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A Revolutionary Toothpaste  
Based Approach to Food  
Allergy Immunotherapy



# Our Mission



INTROMMUNE is developing **simple, safe** and **effective** health solutions for individuals suffering with food allergy so that they and their loved ones can live their lives **without fear**



# Executive Summary



## Experienced team

- Raised over \$8b
- Successfully worked on dozens of clinical programs



## Huge unmet need

- Global opportunity > 220mm worldwide have food allergies, including 32 million in the U.S.
- Peanut allergy market to grow 1700-fold from 2017-2027, expected TAM of \$7b+



## Low risk allergy immunotherapy via toothpaste drug delivery platform with global, exclusive IP rights

- Simple – brush your teeth once per day as part of an already existing daily routine, imbedded adherence
- Safe – Phase 1b study demonstrates the platform is safe
- Efficacious – University studies show food proteins in the oral cavity desensitize patients



## High expected returns on investment

- Comparator acquired for \$2.6 billion with product only 1/10 will use due to significant adverse event profile
- Peanut INT301 is best in class agent – 9/10 will use with total addressable U.S. market in excess of \$7 billion
- Multiple opportunities with platform technology and both near-term and long-term inflection points



## Minimal competition with only one peanut allergy product ever approved for any food allergy

# Proven Successful Leadership Team



**Michael Nelson, JD** | Chief Executive Officer



**Stuart Loesch** | Chief Commercial Officer



**Keith James, MBA CPA** | Chief Financial Officer



**Alain Van Loo** | Chief Operating Officer



**Prof. Dr. Sergi Trilla** | Director, Corporate Strategy



**Erick Berglund, PhD** | Chief Science Officer



**Nandini Murthy** | Head of Regulatory



# Advisors



## BUSINESS

[Jotin Marango, MD, PhD](#) | Corporate Strategy & Finance Advisor, Chair

[Tonya Winders, MBA](#) | Stakeholder Outreach Advisor

[Terrence Tormey](#) | Business Development Advisor

[Jack Levitt, MBA](#) | Executive Development Advisor

[David Sanders](#) | Government Affairs Advisor

[Mark Durham](#) | Human Capital Advisor

[Moe Vela](#) | Government Affairs Advisor



## SCIENCE

[Professor William Reisacher, MD](#) | Inventor of OMIT; Senior Scientific Advisor, Chair

[Sharon Chinthrajah](#) | Medical advisor

[Lara Gross](#) | Medical Advisor

[Greg Plunkett, PhD](#) | CMC Advisor

[Saul Fink](#) | Medical Advisor

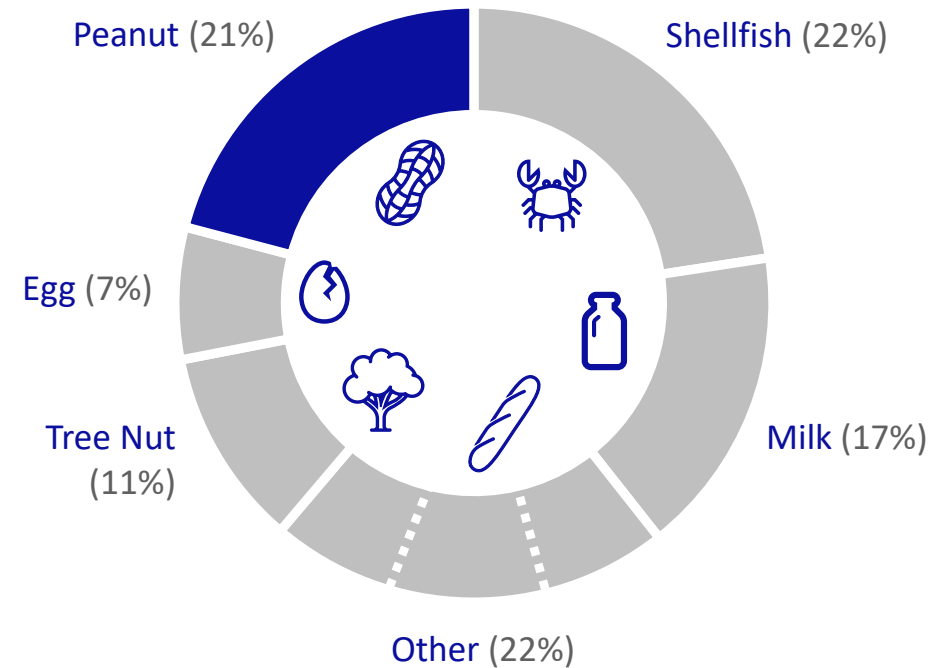
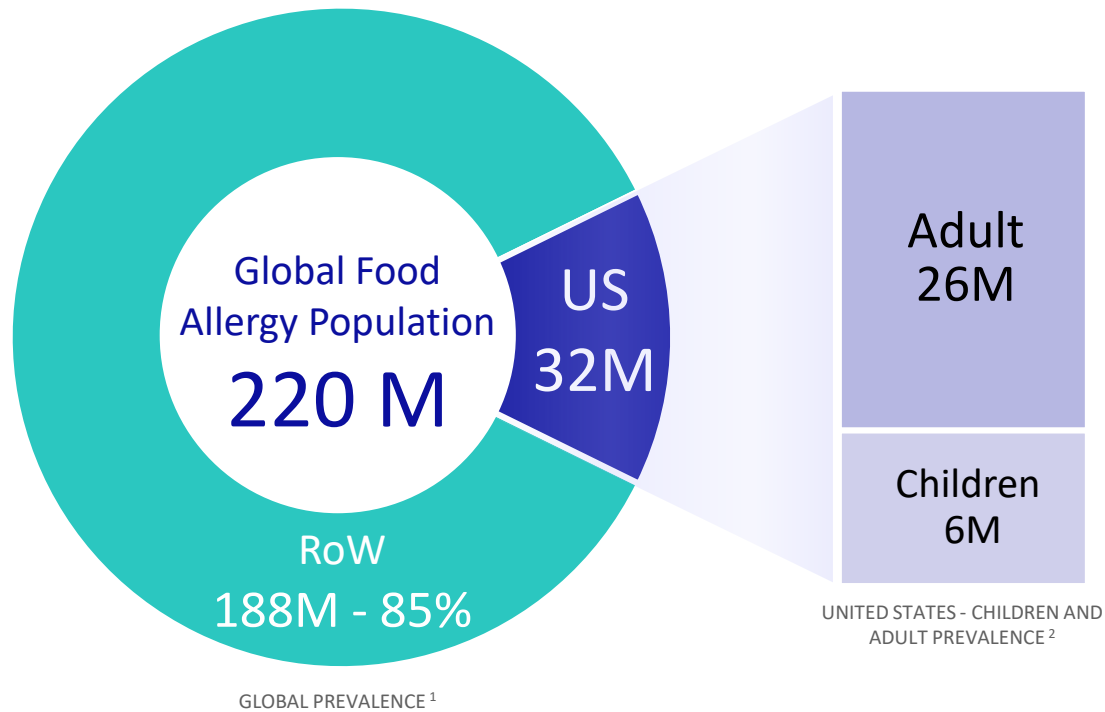
[Anthony Robinson, CRNP, MBA](#) | Clinical Advisor

[Gerry Kugel, DMD, PhD](#) | Dental Advisor





# Global Food Allergy Metrics: Large Addressable & Multi-opportunity Market



“GlobalData is forecasting the peanut allergy market to grow an astounding 1,700-fold from 2017 – 2027.”<sup>3</sup>

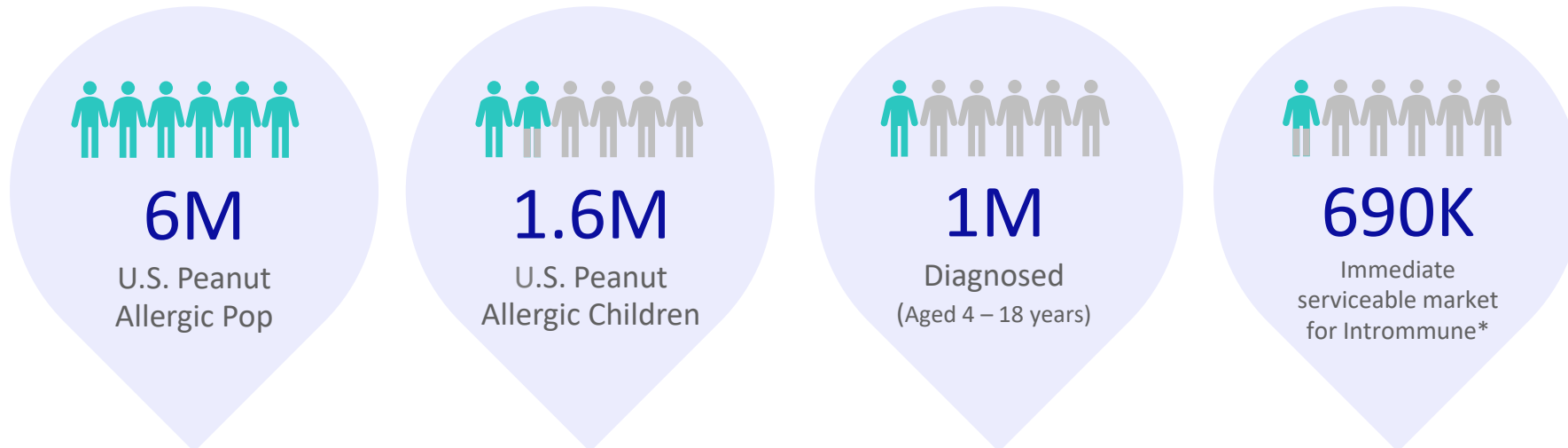
# US Peanut Allergy Key Investment Metrics



## OPPORTUNITY

TAM: <b>\$7,369,200,000</b>	Insurance Coverage: <b>Yes</b>	OIT Price/Year Per Patient: <b>\$10,680</b>	Solutions/Expectations: <ul style="list-style-type: none"><li>• Reduce adverse effects</li><li>• Better adherence</li><li>• Increased efficacy</li><li>• Multi-product platform</li></ul>
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## INCREASINGLY UNMET NEED



# INT301- Introducing a Novel, Simplified Approach to Allergy Desensitization

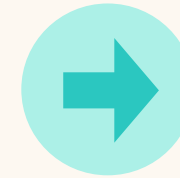
## INT301 Delivers Therapeutic Agents Through Oral Mucosal Immunotherapy (OMIT)



Embedded food derived allergen proteins



Administered at the same time patients brush their teeth



INT301 Convenient Daily Immunotherapy

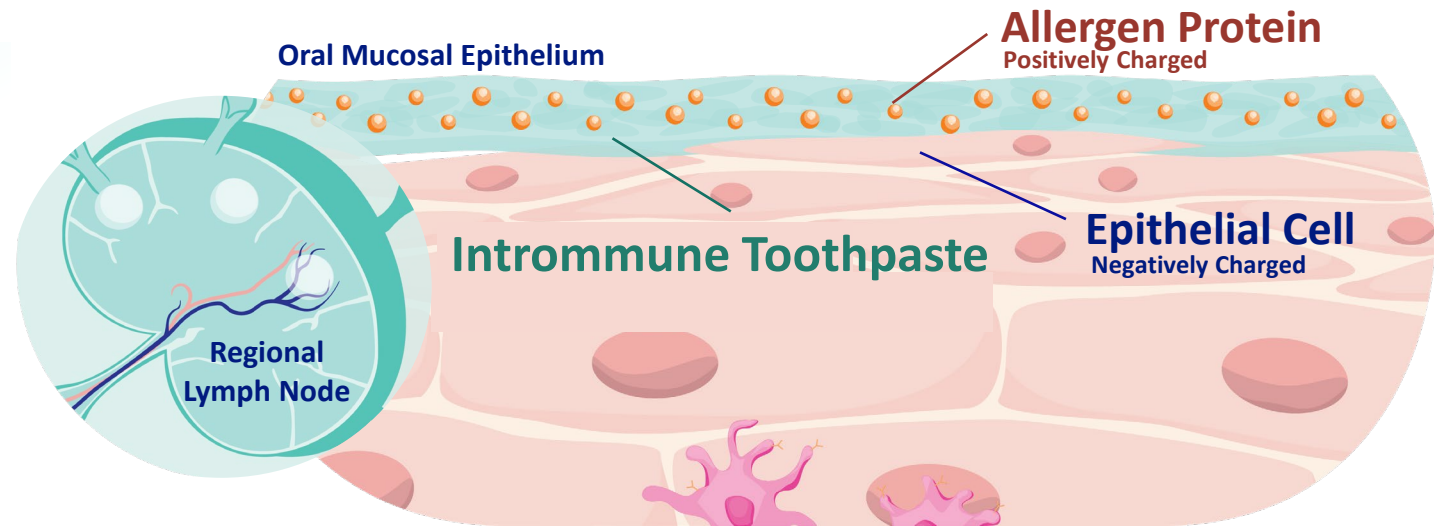




## STEP 1 OF 4

### Intrimmune toothpaste delivers allergen protein

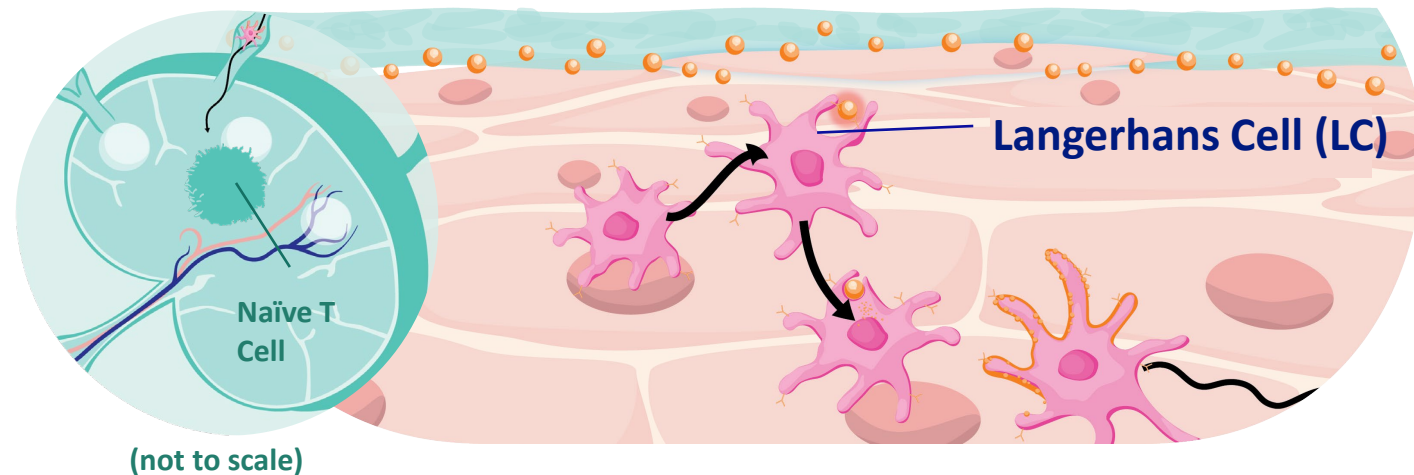
Toothpaste slurry coats the mouth so more allergen protein can bind with cells on the surface of the oral mucosal epithelium. The opposing charges of the protein and surface cells attracts them to each other to form a strong bond.



## STEP 2 OF 4

### Langerhans cells process and display allergen proteins

Oral Langerhans cells capture allergen protein as it diffuses into the oral mucosa, displaying key identifiers on their surface before travelling to regional lymph nodes.



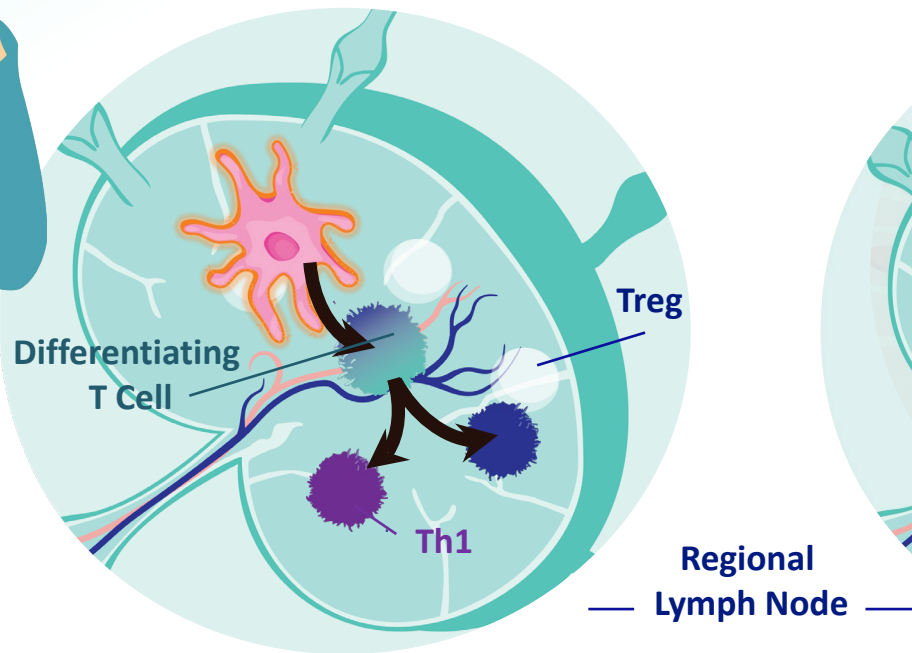
(not to scale)

# INT301 MOA (cont'd)

## STEP 3 OF 4

### Langerhans cells trigger the re-education of the immune system

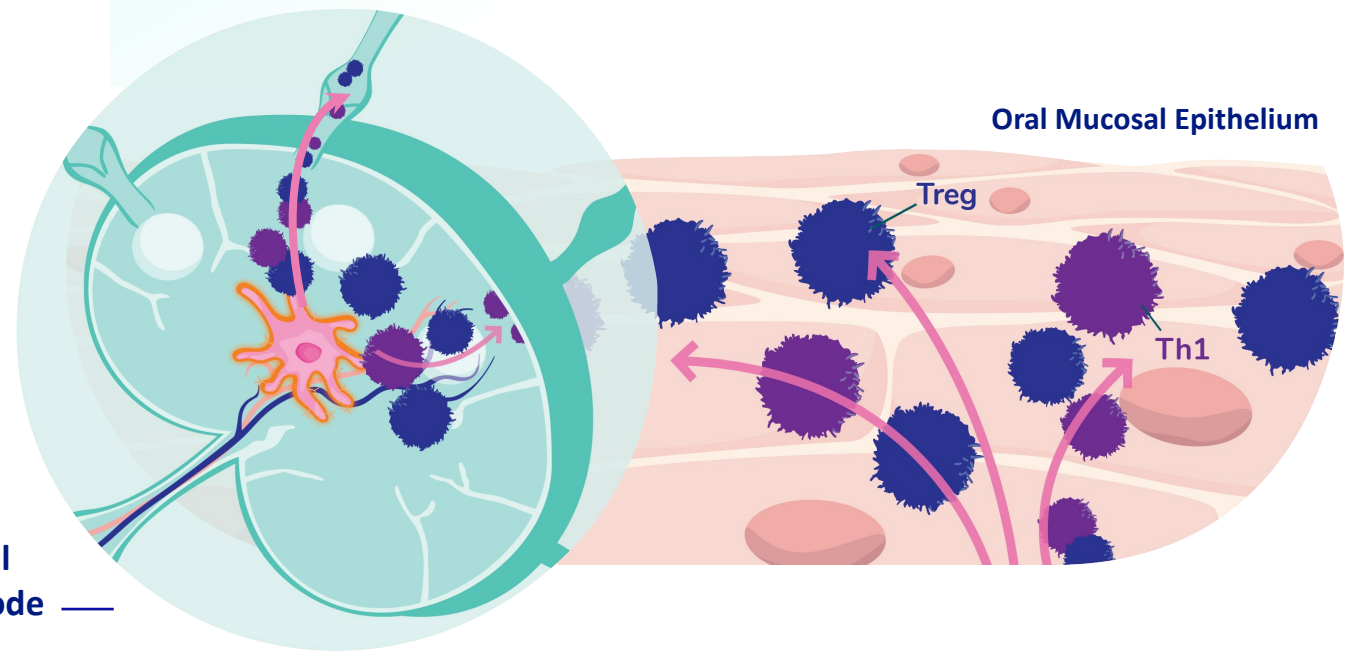
Once in the regional lymph nodes Langerhans cells activate naive T cells causing them to differentiate into either T regulatory (Treg) cells or T helper type 1 (Th1) cells.



## STEP 4 OF 4

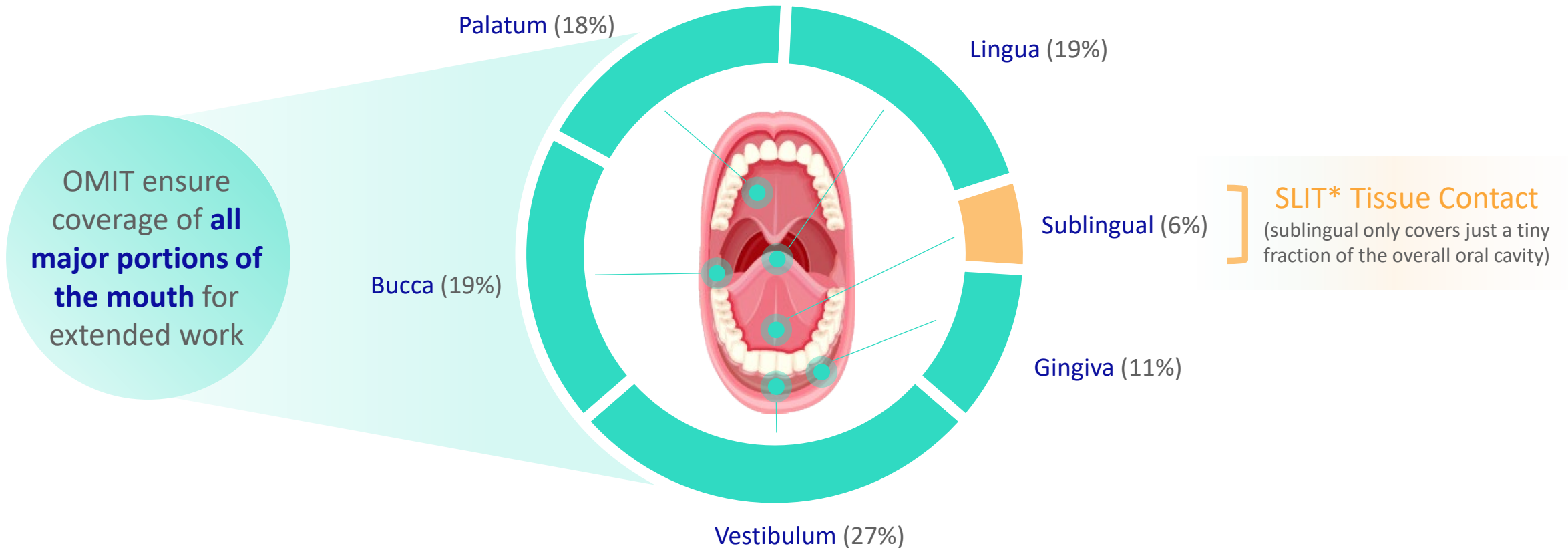
### Differentiated T Cells decrease the allergic response

Treg and Th1 cells travel through lymph vessels and distribute themselves throughout the mucosa of the aerodigestive tract where they decrease the allergic immune response the next time there is exposure to the specific allergen protein.



# Oral Mucosal Therapy (OMIT) Versus Sublingual Therapy (SLIT) Coverage

**INT301 toothpaste allows  
100% tissue contact**



# Significant Peanut SLIT Safety & Efficacy Studies: Precedent for INT301 (OMIT)

PI/First Author	Study Status	Comments	Subjects	Duration	Safety	Efficacy
Wesley Burks/Edwin Kim	Published 2011 <sup>1</sup>	1 <sup>st</sup> clinical evidence of desensitization	<b>18 children age 1-11</b>	<b>12 months, ongoing follow-up</b>	No emergency epinephrine in 4,182 active doses	20x increase in peanut safely consumed
Wesley Burks/David Fleischer	Published 2013 <sup>2</sup> , 2015 <sup>3</sup>	1 <sup>st</sup> double-blind placebo controlled trial	<b>40 subjects age 12-37</b>	<b>68 weeks</b>	1 of 11,854 active doses required epinephrine	Statistically significant desensitization in majority
Robert Wood	Published 2015 <sup>4</sup>	Compare efficacy & safety of peanut SLIT (3.7mg/day) vs. OIT (2000mg/day)	<b>21 children age 7-13</b>	<b>18 months</b>	SLIT significantly superior in safety	SLIT effective; OIT efficacy superior, but 4/11 dropped out
Edwin Kim/Wesley Burks	Published 2019 <sup>5,6,7</sup>	Effect of long-term SLIT (2.0mg/day)	<b>48 children age 1-11</b>	<b>36-60 months</b>	>75,000 doses administered; 0.21% req. antihistamine. No epinephrine use	67% of participants (86% of study completers) protected to ≥750mg peanut protein. Sustained unresponsiveness observed
Robert Wood	Ongoing, unpublished <sup>8</sup>	Efficacy and safety of dissolving sublingual film	<b>15 subjects age 18-50</b>	<b>18 months</b>	Unpublished	Unpublished
Edwin Kim/Wesley Burks	Abstract presented 2021 AAAAI <sup>9</sup>	DBPC study in youngest group of peanut allergic children yet	<b>50 toddlers (age 1-4)</b>	<b>36 months</b>	>20K active doses; less than 0.4% symptom medication use, primarily for oral itch; no epinephrine use	Active dose group protected to median 4443mg peanut; 12 out of 19 treated exhibited sustained unresponsiveness after 3 months off therapy

1. Kim E et al. JACI 2011(3);127:640-6.  
 2. Fleischer DM et al. JACI 2013;131(1):119-27.  
 3. Burks AW et al. JACI 2015;135(5):1240-1248.e3.  
 4. Narisety SD et al. JACI 2015;135(5):1275-1282.  
 5. Hamad A et al. Poster # 193 AAAAI 2017.

6. Yang L et al. JACI 2017 139(2): Abstract 559.  
 7. Kim E et al. JACI 2019 144(5):1320-1326.e1.  
 8. Ongoing, unpublished trials identified through database searches at clinicaltrials.gov  
 9. Kim et al. 2021 AAAAI annual meeting, Late-Breaking Abstracts Presentation L2

# INT301 Offers a Simple, Safe and Unique User Experience



## User Experience

### Single use packaging

- Ensures accurate dosing
- Decreased risk for misuse or dosing mix ups
- Allows for portability/on the go

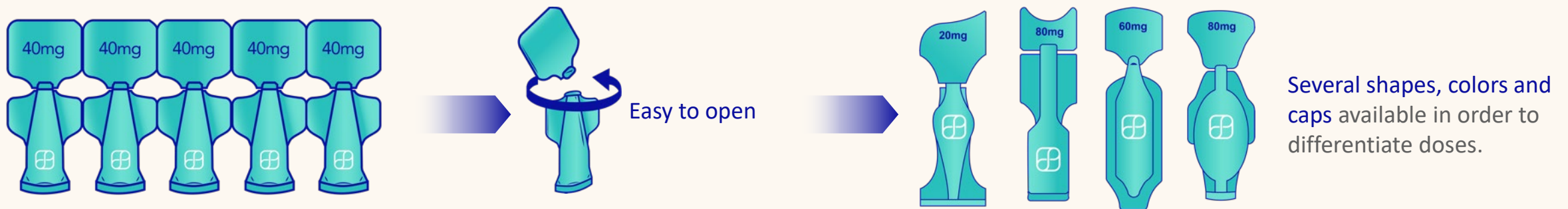
### Significantly reduced AE profile

Patient finishes brushing, the API (peanut protein) is expelled, thus less risk of systemic adverse events

### High compliance

Safe and simple social practice which increases likelihood of continued use

## Multiple Single-Use Packaging





# Intellectual property



## EXCLUSIVE GLOBAL IP

For all food allergy immunotherapy



## GLOBAL PORTFOLIO

- United States
- European Union
- China
- India
- Japan



## TWO PATENT FAMILIES

35 patents to date

- Toothpaste-allergens for immunotherapy
- Formulations to stabilize allergens



## GLOBAL PROTECTION THROUGH 2034

- Potential to extend to 2042



Additional IP grants expected, new filings planned





## Phase 1b Study Underway (INT301-101)

CRO engaged

### IND filed & accepted



Highly collaborative

No toxicology review (API is peanut protein)

No pharmacokinetics due to route of administration

No animal models

# CURRENTLY ENROLLING PATIENTS: Phase 1 Study of the Safety and Feasibility of Up-titration With INT301 in Adults With Sensitivity to Peanut



This is a randomized, double-blind, placebo-controlled study in adult participants with peanut allergy. Participants will be randomized in a 3:1 ratio to receive either an escalating dose of INT301 or placebo. The treatment group will be blinded to the investigator, participants, and the Intromune study team.

This ongoing study will capture diverse sets of clinical data, which we believe will act as value drivers in the near term and help us to define the registrational path of INT-301 in the medium term.



## Primary Outcome Measures:

- To evaluate the safety of INT301 compared to placebo in adult peanut allergic participants as measured by dose escalation during study.
- Percentage of participants able to consistently tolerate the protocol-specified highest dose; Incidence of systemic and non-systemic adverse reactions.



## Secondary Outcome Measures:

- To evaluate pharmacologic requirements as interventions for peanut allergic participants experiencing adverse events on INT301.
- Number of participants requiring treatment for systemic reactions related to experimental treatment or placebo; Adherence to study treatment.



## Exploratory Outcome Measures:

- To explore changes in peanut-specific IgG4 and IgE levels in participants

# Capital Milestones and Goals

Series A  
\$6M  
(closed)

## INVESTORS:



Chemical Angel Network

## ACCOMPLISHED:

- Exclusive global rights to OMIT for food allergy
- INT301 formulation developed
- IND accepted
- Phase 1b

## INVESTORS:

Focus on strategic partners (investors), private and venture capital

## GOALS:

- Launch Phase 2 (2022)
- Chemistry, Manufacturing & Controls (CMC) implementation
- Build management and advisory board teams
- Media and professional branding / marketing push
- Identify liquidity and market opportunities

Series B  
\$40M

# Valuation projections: post-phase 1b



Target Valuation:  
\$300-400mm

Expected target 12 months

With significant upside:

- Safe, simple and controlled manufacture
- Positive social and health impact
- Numerous synergies and partnerships

Valuation: \$145mm

- Complicated manufacturing
- No public comparables at time
- Limited evidence of efficacy



Valuation: \$300mm  
with additional 10% royalties

- DNA vaccine – high risk
- Potential for germline effects



# Key comparator – Aimmune Therapeutics – PALFORZIA®



## OMIT makes lifelong usage easy without the adverse events observed with OIT



















Acquired for \$2.6B

- OIT technology with NO revenue when acquired
- Inconvenient delivery
  - Patients must add peanut powder to semi-solid food daily
- Significant adverse event profile
  - Increased systemic allergic reactions
  - Increased discontinuation due to AEs
  - Increased reports of EoE (chronic, allergic inflammatory disease)
- Restrictive REMS (Risk Evaluation and Mitigation Strategy)
- Increases risk of emergency epinephrine requiring ER visit
- Many patients will have to take product for life

# INT301 Simple, Safe and Effective Versus Competitors



	OMIT (Monotherapy)	OIT – EPIT (Monotherapies)		
				
	INT 301	Palforzia (OIT)	Viaskin Peanut (EPIT)	CA002 (OIT)
SIMPLICITY	 Built in adherence	 Requires adding to food	 Patch adhesion issues	 Requires adding to food
SAFETY	 Significantly reduced AEs	 High rate of anaphylaxis Requires REMS program	 Potential systemic AE's	 Potential systemic AE's
EFFICACY	 Expected to be more efficacious	 Proven efficacy	 Low efficacy	 Efficacy not proven



# Intrommune opportunity at-a-glance



Revolutionary patented  
commercial grade  
toothpaste drug-  
delivery platform



Greater efficacy expected

- 12x mucosal coverage in comparison to SLIT
- Targets entire oral cavity surface
- Contacts more optimal areas of mouth
- Dosing >2mg (2mg = 300mg OIT)



Positive financials

- Series A: \$6mm
- Series B : \$40 mm
- Launched January '22



Expected to  
be safe, no  
epinephrine use



Built-in adherence  
with daily routine

- No adverse taste or difficulty in administration
- Reinforces positive habits – oral health
- Reduces anxiety / Don't have to feel afflicted



Platform for  
multiple food allergy  
treatments

# Disclosures



## Important Information

The information regarding the proposed private placement offering by Intrimmune Therapeutics is being provided to you on a confidential basis only and should not be disclosed to anyone other than your professional advisers on a confidential basis for purposes related to your interest in the company. This information should not be divulged, reproduced or disseminated without our consent.

Only qualified “accredited investors” as defined in Regulation D under the Securities Act of 1933, as amended will be permitted to participate in the proposed offering. Additional suitability requirements may apply.

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We will make available to any prospective purchaser and such person’s advisers the opportunity to ask questions and receive answers concerning the terms and conditions of the proposed offering, the company, or any other relevant matters, and to obtain any additional information to the extent the company possesses such information.

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Thank You