



**Q&A with Michael Nelson, JD, Co-Founder and CEO of Intrimmune Therapeutics
developing a revolutionary new Drug Delivery method using Toothpaste to
Deliver an Oral Mucosal Immunotherapy for People who have a Peanut Allergy**



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CEOCFO: *Mr. Nelson, what is the concept behind Intrimmune Therapeutics?*

Mr. Nelson: Intrimmune Therapeutics is a New York City based biopharmaceutical company. We are developing a new, simple treatment for food allergies. What we have developed is a platform technology. We deliver our drug, which in this case are the allergens that people are allergic to, in a toothpaste delivery vehicle. It offers an easy and safe way to retrain the immune system to reduce the risk of symptoms in food allergies.

CEOCFO: *Would you tell us about the science behind retraining the immune system?*

Mr. Nelson: Allergy immunotherapy has actually been around for over 100 years. Most people know it as allergy shots. Allergy shots are used to treat respiratory allergies and it is really the first personalized medicine. You give injections of extracts from what people are allergic to in doses below what would actually cause their allergic reaction. About thirty plus years ago doctors realized that you could give those same extracts as drops under the tongue, because there are dendritic cells, which are antigen-presenting immune cells, in the mouth. They are called Oral Langerhans Cells (LCs). By exposing these cells in the mouth to allergenic proteins you could retrain the immune system and desensitize people to what they are allergic.

CEO CFO: *How is toothpaste an effective method? What are the advantages in using toothpaste as a delivery mechanism?*

Mr. Nelson: Toothpaste offers a number of advantages. One is that food allergy immunotherapy needs to be done every day to be effective. You need to have that continuous exposure and the one thing that people do every day is brush their teeth. You get that built-in compliance. There is a significant amount of clinical evidence from respiratory allergy suggesting three to five years of regular adherence is needed for optimum and persistent reduction or elimination of symptoms. For food allergy, it is not clear how long therapy needs to continue, but it may require even longer. And with food allergies, you want to be sure the symptoms won't return. Therefore, one of the big advantages of toothpaste for food allergies in particular is the built-in long-term compliance.

A second advantage is that our approach contacts about sixteen-fold more tissue surface area compared to sublingual immunotherapy. You are also contacting tissue in parts of the mouth that have higher populations of LCs than in sublingual immunotherapy. It turns out that where toothpaste tends to gather in the mouth is where you have the highest concentration of LCs. And that makes sense. It is the same place where food tends to congregate, so it is where the body learns to distinguish what is safe and what is harmful.

Finally, in terms of why toothpaste is better than other ways of delivering treatment via the mouth, you learn from a young age to spit out toothpaste. The fact that you do not swallow the proteins greatly reduces the adverse events. You thus may avoid GI issues that can occur by ingesting the proteins, as in sublingual and oral immunotherapy, such as Eosinophilic Esophagitis (EoE).

CEO CFO: *How do dentists feel about this?*

Mr. Nelson: We have had dentists as advisors and we spoke with many dentists during the early stages of development. They love it! Anything that encourages people to brush their teeth is welcome. And when you combine teeth brushing with something that is also going to help treat people, they become big fans.

CEO CFO: *Do you have a range of products for different allergies?*

Mr. Nelson: Our first product, INT301, is a peanut allergy immunotherapy. We are initially targeting peanuts. We do need to go through the FDA development process. We are going to have a pre-investigational new drug (or pre-IND) meeting in July with the FDA. Then we will seek investigational new drug (IND) status so we can begin clinical trials.

While our first target is peanut allergy, eventually this will be a platform for other food allergies as well. There are eight key foods that cause ninety percent of food allergies in the US, so our pipeline is laid out in front of us.

CEOCFO: *Are people so desperate to eat peanuts that they want to go through a perhaps three to five year process or is it more as a protection in case they inadvertently eat a peanut?*

Mr. Nelson: This is a therapy to protect you against accidental exposure. Some people might be able to go ahead and have peanut butter and jelly sandwiches after this therapy. But for most people, they do not even want to eat peanuts. They have been trained all of their life to avoid peanuts. They do not like the taste of it. What they want, however, is to be able to live their lives without fear. They want to be able to go out to a restaurant and not be concerned that peanut oil was used or that there was cross contamination or that peanut butter was mixed into their chili, which happens. They just want to be able to live their lives and their families want to know that their children have been made safe.

Therefore, the goal here is not that you can eat whatever you want. The goal is that you can live your life. "Normal" is within reach.

CEOCFO: *Why are you convinced people will make the effort and stick to the toothpaste? What do you understand about the psychology of allergy sufferers that leads you to believe this will be embraced?*

Mr. Nelson: I will try to answer this in a couple of ways to see if I am getting to what you are asking. There is currently no FDA approved food allergy treatment. If you accidentally get exposed and react to a food to which you are allergic, you must get yourself an epinephrine injection and then get yourself over to the nearest emergency room. There are people who are willing to eat peanuts and try to desensitize themselves over time using a technique called oral immunotherapy, or OIT. It is effective but causes many side effects. There have also been studies at universities using sublingual immunotherapy, where peanut extract is held under the tongue and then spit out. It is effective, but the dose of protein that can be dissolved into liquid is limited. It is also difficult to avoid swallowing or aspirating the liquid you need to hold in your mouth for a period of time, thus potentially increasing adverse events.

We have reasons to believe that the toothpaste will be more effective than SLIT because we contact 16-fold more of the oral tissue surface area, including areas with higher concentrations of LCs. We anticipate that it will be safer than OIT because the peanut protein is not swallowed. Toothpaste also offers built-in compliance by incorporating treatment into people's every day activity. We have also had pilot studies done at Weill Cornell using the toothpaste as a delivery mechanism for immunotherapy. We know from those pilot studies that incorporating proteins into toothpaste does enable desensitization to occur.

CEOCFO: *Has toothpaste been tried in the past?*

Mr. Nelson: No. Our inventor came up with the idea of using toothpaste. While brushing his teeth one day, he realized that immunotherapy delivered via a toothpaste would solve many of the issues that he had

seen with allergy immunotherapy. Plus, he had seen studies showing that LCs are most concentrated in the areas of the mouth where toothpaste collects during brushing. You are contacting the most important parts of the mouth while getting “built-in” compliance by incorporating treatment into something that is already in your routine.

CEO CFO: *What has been the response from the allergy community or at least people that may know what you are working on?*

Mr. Nelson: The allergy community has been very supportive. There are two other products under development by other companies. Each have their own issues. The allergy community’s key opinion leaders are excited to see a product that is expected to have the right balance of safety and efficacy. In addition, the allergy community knows it needs a long-term solution. Each of the competitor products are inconvenient in their own ways, and many people do not relish using them for years. And even if someone starts on another product, they may later want to switch to our toothpaste for long-term maintenance.

CEO CFO: *Are you concerned about skepticism? Have you thought of some ways to counteract that or do you feel more people will be so excited it is very likely to just take off?*

Mr. Nelson: Certainly using toothpaste as a delivery vehicle is atypical. People have not heard about using toothpaste as a way to deliver therapies. But allergy immunotherapy is very different than the typical drug. Again, it is a desensitization therapy. We are not looking to get product or other therapeutic agents into the blood. What we are trying to do is coat the oral mucosa. The proteins then bind very tightly to the surface of the epithelial cells and then, over several hours, they get pulled into the lymphatic system by the LCs and start the whole desensitization process. Compared to a typical drug, it is a very different pathway.

Allergy experts are well aware that this should work. When you talk to an ENT or allergist about using toothpaste as a delivery vehicle, they tend to get a typical surprised look, like “why did I not think of that,” because they know it contacts the optimal areas of the mouth, gets spit out, and resolves that “crisis of compliance” seen with all other allergy immunotherapies.

CEO CFO: *Would this be a prescription product or would it be over the counter?*

Mr. Nelson: This will be a prescription product. We will be going through clinical trials and the FDA approval process.

CEO CFO: *Where are you right now in the process?*

Mr. Nelson: We have spent the last couple of years locking down the intellectual property to make sure we have the freedom to operate and that no one else can turn around and copy us. We have developed clinical trial protocols in coordination with our scientific and medical

advisors who are top names in food allergy immunotherapy. Right now we are in the process of raising money through a [crowdfunding investment campaign](#) via the Netcapital platform to raise the money needed for our pre-IND meeting and to complete our IND application with the FDA. IND approval will enable us to begin clinical trials to develop our peanut allergy oral mucosal immunotherapy delivered while a person brushes their teeth. The market potential and unmet need for this product is tremendous.

CEOCFO: *Have you looked at traditional investment or partnerships?*

Mr. Nelson: Yes, we have. There is substantial interest from VCs, as well as from strategic partners. What we realize is that we need to take this a little further on our own. They want to hear the results of our pre-IND meeting or see us work our way through the IND with the FDA or get that initial first-in-person testing before they are able to partner with us.

CEOCFO: *What experience do you or your team have with the IND, with the FDA and with some of the challenges so that you can do this as smoothly as possible?*

Mr. Nelson: We have had a preliminary call with the FDA in terms of letting them know what we are developing and what we are planning on doing and they were very supportive. There are two other companies that are developing food allergy immunotherapies, as I mentioned before. We get to learn from their mistakes and what they have done. Therefore, we know what we need to do at this point to get through the FDA process.

We also have a very experienced Chief Operating Officer who has taken products through all stages of drug development for large and small pharmaceutical companies and who has worked with and for CROs. So we have a lot of experience in house for developing and getting drugs through the FDA process. We also have extremely experienced advisors. And we have a number of experienced companies that we have contracted with who are going to help us with our development plans.

CEOCFO: *With so many new ideas to look at why pay attention to Intromune Therapeutics?*

Mr. Nelson: This is a huge market. There are two other companies that are developing food allergy immunotherapies. Both appear to have certain clinical shortcomings that we believe our platform will overcome. Both of the companies are currently worth \$1.4 to \$1.8 billion. Neither of their products have yet received FDA approval. The market potential and the unmet need in this area is tremendous. The unmet demand, as well as the very real patient concerns and fears are unfortunately very great. Therefore, from an investor point of view, there is certainly a lot of upside. There are many milestones along the way that will be key value inflection points as well.