



## Food Exposure Toothpaste:

Transforming Lives Through the Prevention  
and Treatment of Food Allergies

# Managing the Food Allergy Epidemic



## Novel food exposure technology platform

- ✓ Addresses food allergies before they manifest
- ✓ Reinvents how food allergies are managed

## Products address multiple, distinct food allergy markets

- ✓ **Food allergy prevention:** Near-term consumer OTC products address a \$13 billion early food exposure market
- ✓ **Food allergy therapy:** FDA-approved prescription product pipeline –\$33+ billion total addressable market



Addressing the unmet needs of people at risk of, or living with, food allergies through the development of solutions that **optimize safety, efficacy, and adherence**

# Experienced Leadership Team

Successfully bringing innovation to market,  
including in **biotech, pharma, and allergy** markets:



[Michael Nelson, JD](#)  
Chief Executive Officer



[William Berger, MD, MBA](#)  
Head of Medical Affairs



[Nicole Faris](#)  
Strategic Director, Medical  
Affairs & Clinical Development



[Christopher Schuster, MBA](#)  
Chief Financial Officer



[Michelle Mantia](#)  
Controller



[Nandini Murthy](#)  
Head of Regulatory



[Ray Forslund](#)  
Head of Chemistry,  
Manufacturing & Controls



[Mariana Reisacher](#)  
Social Media Manager

## ADVISORS



[Sharon Chinthrajah,  
MD](#)  
Medical Advisor

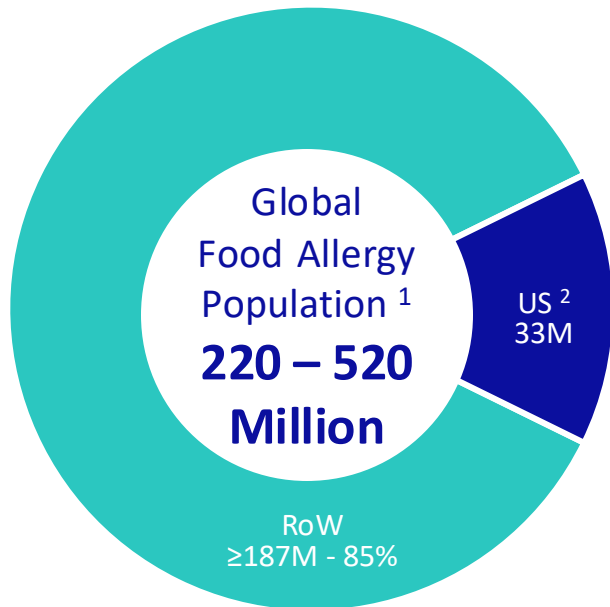


[Stuart Loesch](#)  
Commercial Advisor



# Problem: Food Allergies Impact Millions Globally

Food allergies have become a serious public health concern as prevalence increases globally with **5.6 million US children (1 in 13) living with at least one food allergy**



**Orphan**  
Meat / Alpha-Gal

# Problem: Significant Medical & Lifestyle Impacts



## SEVERE HEALTH EVENTS

**40-50%+**

of people with food allergies have experienced a severe allergic reaction <sup>\*1</sup>



## MEDICAL CARE

**200,000**

Americans require emergency medical care each year for allergic reactions to food <sup>1</sup>



## FEAR

**92%**

of parents feel fearful for their child's safety because of food allergies <sup>2</sup>



## SOCIAL EXCLUSION

**5 in 10**

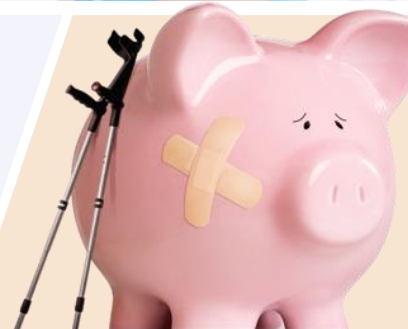
families with food allergies skip out on important school functions <sup>2</sup>



## LIFE DISRUPTION

**44%**

of parents had to make a career change to care for their child with food allergies <sup>2</sup>



## COST

**\$25 Billion**

spent annually by U.S. families caring for children with food allergies <sup>1</sup>

**On average, food allergies will cost US parents \$5,669 per allergic child per year <sup>3</sup>**

<sup>\*</sup>42% of children and 51% of adults

1. FARE Facts and Statistics <https://www.foodallergy.org/resources/facts-and-statistics> Accessed January 27, 2023

2. Asthma and Allergy Foundation of America, My Life with Food Allergies Survey, April 2019

3. <sup>\*</sup>Based on a 2013 survey of the economic impact of childhood food allergies in the US, adjusted for 35.5% inflation since 2013.

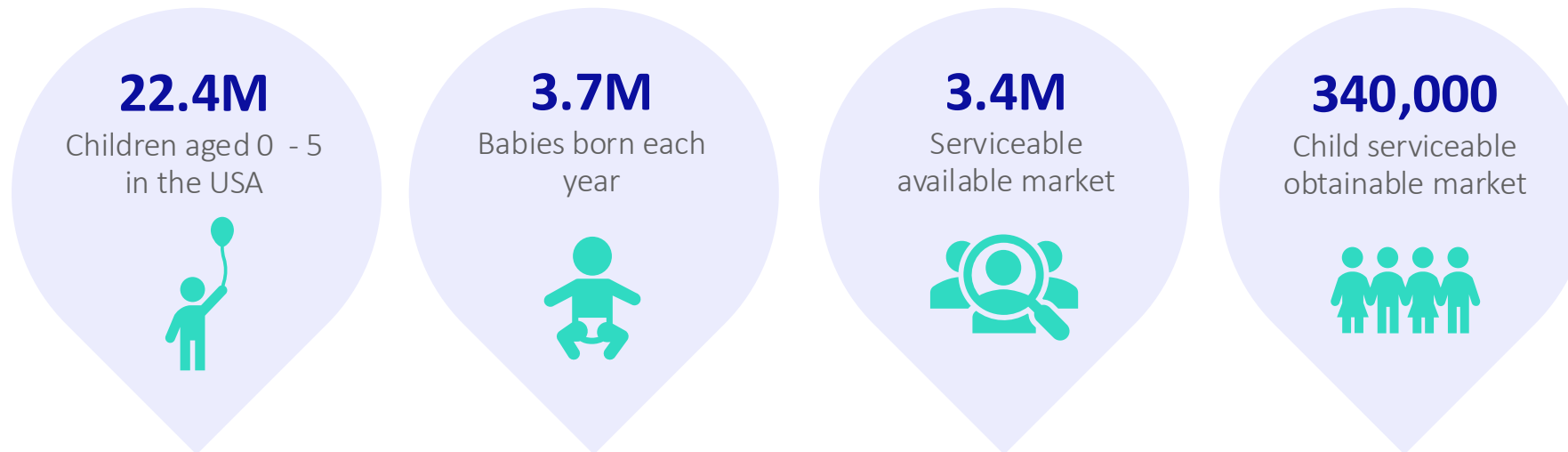
# Food Exposure Represents a New \$13 Billion Untapped Opportunity



## OPPORTUNITY

TAM	SAM	SOM	REVENUE / YEAR PER CHILD
<b>\$13 Billion</b> <sup>1</sup> (USA market only)	<b>\$2.7 Billion</b> <sup>2</sup>	<b>\$270 Million</b> <sup>3</sup>	<b>\$600</b> <sup>4</sup>

## LARGE & GROWING UNMET NEED



1. Total Addressable Market (TAM) are 0-5 year-olds in the US. Does not include the 7.3% of adults in the US with atopic dermatitis (about 40% having moderate or severe symptoms) at higher risk of food allergy  
2. Serviceable Available Market (SAM) is 20% of high risk 0-5 year-olds. Does not include other children or adults. Medicaid and managed care represent upside to these estimates.  
3. Serviceable Obtainable Market (SOM) calculated at 10% market penetration  
4. Target revenue = \$50/month

# Problem: Food Allergies Global Rise Continues Unabated

**Lack of Early Allergen Exposure:** Contrary to current consensus, parents were told to avoid exposing infants to allergenic food during the critical tolerogenic immune window

**Hygiene Hypothesis:** Excessively clean environments may limit crucial microbial exposure in early life, hindering appropriate immune system maturation and development

**Unbalanced Diets:** Westernized diets high in processed foods and low in fruits and vegetables may alter gut bacteria and immune responses

**Antibiotics & Cesarean Births Lead to Gut Microbiome Dysfunction:** Early antibiotic exposure can significantly alter the composition of the gut microbiome, reducing beneficial (tolerogenic) bacteria and potentially increasing gut permeability

- Vaginal births seed a healthy baby gut microbiome

**Vitamin D Deficiency:** Lack of sunlight and insufficient vitamin D intake may disrupt immune regulation, increasing the propensity to develop food allergy

**Skin Disruption (Emulsifiers in Skin Creams and Foods):** Regular washing, dry skin, and eczema lead to food protein exposure through the skin or gut barriers





# Profile of an Infant At High-Risk of Food Allergy



Infants and children with a family history of **atopy or a comorbid atopic disease (eczema)** are at a higher risk of developing a food allergy



## 30% INCREASED RISK

in infants who experience moderate to severe **eczema** <sup>1</sup>

## 260% INCREASED RISK

when both parents have an atopic disease such as **asthma, allergic rhinitis, or food allergy**

## 600% INCREASED RISK

of peanut allergy **if a parent has a peanut allergy** <sup>2</sup>



# Solution: Early Daily Exposure Is Critical For Prevention

81.4%

Reduced risk of developing food allergies after implementing **daily exposure to peanut protein** in high-risk infants and children until age 5<sup>1</sup>

US FDA acknowledged health claim, stating, "For most infants with severe eczema and/or egg allergy who are already eating solid foods, **introducing foods containing ground peanuts between 4 and 10 months of age and continuing consumption may reduce the risk** of developing peanut allergy by 5 years of age." <sup>2</sup>



## Key Barriers to Implementation

- Parental adherence to daily exposure via ingestion is low (only 40% even in a clinical study) <sup>3</sup>
- Most pediatricians (93%) are aware of early allergen exposure guidelines, **but only 30% are fully implementing into guidance for parents** <sup>4</sup>

1. Du Toit G et al. Randomized trial of peanut consumption in infants at risk for peanut allergy. N Engl J Med 2015;372(9):803-813.

2. <https://www.fda.gov/food/hfp-constituent-updates/fda-acknowledges-qualified-health-claim-linking-early-peanut-introduction-and-reduced-risk>.

3. Perkin MR, Logan K, Tseng A, et al. Randomized Trial of Introduction of Allergenic Foods in Breast-Fed Infants. N Engl J Med. 2016;374(18):1733-1743.

4. Gupta RS et al Assessment of Pediatrician Awareness and Implementation of the Addendum Guidelines for the Prevention of Peanut Allergy in the United States. JAMA Netw Open. 2020;3(7):e2010511.

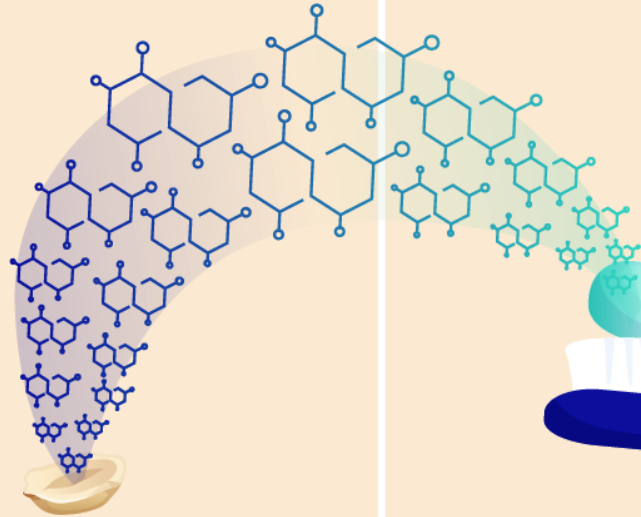
# Evidence: Advocating for Early Allergen Exposure



Date	Study	# of Participants	Allergen/s	Key Findings	Citations
2015	LEAP (Learning Early About Peanut Allergy)	640 high risk infants aged 4-11 months	Peanut	<ol style="list-style-type: none"> <li>Early introduction of peanut <b>reduced the risk of peanut allergy by 81%</b> at age 5</li> <li>Persistent protection in exposure group even after 12 months of avoidance</li> </ol>	Du Toit G et al. Randomized trial of peanut consumption in infants at risk for peanut allergy. N Engl J Med. 2015 Feb 26;372(9):803-13.
2016	LEAP-On	Participants from the LEAP study	Peanut	<ol style="list-style-type: none"> <li><b>Significantly (74%) lower risk of peanut allergy</b> development in peanut consumption group <b>at age 6 years</b></li> <li>Positive immune biomarker modulation consistent with <b>oral tolerance to peanut</b></li> </ol>	Du Toit G et al. Effect of avoidance on peanut allergy after early peanut consumption. N Engl J Med. 2016;374(15):1435-43.
2017	PETIT Study	147 infants	Egg	<ol style="list-style-type: none"> <li>Early egg exposure significantly reduced the risk of egg allergy</li> <li>* Study was terminated early due to the <b>high efficacy</b> observed in the egg introduction group.</li> </ol>	Natsume O et al. Two-step egg introduction for prevention of egg allergy in high-risk infants with eczema (PETIT): a randomized, double-blind, placebo-controlled trial. Lancet. 2017 Jan 21;389(10066):276-286.
2024	LEAP-Trio	508 participants (80 % of LEAP subjects)	Peanut	<ol style="list-style-type: none"> <li>Followed up to age <b>12 years</b></li> <li><b>Persistent protection</b> in adolescence even with inconsistent peanut consumption implicating the <b>critical window</b> for early and consistent exposure</li> <li>Supports the <b>dual allergen exposure hypothesis</b> implicating the importance of oral exposure</li> </ol>	Du Toit G et al. Follow-up to Adolescence after Early Peanut Introduction for Allergy Prevention. NEJM Evid. 2024;3(6):EVID02300311.
2016	EAT Study	1303 infants aged 3-6 months	Peanut Milk Egg Sesame Fish Wheat	<ol style="list-style-type: none"> <li><b>Reduced</b> risk of egg allergy at 1 year in <b>High-Risk Infants</b> with severe eczema</li> <li>Infants with existing food allergy were less likely to develop an egg allergy</li> <li>Study participants reported low protocol adherence (<math>\leq 40\%</math>) to allergen introduction</li> </ol>	Perkin MR et al. Enquiring About Tolerance (EAT) study: Feasibility of an early allergenic food introduction regimen. J Allergy Clin Immunol. 2016;137(5):1477-1486.
2017-Ongoing	CHILD Study	2124 infants < 1 year	Egg Milk Peanut	<ol style="list-style-type: none"> <li>Delayed introduction of each allergen significantly increased risk of allergic sensitization <ul style="list-style-type: none"> <li><b>Cows Milk: 269% @3-fold</b></li> <li><b>Egg: 89%</b></li> <li><b>Peanut: 76%</b></li> </ul> </li> </ol>	Tran MM et al. (CHILD study investigators) Timing of food introduction and development of food sensitization in a prospective birth cohort. Pediatr Allergy Immunol. 2017;28(5):471-7.
2013	STAR Study	86 infants 4-6 months	Egg	<ol style="list-style-type: none"> <li>Regular <b>consumption <math>\geq 4</math> months in high-risk infants</b>, significantly <b>reduced IgE sensitization and increased IgG4</b> antibody, a biomarker of oral tolerance</li> <li>As many as <b>36%</b> of infants were already sensitized to egg even with no previous oral exposure – suggesting <b>sensitization occurred through the skin</b></li> </ol>	Palmer, DJ et al. (2013). Early regular egg exposure in infants with eczema: a randomized controlled trial. Journal of Allergy and Clinical Immunology, 132(2), 387-392.e1

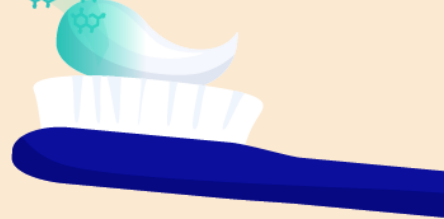
# Localized: Daily Toothbrushing Supports Early Food Exposure

1



Allergenic proteins (API)  
mechanically & chemically  
**processed via innovative  
methods**

2



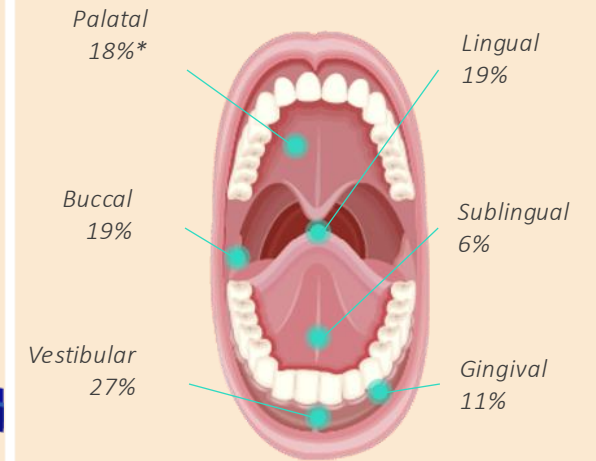
**API stabilized & embedded**  
in functional toothpaste  
in metered-dose dispenser

3



Low dose allergen exposure  
**conveniently administered**  
through daily toothbrushing

4



Novel pathway leverages  
Langerhans cells in entire oral  
cavity to **support oral tolerance  
development through low dose  
allergen exposure**

## Powered by Oral Mucosal Immunotherapy (OMIT):

The process of gradually exposing the immune system to low doses of allergen in the oral cavity using a fully functional toothpaste

# How Oral Mucosal Immunotherapy (OMIT) Works

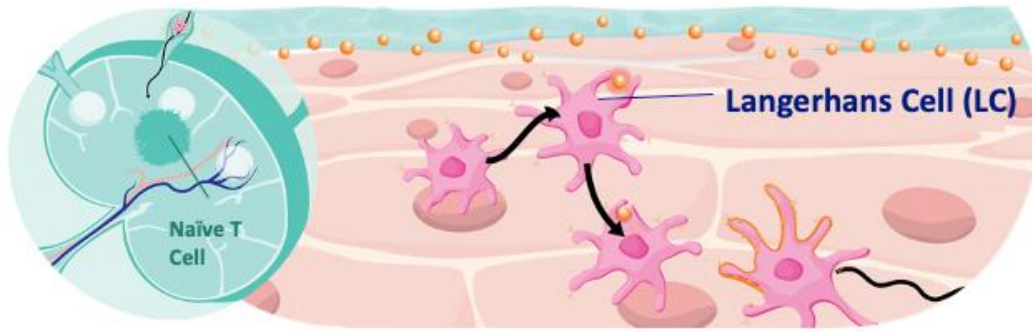
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Proprietary formula delivers allergenic protein to oral cavity via toothpaste, binding to mucosa



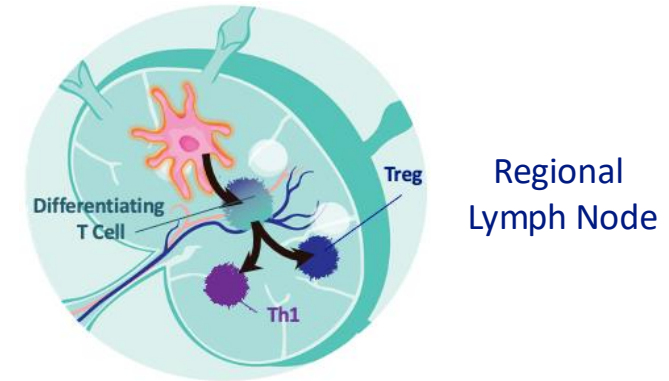
2

Langerhans cells pull allergenic protein into the lymph system



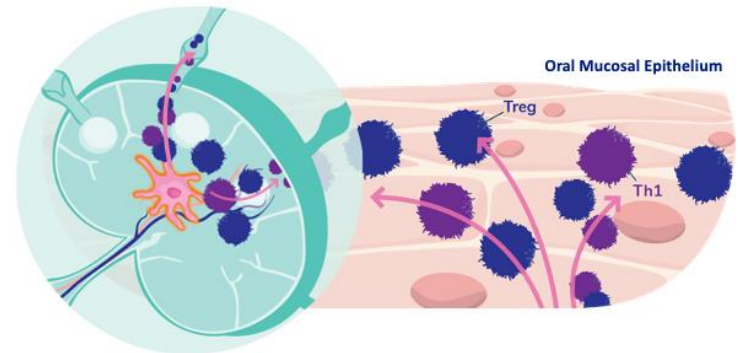
3

Langerhans cells trigger the reeducation of immune system



4

Differentiated T cells decrease the allergic response





# Early Food Exposure Strategy: Remove Impediments

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Intromune's innovative toothpaste delivers consistent amounts of allergens directly to the oral mucosa simply and conveniently, as part of the normal daily toothbrushing routine

*"There is no doubt food allergies can be prevented.  
The key is early and consistent exposure."*

- Former J&J Executive and Top Key Opinion Leader



# Food Exposure Toothpaste Product Profile

A **unique formulation** featuring allergens stabilized and embedded in a **fully functional toothpaste\***



## FIRST OFFERING

**Four allergenic foods:** Peanut and three tree nuts (hazelnut, walnut, and cashew)



## PROTEIN EXPOSURE

**Baby:** 0.75mg/0.5 mL protein per food (pea-sized amount)

**Young child:** 3.0mg/1.0 mL protein per food

**Child/adult:** 6.0mg/1.0 mL protein per food plus Fluoride



## GREAT-TASTING AND EASY TO USE

**Fresh flavors** and a **metered pump** make it easy and convenient to brush teeth and gums up to 2 minutes

# Enables Convenient Food Exposure Without Requiring Ingestion



Dental hygiene and early food allergen exposure completed in **one simple, convenient step**



- Offers a truly differentiated unique selling proposition (USP) by incorporating dental hygiene and early food exposure in one single step
- Aligns with evolving evidence supporting early introduction of certain allergenic proteins in high-risk infants less than 1 year of age
- Enables early food exposure while minimizing the fear of early ingestion and the potential risk of choking
- Overcomes barriers to food exposure associated with fussy / picky eaters
- Aligns with WHO guidelines on exclusive breastfeeding until at least 6 months of age
- May offer some protection to potential allergic sensitization to other cross reacting tree nuts (ex: pistachio, pecan)
- Provides the same protection from dental caries as standard toothpaste
- Helps to establish a consistent brushing routine and healthy dental hygiene habits in early life
- Potential to gamify and educate with a kit (Bluetooth toothbrush, app & toothpaste) for older children

# Food Exposure Toothpaste Offers Unique Benefits



## Localized administration

Targeted allergen delivery



## Specifically formulated

Stabilized for optimal oral mucosal exposure



## Consistent quantity

Formulations tailored to the child's age and risk profile



## Delivered conveniently

Encourage healthy daily hygiene habits early in life

QR Code and monthly subscription programs in partnership with physician offices will leverage the growing HCP awareness of the value of early food exposure

**Improve patient care** | **Save time for physicians** | **Create recurring revenue for physicians**



# Early Dietary Introduction Category



## Existing Early Introduction Brands

- Brands active in the market include **Ready, Set, Food**, **Lil Mixins**, **Tiny Human Food**, **Grow Happy**, **Bamba**, and **SpoonfulONE (EU)**
- Product ranges include powders, puffs, purees, and finger foods
  - Offering 1 – 3 grams of protein to deliver allergens as early as 4 – 6 months



## Challenges Faced

- **Problematic for fussy eaters** as all existing options require ingestion
- **Contrary to World Health Organization guidelines** promoting exclusive breastfeeding until at least six months of age
- **Poor adherence** despite effectiveness
  - Reported sustained oral tolerance even after 12 months of peanut avoidance
  - Significantly (74%) lower risk of peanut allergy development in peanut consumption group

### KEY TAKEAWAY

**Early (less than 1 year) food exposure is critical and offers the potential for durable oral tolerance\***

# Extensive Global IP Protection



IP covers all food allergens across multiple oral care formats, with **51 patents to-date**



## EXCLUSIVE GLOBAL IP

- For all food allergy
- Freedom to operate



## GLOBAL PORTFOLIO

- USA
- EU, UK, Israel
- Japan, Korea, Australia
- Canada
- India
- Brazil
- China (pending)



## SEVERAL PATENT FAMILIES

- Immunotherapy via multiple oral care modalities
- Formulations to stabilize allergens
- Applications filed - confidential



## GLOBAL PROTECTION

- Expected to extend to 2049 \*



## ADDITIONAL IP EXPECTED

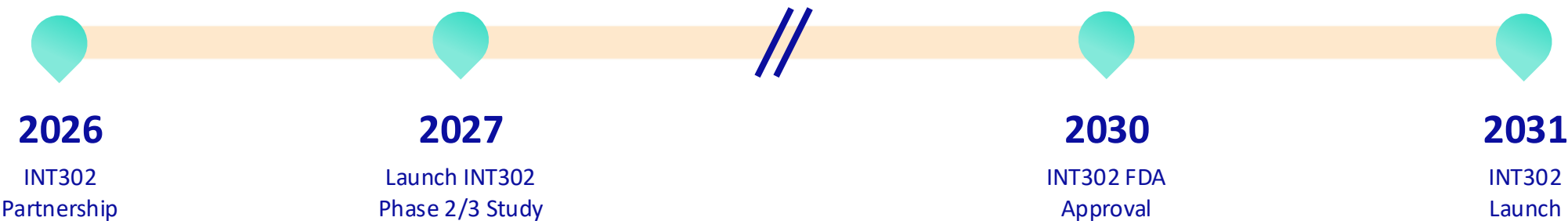
- Additional innovation
- New filings - dosing, CMC & design
- Regulatory extension
- Unique biologic – no generic pathway available

# Intromune Product Pipeline

## EARLY FOOD EXPOSURE

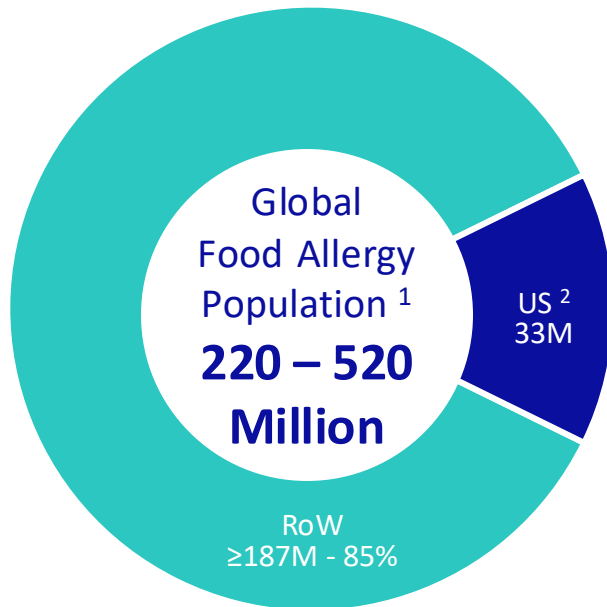


## THERAPEUTICS



# Problem: Food Allergies Impact Millions Globally

Food allergies have become a serious public health concern as prevalence increases globally with **5.6 million US children (1 in 13) living with at least one food allergy**



Multi-Food Therapy

**\$33 Billion**

TAM for US market <sup>4</sup>




**Orphan**  
Meat / Alpha-Gal





# Highlights from OMEGA Phase 1 / 2 OMIT Clinical Trial Results




## Met primary and secondary endpoints, with indications of efficacy\*

-  **Safety**

Demonstrated safety: **No moderate or severe systemic reactions** occurred in active participants. Non-systemic adverse reactions were mostly local (oral itching), mild, and transient
-  **Adherence**

**97% adherence** to study treatments
-  **Efficacy**

Exploratory objective provided indications of efficacy in difficult-to-treat adult population:

  - ✓ 3/3 (100%) of DBPCOFC<sup>†</sup> subjects were protected to at least 600mg peanut
    - Mean dose tolerated at entry was 16mg
  - ✓ **Statistically significant sIgG4 increases in active arm** consistent with response to treatment
-  **Dropout**

**0% product-related participant dropout rate**

  - ✓ 22% of OIT patients drop out within first year and as many as 50% within 3 years

*[Additional OMEGA Clinical Study Details](#)*

# OMIT Results Presented: Safe, Adherent, Indications of Efficacy

Generated **140 + pieces of news coverage** and featured on **900 + TV/cable/radio shows** in 36 hours

## Late-Breaking ACAAI Abstract

- Oral presentation given Nov. 11, 2023 at American College of Allergy, Asthma and Immunology Scientific Meeting



- Published in Annals of Allergy, Asthma, and Immunology

## Late-Breaking AAAAI Abstract

- Oral presentation given Feb. 23, 2024 at American Academy of Allergy, Asthma and Immunology Scientific Meeting



## Media Coverage

- Press release picked up by 362 outlets, generating 143 instances of news coverage in the first few days:

### Online/Print



### TV



*"This toothpaste offers an easier option that families can fit into their everyday schedules... I'm always looking for options like that."*

Kristin Sokol  
MD, MPH, FAAAAI  
Allergist & Immunologist at Schreiber Allergy



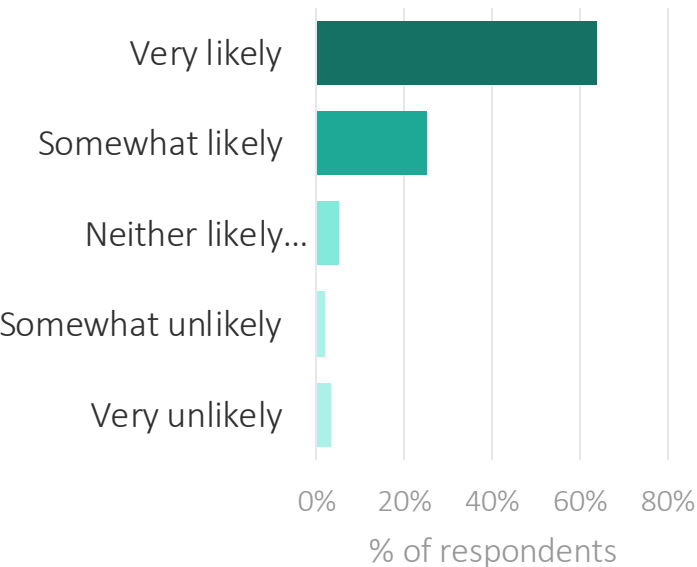
**Publication of OMIT Study Results in Peer-Reviewed Medical Journal (Feb. 2025) Plus Independent Editorial\***

# Strong HCP & Consumer Interest in Intrimmune's OMIT Solution



## Patients

### Likelihood to Try Immunotherapy-based Toothpaste for Peanut Allergy



## Healthcare Professionals

*"I was pleased to see a Late Breaking Abstract introducing Oral Mucosal Immunotherapy (OMIT) as a new treatment option for peanut allergies. OMIT is being studied to **address the large, unmet need in food allergies** by providing a convenient, safe and effective choice which is administered in a fully-functional toothpaste that is incorporated into the patient's daily routine activities"*

**Todd Mahr**  
MD, FAAAAI, FAAAAI,

Executive Medical Director, ACAAI  
Pediatric Allergist, Gundersen Health System



*"The results of the OMEGA trial demonstrate the safety of INT301 for adults with peanut allergy. The exploratory findings also support its potential as an effective treatment to protect patients from accidental peanut exposure. By embedding the proteins in a fully-functional toothpaste, and **addressing many of the concerns associated with existing peanut immunotherapy**, INT301 is being developed to address the unmet needs in the market"*

**Michael S. Blaiss**  
MD, FAAAAI, FAAAAI

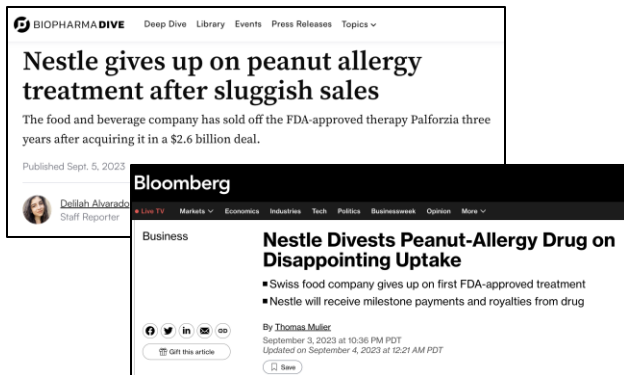
Clinical Professor, Medical College of Georgia at Augusta



# Competitive Analysis: Learnings & Market Impact

## Palforzia

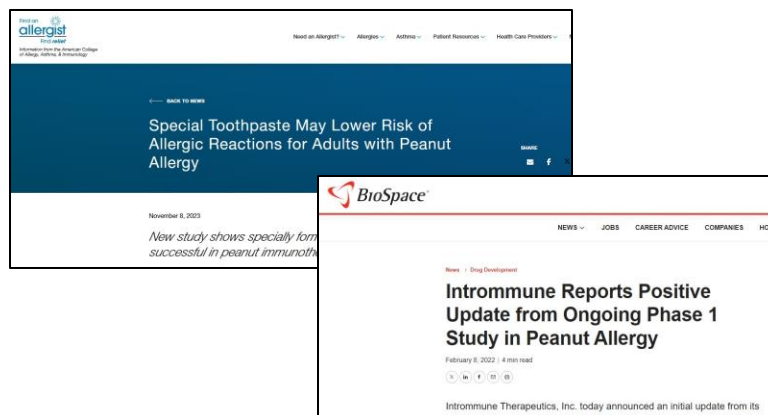
(Nestlé & Aimmune)



- Palforzia has a challenging up dosing schedule with a high risk of severe AEs — Intrommune’s novel toothpaste platform addresses adherence and safety from the start
- Parents of children with food allergies are driving the multi-billion-dollar industry so Intrommune is determined to prove itself in the pediatric space with the next rounds of funding

## INT301

(Intrommune)



- Intrommune committed to a focused, step-wise approach, first tackling peanut / tree nut allergies, which remains a \$14 billion market primed for the taking
- Intrommune and its esteemed KOLs understand and rightly anticipated the pitfalls of OIT—and conversely the continued massive potential for OMIT
- Xolair is not disease modifying – expectation is that patients on Xolair will transition to OMIT

## Xolair

(Novartis & Genentech)



- Although this moves the food allergy space in the right direction, those with food allergies do not view Xolair as a long-term solution and continue to seek out new treatments
- Cost of Xolair remains a huge barrier to uptake, leaving many to feel defeated
- Positive attention to the food allergy space has reignited discussions between Intrommune and Big Pharma and other manufacturers



# Disclosures



## Important Information

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# THANK YOU

Contact us for more information  
and partnering opportunities

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