

# ALLERGENIS OVERVIEW

Global AgInvesting Webinar

March 17, 2021

# 1 OUT OF 4 AMERICAN CONSUMERS

DON'T BUY PRODUCTS THAT CONTAIN THE  
**TOP 9 FOOD ALLERGENS**



**9 MAJOR PROTEINS**  
that trigger allergic reaction

**85**

**MILLION AMERICANS**  
avoid purchasing food with the  
**top 9 allergens** and spend

**\$19**  
**BILLION**  
annually

**32**

**MILLION AMERICANS**  
are at risk of anaphylaxis,  
a **life-threatening**  
**allergic reaction,**



Nutrition Facts

## CONSUMER RESEARCH SHOWS

**“I need  
to be able to  
find allergen  
labels prominently and easily.”**

~ Food Allergy Mom

**71%**

check food labels  
every time they shop —  
some for 3–5 minutes  
per product

**68%**

trust allergy-friendly  
brands

**27%**

Compound annual  
growth rate (CAGR)  
for allergy-friendly food

**53%** want clearer and  
consistent food  
allergen labeling

Food allergy consumers reward companies that provide clear, consistent labeling and affordable products that keep them safe & save time & money

[foodallergy.org](http://foodallergy.org)

# CONSUMER IMPACT

- 85 Million US consumers don't buy products containing the top 9 food allergens
  - Spend \$19 Billion annually on allergy-friendly food
- Research shows
  - 71% check labels every time the shop
    - 3 to 5 minutes per product
  - 68% trust allergy-friendly brands
  - 27% Compound annual growth rate (CAGR) for allergy-friendly food

“Back at the beginning,  
I sold a lot of my  
belongings along with  
receiving food stamps  
and WIC just to afford  
food, as you can't use  
food banks when you  
have allergies. They  
think it's a luxury.  
For us, it's life.”

~ Food Allergy Mom, with annual  
income <\$5K

Food allergy consumers reward companies that provide clear, consistent labeling and affordable products that keep them safe & save time and money





# OUR FOUNDING PRINCIPLE

*AllerGenis believes individuals and families living with food allergies should feel safe, in control and have the same quality of life as the rest of the community.*

# THE OPPORTUNITY

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## Market

- **30 Million Americans are diagnosed with Food Allergies**
  - Over **5 million children** with highly **engaged parents/care-givers**
    - *More than **60% over-diagnosed***

## Platform

- AllerGenis has a proprietary and disruptive blood-based technology solving current clinical unmet needs
  - **Created by the World's top food allergy expert** dedicating over 20 years of research to the solution (cited more than any other thought leader globally)
  - Intellectual Property is secured and growing
  - **In Market peanut diagnostic test; second product in final development**

## Providers

- **Concentrated target market:** 3,000 Allergists treating patients with food allergy
- **Test enables their practice**
  - Better outcomes
  - Financial benefits

## Raising \$15 Million

- Capture **market share** & advance commercial launch
- Accelerate **product development** & secure **FDA regulatory approval**

# WHAT LEADS TO OVERDIAGNOSIS?

## No or Ambiguous History

- Ordering IgE testing in individuals without a history consistent with or suggestive for food allergy frequently reveals positive tests that are unlikely to be clinically relevant.

## Food Panels

- Ordering panels of food tests leads to many incorrectly identified food allergies and inappropriate recommendations to avoid foods that are positive on testing.

## Test Performance

- Current skin or serologic testing for specific-IgE to food antigens has excellent sensitivity and high negative predictive value but low specificity and low positive predictive value.

Bernstein LE, Li JT, Bernstein DI, et al. Allergy diagnostic testing: an updated practice parameter. *Ann Allergy Asthma Immunol.* 2008;100(3 suppl 3):S1-S148.

NIAID-Sponsored Expert Panel, Boyce JA, Assa'ad A, Burks AW, Jones SM, Sampson HA, et al. Guidelines for the diagnosis and management of food allergy in the United States: report of the NIAID-sponsored expert panel. *J Allergy Clin Immunol.* 2010;126(6 Suppl):S1-S58.

American Academy of Allergy, Asthma & Immunology. "Ten Things Physicians and Patients Should Question." Retrieved from: <https://www.choosingwisely.org/societies/american-academy-of-allergy-asthma-immunology/>

# ALLERGENIS' TEAM FORMED TO SOLVE THESE UNMET NEEDS

Current diagnostic tools fall short, are impractical, and risky

## Skin and Serologic Testing Inadequate

- Current skin or serologic testing for specific-IgE to food have low specificity and low positive predictive value **leading to inconclusive test** results and **overdiagnosis** (OD)

## No Surrogate for Food Challenges

- The most accurate tests – food challenges – exact an **unnecessary toll of stress and potential dangers**
- There is an expressed need across stakeholders for a **surrogate for oral food challenges** both in clinical practice and in therapeutic trials to assess response to therapy over time – most allergists do not perform food challenges due to risks

## Lack of Prognostic Biomarkers

- A need to **predict allergy resolution** or **outgrowth**
- The ability to stratify likely responders and non-responders prior to therapy and those likely to experience **sustained unresponsiveness post-therapy**

Source: Parthenon-EY Interviews; AllerGenis Focus Groups and Advisories; FARE: Strategic Plan 2020

# ALLERGENIS' PORTFOLIO OF TESTS ADDRESSES EACH UNMET NEED

Unique to AllerGenis

TEST TYPE	VeriMAP™ Diagnostic	VeriMAP Reactivity Threshold	VeriMAP Outgrowth	VeriMAP Form	VeriMAP Response
<b>Intended use</b>	To be used to confirm a patient's food allergy status	To determine the amount of allergen protein causing a clinical allergic reaction	To predict likelihood of future allergy outgrowth	To identify reactivity to specific forms of milk or egg allergen (baked, raw)	To assess progression of desensitization during therapy and post-therapy
<b>Products Addressing Current Food Allergy Testing Unmet Needs</b>					
<b>Replaces Current Skin and Serologic Testing</b>	✓				
<b>Surrogate for Oral Food Challenges</b>	✓	✓		✓	✓
<b>Fills clinical question otherwise unanswered</b>		✓	✓		
<b>Prognostic Biomarker</b>			✓		✓

VeriMAP™ establishes product branding

No competitive blood tests

# AllerGenis is at the Forefront of Bringing Data Analytics to the Food Allergy Community

OFC Results

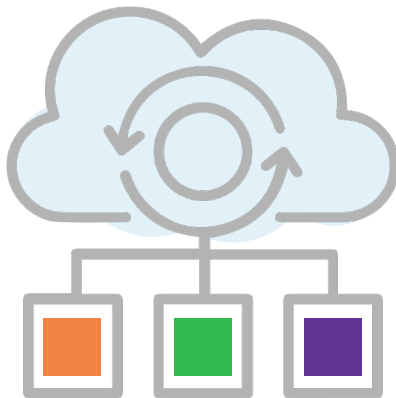
Add-on Epitope Services

*(Sensitivity & Diagnostic Predictors)*

Historical Data

Demographics

*(Age, Gender, etc)*



Allergen

*(Peanut, Milk, Egg, etc)*

Therapy

*(AIT)*

Measurements

*(sIgE, CRD, Epitopes, SPT, etc)*

Comorbidities

*(Asthma, Eczema, etc)*

Provides **LARGE-SCALE DATA MINING** of Clinical Insights





**COVERING  
THESE KEY  
ELEMENTS OF  
THE  
BUSINESS**

- 1. Proven team**
- 2. Market opportunity**
- 3. Technology: AllerGenis platform**
- 4. Business plan summary**

# ALLERGENIS LEADERSHIP TEAM

*Leaders and experts in scaling and divesting enterprises, as well as developing clinical diagnostics, sales & marketing, and regulatory affairs responsible for commercializing diagnostic products currently in use.*



**Jim Garner, CEO and Board Member**  
30 years of successful leadership experience in life science commercializing, distributing, and licensing over 40 diagnostic products and services, and central in four mergers & acquisitions.

**Russ Fein, CFO and Board Member**  
Over 30 years of M&A, finance experience on over 20 transactions, with operations experience holding C-level roles at 10 companies and has led three exits. On the board, Russ represents Corporate Fuel.

**Thomas Vollmers, Head of Strategic Partnerships & Commercial Strategy**  
Accomplished leader with more than 30 years industry and domain expertise in precision medicine and companion diagnostics responsible for commercializing seven diagnostic products.

**Paul Kearney, PhD, Head of Product & Clinical Development**  
20 years of deep expertise in bioinformatics, study design, and product development. Developer of five complex, high value diagnostic products currently in clinical use, and pivotal in three exits.



**Bob Getts, PhD, Chief Scientific Officer**  
Over 25 years of biotech research and development experience focused on biologic assays and reagents, culminating in 13 products, as well as scaling three life science businesses.



**Cindy Yule, Business Analyst**  
Cindy brings over 15 years expertise in financial modeling, planning, and sales forecasting.



**Bill Pignato, Regulatory Affairs**  
35 years of strategic global regulatory affairs experience bringing more than 60 diagnostic products to market.

# ENGAGED BOARD OF DIRECTORS

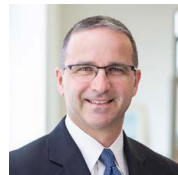
*Experts in clinical diagnostics, consumer marketing, and leaders responsible for developing and commercializing the diagnostics currently used in the food allergy testing market.*



## **Hugh A. Sampson, M.D., Creator of AllerGenis Technology**

Dr. Sampson is the world's leading expert in food allergy diagnosis, treatment, and management, and the most cited clinician and researcher in the field. Hugh pioneered with Phadia the development of ImmunoCAP and dedicated the next two decades of his research on the diagnostic technology deployed by AllerGenis.

Dr. Sampson is DBV Technologies' Chief Scientific Officer and the Kurt Hirschhorn Professor of Pediatrics at the Icahn School of Medicine and Mount Sinai & Director of the Jaffe Food Allergy Institute. He is Director and PI of the NIH-sponsored CTSA program, and PI of the NIH-sponsored Consortium of Food Allergy Research.



Phadia



## **David Esposito, Board Member**

David brings relevant expertise and experience to AllerGenis having served as President of Phadia US Inc. (allergy and autoimmune diagnostics), where he played the pivotal role in the sale of the business to Thermo Fisher Scientific.

Most recently, David was President and CEO of Armune BioScience, a diagnostic company focused on prostate, lung, and breast cancers, acquired by Exact Sciences.

He is currently President and CEO of ONL Therapeutics.



Jazz Pharmaceuticals



GlaxoSmithKline



MERCK

## **Kim Sablich, Board Member**

Kim offers AllerGenis her experience marketing to caregivers of pediatric patients in the field of allergy. In addition, throughout her 23-year career she has either led or/and supported commercial teams with a heavy focus on both physician and consumer marketing.



## **Vijay Aggarwal, PhD, Chairman**

With over 35 years of experience in both pharmaceutical services and clinical diagnostics Vijay offers strategic insights in supporting AllerGenis' executive team. As former President of Quest Diagnostic Ventures, he had responsibility for new technology, new business models, clinical trials testing, direct-to-consumer strategies, and served on the Executive Management team of Quest Diagnostics.



# DIAGNOSTIC OPPORTUNITY

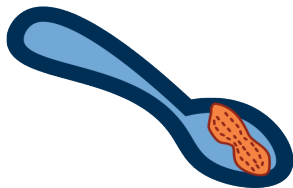
# THE EVOLUTION OF DIAGNOSTIC ALLERGY TESTING

Skin Prick Test



1959  
Provocation Testing

Oral Food Challenge



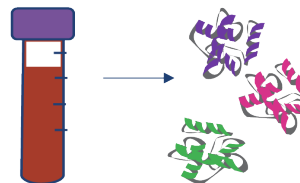
1976

sIgE blood test



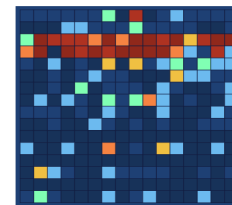
1989  
1974 (RAST)

Component-Resolved  
Diagnostics



2009

Precision Diagnostics

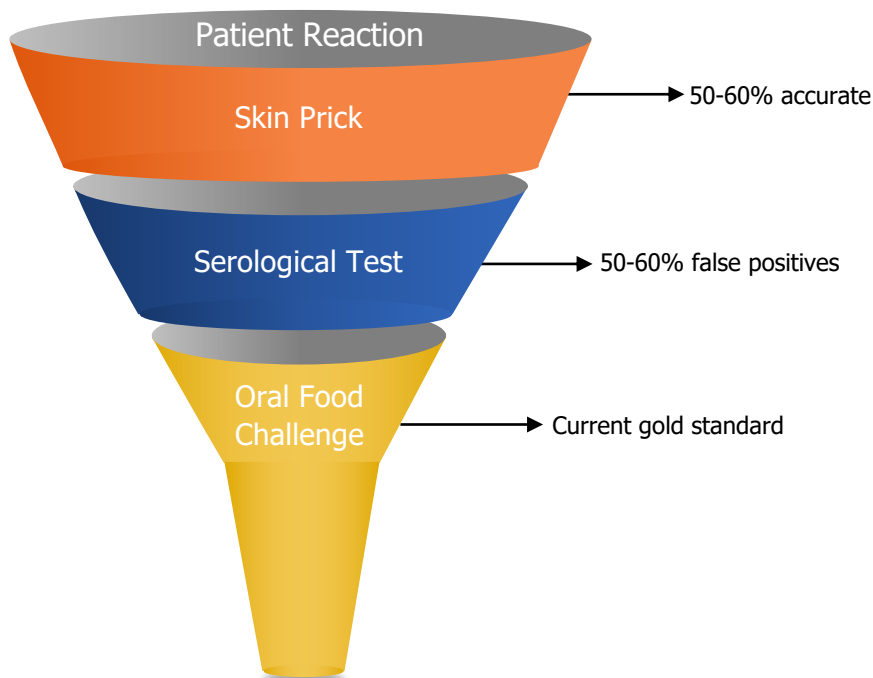


2020 and Beyond

1. Allergic Reactions Occur at the Individual Epitope Level on the Allergen Protein
2. Prior Technologies Monitor Reactions at the Whole Allergen Level Reducing Their Accuracy
3. The AllerGenis Platform Enables the Monitoring of Individual Epitopes Resulting in Unmatched Accuracy

# THE CURRENT ALLERGY DIAGNOSTIC PROCESS IS EITHER INACCURATE OR IMPRACTICAL

## The Current Allergy Diagnostic Process



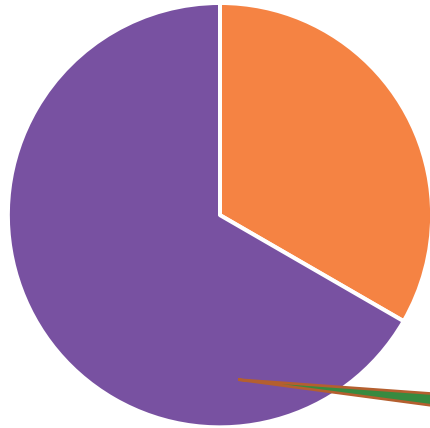
Negative results almost always mean that you are not **allergic** to a food. Positive **tests**, however, are not always **accurate**. About 50-60 percent of all SPTs yield “false positive” (Source: *Food Allergy Research*)

“A positive IgE test result is not a diagnostic for food allergy. They have high rates of falsely elevated and meaningless results and are not useful screening tools;” (Source: *David Stukus, MD, National Children’s Hospital*)

OFC is the gold standard, but is expensive, time consuming for both practice and patient, and potentially dangerous. Only performed in academic hospitals and/or select allergy practices. (Source: *Dx of Food Allergies and Role of OFC, March 2016*)

# CURRENT INACCURATE TESTS RESULT IN OVERDIAGNOSIS CAUSING UNDO STRESS, AND ANXIETY

## Prevalent Peanut Allergy Patient Population



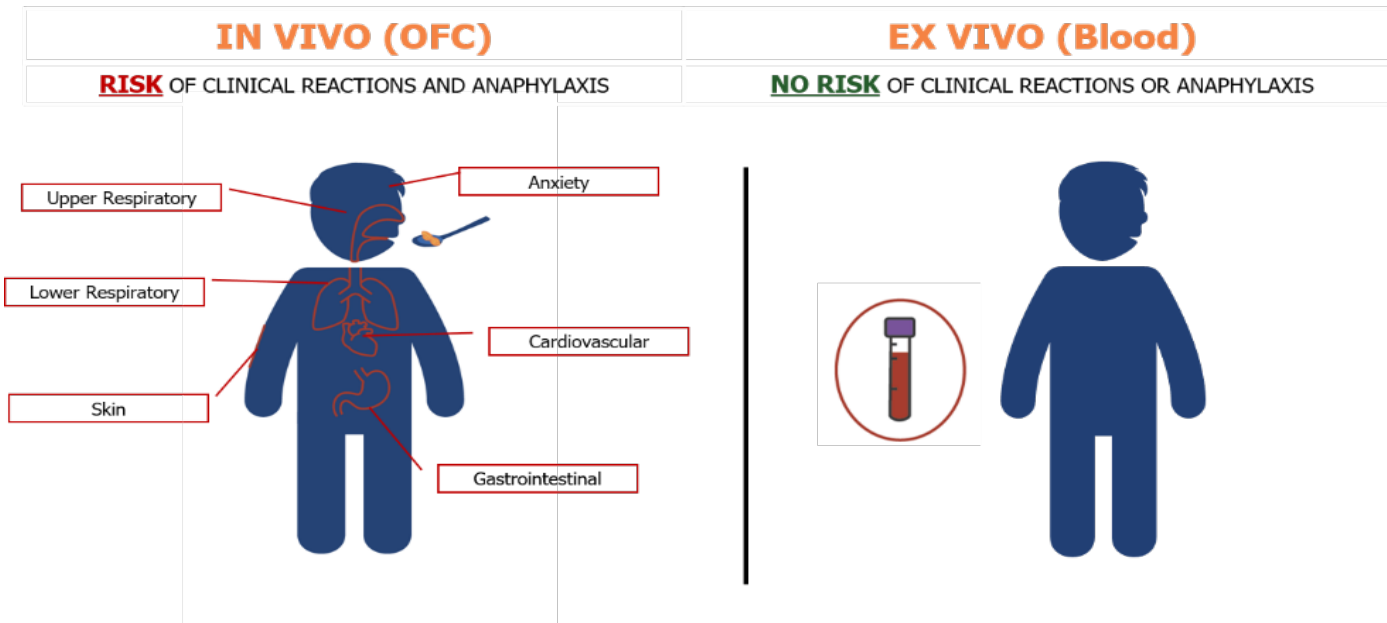
■ Allergic ■ False Positives

- 30 million people in the U.S. are diagnosed with a food allergy, 5 million are children
- Annual cost of food allergy in the U.S. over \$25 Billion – a significant burden to families
- Without accurate diagnosis, diminished quality of life persists unnecessarily due to high stress and anxiety levels of children and parents.

Up to 840,000 children are living with a misdiagnosis of peanut allergy in the U.S.

Gupta RS, Springston, EE, Warrier, MR, et al. The prevalence, severity, and distribution of childhood food allergy in the United States. *Pediatrics*. 2011;128(1).  
Bird JA, Crain M, Varshney P. Food allergen panel testing often results in misdiagnosis of food allergy. *J Pediatr*. 2015;166(1):97-100.  
Gupta RS, Holdford D, Bilaver L, et al. The economic impact of childhood food allergy in the United States. *JAMA Pediatr*. 2013;167(11):1026-1031.  
Food Allergy Research & Education. "Blood Tests." Retrieved from: <https://www.foodallergy.org/resources/blood-tests>.

# OUR GOAL IS FOR THE VERIMAP TESTING PLATFORM TO BE AN “EX VIVO” ALTERNATIVE TO ORAL FOOD CHALLENGE (OFC)



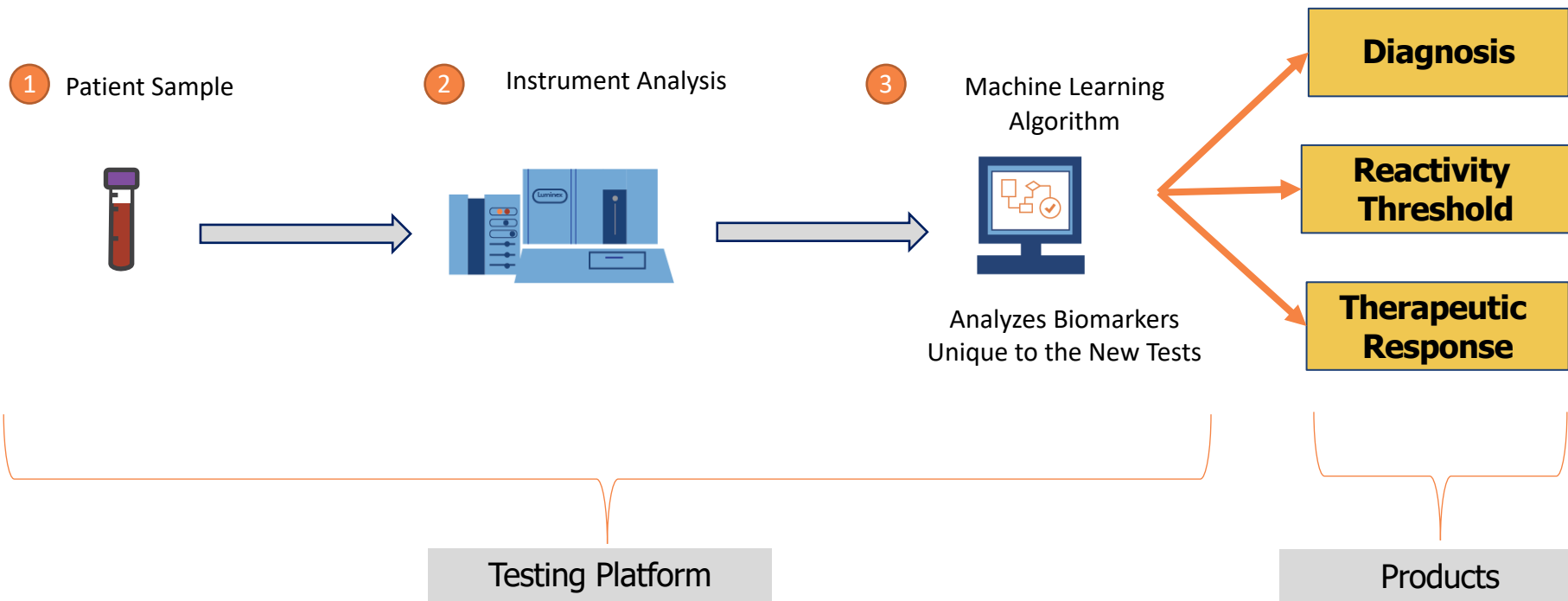
Enabling routine, safe, and accurate diagnosis and assessment of food allergy status across the continuum of care





**THE SOLUTION:**  
**THE ALLERGENIS PLATFORM & PRODUCTS**

# ALLERGENIS PLATFORM AND PEANUT PRODUCTS



# DEVELOPMENT OF THE VERIMAP™ PEANUT SUITE

FA Assessment – Rx agnostic

Assessment of Desensitization

1

2

3

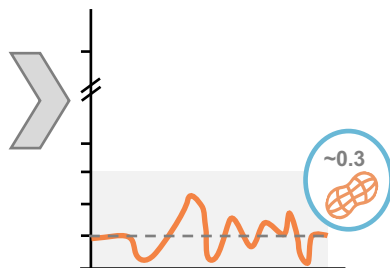
VeriMAP™ Peanut Dx

VeriMAP™ Peanut RT

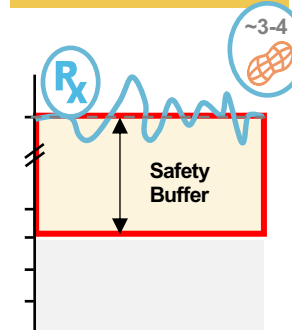
VeriMAP™ Peanut Rx Response

**Intended Use:** This test is to be used to confirm a patient's peanut allergy status in conjunction with other clinical findings

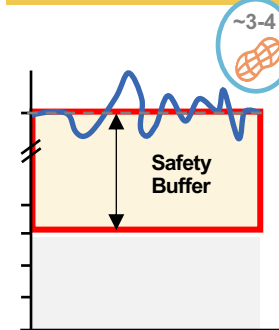
Baseline Reactivity Threshold



Maintenance Period



Post-Therapy



**Intended Use**

- Determine amount of peanut protein (eliciting dose) at which a patient has an allergic reaction prior to therapy
- Assess changes in eliciting dose due to therapy during the maintenance period
- Assess sustained unresponsiveness or tolerance post-therapy

# PIPELINE STATUS

- Peanut product launched and others in the family maturing to commercialization
- Milk and Egg panels are complete and verified on multiple cohorts
- Tree nuts, wheat and other allergen panels are in development

VeriMAP™ Peanut	Research/Biomarker Discovery*	Assay Development	Analytical Validation	Clinical Validation	Commercial Launch
Peanut Diagnostic	✓	✓	✓	✓	✓
Reactivity Threshold	✓	✓	✓	✓	●
Rx Reponse	✓	✓	✓	○	●
<b>VeriMAP™ Milk</b>					
Milk Diagnostic	✓	✓	○	○	●
Reactivity Threshold	✓	✓	○	○	●
Milk Form	✓	✓	○	○	●
Milk Outgrowth	✓	○	○	○	●
Rx Response	✓	○	○	○	●
<b>VeriMAP™ Egg</b>					
Egg Diagnostic	✓	✓	○	○	●
Reactivity Threshold	✓	○	○	○	●
Egg Form	✓	○	○	○	●
Egg Outgrowth	✓	○	○	○	●
Egg Rx Response	✓	○	○	○	●

\*Epitope Panel Identification



# THE MARKET OPPORTUNITY

## VAST AND GROWING

# WE ARE FOCUSED ON “THE BIG THREE”

*Three foods account for 80% of initial pediatric food allergies, physician encounters, and diagnostic testing*

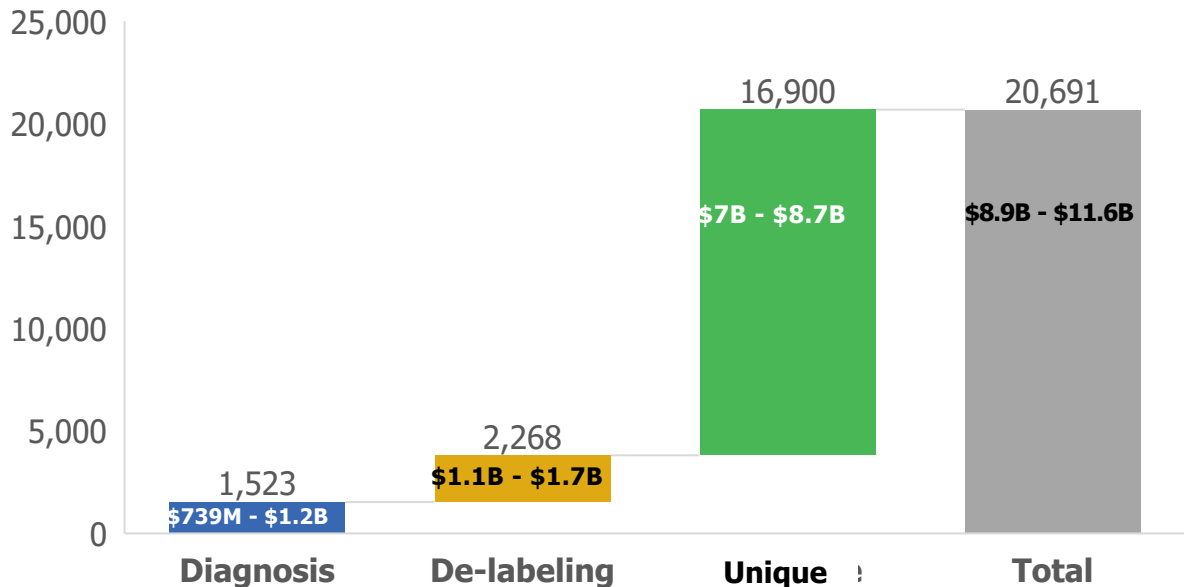


Jiang J., Warren C.M., Gupta R.S. (2020) Epidemiology and Racial/Ethnic Differences in Food Allergy. In: Gupta R. (eds) Pediatric Food Allergy. Springer, Cham

# MARKET OPPORTUNITY INCLUDING MONITORING TESTING EVENTS

VeriMAP Diagnostic tests and additional unique tests enable significant increased testing events and revenue

The Big 3 Food Allergens (Annual Serologic Testing Events/\$USD)



## Definitions

- **Diagnosis:** Testing events associated with current serologic testing (sIgE, CRD) used to diagnose and monitor allergic status
- **De-labeling:** Testing events associated with the use of VeriMAP Diagnostic as a surrogate for OFC to correctly classify patients with inconclusive test results obtained from current skin and serologic testing methods (SPT, sIgE or CRD)
- **Unique:** Testing events associated with new indications using AllerGenis tests which cannot be assessed using current skin, serologic, or OFC testing methods

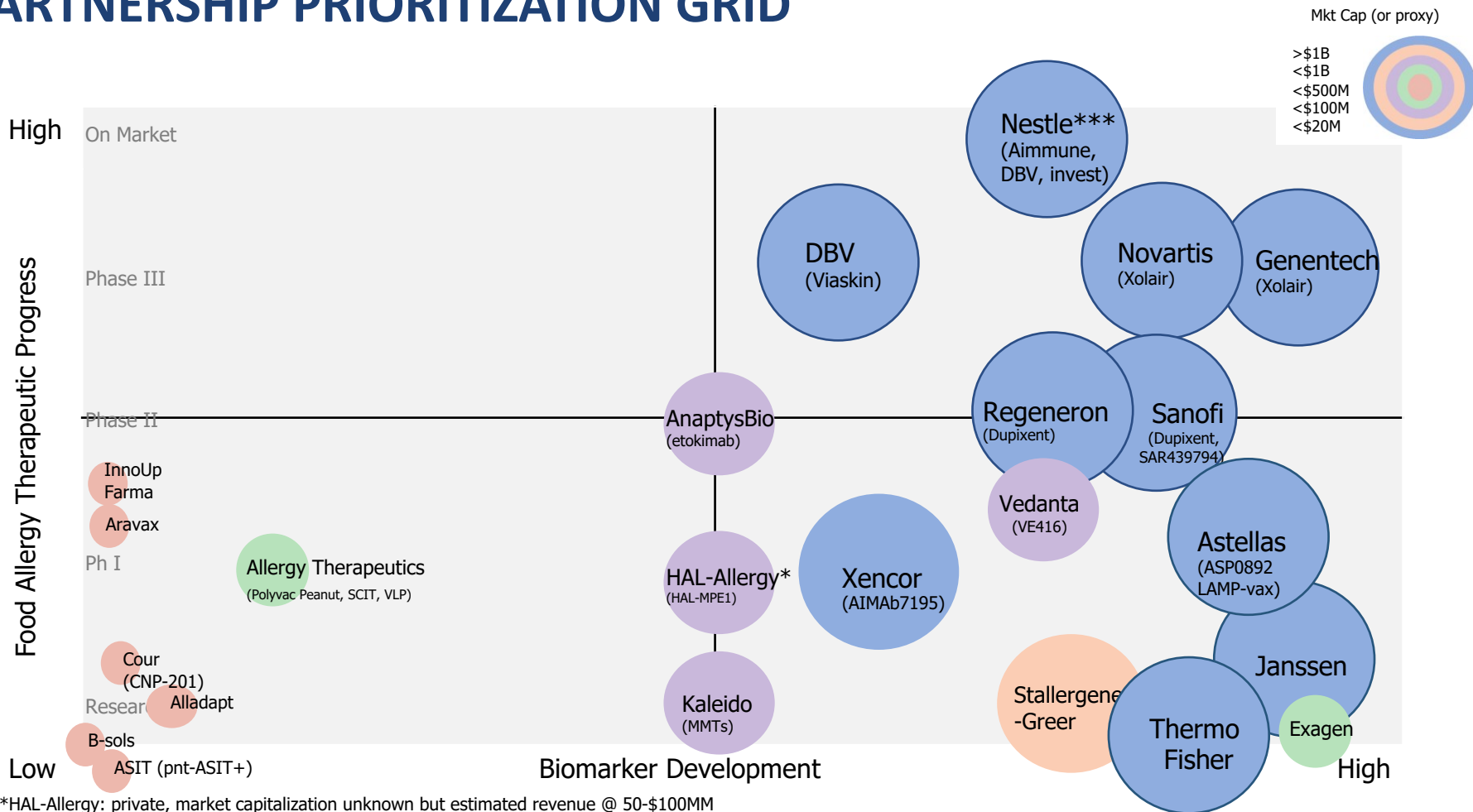
Sources: Parthenon-EY Interviews; Parthenon-EY Analysis and internal AllerGenis Market Analysis Based on Publicly Available Information from Aimmune's Peak Market Opportunity



# RX COLLABORATION TARGETS



# PARTNERSHIP PRIORITIZATION GRID



\*HAL-Allergy: private, market capitalization unknown but estimated revenue @ 50-\$100MM

\*\*\*Nestle placement due to Before Brands investment, DBV partnership and AIMMUNE (Palforzia) acquisition



# INVESTMENT OPPORTUNITY: **SEEKING \$15M**

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# FOUR-YEAR INVESTMENT & BUSINESS PLAN

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Series A enables execution of Allergenis' short-term business plan:

- Scaling commercial operations, revenue generation, & profitability
- Accelerate and advance robust product development pipeline & process
- FDA regulatory approval of LDT
- Increased valuation & attractive exit

# VALUATION INFLECTION POINTS

Scientific discovery	1998 - 2017
Analytical validation	✓ 2018
Clinical validation (surrogate for OFC)	✓ 2019
Regulatory Approval CLIA (required) FDA approved LDT (value add)	✓ Q2 '20 <i>Underway</i>
Commercial launch	✓ Q3 '20
Execution of business plan	✓ Q3 '20
Government and private payer approval	2022
Guidelines inclusion	2023
Expanded product offering(s)	On-going
Collaborations with therapeutics	On-going
Strategic mergers/acquisitions	2024

# RISK MITIGATION MEASURES

<b>Discrete Addressable Market:</b> 3,000 Allergists; products complement their clinical work-up	✓
<b>Broad Product Suite with Multiple Assays:</b> Test/platform applies to full panel of food allergens	✓
<b>Reimbursement Established:</b> Clear Path to Revenue Generation	✓
<b>Clear FDA Strategy:</b> Leverage traditional 510k; early approach	✓
<b>Access to Clinical Cohorts:</b> Clinical Studies with prospective collection of specimens for product development	✓
<b>Platform:</b> Luminex license in place; global install base; high throughput instrument	✓
<b>Robust IP Portfolio:</b> Mount Sinai in-license in place; multiple new patent applications; significant know-how	✓
<b>Early Partnering:</b> DBV collaboration well established; others evolving and expected	✓

# EXIT CONSIDERATIONS

**Timeframe:** Over next 3 to 4 years, the business will be positioning for an attractive exit

## **Multiple Potential Exit Scenarios:**

- Industry Buyer: Prime candidate as a strategic target
  - *Thermo Fisher* – to improve product offering & prevent our eroding allergy market share
  - *Perkin Elmer/Roche/Siemens etc.* – Competitors to Thermo Fisher (Phadia)
  - *DBV/Genentech/Novartis/Sanofi-Regeneron etc.* – to supplement their immunotherapies/therapeutics
  - *Nestlé/Aimmune* – to enhance their existing capabilities and augment their food allergy focus
- Financial Acquirer: Strong performance will attract financial buyers
- IPO: Given emotional nature of product and market, greater scale will make Allergis a strong IPO candidate

## **Strong Valuation Comp:**

Thermo Fisher acquired Phadia for **\$3.5 Billion** (7x revenues and 17x EBITDA)

Nestlé Health Science acquired Aimmune for **\$2.6 Billion**

# PROGRESS UPDATE

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- **We have an in-market product**
  - The company began clinical testing in our CLIA laboratory
  - Initial providers include over 51 allergists in 19 food allergy centers of excellence
- In addition to the initial test for the diagnosis of peanut allergy, the second test in this suite of test offerings is in final development
  - This test provides a quantitative determination of the level of sensitivity to peanuts and should find application as patients are considered for active therapy of their food sensitivity
- Allergenics has continued to deepen support from a panel of the leading thought leaders in food allergy and have utilized their advice in development of follow-on test offerings
- Our development partnership with a leading therapeutic company has successfully passed another significant milestone towards a complementary diagnostic
- Our research has discovered a unique patentable epitope that has shown significant potential as a therapeutic target

# SUMMARY

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- Proven team raising \$15M Series A to scale commercial company
- Vast & growing addressable market through established relationships/channels
- Exclusive technology addresses unmet clinical needs
- De-risked executable & realistic plan to achieve significant exit