

A Revolutionary Toothpaste Based Approach To Food Allergy Immunotherapy





## Our mission



INTROMMUNE is developing *safe* and *effective* options for food allergy sufferers so that they and their loved ones can live their lives *without fear* 





Food allergies affect 32mm Americans (220mm+ worldwide)





Total cost of childhood food allergies -\$25B/year

9 common foods account for over 90% of all food allergies





The oral cavity is the natural classroom where the body learns its relationship with food

Current best option is avoidance





Intrommune's first product will address peanut allergies



## Introducing a novel approach to allergy desensitization

## Delivering therapeutic agents through oral mucosal immunotherapy (OMIT)



Embedded food derived allergen proteins





patients brush their teeth

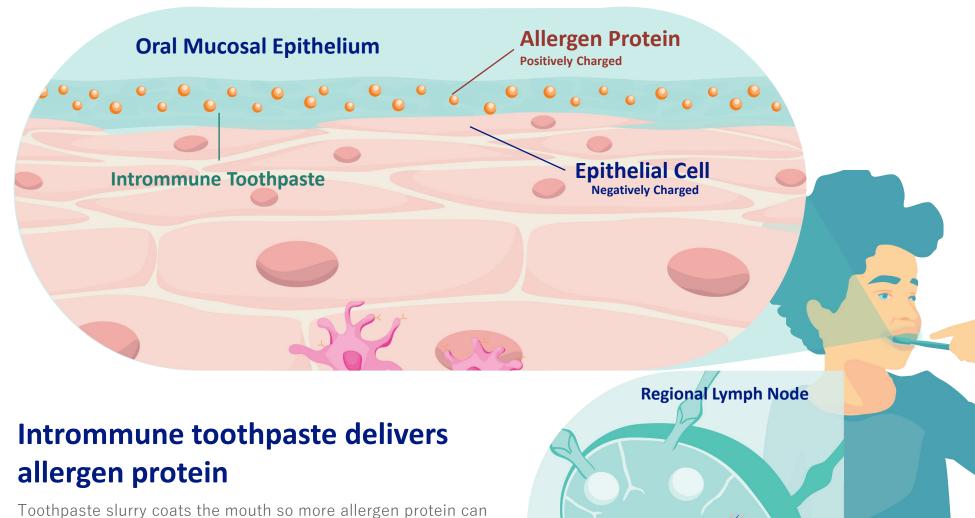


Administered at the same time



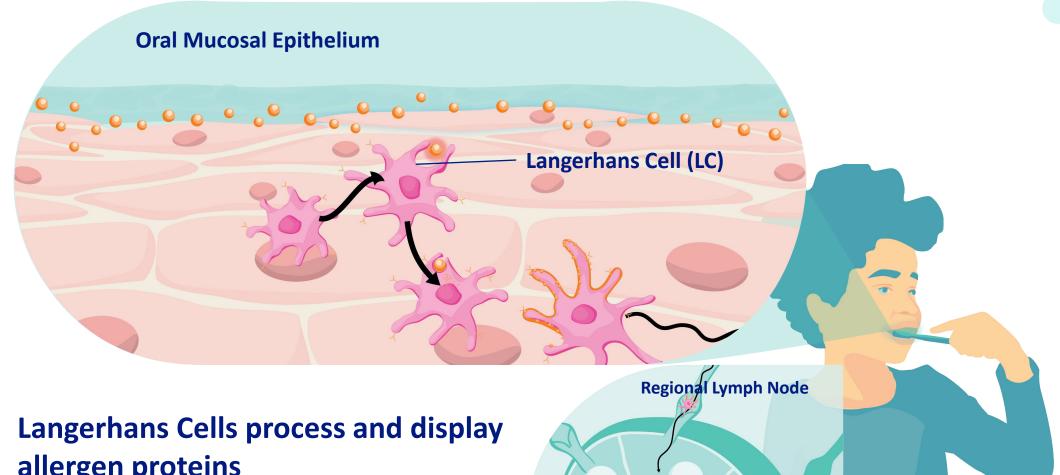
Convenient daily immunotherapy





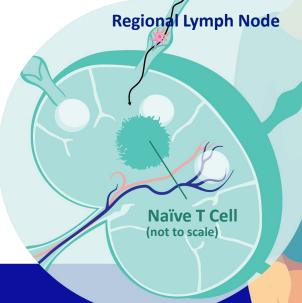
Toothpaste slurry coats the mouth so more allergen protein can bind with cells on the surface of the oral mucosal epithelium. The opposing charges of the protein and surface cells attracts them to each other to form a strong bond.

INTROMMUNE THERAPEUTICS

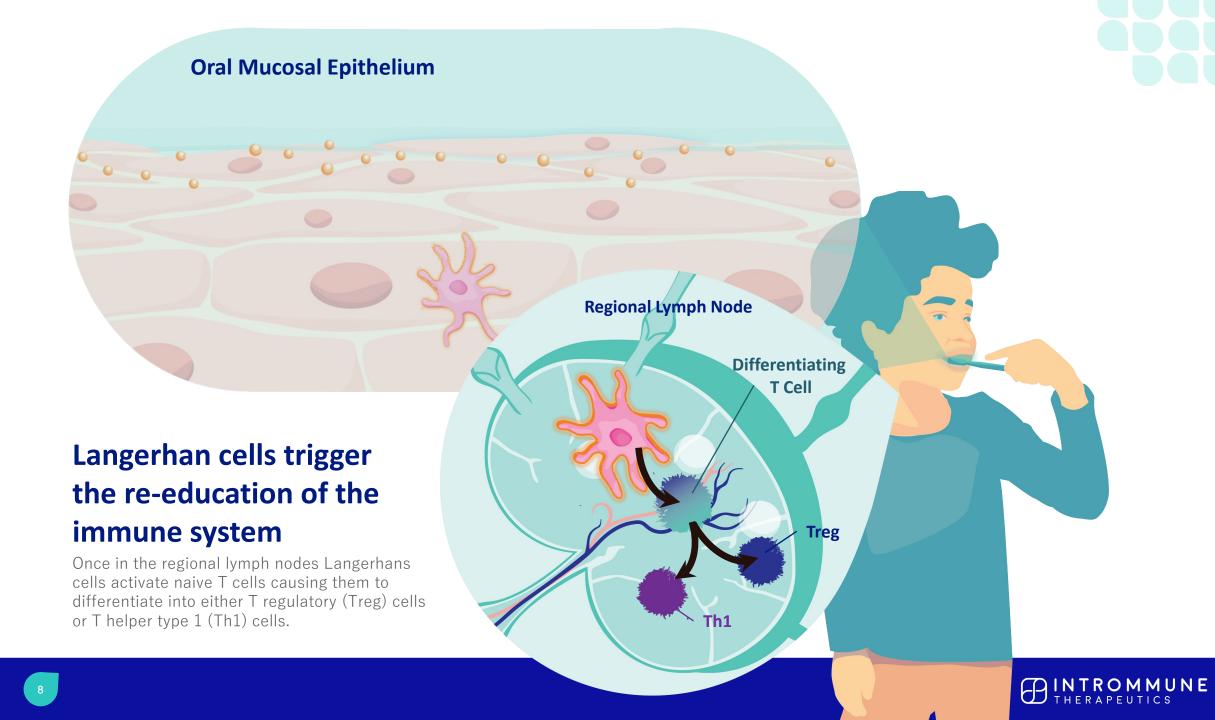


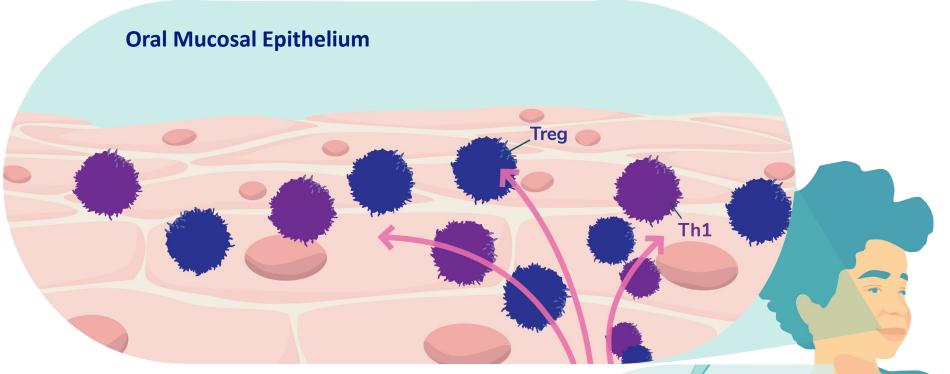
allergen proteins

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.



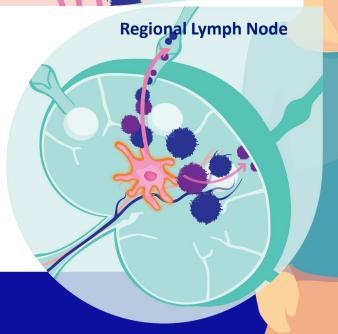






# Differentiated T Cells decrease the allergic response

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.





## OMIT – Peanut key investment metrics



## **OPPORTUNITY**



6M

U.S. Peanut Allergic Pop



1.6M

U.S. Peanut Allergic Children



1 M

Diagnosed
(Aged 4 – 18 years)



690K

Immediate serviceable market for Intrommune\*

## UNMET NEED

TAM: \$7,369,200,000 Insurance Coverage: Yes

OIT Price/Year Per Patient: \$10,680

## Solutions / Expectations

- ✓ Reduce adverse effects
- ✓ Better adherence
- ✓ Synergies
- ✓ Multi-product platform





## Intellectual property











Exclusive global IP license for food allergy immunotherapy

## Global portfolio

(Including U.S., EU, China, India, Japan)

## Two patent families

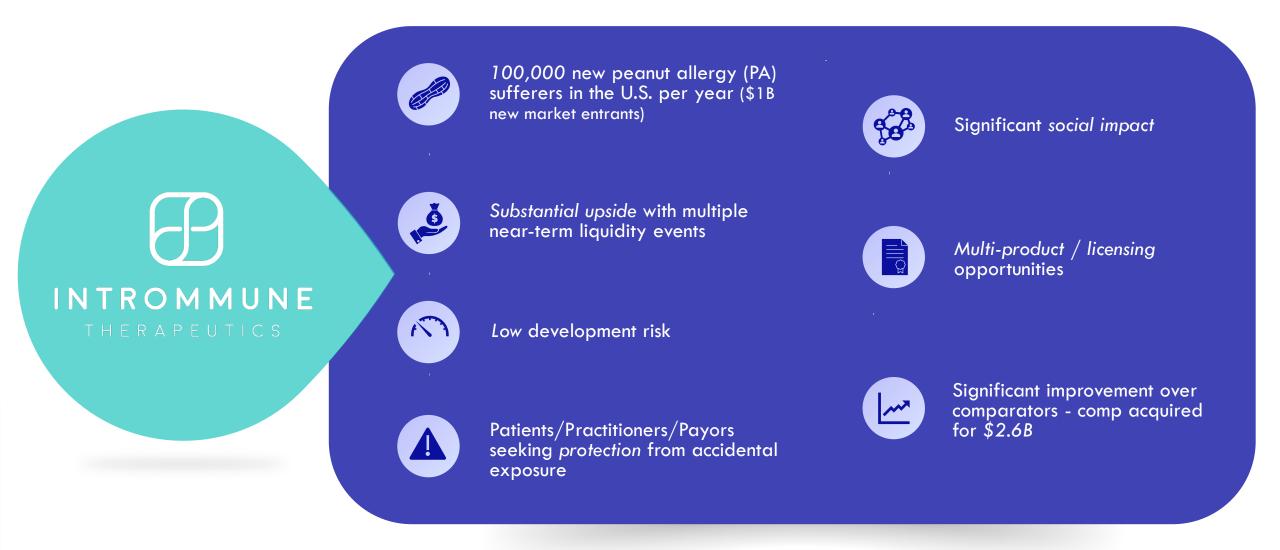
- 35 patents to date
- Toothpaste + allergens for immunotherapy
- Formulations to stabilize allergens

# Global protection through 2034

• Potential to extend to 2041

Additional IP grants expected, and new filings planned

## Intrommune OMIT: A clinically de-risked biotech opportunity



## Intrommune Peanut OMIT — Clear approval pathway



# Phase 1b Study Underway (INT301-101)



CRO engaged - Circuit Clinical

## IND filed & accepted



Highly collaborative

No toxicology review (API is peanut protein)

No pharmacokinetics due to route of administration

No animal models

## Milestones & goals

Series A \$3.7mm

#### **INVESTORS:**

Robin Hood Ventures / Rowan
Innovation / Argonne Capital /
Timberline Holdings / Chemical
Angel Network / Red Bear Angels

#### **ACCOMPLISH:**

- Exclusive OMIT rights for food allergy
- Developed INT301 formulation
- IND accepted
- Phase 1b

#### **INVESTORS:**

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

#### **GOALS:**

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

Series B \$20mm



## Valuation projections: post-phase 1b



## Expected target 6 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





## Valuation projections: post-phase 2

## Target Valuation: \$1B+

## Expected target H1 2023

#### With significant upside:

- Expectation for multi-allergen innovation with parallel development tracks



## Valuation: \$4B+

- Believed to have received multiple offers when considered a safe and effective alternative
- Regulatory complications



## Valuation: \$650mm

- Known high risks
- Epinephrine use, GI and EoE
- Inefficient application





## Key comparator – Aimmune Therapeutics



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



Acquired for \$2.6B

- OIT technology with NO current revenue
- 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

## Key comparator – DBV Technologies



OMIT is the *only* safe and effective immunotherapy under development



**EPIT** technology received an FDA complete response letter

- Skin patch containing peanut proteins irritates skin
- Issues with patch adhesion
- Reworking of CMC required
- Continued extended delay, approval uncertain
- Corporate restructuring occurring, making talent available
- Efficacy low
  - 2 years of constant use before protection potentially achieved
  - Phase 3 efficacy endpoint missed

## Management





Michael Nelson, JD
CEO



Erick Berglund, PhD.



Michelle Mantia
Operations Manager



Alain Van Loo



Keith James, MBA CPA



Abhit Singh, MD

## **Advisory Board**

William Reisacher, MD | Inventor of OMIT; Senior Scientific

Advisor, Chair

Greg Plunkett, PhD | CMC Advisor

Anthony Robinson, CRNP, MBA | Clinical Advisor

Tonya Winders, MBA | Stakeholder Outreach Advisor

Terrence Tormey | Business Development Advisor

Jotin Marango, MD, PhD | Corporate Development & Finance

Advisor, Chair

Greg Van Gasse, MBA | Marketing Advisor

Jack Levitt, MBA | Executive Development Advisor

David Sanders | Government Affairs Advisor

Mark Durham | Human Capital Advisor

## Intrommune opportunity at-a-glance







Revolutionary patented commercial grade toothpaste drug-delivery platform

Current product name: Peanut INT301

Greater efficacy expected

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







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



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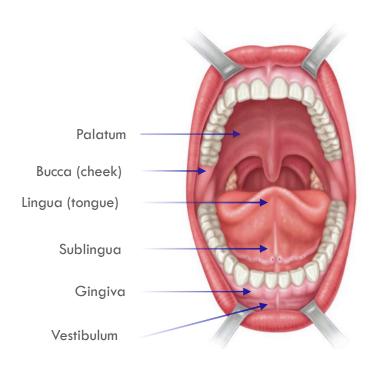
## INTROMMUNE THERAPEUTICS



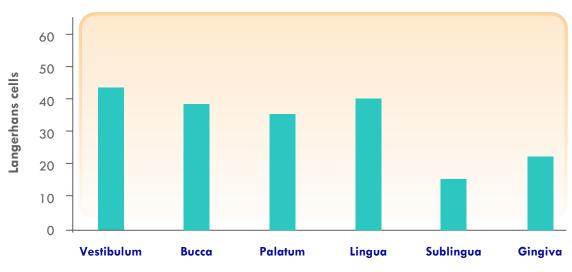
Appendix

## OMIT targets entire oral mucosa

## Exposure to oral immune cells optimized with OMIT



## **OMIT Toothpaste Tissue Contact**



Number of LCs in different anatomical locations of the oral cavity