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A Fresh Approach To  
Desensitizing People With  
Food Allergies



# Our Mission



INTROMMUNE is developing **safe**,  
**effective** and **easy to use** 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

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



## 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 1 / 2 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 Leadership Team



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



**Stuart Loesch** | President



**Alain Van Loo** | Chief Operating Officer



**Christopher Schuster** | Chief Financial Officer



**Nandini Murthy** | Head of Regulatory



**Wendy Perrow, MBA** | Head of Innovation



**Ray Forslund** | Head of Chemistry, Manufacturing & Controls



**Dr. William Berger** | Head of Clinical Development



# Advisors



## BUSINESS



Jotin Marango, MD, PhD | Corporate Strategy Advisor & Finance, Chair

Tonya Winders, MBA | Stakeholder Outreach

Terrence Tormey | Business Development

Jack Levitt, MBA | Executive Development

Mark Durham, MA | Human Capital

Moe Vela, JD | Government Affairs

Miles McLennan, MBA | Trial Management

## SCIENCE



Professor William Reisacher, MD | Inventor of OMIT; Senior Scientific Advisor, Chair

Sharon Chinthrajah, MD | Medical

Lara Gross, MD | Medical

Greg Plunkett, PhD | Extract

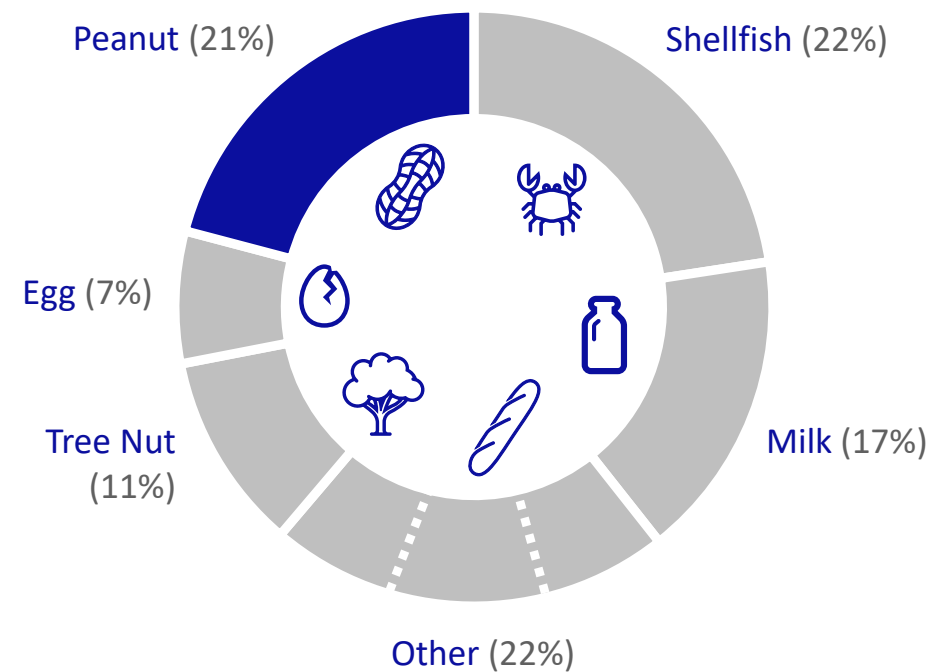
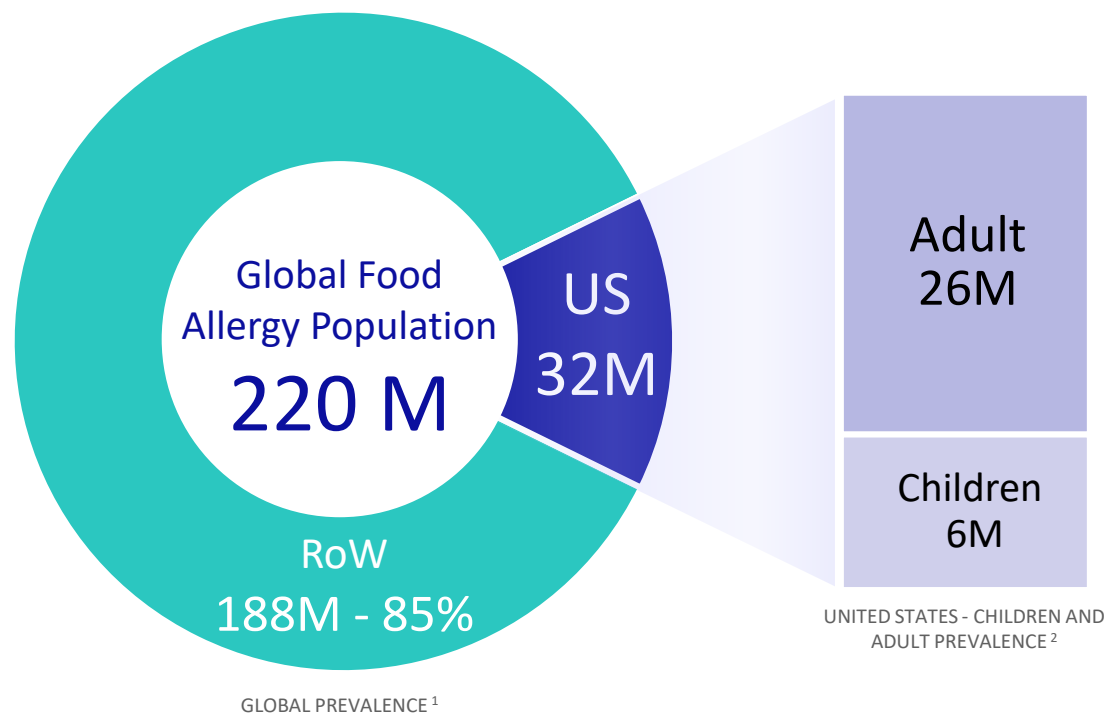
Saul Fink, PhD | CMC

Anthony Robinson, CRNP, MBA | Clinical

Gerry Kugel, DMD, PhD | Dental



# 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>

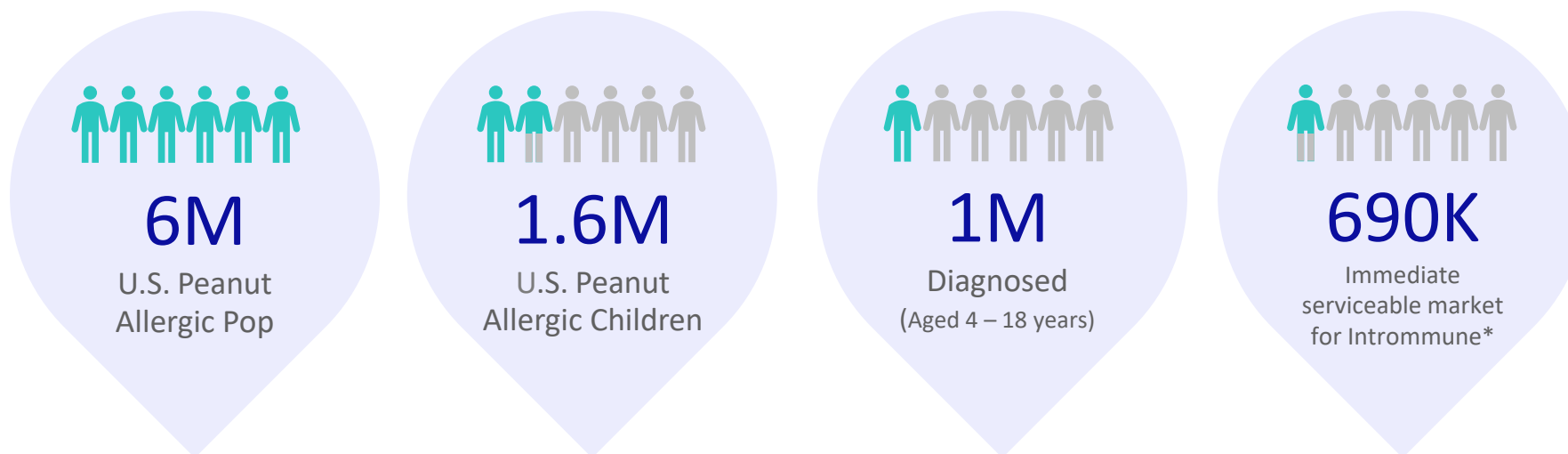
# U.S. Peanut Allergy Key Investment Metrics



## OPPORTUNITY

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

## INCREASINGLY UNMET NEED

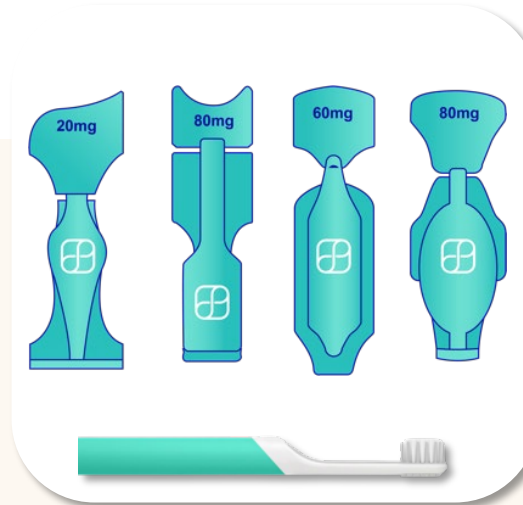


# INT301 - Introducing a Novel, Simplified Approach to Allergy Desensitization

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



Embedded food derived  
allergen proteins



INT301 convenient daily  
immunotherapy



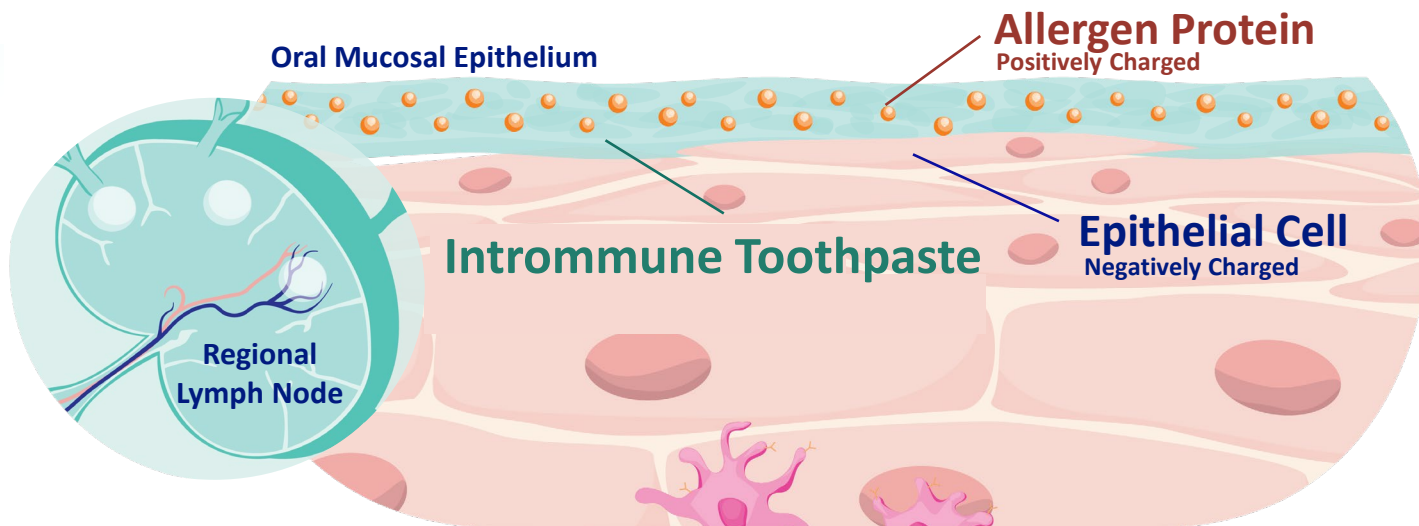
Administered at the same time  
patients brush their teeth



## STEP 1 OF 4

### Intrimmune toothpaste delivers allergen protein

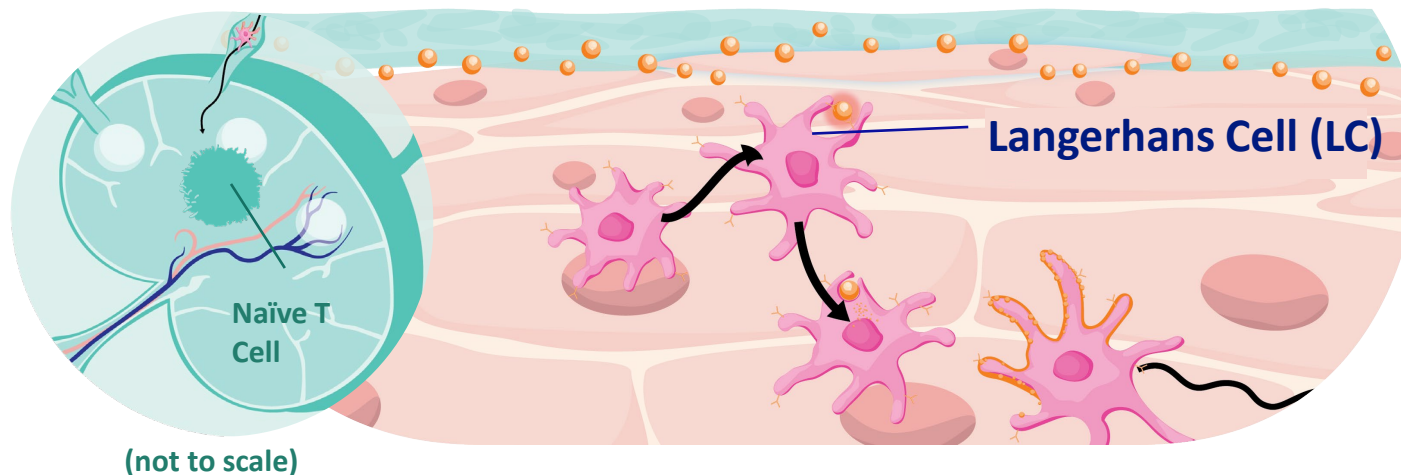
Toothpaste slurry coats the mouth so more allergen protein can bind with cells on the surface of the oral mucosal epithelium. The opposing charges of the protein and surface cells attracts them to each other to form a strong bond.



## 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.

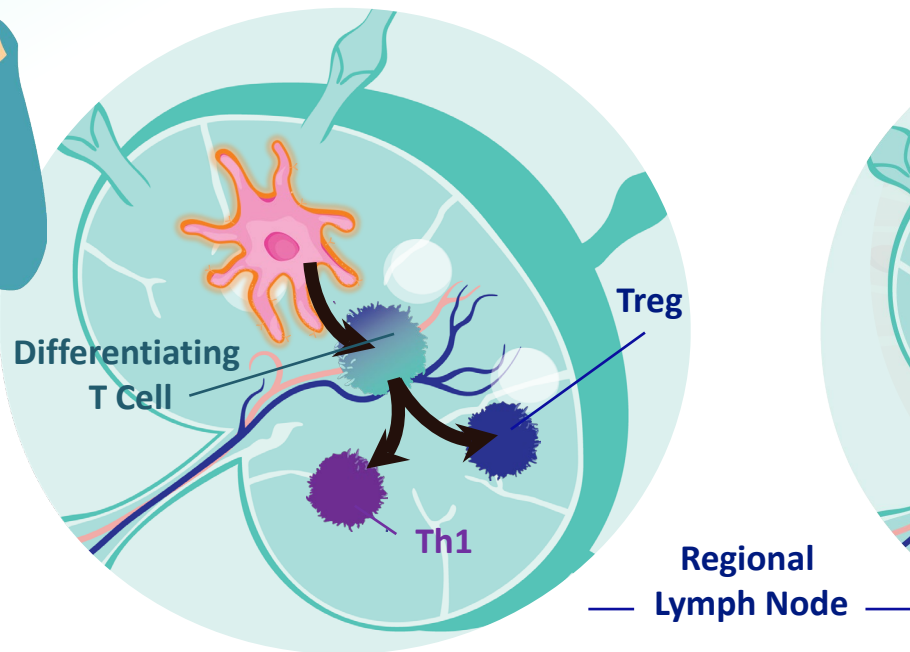


# INT301 MOA (cont'd)

## STEP 3 OF 4

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

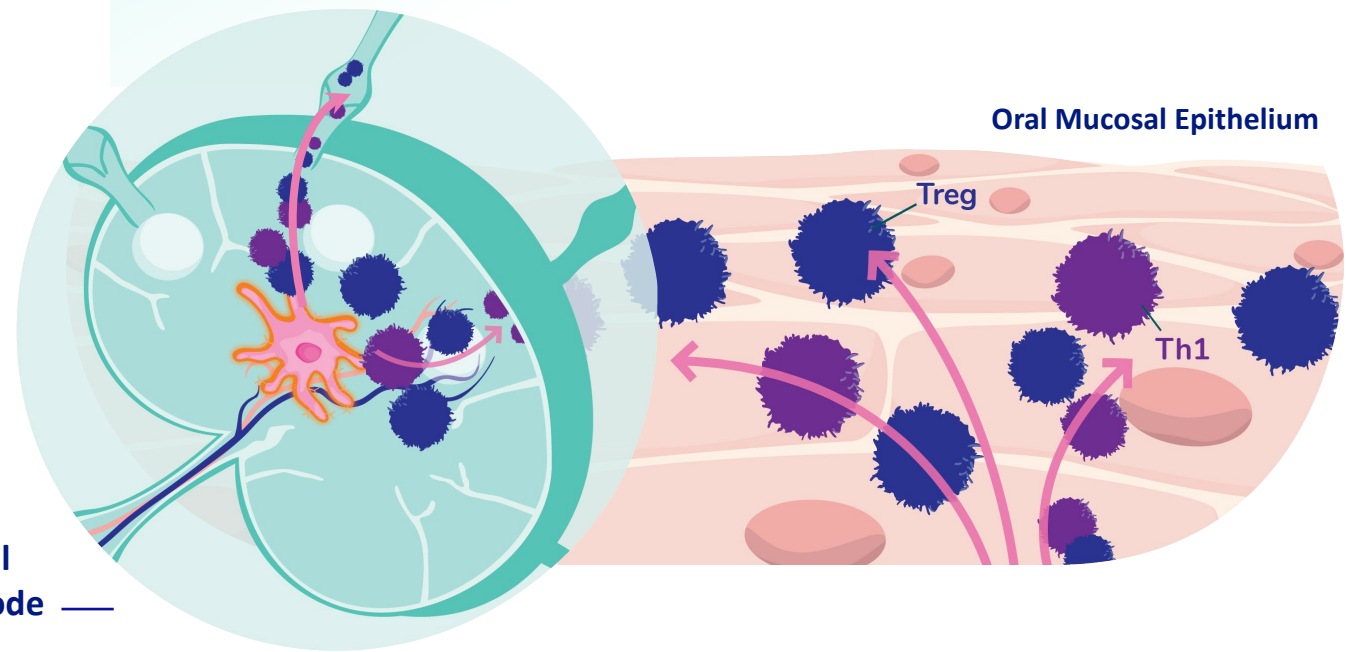
Once in the regional lymph nodes Langerhans cells activate naive T cells causing them to differentiate into either T regulatory (Treg) cells or T helper type 1 (Th1) cells.



## STEP 4 OF 4

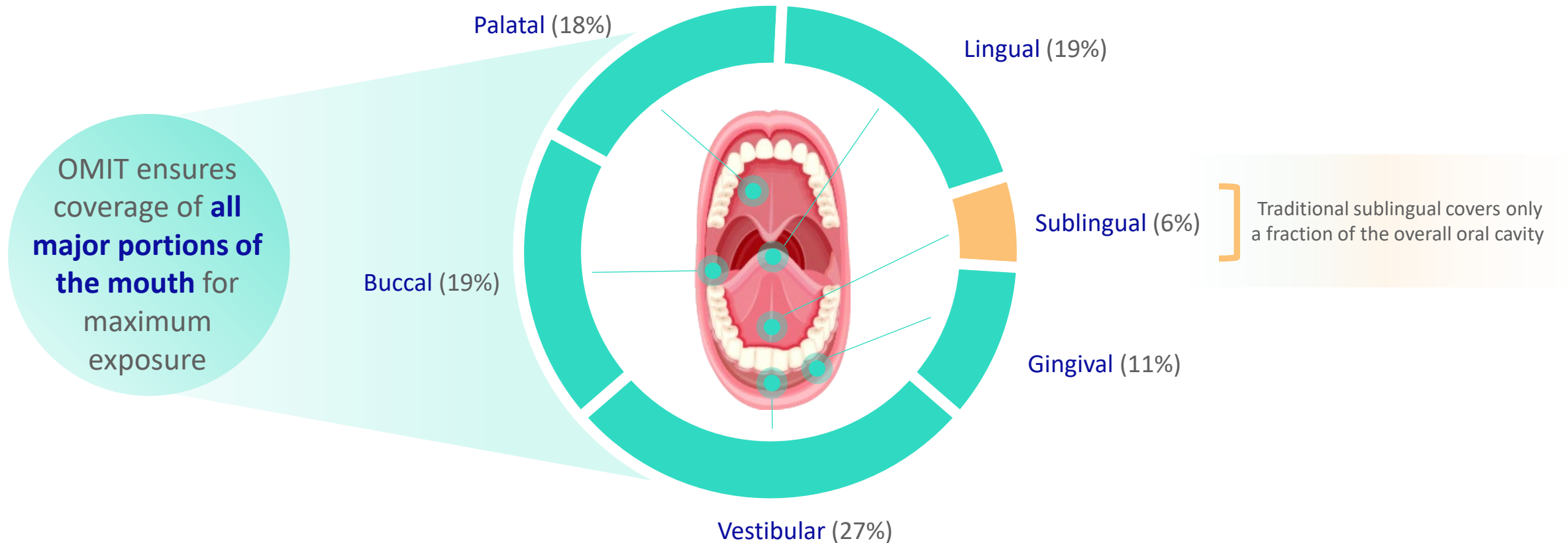
### Differentiated T Cells decrease the allergic response

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 Leverages Efficacy Within The Entire Oral Cavity

**INT301 toothpaste allows  
comprehensive tissue contact**



# INT301 Offers a Simple, Safe and Unique User Experience

## User Experience

### Metered dose packaging

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

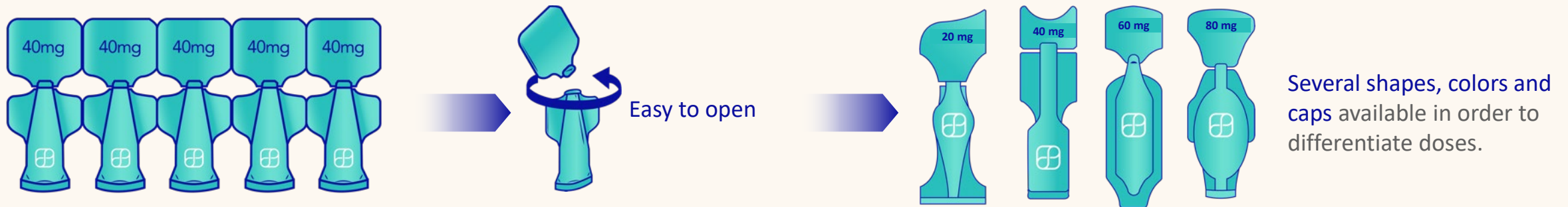
### Significantly reduced AE profile

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





## EXCLUSIVE GLOBAL IP

- For all food allergy immunotherapy
- Freedom to operate



## GLOBAL PORTFOLIO

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



## TWO PATENT FAMILIES

### 46 patents to date

- Toothpaste-allergens for immunotherapy
- Formulations to stabilize allergens



## GLOBAL PROTECTION

- Expected to extend to 2043



## ADDITIONAL IP EXPECTED

- Additional issuances (innovation)
- New filings
  - Dosing, CMC & design
- Regulatory extension

# Intrommune Peanut OMIT — Clear Approval Pathway

## Phase 1 / 2 Study (Adults) Underway OMEGA (INT301-101)\*

### IND filed & accepted



Highly collaborative

No toxicology review (API is peanut protein)

No pharmacokinetics due to route of administration

No animal models



# FULLY ENROLLED TRIAL: Phase 1 / 2 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 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 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.
- To explore changes in patient response to oral food challenge pre-treatment and post treatment.

# Update on Ongoing Phase 1 / 2 OMEGA (Adults)



## Trial Safety, Potential Desensitization, and Adherence

- The ongoing Phase 1 / 2 is designed for safety and efficacy endpoints and to explore changes in patient response to oral food challenge:
  - Percentage of participants able to consistently tolerate the protocol-specified highest dose
  - Incidence of systemic and non-systemic adverse reactions
  - Dose amount tolerated without AEs requiring discontinuation
- Enrollment is complete for all 4 cohorts and may provide early insights
- Adverse events due to peanut exposure appear to decrease over time – potential desensitization
- Safety: Mild, transient AEs, and no Severe AEs thus far (n=32)
  - Each cohort safely started on a higher dose
- Adherence rate: 98% adherence to daily toothbrushing requirement (patient-reported)
- Product related patient dropout rate: 0%

# Capital Milestones and Goals

Series A  
\$8M  
(closed)

## INVESTORS:



**Chemical Angel Network**

## ACCOMPLISHED:

- Exclusive global rights to OMIT for food allergy
- INT301 formulation developed
- IND accepted
- Ongoing Phase 1 / 2 (Adults)

## INVESTORS:

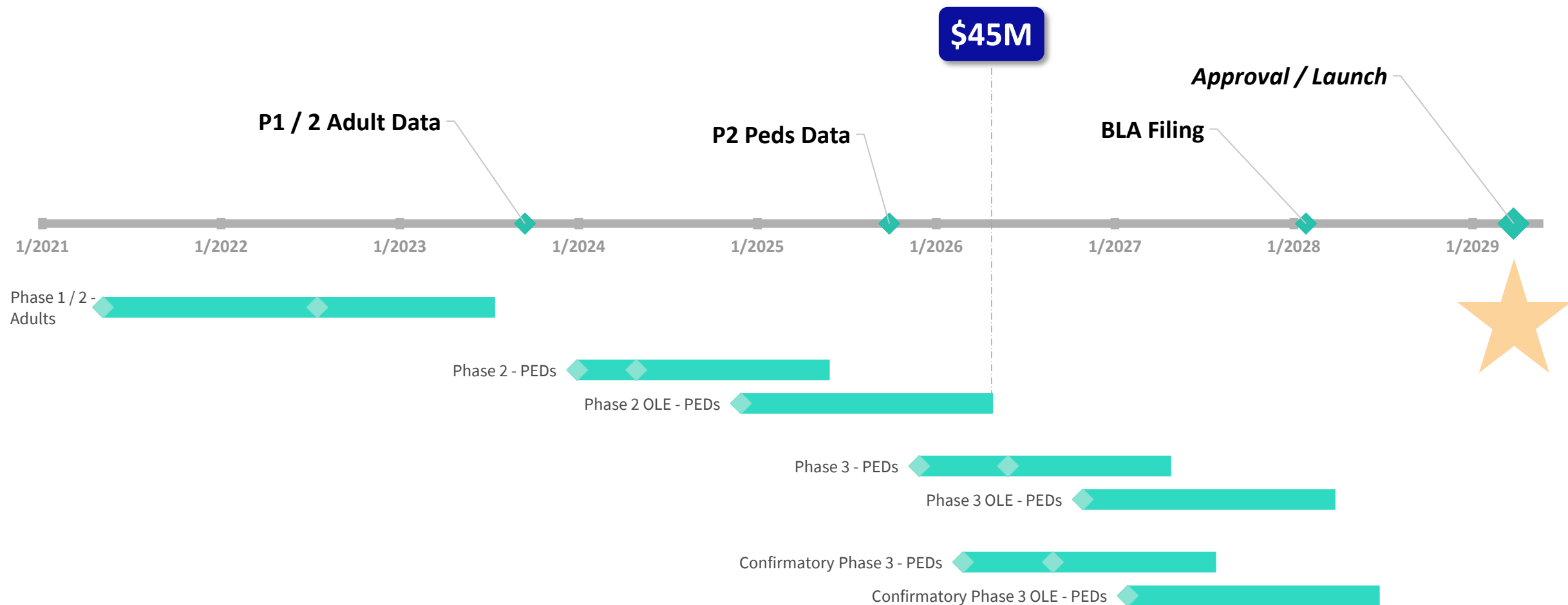
Focus on strategic partners (investors), private and venture capital

## GOALS:

- Complete Phase 1 / 2 (Adults), Complete Phase 2 study in PEDS
- Finalization of Chemistry, Manufacturing & Controls (CMC) process and preparation for full commercialization
- Onboarding and securing key resources
- Media-professional branding / market shaping
- Identify strategic and market opportunities

Series B  
\$45M

# Intrommune Therapeutics INT301 Clinical Timeline



# INT301: Phase 1 & 2 - Milestones

For delivery of:

- Extension to Phase 1/2 in adults (LT data)
- Contract with CRO for Phase 2 in pediatrics
- Finalize CMC and regulatory strategy
- Onboarding of key resources & expertise
- Product 2 innovation / research results
- Patent profile

**\$16mm**

For delivery of:

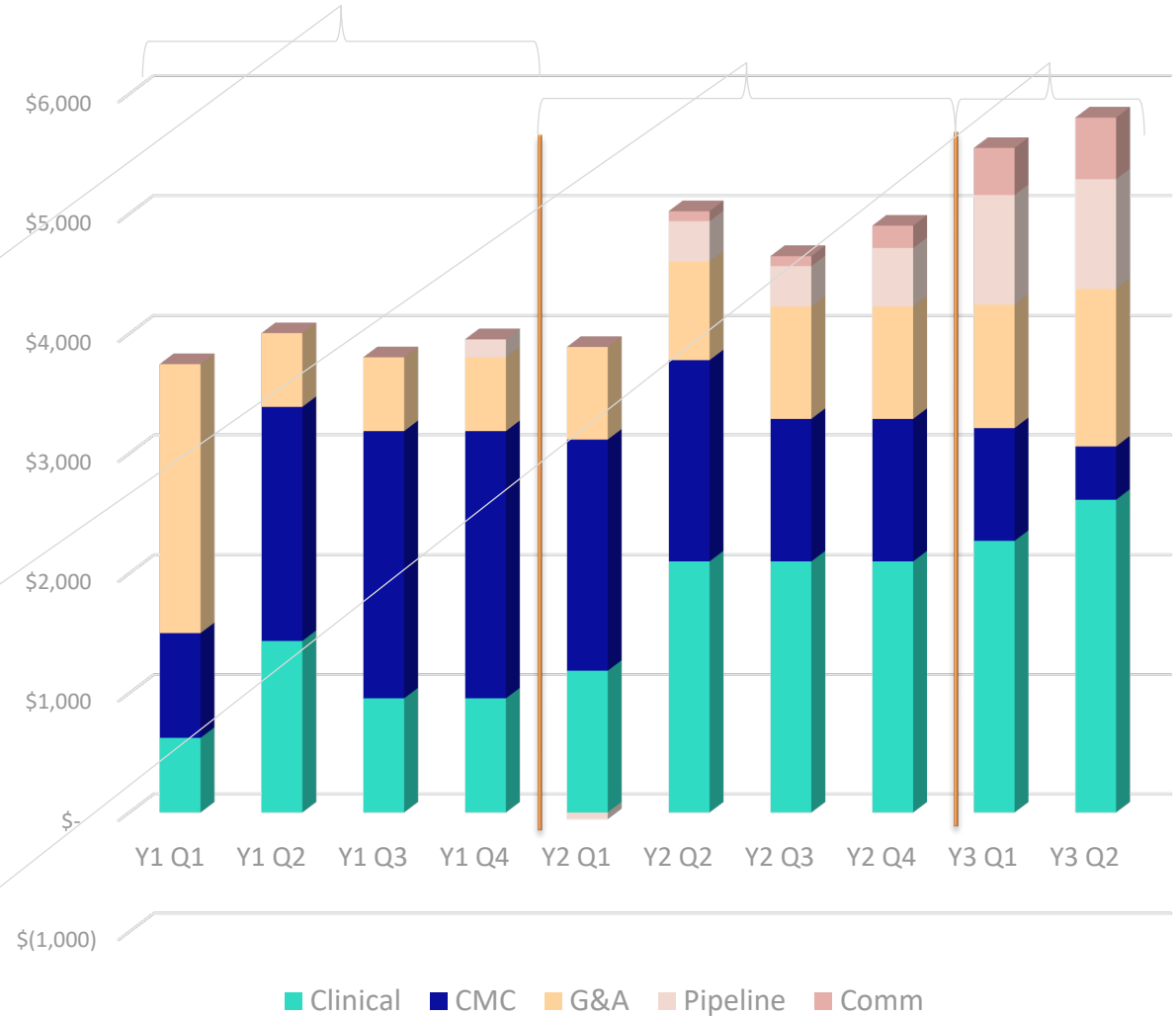
- Full engagement of Phase 2 trial in pediatrics
- Extend clinics footprint to 25+
- Conclude long term extension of Phase 1b/2 in adults
- Build out of CMC and regulatory resources

**\$18mm**

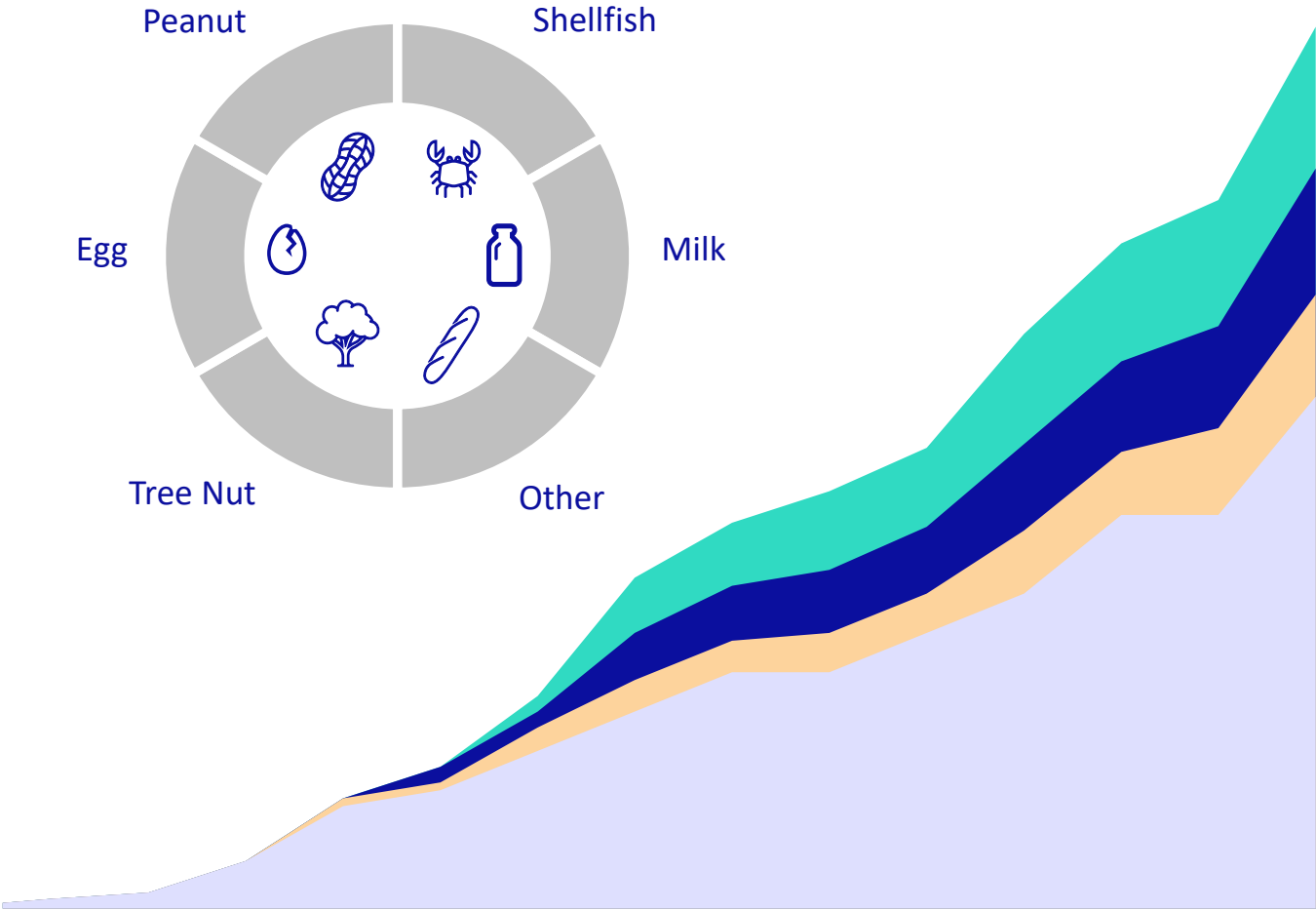
For delivery of:

- Proof of safety in Phase 1/2 data
- Pediatric data for Phase 2
- Extend pediatrics into OLE
- Dosing, processing, design patent filing
- Phase 3 CMC
- Pipeline finalization, commence work on Product 2

**\$11mm**



# Global Delivery Platform - Strategic Potential

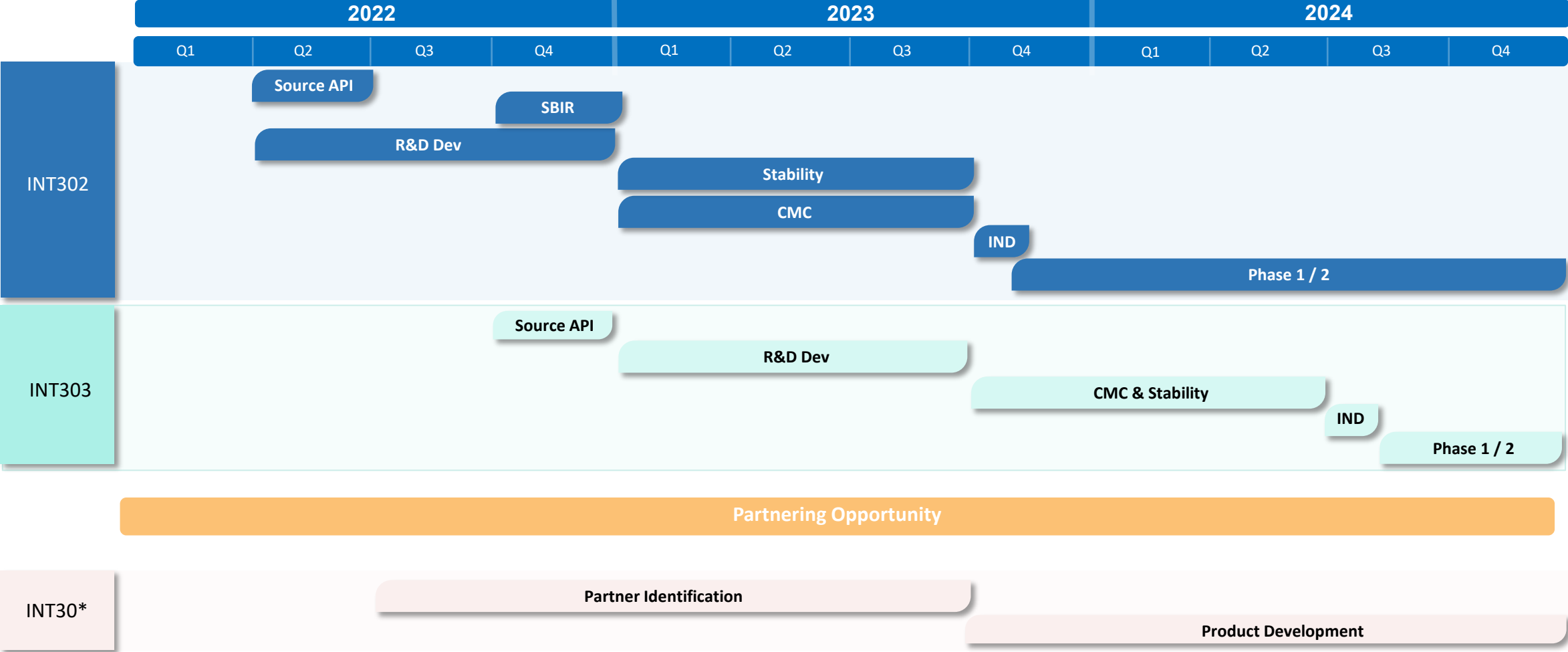


## VALUE ADD THROUGH PIPELINE DEVELOPMENT

- INT301 U.S. Base Valuation Projection
- Ex-U.S. INT301
- Global INT302
- Global INT30\*



# Pipeline Development Timeline



# 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 Safe, Effective and Easier To Use Versus Competitors

		  	 	 
	OMIT	OIT	EPIT	Injection
EASE OF USE	 Built in adherence	 Requires adding to food daily	 Patch adhesion issues	 Requires injection
SAFETY	 Significantly reduced AEs	 High rate of anaphylaxis Requires REMS program	 Potential exposure risk	 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**



**Long-term efficacy**

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



**High expected return  
on investment**

- Highly efficient use of capital
- Near-term value inflection points



**Demonstrated safety  
thus far in clinical trial**



**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

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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