BIOPHARMACEUTICALS

Tunitas Therapeutics Inc.

Inhibiting allergic reactions at the cellular level

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Contact: Nolan Sigal, MD, PhD, President & CEO
Business: Innovative protein therapies for allergic diseases
Founded: 2007
Founders: Nolan Sigal; Andrew Saxon, MD, Acting CSO
Employees: 7
Financing To Date: $7 million in NIH grants
Board Of Directors: Nolan Sigal; Ken Clark, Corporate Secretary (Wilson Sonsini)
Scientific Advisory Board: Andrew Saxon, Chairman (UCLA School of Medicine); Jean-Pierre Kinet, MD (Harvard Medical School); Steve Galli, MD (Stanford University School of Medicine); Steve Durham, MD, PhD (Imperial College, London); Lanny Rosenwasser, MD (University of Missouri-Kansas City School of Medicine)

Tunitas Therapeutics Inc. *thinks* its research could go a long way toward relieving the suffering of the 40% of Americans with allergies to one or more common inhalant or food allergan. The San Francisco-based biopharma is developing precisely targeted protein therapeutics to target pet and food allergies, life-threatening conditions such as peanut allergy, and allergic diseases such as asthma.

Tunitas' fusion proteins are designed to alter the natural course of allergic diseases at the cellular level, inhibiting allergic reactions from occurring. The start-up believes they could be widely applicable to an expansive range of allergies and allergy diseases and could be applied to a multitude of products. While the prescription market for asthma and allergy medications presently is dominated by oral and inhaled steroids and leukotriene antagonists, newer therapeutics like the ones being developed by Tunitas are expected to increase from 5% to12% of the market. The first biological therapeutic to be approved for asthma, **Genentech Inc.**'s *Xolair* (omalizumab), posted sales of $1 billion in 2010 and is expected to top $1.5 billion by 2016.

At present, Tunitas has two main projects. The first, GE2, is a therapeutic fusion protein for asthma that uses a unique dual mechanism of action, shutting down both mediator and cytokine release from the body's key allergic cells and allergen-specific IgE production, the root cause of allergy, thereby stopping the allergic reaction before it starts. The unique aspect of these fusion proteins is that they only interact with the specific cells that are key to an allergic response.

GE2 would be administered by an allergist or general practitioner via subcutaneous injection. "We would hope that, based on its novel mechanisms, [it would] relieve asthma sufferers from a lot of their inhalers, from their missed days of school, from hospital admissions, etc. In that respect, from a lifestyle standpoint, we think that this is novel and unique enough that it could change people's lives," says Tunitas president and CEO Nolan Sigal.

Sigal acknowledges that asthma clinical trials are difficult to execute. And asthma is a competitive space, because it is such a huge market – about $20 billion worldwide. However, most of the market is composed of inhaled bronchodilators and steroids and the like, and Sigal feels that Tunitas' therapeutics may have a competitive advantage.

The start-up's second project is a broad platform for the development of allergy vaccines, with cat and peanut allergies being the first targets. Peanut allergy is the most common and well-known food allergy, and results in 200,000 emergency room visits and more than 10,000 hospital admissions yearly. Today, there is no effective therapy for peanut allergy other than attempted strict avoidance. Tunitas says its vaccine platform would be similar to current vaccine technology, but would offer a safer and much more rapid (months vs. years) means to allergy desensitization. If successful, the platform would produce therapies requiring three to six months of visits to an allergist as opposed to current methods that require injections for three to five years.

If the company's fusion protein is effective in treating these two allergies, Sigal says it should be straightforward to use the same engineering for a wide variety of other food allergy vaccines, such as milk, egg, shrimp, crab, and lobster. But rather than trying to do too much, he says Tunitas' view is that "if we prove this works for peanut – clearly the most significant and largest population, [as well as] the most life-threatening – it gives either the company or our acquirer the opportunity to do the market research and decide which of the other 20 or 30 products it would like to pursue."

Tunitas was co-founded by Sigal and his former academic colleague Andrew Saxon, professor and former chief of clinical immunology and allergy at the **University of California, Los Angeles School of Medicine**. Saxon's research yielded the proteins that inhibit allergic reactions, and his desire to commercialize this novel discovery led to Tunitas' formation. The company was incorporated in 2007 to negotiate the license agreement from UCLA, but it took another year or so before Tunitas got off the ground.

An entrepreneur with a track record of success in biopharma start-ups and more than 25 years of experience in the academic, pharmaceutical, and biotechnology communities, Sigal earned his MD/PhD at the University of Pennsylvania and completed a pediatric residency there. He was on the faculty at the University of Toronto before holding management positions at Merck & Co. Inc., including executive director of immunology research.

Sigal left Merck to venture into the start-up world and co-founded a company called Pharmacopeia, which went public. He then moved on to another start-up on the West Coast called Cytokinetics Inc., where he served as chief science officer and developed a pipeline of successful therapeutics.

About starting Tunitas, Sigal says, "I've had experience in lots of different areas but, in my heart, I'm still an immunologist. When I saw what Saxon had discov-

ered, I thought that it was one of the most exciting things in science that I had come across in years. I thought it offered extraordinary potential for novel therapeutics in allergy and asthma."

Sigal appreciates, especially concerning GE2, that the company needs to demonstrate some clinical benefit. He foresees partnering the program after Phase I or Phase II because Phase III clinical trials in asthma generally are too complicated and large for any small company to take on.

Over the past four years, except for the co-founders' personal investments, Tunitas has not raised any money. The company has received approximately $7 million in **National Institutes of Health** grant funding to date. Half of that has been spent in the last two years, and the remainder will come to Tunitas in the next two years as the research is performed.

The company also has received a review notice for an additional $3 million grant, which will fund another three years of research, bringing the total non-dilutive financing to $10 million from the NIH. While not official yet, Sigal says he anticipates the grant will be funded in the next few months.

NIH prioritized the Tunitas grant among the top of all grants under review, Sigal says. This puts the company in a position to both reach clinical development with its lead program and seek investors.

"This is the model. Certainly, there still is early-stage investing in certain respects, but I think the way that Tunitas has been built is going to be more the rule in the future rather than the exception. That's simply because of what's going on in the venture community", Sigal opines.

The new grant money has allowed Tunitas to speed up plans to move GE2 toward clinical trials while also attracting significant interest among potential investors, both smaller (angel) groups and larger, traditional VCs.

"I'm not turning anyone away at this point," says Sigal. Saxon and Sigal will be seeking more grants in 2013, which theoretically would be funded in 2014, but there are no guarantees.

GE2, the start-up's lead candidate, is expected to start clinical human trials in about a year or so. The grants Tunitas has received will not cover those clinical trials, which is why the company is talking to investors. "We do need a little bit of money, not a lot, but enough to get through those initial clinical trials", says Sigal.

If all goes well, Sigal predicts that GE2 could be ready to go to market around five to six years from now, if developed for asthma.

Tunitas has also started talking to clinical-stage companies about potential partnerships. "I guess I'm open, like a general manager on a baseball team, to the right kind of deal," Sigal explains.

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– Amber Hurwitz