



Transforming Food Allergy Treatment Via a  
Novel Immunotherapy Technology Platform

# Our Technology Will Transform How Millions Manage Food Allergies

We are developing a novel **immunotherapy technology platform** with multiple applications that reinvents how food allergies are managed in a **multi-billion \$ market**.

We will transform lives by addressing the unmet needs of people living with food allergies through development of solutions that optimize **safety, efficacy and adherence**.



**Our first application targets the >\$7 billion peanut allergy market**

# Executive Summary



## Problem

- **Large, growing market:**  
>220 million people globally with food allergies; 32 million in U.S.
- **Significant unmet need:**  
Causes severe health events & lifestyle impacts, with no cure
- **Sub-optimal treatment options:**  
Current solution doesn't deliver robust safety, efficacy & adherence profile



## Our Solution

- **Novel approach, multiple applications:**  
Oral Mucosal Immunotherapy (OMIT) for food allergy desensitization
- **Significant differentiation:**  
Dramatically reduced risk profile vs competition\*; built-in adherence via toothpaste delivery
- **Positive Phase 1 / 2 study results:**  
Met primary and secondary objectives demonstrating safety and adherence; indications of efficacy; provides clear direction for Phase 2 pediatric trial



## Opportunity

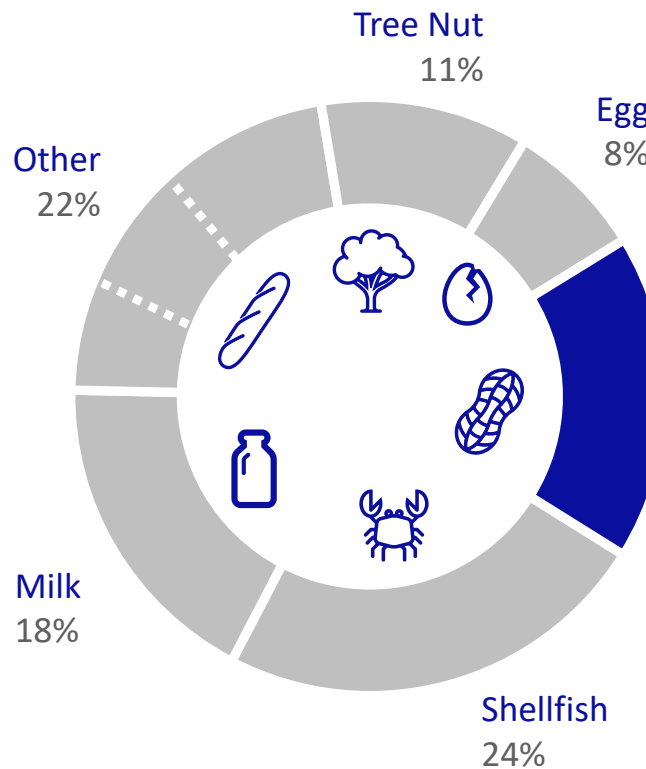
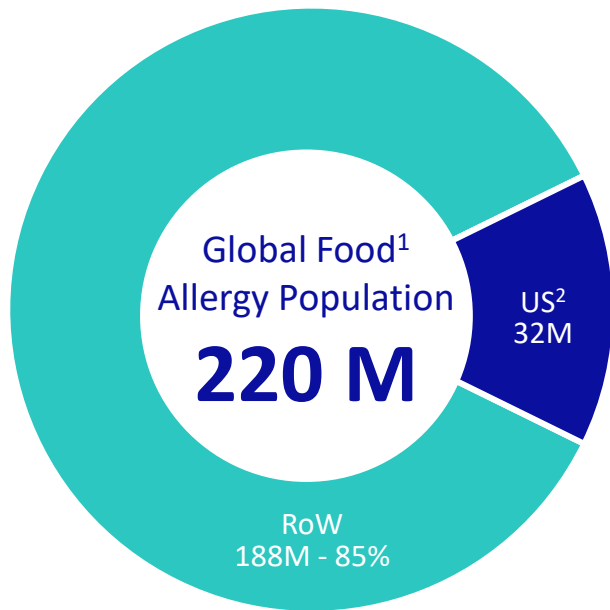
- **Multi-billion \$ market:**  
First application targets peanut allergies; ~\$7B TAM in U.S. alone
- **Minimal competition:**  
Only one peanut allergy product approved & acquired for \$2.6B
- **Opportunity to get in early, high expected ROI:**  
Clinical trials showing early positive results; strong IP portfolio

**Intromune is currently seeking \$38 million in Series B funding**

# Food Allergies Impact Millions Globally



Food allergies have become a serious public health concern as prevalence increases globally



Peanut  
(18%)

Peanut Allergy

**\$7.4 Billion**

TAM for U.S. market only<sup>3</sup>

# 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>



## 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>

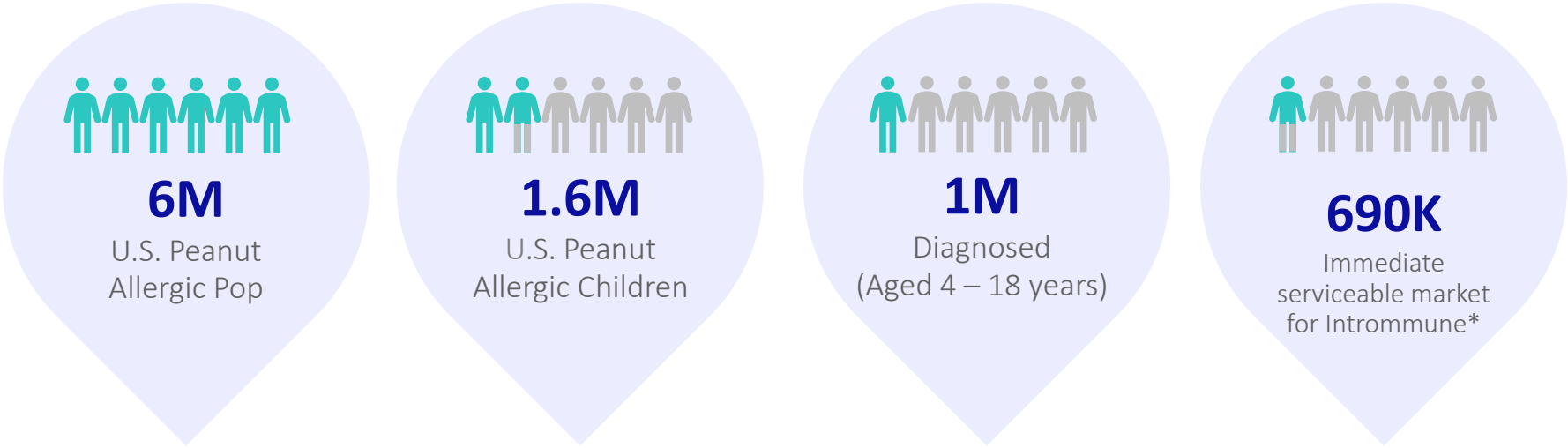
# Food Allergies Represent a Multi-Billion Dollar Opportunity



## PEANUT ALLERGY OPPORTUNITY

TAM	GROWTH	INSURANCE COVERAGE	OI PRICE/YEAR PER PATIENT
<b>\$7.4 Billion</b> (U.S. market only)	Market forecasted to grow <b>1,700-fold</b> from 2017 to 2027 <sup>1</sup>	<b>Yes</b>	<b>\$10,680<sup>2</sup></b>

## LARGE & GROWING UNMET NEED



\*Assumes 60% (child), 2% (adult) seek treatment

<sup>1</sup> GlobalData Peanut Allergy Report 2018

<sup>2</sup> Price at January 2020 approval. price on September 10, 2023 is \$14,880/year per

# No Cure & Current Solutions Are Lacking

## LIFESTYLE SOLUTIONS

- Avoidance of problem foods
- Learn to recognize and treat reaction symptoms (e.g. EpiPen®)



## IMMUNOTHERAPY SOLUTIONS

- Only one product ever approved for food allergy (Palforzia® for peanuts)
- Does not fully deliver on safety, ease of adoption & adherence:

### Safety

- ~9.5% experienced anaphylaxis, which may be life-threatening<sup>1</sup>
- 14% use of epinephrine reported in one Phase 3 pivotal trial<sup>1</sup>
- >35% experienced moderate\* treatment-related adverse events<sup>2</sup>

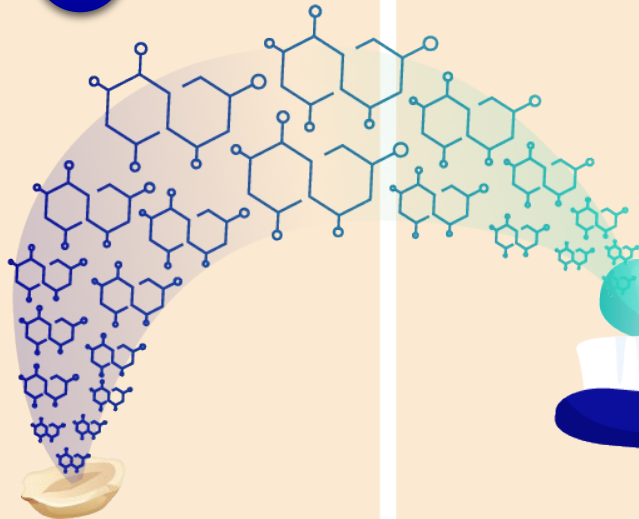
### Adoption Barriers

- Requires frequent visits to allergy clinic every 2 weeks for ~6 months
- 5-hour initial office visit; issue given lack of physician compensation
- Discontinuation rate of ~22%<sup>1</sup>

# Our Solution: Novel Technology Simplifying Allergy Immunotherapy

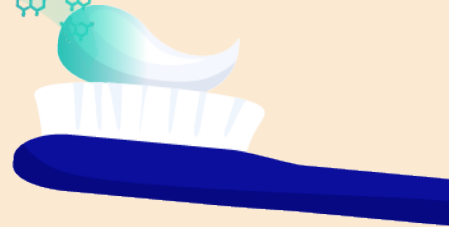
## Food allergy desensitization transformed into easy-to-use platform via proprietary technology: Oral Mucosal Immunotherapy (OMIT)

1



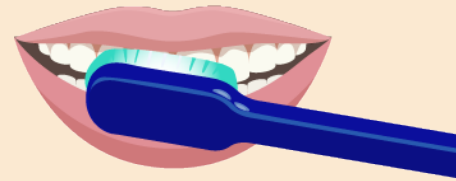
Peanut allergenic proteins (API)  
mechanically & chemically  
**extracted via proprietary methods**

2



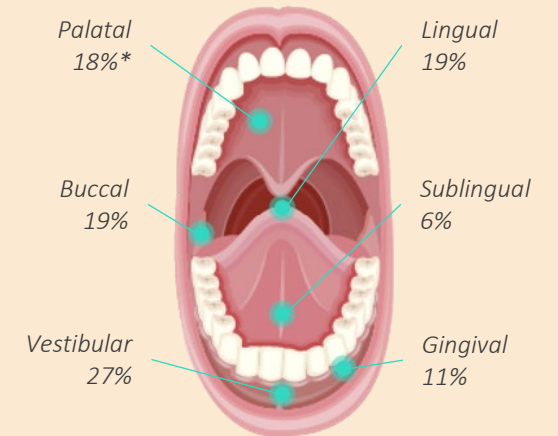
**API stabilized & embedded**  
in functional toothpaste  
in metered-dose dispenser

3



Immunotherapy  
**conveniently administered**  
with daily teeth brushing

4



Novel OMIT pathway leverages  
Langerhans cells in entire oral cavity  
**to reeducate immune system,**  
desensitizing users to allergens

# How Oral Mucosal Immunotherapy Works

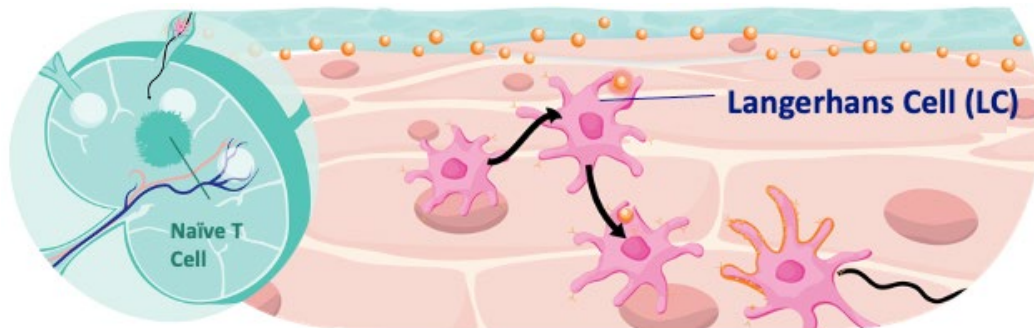
1

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



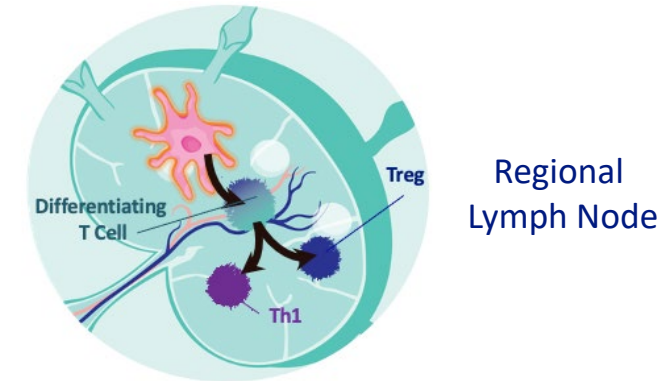
2

Langerhans cells pull allergenic protein into the lymph system



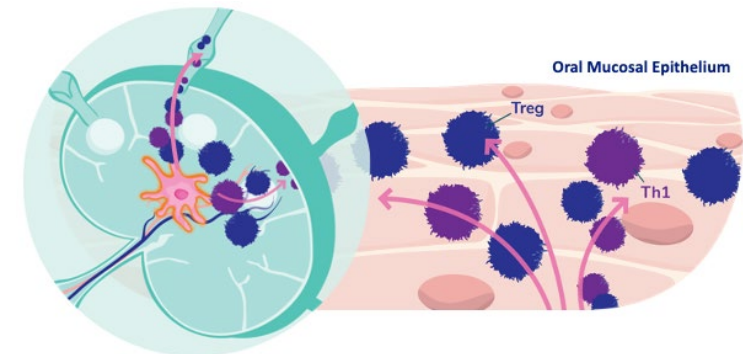
3

Langerhans cells trigger the reeducation of immune system



4

Differentiated T cells decrease the allergic response



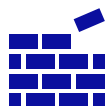
# Intromune's Solution Is *Highly* Differentiated vs. Competition

## Why OMIT?



### Built-in Adherence

- ✓ Simple toothpaste delivery integrates into existing daily routine
- ✓ Power Bluetooth-integrated toothbrush + app allows adherence tracking and gamification
- ✓ Opportunity to be maintenance product for patients started on other solutions



### Lower Adoption Barriers

- ✓ Fewer, shorter up-dosing office visits required
- ✓ No peanut flavor
- ✓ Ease of use enables patients to live their lives without fear



### Significantly Reduced Risk Profile

- ✓ Absorbed in mouth (processed via lymph system) then spat out, reducing risk of systemic reactions and GI distress
- ✓ Phase 1 / 2 OMEGA study indicates the platform is safe



### Efficacious - Maximizes Oral Absorption

- ✓ Covers all major portions of mouth, activating 16x number of Langerhans cells\*
- ✓ Targeting faster time to reach efficacy target

## OMIT vs. Palforzia®

	OMIT / Intromune (oral mucosal)	OIT / Palforzia® (oral)
DELIVERY	Embedded in toothpaste (spat out after brushing)	Ingested with food (enters GI system)
SIMPLICITY	 Integrated with daily care	 Must add daily to food
SAFETY	 Significantly reduced adverse events	 High rate of anaphylaxis and GI pain
EFFICACY	 Expected to be more efficacious	 Proven efficacy

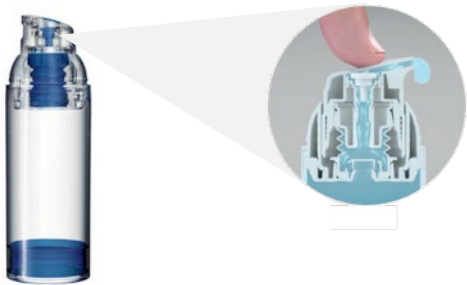
# Development Substantially Advanced for Peanut Allergy Solution



## Significant progress made to advance and de-risk development

### Product Development

- Process established for extracting peanut allergen protein
- Method created for stabilizing protein in functional toothpaste
- Packaging developed: pump dispenser



### Regulatory

- Clear approval pathway identified
- IND filed & accepted; highly collaborative FDA review
- Faster path to market: No toxicology, pharmacokinetics or animal models required
- Exploring breakthrough designation







### Clinical

- Phase 1 / 2 DBPC OMEGA Trial\* in adults complete
  - Met all primary and secondary safety endpoints
  - Exploratory objectives evaluated efficacy
- Due to impressive safety profile to date, FDA greenlit pediatric Phase 2 study prior to completion of our adult Phase 1 / 2 study

# OMEGA Phase 1 / 2 Clinical Trial Results



## Clinical Data for Primary, Secondary and Exploratory Endpoints Available Under NDA

-  **Safety** Met primary and secondary objectives. Demonstrated exemplary safety throughout all 4 cohorts, reflected in both number and type of AEs
-  **Adherence** 97% adherence to study treatments (patient reported)
-  **Efficacy** Exploratory objective provided indications of efficacy in difficult to treat adult population
-  **Dropout** 0% product-related participant dropout rate

# Extensive Global IP Protection

**IP covers all food allergens across multiple oral care formats, with 48 patents to date**



## **EXCLUSIVE GLOBAL IP**

- For all food allergy immunotherapy
- Freedom to operate



## **GLOBAL PORTFOLIO**

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



## **TWO PATENT FAMILIES**

- Immunotherapy via multiple oral care modalities
- Formulations to stabilize allergens



## **GLOBAL PROTECTION**

- Expected to extend to 2044 and beyond



## **ADDITIONAL IP EXPECTED**

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

# Series B Funding Requirements

## \$38 million in funding for Phase 2 pediatric study and for pipeline development

### Series A and Bridge - \$10 Million

#### Accomplished

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

#### Investors



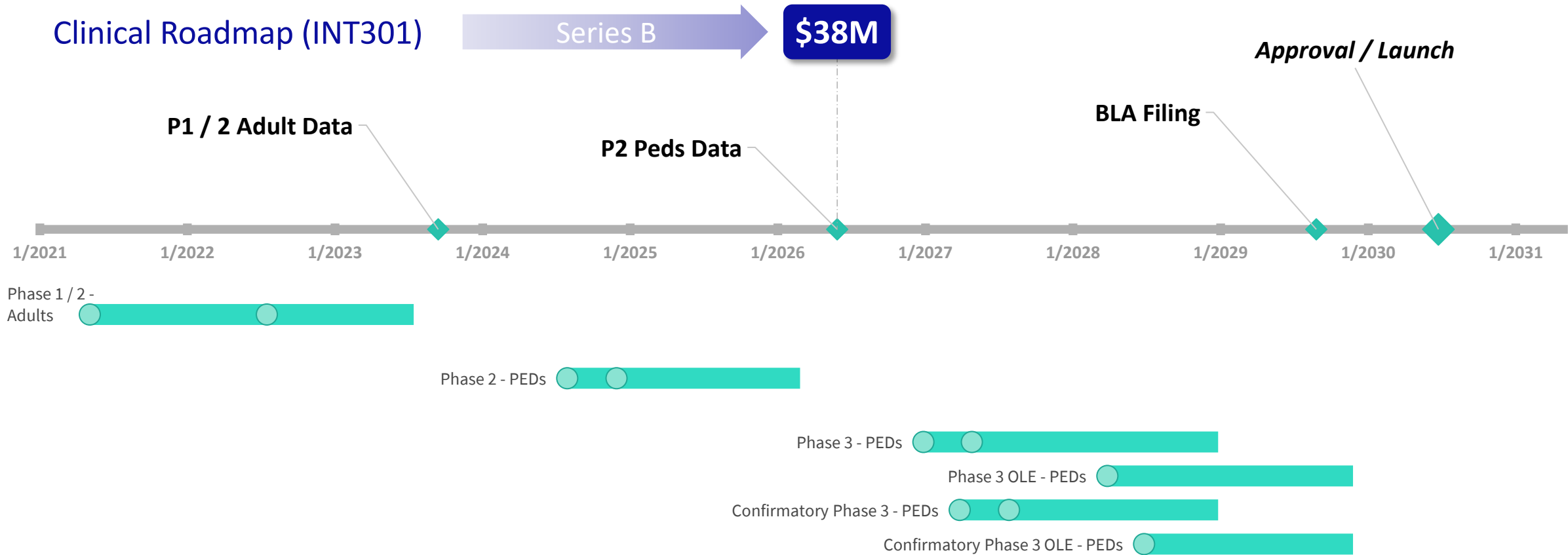
**Chemical Angel Network**

### Series B - \$38 Million

#### Goals

- Phase 2 clinical trial in pediatric population
- Finalize CMC processes, prepare for full commercialization
- Product development to expand to new applications
- Identify strategic and market opportunities
- Shape market & establish brand prior to launch

# Series B Funding Will Cover Phase 2 Studies



# Experienced Leadership Team

Experience successfully bringing innovation to market, including in biotech, pharma and allergy markets:



**Michael Nelson, JD**  
Chief Executive Officer



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



**Stuart Loesch**  
President & Chief  
Commercial Officer



**William Berger, MD, MBA**  
Head of Medical Affairs



**Alain Van Loo**  
Chief Operating Officer



**Wendy Perrow, MBA**  
Head of Innovation



**Nandini Murthy**  
Head of Regulatory



**Christopher Schuster, MBA**  
Chief Financial Officer

# Opportunity to Get in Early on Technology with High Expected ROI



## Intromune offers attractive opportunity that targets an established, reimbursed market

- ✓ **Large, growing market** with established reimbursement – Peanut allergy TAM of ~\$7B in U.S. alone
- ✓ **Multiple applications & opportunities** enabled by unique immunotherapy platform technology
- ✓ **Minimal competition** - Only one peanut allergy product ever approved for any food allergy
- ✓ **OMIT highly differentiated** vs. current OIT solution, with expected safety, efficacy & adherence benefits:
  - Intromune's Peanut INT301 is best-in-class agent – 9 in 10 subjects<sup>1</sup> will use
  - Opportunity to position as “maintenance product of choice” for those started on other immunotherapies
- ✓ **Comparator Aimmune acquired for \$2.6 billion** with Palforzia® product only 1 in 10 subjects<sup>2</sup> will use; administered via GI tract, has significant side effects, is difficult to administer, experiences poor patient adherence

# Disclosures



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# THANK YOU



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