

ImmunoDispense Pro Executive Summary

Eating in a restaurant is a typical activity for Americans, but, for Josef Griffiths, age 9, this meal can cost him his life. Within seconds of entering a restaurant, he experiences classic symptoms of anaphylaxis: constrictions of the airways, shock, low blood pressure, a rapid pulse, and loss of consciousness. Josef, along with 3 million Americans¹, has a peanut allergy and this condition is the leading cause of anaphylactic fatalities in the United States². A severe reaction to peanut molecules is a daily threat to these sufferers and current treatments offer only temporary solutions to this life-long burden.

Physicians are now looking to immunotherapy (the desensitization of the body to allergens through gradual intake, whether oral or intravenous) as the only treatment which proves long-term effectiveness in desensitizing allergic patients to food allergens. Unfortunately, the present protocol for oral immunotherapy requires a significant amount of time and money to obtain precise measurements of peanut powder.

To solve this problem, the ImmunoDispense Pro is leading the development of an automatic, user-friendly device which dispenses and accurately weighs peanut powder, while safely streamlining oral immunotherapy procedures. The ImmunoDispense Pro accomplishes this feat by controlling the rate of the peanut powder flow to the scale through a dispensing system and using a continuous feedback signal from the electronic scale to measure the correct amount of peanut powder.

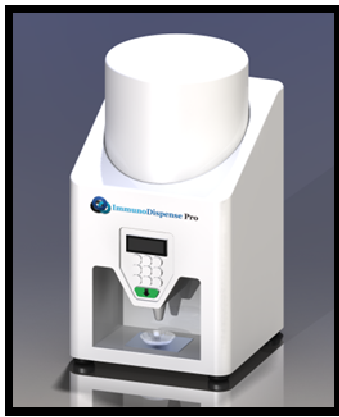


Figure 1: ImmunoDispense Pro

Due to oral immunotherapy's effectiveness in children, the target market for the ImmunoDispense Pro is the approximately 600,000 children in the United States with peanut allergies. This market is growing as the rate of allergy incidence in children has doubled³ in the last five years. Also, the device may be used to treat milk and egg allergies, adding roughly 2 million⁴ and 1.5 million⁵ children, respectively, to the device's U.S. market. Although further research is necessary to determine the effectiveness of oral immunotherapy in adults, such advances would enable additional marketing to the adult population.

While dry powder dispensers currently exist in the marketplace, these automatic dispensers are not suitable for the specific needs of oral immunotherapy. These potential competitors share a similar design, but do not meet the necessary safety requirements for the treatment as they are only designed to measure foods and spices. Additionally, these devices are not direct competitors because they do not have the pinpoint accuracy of the ImmunoDispense Pro. Our strongest competitor is the current paradigm which encourages complete avoidance of allergens. We will combat the

¹ Branum AM, Lukacs SL. Food allergy among U.S. children: Trends in prevalence and hospitalizations. NCHS data brief, no 10. Hyattsville, MD: National Center for Health Statistics. 2008.

² "Allergy Facts and Figures," Asthma and Allergy Foundation of America. 2005.

³ Sicherer, S. H., Munoz-Furlong, A., & Sampson, H. A. (2003). Prevalence of peanut and tree nut allergy in the United States determined by means of a random digit dial telephone survey: A 5-year follow-up study. *Journal of Allergy and Clinical Immunology*, 112, 1203-1207.

⁴ Skripak, Nash, Rowley, Brereton, Oh, Hamilton, Matsui, Burks, & Wood (2008). A randomized, double-blind, placebo-controlled study of milk oral immunotherapy for cow's milk allergy. *Journal of Allergy and Clinical Immunology*, 122, 1154-1160.

⁵ Jessica H. Savage, MD, Elizabeth C. Matsui, MD, MHS, Justin M. Skripak, MD, and Robert A. Wood, MD Baltimore, MD (2007). The natural history of egg allergy. *Journal of Allergy and Clinical Immunology*, 120, 1413-1417.

effects of this status quo with strong clinical results, effective advertising, and distribution through certified allergists.

To protect our technology, we are pursuing intellectual property rights for the rotating powder dispenser mechanism and for the safety and sealing elements of the ImmunoDispense Pro. Although patents exist for several automatic dispensers, most are related to the distribution of spices. The specifications of one such patent *Measuring Dispenser for Particulates* is very similar to the ImmunoDispense Pro but, as with other spice dispensers, the volume-dependent measuring mechanism does not allow for the accuracy required for oral immunotherapy treatments and, therefore, our product will not infringe on such patents.

Once the device is market-ready, it will be marketed through two initiatives:

- An educational program for physicians which will be centered on hands-on product demonstrations and communication of clinical trials. Additionally, literature will be distributed to medical personnel explaining how to become an approved vendor for the dispenser's powder.
- A public awareness campaign which will consist of publications and advertisements in journals, newspapers, and websites that are distributed to families connected with allergy patients.

The ImmunoDispense Pro: Improving oral immunotherapy treatment for over three million peanut allergy patients

The ImmunoDispense Pro's immediate goals are contingent on FDA approval of oral immunotherapy as a treatment for food allergies. At this time, a dedicated sales force will sell the device through certified allergists to patients. Thorough instruction on the device and frequent communication between the patient and the doctor will ensure patient safety and proper dosage each week. Also, by distributing the dispenser through doctors, almost all of the device's costs will be reimbursed by insurance.

In order to execute the business strategy for the ImmunoDispense Pro, we have compiled a strong four-member management team. Three Duke University students with biomedical, electrical and mechanical engineering experience provide a strong scientific foundation and technical understanding of the device. They join a Duke University economics and statistics double-major to create an effective, cross-disciplinary leadership lineup. The team is especially passionate about this project due to their personal experiences with the inconveniences associated with traditional immunotherapy methods. Also, they have exclusive access to the leading researchers in oral immunotherapy, including Dr. Wesley Burks, the head of the Pediatric Allergy and Immunology Department at the Duke Medical Hospital.

Financially, the ImmunoDispense Pro is an excellent investment and its impressive results are attainable because the dispenser will improve the lives of over three million Americans. The cost of the dispenser in the first year is \$500, but costs will decrease with economies of scale. We project an initial market price of \$1000, which is a great value considering the convenience and time saved from using the ImmunoDispense Pro. In the fifth year, we predict a 15% adoption rate among diagnosed peanut allergy patients, yielding projected financial revenues of \$95 million for that year. Finally, to cover our initial costs and final stages of research, the ImmunoDispense Pro requires a capital investment of \$1.5 million for a 40% share in the company. After five years, this initial investment will yield a 23 times cash on cash return and a 95% IRR. With continued growth through the first five years, the ImmunoDispense Pro will be well positioned at that time to be acquired by a larger medical device company.