



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



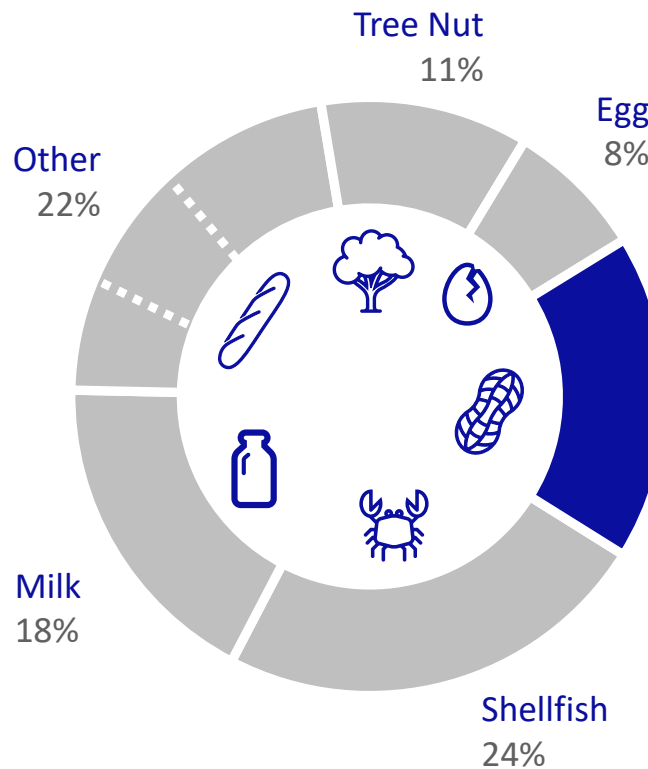
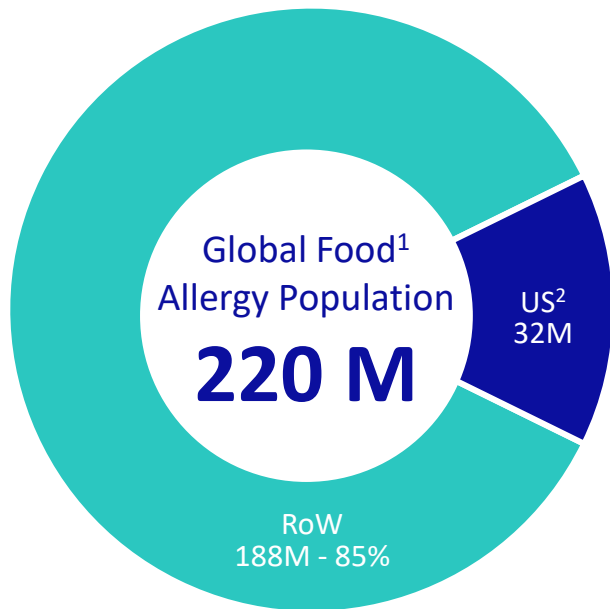
Opportunity

- **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

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 only³

1 FARE Facts and Statistics <https://www.foodallergy.org/resources/facts-and-statistics> Accessed January 27, 2023

2 Asthma and Allergy Foundation of America

3 Intrommune estimate

Significant Medical & Lifestyle Impacts



SEVERE HEALTH EVENTS

40-50%+

of people with food allergies have experienced a severe allergic reaction*¹



MEDICAL CARE

200,000

Americans require emergency medical care each year for allergic reactions to food¹



FEAR

92%

of parents feel fearful for their child's safety because of food allergies²



SOCIAL EXCLUSION

5 in 10

families with food allergies skip out on important school functions²



DISRUPTION

44%

of parents had to make a career change to care for their child with food allergies²



COST

\$25 Billion

spent annually by U.S. families caring for children with food allergies¹

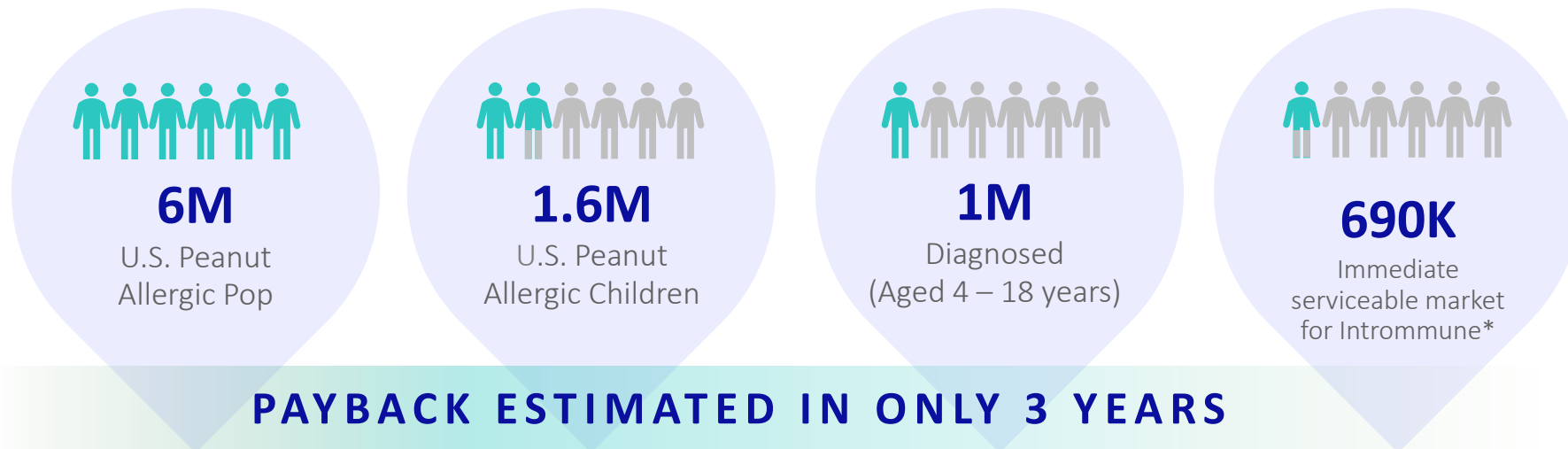
Food Allergies Represent a Multi-Billion Dollar Opportunity



PEANUT ALLERGY OPPORTUNITY

TAM	GROWTH	INSURANCE COVERAGE	OIT PRICE/YEAR PER PATIENT
\$7.4 Billion (U.S. market only)	Market forecasted to grow 1,700-fold from 2017 to 2027 ¹	Yes	\$10,680²

LARGE & GROWING UNMET NEED



PAYBACK ESTIMATED IN ONLY 3 YEARS

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

¹ GlobalData Peanut Allergy Report 2018

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

No Cure & Current Solutions Are Lacking

LIMITED LIFESTYLE SOLUTIONS

- Avoidance of problem foods
- Must anxiously anticipate and prepare for the next reaction (e.g., EpiPen®)



LIMITED IMMUNOTHERAPY SOLUTIONS

- Only one product ever approved for food allergy (Palforzia® for peanuts)
- Does not fully deliver on safety, ease of adoption, nor adherence:

Not Safe

- ~9.5% experienced anaphylaxis, which may be life-threatening¹
- 14% use of epinephrine reported in one Phase 3 pivotal trial¹
- >35% experienced moderate* treatment-related adverse events²

Adoption Barriers

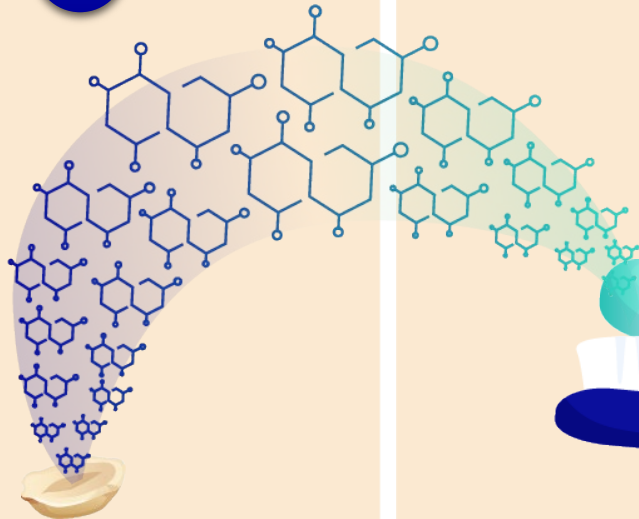
- Requires frequent visits to allergy clinic every 2 weeks for ~6 months
- 5-hour initial office visit; issue given lack of physician compensation
- Discontinuation rate of ~22%¹

Our Solution: Novel Technology Simplifying Allergy Immunotherapy



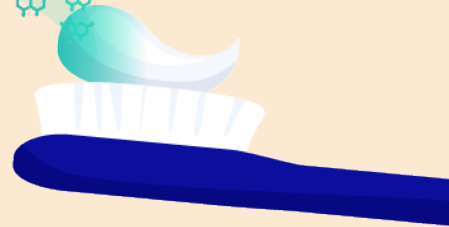
Food allergy desensitization transformed into easy-to-use platform via proprietary technology: Oral Mucosal Immunotherapy (OMIT)

1



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

2



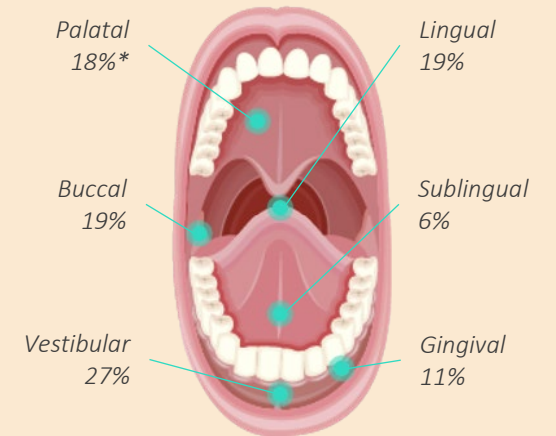
API stabilized & embedded
in functional toothpaste
in metered-dose dispenser

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

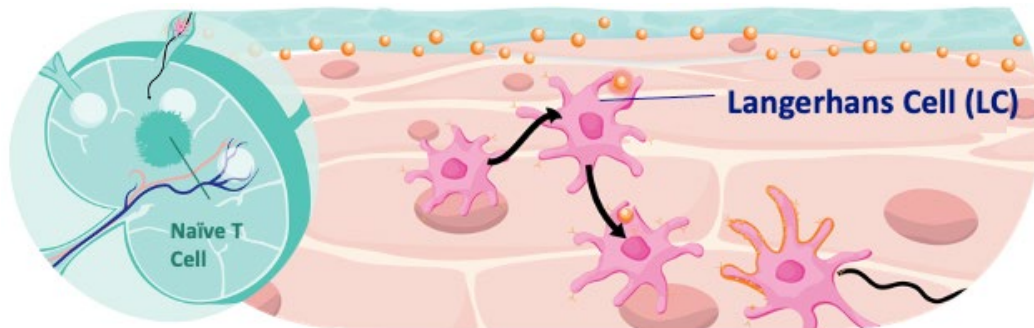
1

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



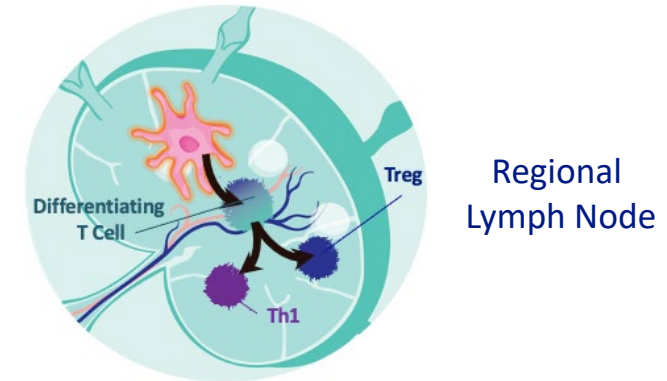
2

Langerhans cells pull allergenic protein into the lymph system



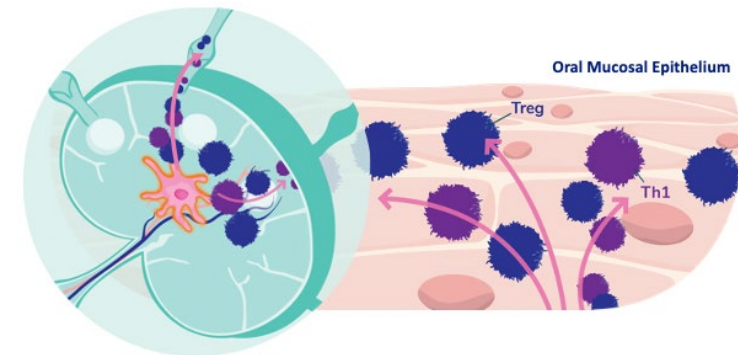
3

Langerhans cells trigger the reeducation of immune system



4

Differentiated T cells decrease the allergic response



Intrommune'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 / Intrommune (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

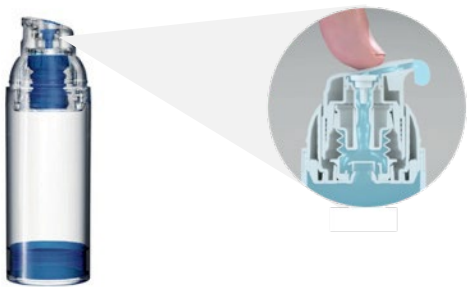
Development Substantially Advanced for Peanut Allergy Solution



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 objective provided indications of efficacy
- Due to impressive safety profile to date, FDA greenlit pediatric Phase 2 study prior to completion of our adult Phase 1 / 2 study

What is the OMEGA study?



OMEGA = Oral Mucosal Escalation Goal Assessment

- Randomized, double-blind, placebo-controlled Phase 1 / 2 study with INT301 in adults with peanut allergies

Objectives

- Evaluate the safety of INT301 compared to placebo
- Demonstrate adherence to investigational drug product
- Explore indications of efficacy
- Provide guidance for Phase 2 study





Designed to address FDA feedback

- Concerned that toothbrushing could result in micro abrasions
- Study conducted with adults first
- Eliminated participants that had severe anaphylaxis

Highlights from OMEGA Phase 1 / 2 Clinical Trial Results



Met primary and secondary endpoints – clinical data available

-  **Safety** 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

OMEGA Study Results Support Continued Development of INT301



Based on high absolute response data, favorable risk, ease of use, and adherence profile



Primary/Secondary Objectives

INT301 met all primary and secondary objectives

- Demonstrated safety of investigational product – majority of AEs mild with no severe AEs or anaphylaxis observed
- Demonstrated adherence of INT301
- No reported dental AEs



Exploratory Objectives

Provided documented indications of efficacy of investigational product INT301

- Indications of efficacy in a difficult to treat, adult population
- Indications of immune response in the INT301/active treatment arm
- Biomarker analyses support immunologic response and treatment effect



Learnings

Learnings provide direction to optimize Phase 2 pediatric study

- Expect greater effect size based on learnings and experience of other investigators
- Strong foundation provided for moving into Phase 2

Go-to-Market Plan Targets Allergists Seeking FDA-Approved Solutions



Target is the large number of allergists who currently do not treat food allergies due to lack of safety, legal risk & complicated dosing protocols



~300 Allergists

Prescribe off-label “home-brew” food allergy solutions



~6000 Allergists¹

Lack FDA-approved solutions with strong efficacy/safety profile to offer their food allergy patients

 = ~200 allergists/immunologists

Targeted, Highly Efficient Demand Generation Model



Shape the Market

Drive awareness and interest in OMIT as a new & better solution

- Activate MSLs 2-2.5 years in advance
 - Medical conferences
 - KOL engagement
 - Publications
 - Webinars/presentations
 - Educational web content
- PR & social/influencer marketing to patients 12-18 months in advance



Drive HCP Recommendations

Influence top prescribers & thought leaders amongst ~6000 targeted allergists

- 80-person sales force will cover 70-80% of target universe
- Leverage rent-to-own sales model
- Start with smaller # of high-prescribers at high call frequency, then expand reach over time
- Focus on the large allergy practices (such as Allergy Partners and Family Allergy) to drive quick, targeted uptake



Ignite Consumer Demand

Engage directly with consumers to get them to ask a doctor for INT301

- DTC advertising (once critical mass of HCP awareness achieved)
 - Geo-targeted TV & digital ads
 - Lead capture, email nurture, local doctor finder
- Augment with in-office promotion
 - Promotional materials
 - QR code linked to website

Competitively Differentiated Business Model Will Drive HCP Support

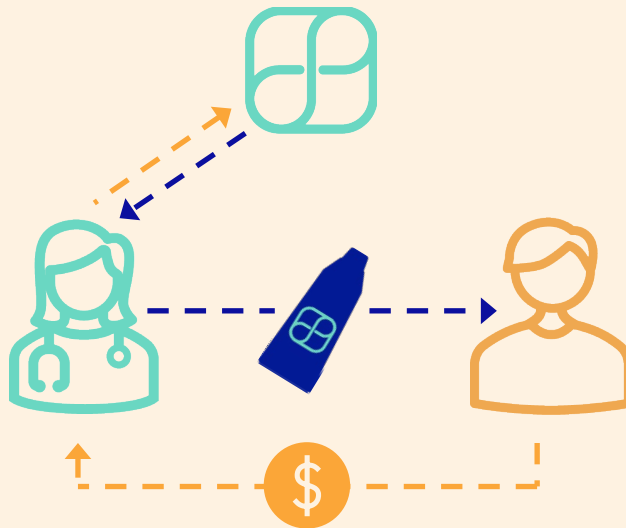


Buy and bill model during initiation/updosing, transitioning to Rx mail order for maintenance

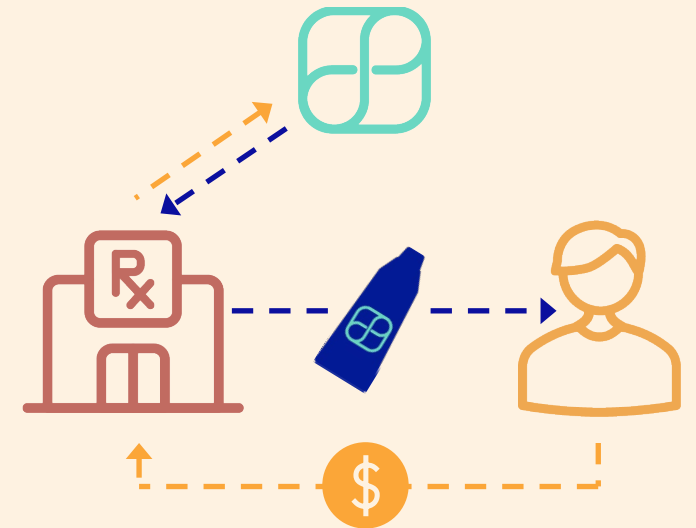
Food allergy confirmed via test*; doctor prescribes Intromune INT301



HCP sells to patient in-office via “buy & bill” model for initiation & updosing



Transitions to prescription mail order pharmacy for maintenance



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



SEVERAL PATENT FAMILIES

- Immunotherapy via multiple oral care modalities
- Formulations to stabilize allergens
- Provisional applications filed - confidential



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

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



Intrommune 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:
 - Intrommune’s Peanut INT301 is best-in-class agent – 9 in 10 subjects¹ 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 subjects² 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

Contact us for more information
and partnering opportunities

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The background features a gradient from light teal on the left to dark blue on the right. A pattern of white hexagons is overlaid, with some hexagons containing small teal dots at their vertices, resembling a molecular or network structure.

Additional OMEGA Clinical Study Details