PYY is made by special cells in the small intestine and secreted into the bloodstream in response to food intake. The Florida scientists found that, shortly after blood levels rise, the hormone appears in saliva which brings it to receptors on the tongue signaling directly to the brain. Much like activation of salty or sweet taste receptors sends an immediate signal to the brain, the hormone receptors send a fullness signal.

The scientists further found that application to the tongue in obese mice made them eat less and lose a mean of twenty three percent of their body mass over eight weeks. Our results suggest that this application method results in little or no systemic absorption and no nausea.

At Gila, our objective is to replicate this result in humans. Testing of our approach in two species, rat and dog, and our Phase 1 clinical trial results showed no safety or tolerability issues. In addition to this, the people tested reported a significant feeling of fullness lasting at least two hours after treatment.

I should point out that we must be careful to not make claims here, because of regulatory compliance, but we could not be more excited about our results so far!

CEOFCO: *Do most people stop eating when they feel full?*

Dr. Vasicek: Some do not. Twenty two percent of the two hundred million Americans who are overweight or suffering from obesity do not experience a feeling of fullness after eating. Furthermore, paradoxically, the more overweight we are, the less of these hormones we make, and the more food it takes for us to feel full. Thus, we need to reduce food intake but actually eat more to feel full. With Gila's new treatments, we hope to be able to provide that feeling of fullness for those who never experience it and intensify it in those who for whom it is not so intense. Animal studies and our phase I clinical trial results suggest that we may have a very promising solution.

CEOFCO: *What has been the reaction from the medical community or people who have paid attention to what you are doing so far?*

Dr. Vasicek: Among those we have told about it, there is a lot of excitement! We plan to offer a safe, non-invasive treatment using natural hormones. No injections, no absorption, no side effects. If we are successful in our efforts, this treatment promises to be something that, because of the safety of our approach, ANY physician could prescribe to the obese patient who needs help with appetite to lose weight and improve health.

Obesity is a devastating global epidemic. According to the National Health and Nutrition Examination Survey (NHANES), more than 1 in 3 adults are overweight or suffering from obesity, costing the healthcare system one hundred and ninety billion dollars a year. This is because

obesity is a major cause of diabetes, cardiovascular disease and many others. One hundred million Americans attempt diets every year, four or five attempts a year, but only one percent succeed in losing and sustaining weight loss. The five obesity drugs currently on the market have captured only a tiny fraction of the sixty billion dollars we Americans spend each year on weight loss products, diets and surgery. That is a remarkable statistic; given that drugs for such a huge indication would typically be multibillion-dollar products.

That suggests that given alone, no one medication can produce enough weight loss to satisfy patient expectations. Since our product has such a favorable safety profile, we expect it to be used in combination with other products, increasing the efficacy and amount of weight loss and thus, health benefits. Prescribed along with other drugs, behavior therapy and diets, we hope to provide an effective solution to turn the tide of this epidemic.

CEOCFO: *What is happening today at Gila?*

Dr. Vasicek: Having demonstrated safety and found a significant satiety signal in our phase I clinical trial, we are planning our next clinical studies. Also, based on the phase I success, we are launching into our Series B fundraising effort to support ongoing clinical development as well as our R&D platform to expand the product pipeline.

In April of 2016 we raised the first Tranche of our Series A financing and that enabled us to proceed with the FDA pre-IND briefing. This allowed us to go forward with the preclinical work, which led to our active IND, Investigational New Drug, in July of 2017. By Q3 2016, we had a stable formulation, which we took into preclinical animal studies. These toxicology studies demonstrated safety at doses up to several hundred times our therapeutic range. We started our clinical trial in July and finished it in August. While the goal of that trial was to demonstrate safety, we also saw a significant satiety signal, a persistent elevated feeling of fullness that looks very promising as we move forward into food intake and weight loss studies. We not only achieved our safety endpoint, we also identified promising doses over a very broad range enabling us to go forward into our next clinical trials.

CEOCFO: *Where do you stand today with funding?*

Dr. Vasicek: We currently are funded through Q2 2018. To date we have raised four million dollars from venture and angel investors. This Series A round was led by Broadview Ventures in Boston and includes many savvy angels, significantly, a former major pharma CEO and biotech VCs who have invested privately. In the light of our successes, having assembled a terrific team, completed all the preclinical development and the clinical trial, we believe Gila presents a compelling investment opportunity.

We also have applied for a grant from the National Institutes of Health and are in the process of applying for two more, as well as two grants from the Department of Defense.

CEOCFO: *Can you talk about the other products?*

Dr. Vasicek: At this point we are focusing on our lead molecule, Peptide YY or PYY. We have a robust pipeline exploiting our novel delivery method.

CEOCFO: *Do you find that, when you are speaking with potential investors who are unaware of your company, it is a relatively easy concept to understand?*

Dr. Vasicek: Yes, the pathway we are exploiting is very new but we have worked out the biology in great detail. Furthermore, the market opportunity is large, the compelling need is clear and the issues of co-morbidities associated with obesity are widely known. What is not so well known is how impactful it is to lose a little bit of weight on those co-morbidities, greatly improving health and quality of life while reducing healthcare costs in ways that are much broader than being lighter and feeling better about yourself.

Many people, particularly in the pharmaceutical industry, were skeptical that we would not induce nausea or have other tolerability issues, but now we have clinical proof.

CEOCFO: *Why should people pay attention to Gila Therapeutics today?*

Dr. Vasicek: We at Gila are developing a revolutionary treatment that promises to be safe, economical and effective for obesity, the devastating epidemic sweeping the globe. We have exclusively licensed ground-breaking technology from the University of Florida and have a rapidly expanding patent portfolio. We have assembled a world-class team and proven that we can execute effectively in record time and on budget. Furthermore, we have demonstrated interest among leading clinicians and investors in the field, and we now have clinical proof that we can induce a feeling of fullness with no safety or tolerability issues. The path forward from here to proving that we can reduce food intake and ultimately help people lose weight is clear. We can proceed with confidence and easily forecast our next steps through the development process.

