HERAPEUTICS

A Revolutionary Delivery Platform for 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, collaborated on over 160 life science deals
- 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

- <u>Simple</u> Brush your teeth once per day as part of an already existing daily routine, imbedded adherence
- <u>Safe</u> 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

Raising \$45 million Series B



Proven Leadership Team









Advisors



BUSINESS

Jotin Marango, MD, PhD | Corporate Strategy

& Finance Advisor, Chair

Tonya Winders, MBA | Stakeholder Outreach Advisor



Advisor

Terrence Tormey | Business Development

Advisor

Jack Levitt, MBA | Executive Development

Mark Durham | Human Capital Advisor

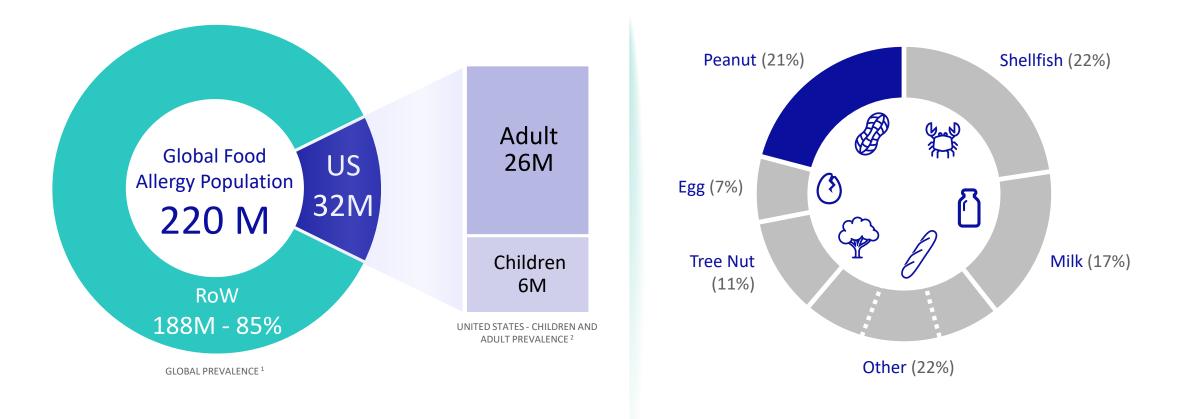
Moe Vela | Government Affairs Advisor

SCIENCE

Professor William Reisacher, MD | Inventor of OMIT; Senior Scientific Advisor, Chair Sharon Chinthrajah, MD | Medical advisor Lara Gross, MD | Medical Advisor Greg Plunkett, PhD | Extract Advisor Saul Fink | CMC 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."³



- 1. FARE Facts and Statistics https://www.foodallergy.org/resources/facts-and-statistics Accessed October 27, 2021
- 2. Asthma and Allergy Foundation of America
- 3. GlobalData Peanut Allergy Report 2018





OPPORTUNITY

TAM: \$7,369,200,000 Insurance Coverage: Yes OIT Price/Year Per Patient:

\$10,680

Solutions/Expectations:

- Reduce adverse effects
- Better adherence
- Increased efficacy
- Multi-product platform

INCREASINGLY UNMET NEED

6M U.S. Peanut Allergic Pop

1.6M

U.S. Peanut Allergic Children 1M Diagnosed

(Aged 4 – 18 years)

690K Immediate

serviceable market for Intrommune*





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

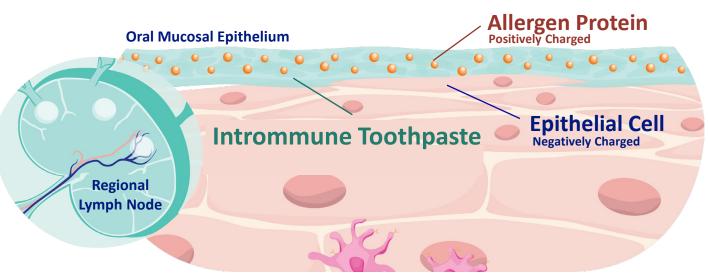


INT301 MOA



STEP 1 OF 4 Intrommune toothpaste delivers allergen protein

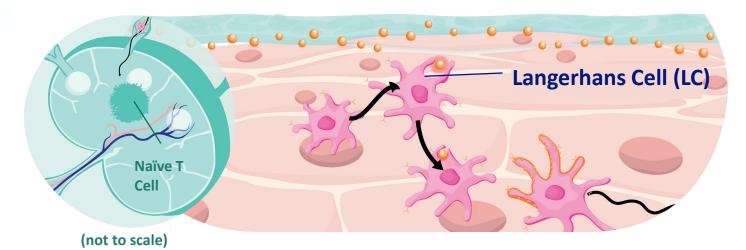
Toothpaste slurry coats the mouth so more allergen protein can bind with cells on the surface of the oral mucosal epithelium. The opposing charges of the protein and surface cells attracts them to each other to form a strong bond.



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.





INT301 MOA (cont'd)



STEP 3 OF 4

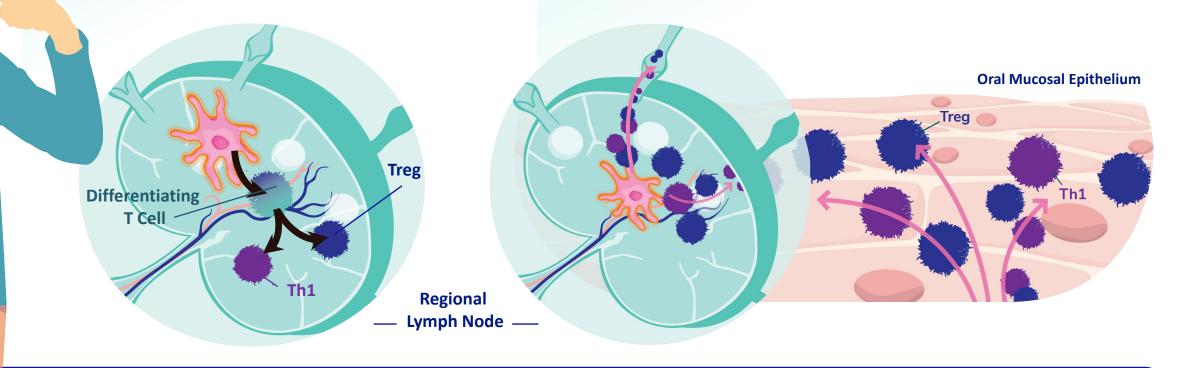
Langerhans cells trigger the re-education of the immune system

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

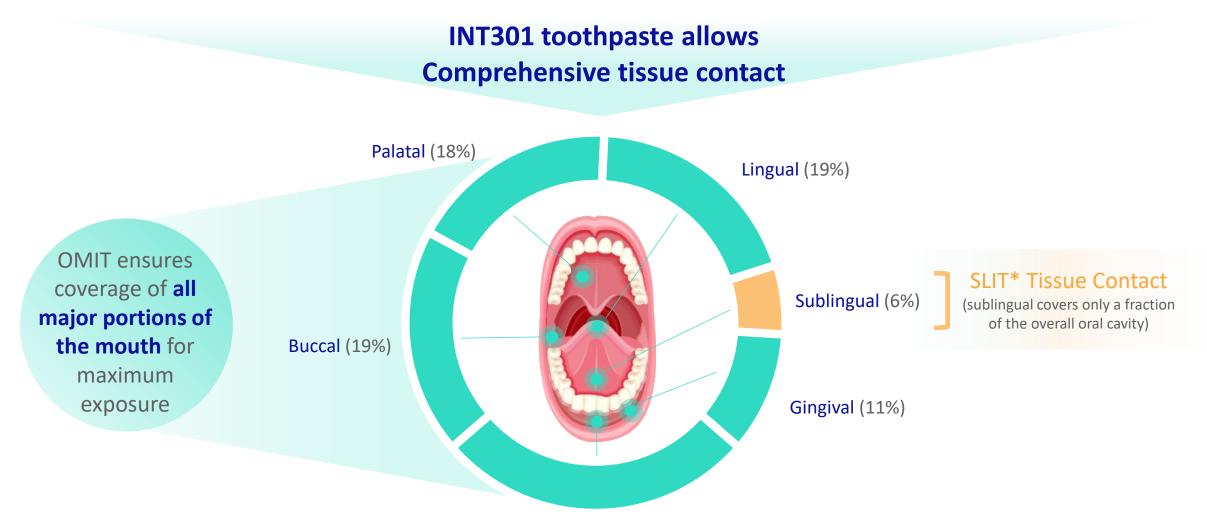
Differentiated T Cells decrease the allergic response

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 Immunotherapy (OMIT) Versus Sublingual (SLIT) Coverage



Vestibular (27%)

OMMUNE



Allam JP, et al. Allergy. 2008; 63(6):720-727. *OMIT - Optimizes Exposure to Oral Immune Cells *Sublingual Immunotherapy

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 ¹	1 st clinical evidence of desensitization	18 children age 1-11	12 months, ongoing follow-up	No emergency epinephrine in 4,182 active doses	20x increase in peanut safely consumed
Wesley Burks/David Fleischer	Published 2013 ² , 2015 ³	1 st double-blind placebo controlled trial	40 subjects age 12-37	68 weeks	1 of 11,854 active doses required epinephrine	Statistically significant desensitization in majority
Robert Wood	Published 2015 ⁴	Compare efficacy & safety of peanut SLIT (3.7mg/day) vs. OIT (2000mg/day)	21 children age 7-13	18 months	SLIT significantly superior in safety	SLIT effective; OIT efficacy superior, but 4/11 dropped out
Edwin Kim/ Wesley Burks	Published 2019 ^{5,6,7}	Effect of long-term SLIT (2.0mg/day)	48 children age 1-11	36-60 months	>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
Edwin Kim/Wesley Burks	Abstract presented 2021 AAAAI ⁹	DBPC study in youngest group of peanut allergic children yet	50 toddlers (age 1-4)	36 months	>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



Kim E et al. JACI 2011(3);127:640-6.
 Fleischer DM et al. JACI 2013;131(1):119-27.
 Burks AW et al. JACI 2015;135(5):1240-1248.e3.
 Narisety SD et al. JACI 2015;135(5):1275-1282.
 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. Kim et al. 2021 AAAAI annual meeting, Late-Breaking Abstracts Presentation L2



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

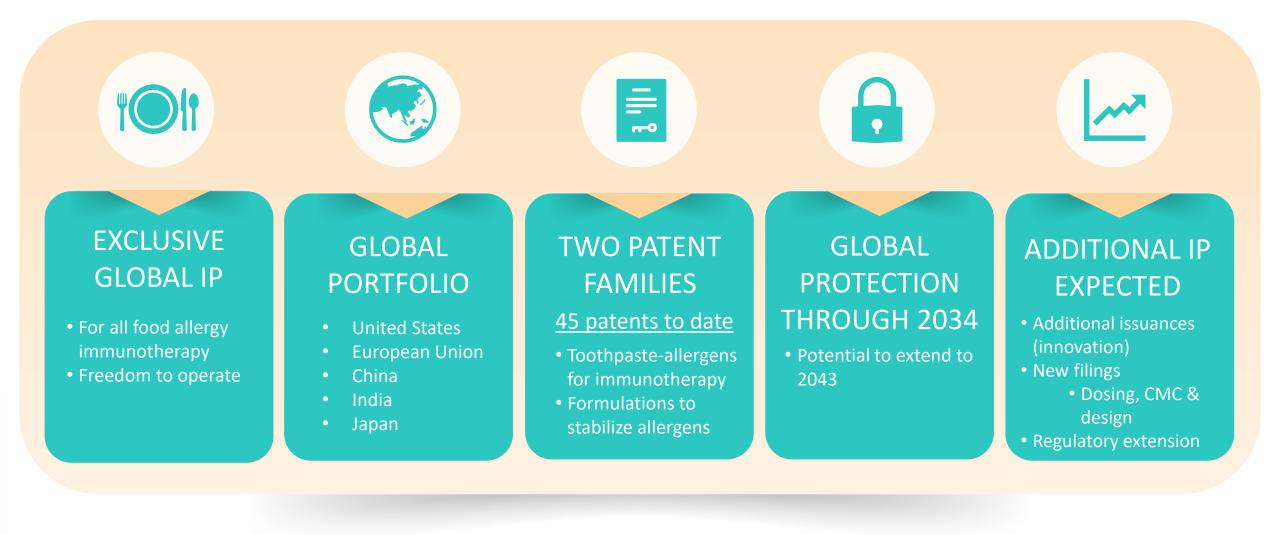
Safe and simple social practice which increases likelihood of continued use

Multiple Single-Use Packaging



Several shapes, colors and caps available in order to differentiate doses.

Intellectual Property







Phase 1b Study Underway OMEGA (INT301-101)

CRO engaged

IND filed & accepted

FDA

Highly collaborative

No toxicology review (API is peanut protein)

No pharmacokinetics due to route of administration

No animal models





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

OMEGA (Oral Mucosal Escalation Goal Assessment) 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 Intrommune 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 INT301 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





INVESTORS:

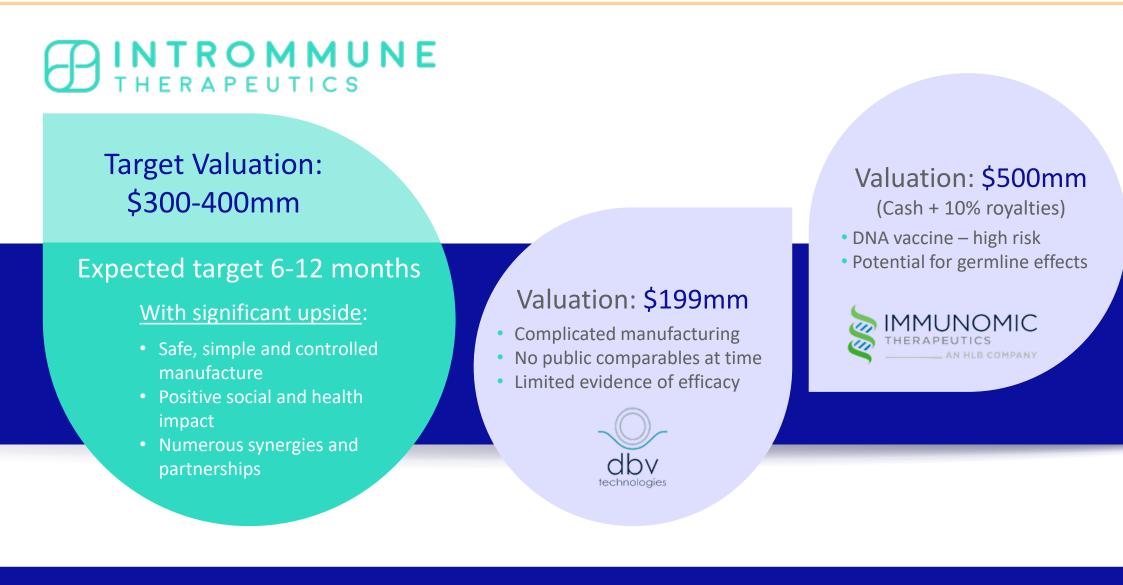
Focus on strategic partners (investors), private and venture capital

GOALS:

- Launch Phase 2 (2022)
- Chemistry, Manufacturing & Controls (CMC) implementation
- Onboarding and securing key resources
- Media and professional branding / marketing push
- Identify liquidity and market opportunities

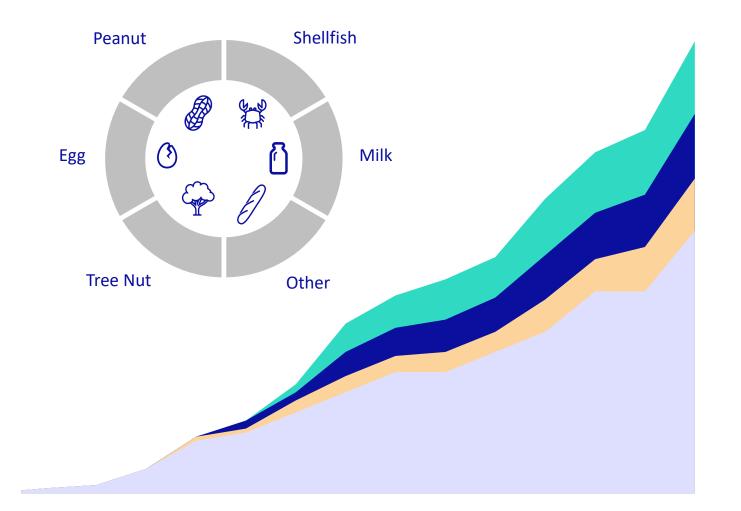
Series B \$45M





Global Delivery Platform - Strategic Potential





POTENTIAL VALUE ADD THROUGH GLOBAL PARTNERSHIPS/LICENSING OPPORTUNITIES

- INT301 U.S. Base Valuation Projection
- Ex-U.S. INT301
- Global INT3** Single Protein
- Global INT3** Multi-protein



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

	INTROMMUNE THERAPEUTICS			Allergy Therapeutics ^{PLC} → astellas
	OMIT	OIT	EPIT	Injection
SIMPLICITY	Built in adherence	Requires adding to food daily	Patch adhesion issues	Requires injection
SAFETY	Significantly reduced AEs	High rate of anaphylaxis Requires REMS program	Otential exposure risk	Potential systemic AE's
EFFICACY	Expected to be more efficacious	Proven efficacy	Low efficacy	Efficacy not proven

OMIT (toothpaste): Oral Mucosal Immunotherapy OIT (ingestion): Oral Immunotherapy EPIT (skin patch): Epicutaneous Immunotherapy



THERAPEUTICS

Intrommune opportunity at-a-glance Revolutionary patented commercial grade toothpaste drugdelivery platform

/-



Expected to be safe, no epinephrine use



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 : \$45mm

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





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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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HERAPEUTICS



Thank You