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Investor Presentation • Jan 2023

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Diagnostic Guided Therapy

Using Science, Diet and Technology
to Revolutionize the GI Market

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Investment Highlights

Disruptive Patented Platform Technology redefining the GI Market

First ever FDA-regulated diagnostic therapy

Large Growing Market

- $30+ Billion expansive market opportunity
- Robust patent portfolio (11 issued patents; 100+ patents pending)

Significant Milestones Driving Growth

- InFoods® IBS clinical trial complete & LDT launch planned
- H. Pylori antigen test approval & launch
- ez+detect (Colon Disease Test) & Aware (Breast Exam)

Conservative Capital Structure

- ~18% Insider ownership
- No warrants, no preferred equity and no debt

Depth of Scientific Leadership

- SAB Leadership includes US Members of the Rome Foundation
- Clinical studies lead by principal investigators who set GI “treatment guidelines”

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Leadership, Board & Depth in Science

Management



ZACK IRANI
- Chief Executive Officer & Chairman
- Previous CEO & Chairman of Lancer Orthodontics Inc.



ALLEN BARBIERI
- Executive Vice Chairman
- Previous CEO of numerous public and private companies
- Board member at CareTrust REIT



STEVE SLOAN
- Chief Financial Officer
- Previously held various roles at General Electric and Medtronic

Board of Directors

Cathy Coste, CPA

Jane Emerson, MD, PhD

Mark Sirgo, PharmD

Scientific Advisory Board



DOUGLAS DROSSMAN, MD
- President Emeritus, Rome Foundation
- Co-Director Emeritus, UNC Center for Functional GI and Motility Disorders



LIN CHANG, MD
- Professor of Medicine, UCLA, Division of Digestive Diseases
- Rome Board member
- Served on FDA GI advisory panel



WILLIAM CHEY, MD, AGAF, FACG, FACP
- Professor GI & Nutrition Sciences, Univ. of Michigan
- Rome Board member
- Co-Director Michigan Bowel Program



WILLIAM WHITEHEAD, PHD
- Director, UNC Center for Functional GI and Motility Disorders



ANTHONY LEMBO, MD
- Harvard Medical & Beth Israel Deaconess Medical Center
- Associate Editor of Journal of Clinical Gastroenterology and Digestive Diseases and Science

Principal Investigators or Collaborators for:

Linzess

Xifaxan

Linzess
Viberzi
Xifaxan

amitiza lubiprostone

Linzess
Viberzi

InFoods® Principal Investigators

WILLIAM CHEY, MD, AGAF, FACG, FACP
- University of Michigan – Ann Arbor
- Director of the Digestive Diseases Center
- Co-Author of ACG Guidelines

ANTHONY LEMBO, MD
- Harvard – Beth Israel Deaconess Medical Center

TISHA LUNSFORD, MD
- Mayo Clinic
- Director of the Motility Interest Group

BRIAN LACY, MD, PHD
- Mayo Clinic
- Current co-Editor in Chief of the American Journal of Gastroenterology
- Co-Author of ACG Guidelines

EAMONN QUIGLEY, MD
- Chief, Division of Gastroenterology and Hepatology at Houston Methodist

BROOKS CASH, MD, AGAF, FACG, FACP, FASGE
- Chief of Gastroenterology, University of Texas Health Science Center at Houston

University of Michigan Health System

HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

MAYO CLINIC

MAYO CLINIC

Houston Methodist

UTHealth | McGovern Medical School

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Background & Innovation

Leveraging diagnostic expertise to transition into diagnostic-guided therapeutics

Specialty diagnostics *enabling early disease detection and monitoring*

- Two FDA, CE, CFDA registered manufacturing facilities in California and Mexico
- Commercially launched FDA cleared diagnostic tests

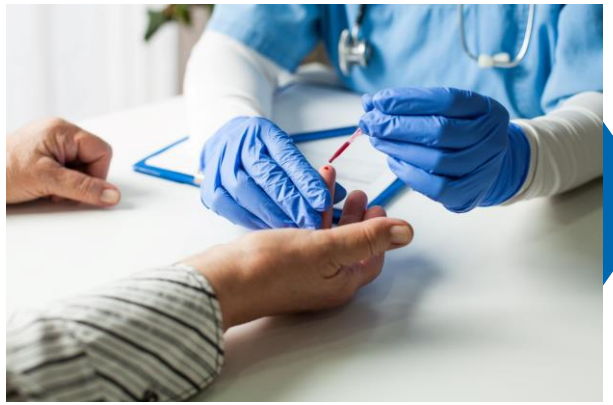
Disruptive patented technology platform *enabling diagnostic therapies*

- Redefining the treatment of GI diseases
- Also applicable for treating non-GI chronic inflammatory diseases
- Gross margin opportunities similar to drugs

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InFoods® – Diagnostic Guided Therapy (DGT) Personalize Medicine for IBS patients





- FDA-regulated diagnostic to be used as therapy
- Measures immunoreactivity for a panel of foods to determine which foods are above normal range and problematic for a specific patient
- Allows physicians to identify patient-specific foods which, when removed from diet, may alleviate or improve the patient's gastrointestinal symptoms and suffering
- Clinical trial guided by U.S. members of the Rome Foundation, the leading organization that sets IBS treatment guidelines

Note: Clinical lab product in clinical studies. Point of care product under development

Example of Patient-Specific Results

Food	Result
Blueberry	**+ POSITIVE**
Chicken	NEGATIVE
Cabbage	NEGATIVE
Egg	**+ POSITIVE**
Garlic	NEGATIVE
Lemon	NEGATIVE
Mustard	NEGATIVE
Pork	**+ POSITIVE**
Potato	NEGATIVE
Sugar	NEGATIVE

Positive for: egg, blueberry, and pork

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Irritable Bowel Syndrome (IBS) is Very Common and Costly

IBS is the **#1 most common diagnosis** made by gastroenterologists[1]

IBS is the **#7** most common diagnosis made by **all physicians**[1]

IBS patients visit doctors **3x more** than non-IBS patients

IBS sufferers have **74% more** direct healthcare costs vs. non-IBS sufferers

The Majority of IBS patients believe **foods trigger** their **symptoms**

[1]Recent AGA Survey (American Gastroenterological Association).

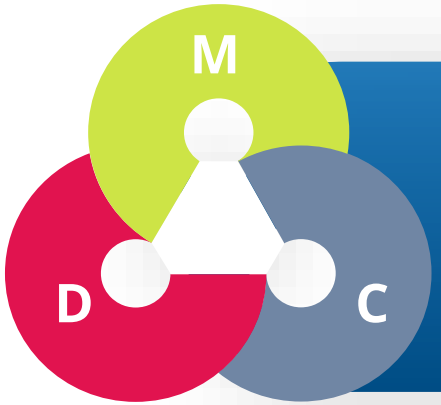
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IBS Market is Significant Today and Growing

$30B+

U.S. TAM[1]



40 Million
IBS Patients in the US

1/3 IBS-C (Constipation)

1/3 IBS-D (Diarrhea)

1/3 IBS-M (Mixed: Alternates C+D)

~16 MILLION
US IBS Patients: seeking consistent physician treatment

~13 MILLION
IBS-M Patients: No approved therapy/drug[2]

[1]Global prevalence of and risk factors for irritable bowel syndrome: a meta-analysis. *Clinical gastroenterology and hepatology*. 2012 Jul 1;10(7):712-21.
[2]Irritable bowel syndrome in the United States: prevalence, symptom patterns and impact. *Alimentary pharmacology & therapeutics.* 2005 Jun;21(11):1365-75.

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InFoods® IBS: Broad Benefits to Patients, Physicians, and Healthcare Insurers

Targets 100% of the IBS Market (IBS-M, IBS-C, IBS-D)[1]

Patient Benefits

InFoods® targets underlying causes **without causing side effects**

VS

IBS Drugs – Primarily treat symptoms AND can cause **major side effects**

Physician Benefits

InFoods®: Recurring revenue potential as problem foods change in patients

VS

IBS Drugs = $0 revenue to physician

Payer/insurer Benefits

InFoods® insurer savings
Currently: IBS Patients require 3x doctor visits & monthly drug costs

U.S. Healthcare annual costs of IBS ~$30B/year

[1]IBS-M = Mixed: Alternates C+D; IBS-C = Constipation; IBS-D = Diarrhea.

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FDA Approved Drugs are Expensive and have Efficacy and Safety Limitations

Indication	Drug	FDA Approval	Treatment Response	Placebo Response	Treatment minus Placebo	Monthly Cost	Annualized U.S. Sale	Limitations
IBS-C	**Linzess**	2012	20% - 34%	6% - 27%	**7% - 14%**	$467	$1,963M	• Diarrhea side effect (20%)
	Amitiza	2008	14%	8%	**6%**	$371	$410M	• Indicated for women only; not studied for men
IBS-D	**Xifaxan**	2015	41%	32%	**9%**	$2,757[1]	$1,905M	• Not for chronic use
	Viberzi	2015	25% - 30%	17% - 16%	**8% - 14%**	$1,383	$266M	• Abdominal pain (secondary) endpoint not met
	Lotronex	2002	NA	NA	**13% - 20%**	$2,240[2]	$6M	• For women only • Black box warning
IBS-C IBS-D IBS-M	**InFoods**	Pending LDT launch	58% 58%	48% 43%	**10% to 15%**	N/A	New	• No side effects • 10% all patients • 15% women only

IBS Drug Side Effects Can Be Dangerous | **Lotronex carries a black box warning related to the risk of potentially serious GI events**

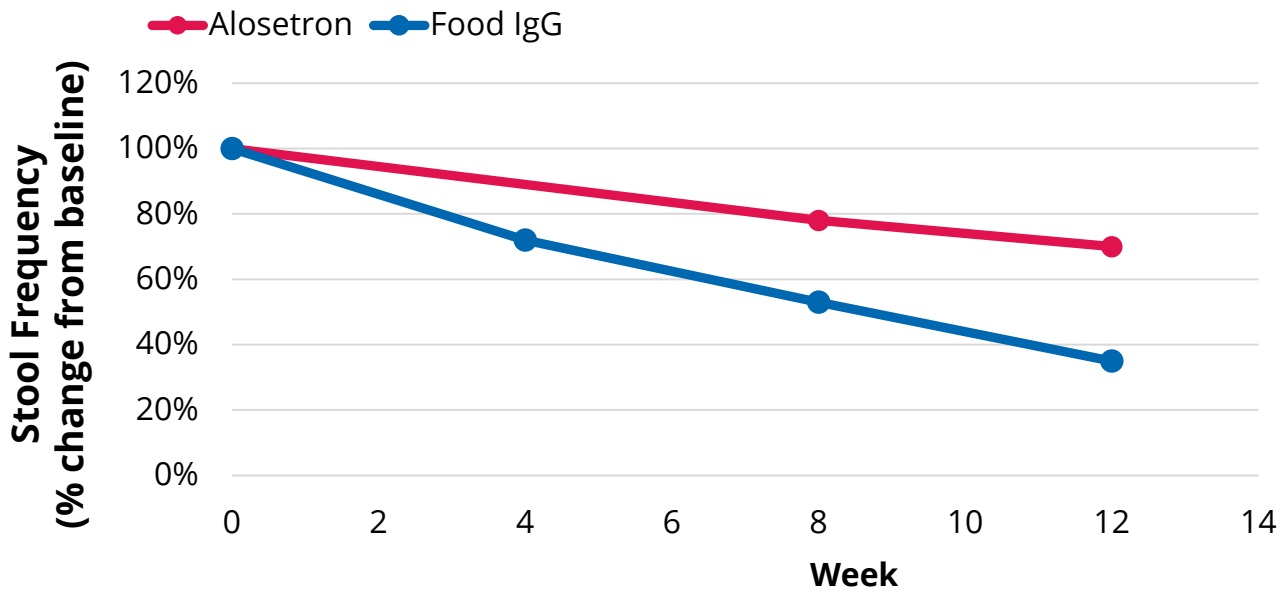
[1]Denotes cost for 550mg Xifaxan dose; 200mg dose WAC is $723. [2]Denotes cost for 1mg Lotronex dose; 0.5mg dose WAC is $1,120.
Source: IQVIA FY2020 sales and monthly WAC.

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Biomerica First-Generation Product vs. Lotronex™

(Diarrhea Stool Frequency: an FDA endpoint)

IBS-Diarrhea



Alosetron (Lotronex™)
Drop from Baseline: **30%**

Biomerica First-Gen Product
Drop from Baseline: **65%**

Separate Independent studies: Ther Adv Gastroenterol 2018, Vol. 11: 1–11 J Int Med Res. 2012;40(1):204-10.

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InFoods® Regulatory & Commercial Pathway



- CLIA Lab Developed Test to be launched on fiscal Q3
- FDA has determined proposed IBS clinical study is **a non-significant risk** → De Novo
- Recently competed Endpoint Trial results driving significant interest from physician groups

Endpoint and Pivotal Trials Overview

Sites

Mayo Clinic, **Harvard BID, University of Michigan, Houston Methodist, University of Texas Houston & others**

Design

Double-blind randomized placebo controlled trial of true diet for foods with a positive immune response v. sham diet of random foods

Primary Endpoint

All 9 FDA endpoints QOL, API, BSS, SSS, etc. for Endpoint Trial; one endpoint to be selected for Pivotal Trial (e.g. API)

Participants

N=180 (Endpoint Trial); N=500-700 (Expected for Pivotal Trial)

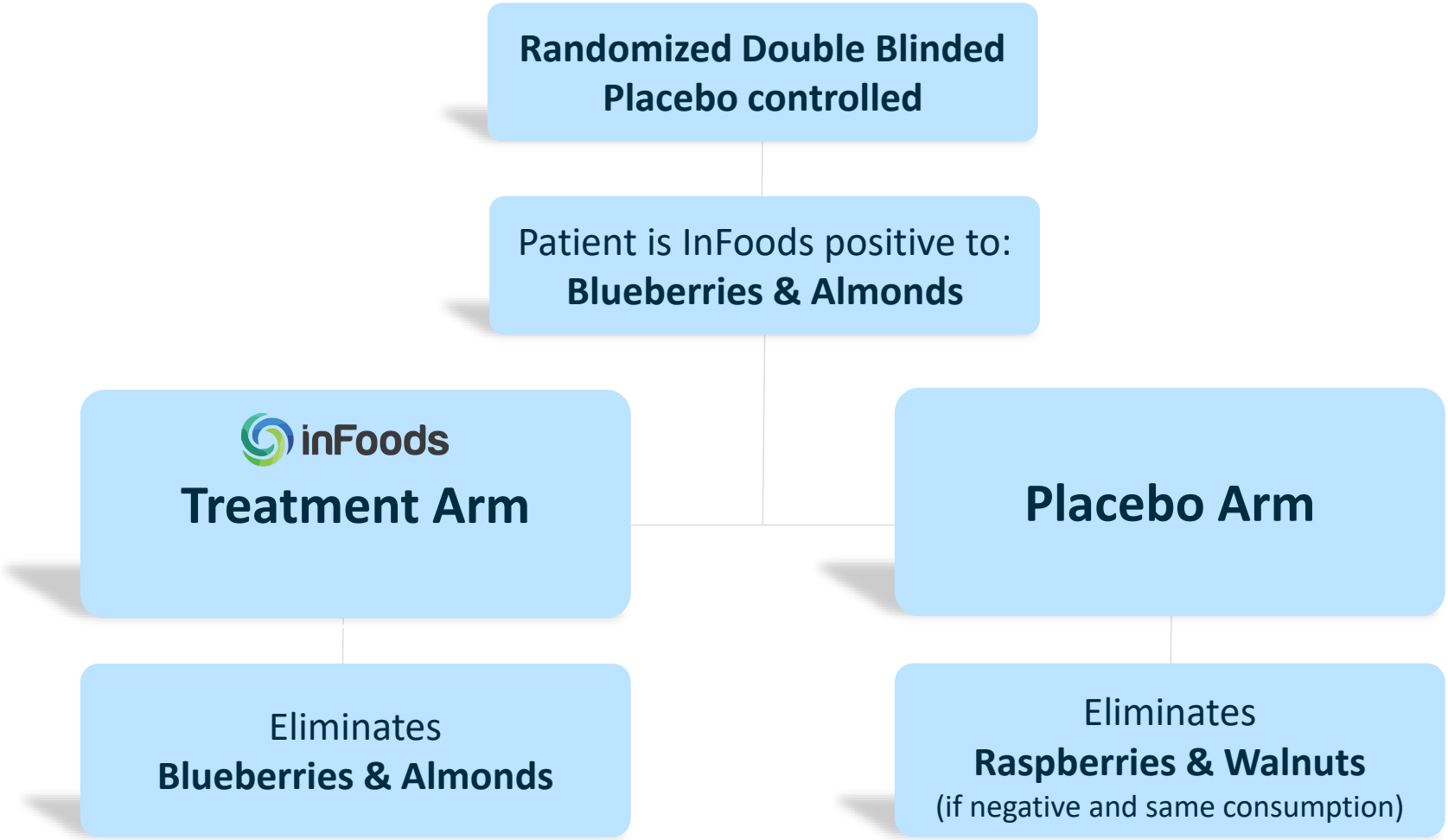
Complete

Completed Endpoint Clinical Trial shows improvements in Multiple Symptoms for IBS Patients

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InFoods® IBS: Clinical Trial Design Summary



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Highlights

Statistically meaningful improvements were seen in multiple endpoints (symptoms), this is only a selection of topline results from the InFoods® IBS endpoint trial

Global Endpoints

SGA

GIS

InFoods® IBS
Top Line - Global Endpoints

inFoods **Treatment Arm** **Vs.** **Placebo Arm**

P-value of 0.007 for improvement in the **Subject's Global Assessment of Relief (SGA)** endpoint for all patient subtypes as a group (baseline vs 8 weeks)

Subject's global assessment (SGA) of relief is a single measure (endpoint) encompassing abdominal pain/discomfort, altered bowel function, and overall well-being. This measure, which has been validated in populations with IBS, was considered the standard assessment of symptoms for IBS trials in the past[1]

P-value of 0.040 for improvement in the **Global Improvement Scale (GIS)** endpoint for all patient subtypes as a group (baseline vs 8 weeks)

Global Improvement Scale (GIS) assesses multiple irritable bowel syndrome (IBS) symptoms using a patient-defined 7-point Likert scale ranging from symptoms substantially worse to substantially improved

1. Aliment Pharmacol Ther 2001;15:1655–66 & Gastroenterology 2000;118:A145

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Highlights

Statistically meaningful improvements were seen in multiple endpoints (symptoms), this is only a selection of topline results from the InFoods® IBS endpoint trial

Pain and Bloating

API

Bloating

InFoods® IBS
Top Line - Global Endpoints

inFoods Treatment Arm **Vs.** **Placebo Arm**

P-value of 0.012 for improvement in the **Abdominal Pain Intensity (API)** endpoint for IBS-Mixed & IBS-Constipation patients as a group (baseline vs 8 weeks)

IBS is partly defined by pain, and pain is the cornerstone of the IBS illness experience for many patients. Abdominal Pain Index (API) is the only instrument that can be scored as a composite measure of overall abdominal pain severity composed of pain frequency, intensity, and duration[1]

P-value of 0.022 for improvement in the **Bloating** endpoint for IBS-Mixed & IBS-Constipation patients as a group (baseline vs 8 weeks)

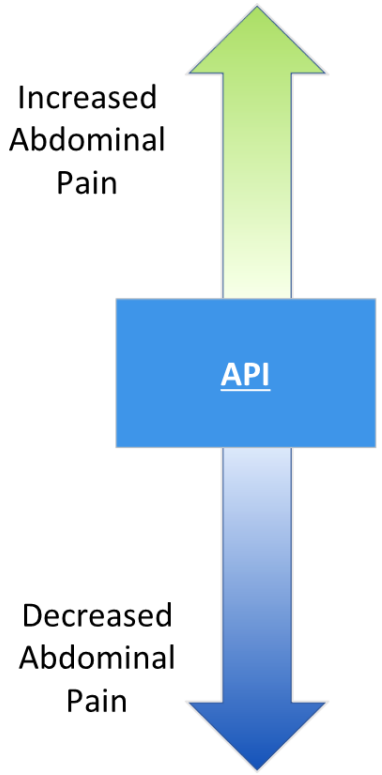
Bloating is reported by up to 96% of patients with irritable bowel syndrome (IBS), is more common in females, and is often ranked as their most bothersome symptom[2]

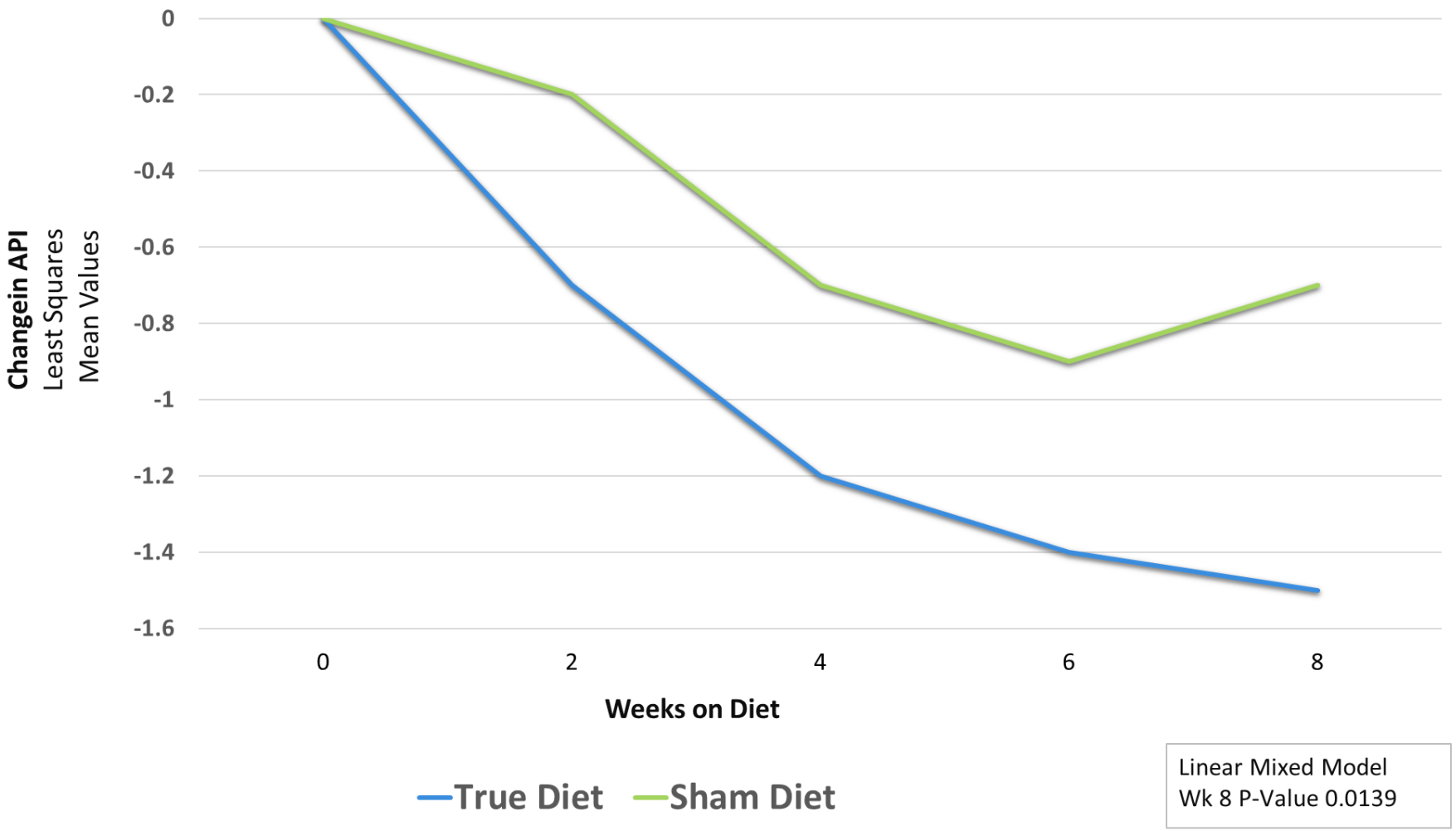
1. J Pediatr Psychol. 2015 Jun; 40(5): 517–525 & Aliment Pharmacol Ther. 2010 Nov; 32(9): 1192–1202.
2. Gastroenterology Volume 131, Issue 4, P1003-1010, October 2006

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Abdominal Pain Index (API) Change from Baseline
IBS non-D Population

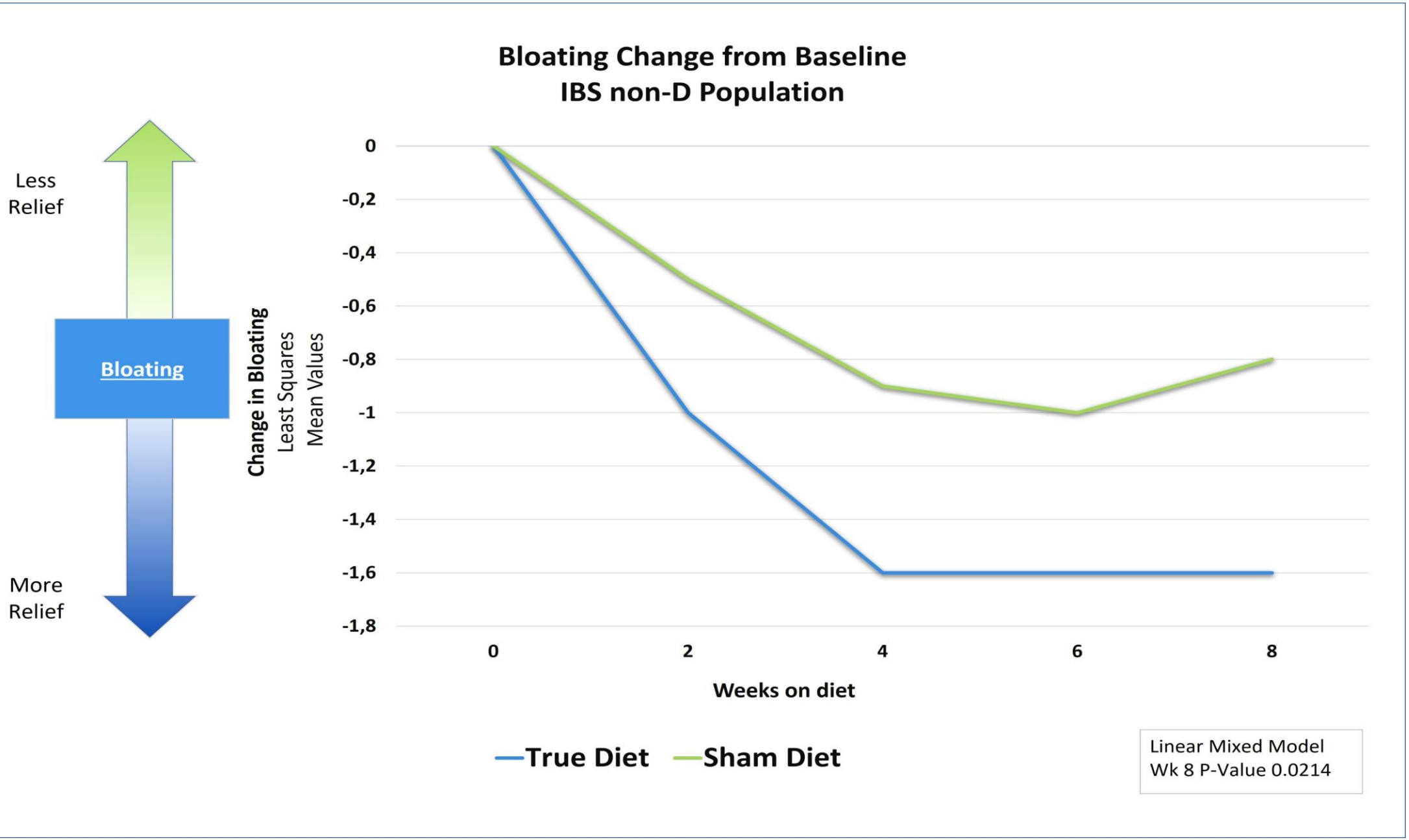




Linear Mixed Model
Wk 8 P-Value 0.0139

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InFoods® Commercialization Strategy

Multiple Avenues to Drive Adoption

Inclusion in Guidelines

- Inclusion in the IBS treatment guidelines will accelerate product adoption
- The Rome Foundation holds significant influence in setting the treatment guidelines

Reimbursement Awareness and Enhanced Coverage

- Help GI physicians monetize their largest patient population: reimbursement code already exists for Medicare patients
- Initiate conversations with payors to enhance access to product at both the point of care and outpatient diagnostic centers

Broad Physician Interest

- Capitalize on strong physician interest evidenced by market research[1]
- GI physician and PCP respondents indicated they would adopt this product for 95% - 100% of their patients, depending on the IBS subtype[1]

95% GI Physicians and PCPs Would Adopt InFoods® for Their Patients Depending on Subtype

[1]Market Research Source: Market Vision. Percentages shown represent medians for both GI physicians and PCPs based on the information they were presented as part of the market research survey.

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SAB: Rome Foundation- Sets IBS Guidelines Expertise in Clinical Trials

Rome Foundation
(Leading IBS organization)

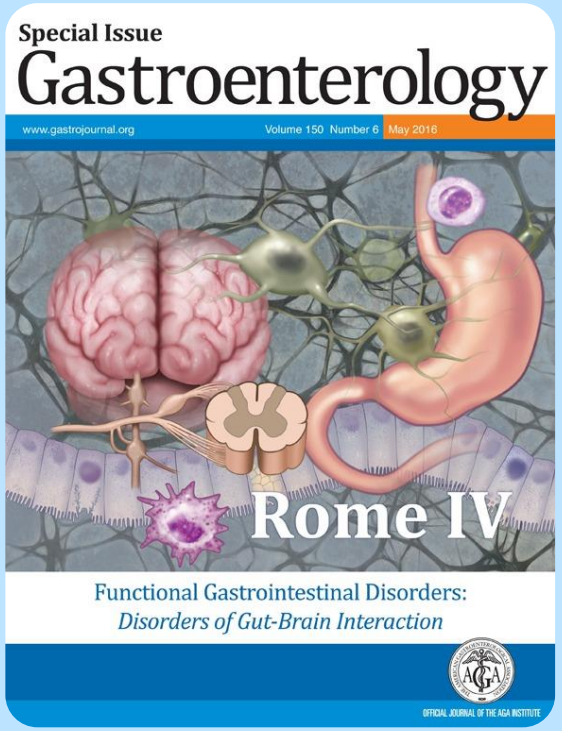
- Leading independent non-profit organization focused on the diagnosis and treatment of functional gastrointestinal disorders, including IBS
- Rome creates the diagnostic criteria and guidelines that FDA and physicians use to define an IBS patient, and treat those patients

Dr. Doug Drossman
(Biomerica SAB Chair)

- Dr. Doug Drossman (President Emeritus of the Rome Foundation) is one of the foremost opinion leaders in IBS
  - Participated in 50+ Clinical Studies for IBS

Key Expertise on IBS Clinical Trials

- SAB members were the PI's on clinical trials for multiple approved GI drugs, including Linzess®, Viberzi®, and Xifaxan®
- Members serve on FDA GI advisory panel



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Platform Technology:

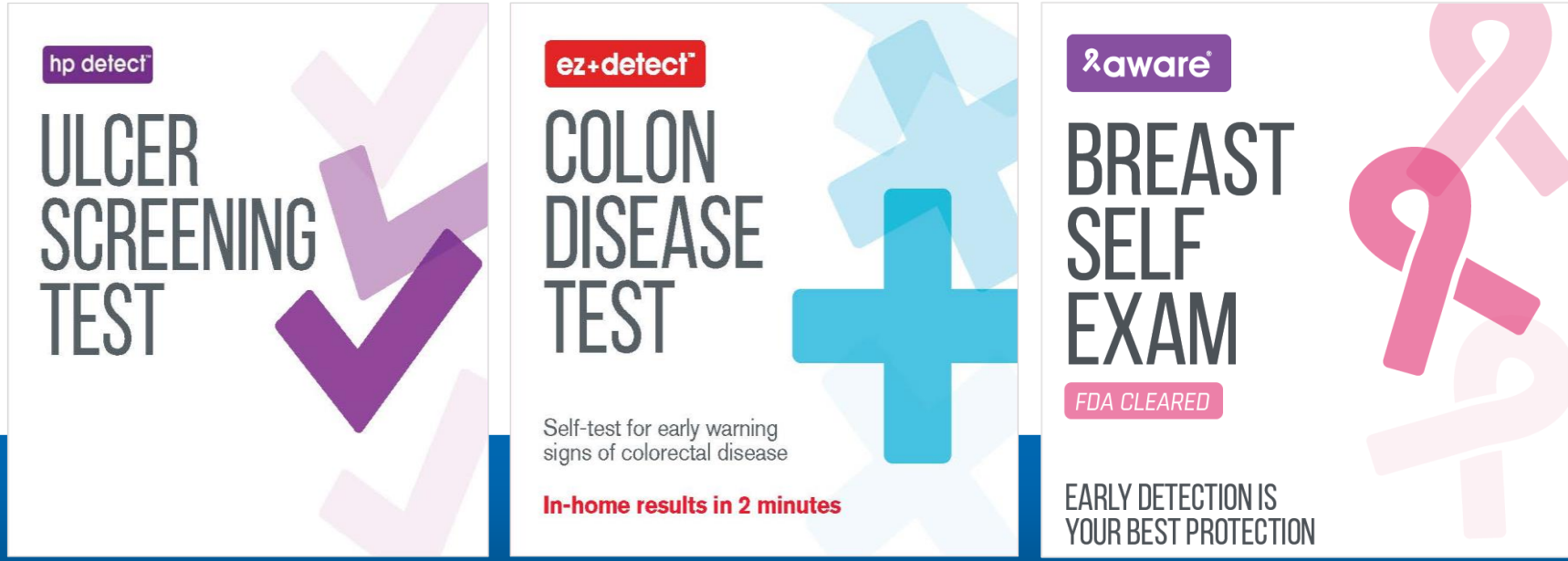
InFoods®
Development Pipeline

	IP & Data	Product Dev. R&D	FDA Sub Q	End Point Trial	Pivotal Trial	FDA Approval
Functional Gastrointestinal Disorders	Irritable Bowel Syndrome (IBS)					
	Functional Dyspepsia					
	GERD disease					
Gastrointestinal Diseases	Ulcerative Colitis (UC)					
	Crohn's					
Other Chronic Inflammatory Diseases	Migraines					
	Dermatology					
	Depression					

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Specialty Diagnostics



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2022 Growth opportunity - H. pylori

hp detect™

Detects H. pylori Antigen

H. pylori is a bacteria that infects approximately 35% of the U.S. population and 45% of the population in the five major countries in the Europe. Approximately 20% of *H. Pylori* infected patients develop a range of issues including peptic ulcer disease, dyspepsia and gastric cancer.

- **Status:** Biomerica has submitted a 510k to FDA 510K submission. Approval expected soon.
- **Gastric Cancer:** Gastric cancer is the 3rd most common cause of cancer related death in the world. Over 80% of gastric cancers are attributed to *H. pylori* infection. In 2017, the World Health Organization (WHO) listed *H. pylori* among the 16 antibiotic-resistant bacteria that pose the greatest threat to human health and designated *H. pylori* as a Class 1 carcinogen.
- **Profit Opportunity:** Once approved by the FDA, Biomerica could sell its H. pylori product at a significant discount to competitive products and still earn 80% gross margin.
- **Customers:** The majority of H. pylori diagnostic tests are sold to large labs such as Quest, LabCorp and ARUP. Therefore, less marketing effort is needed to achieve material market penetration.

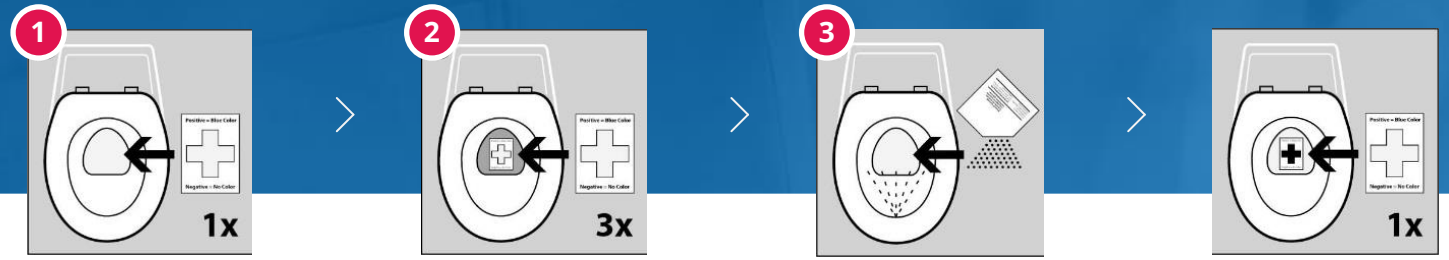
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Colorectal Disease Test: EZ Detect™

EZ Detect is a 2-minute, at-home test for the determination of fecal occult blood, an early warning sign of colorectal cancer (CRC) and other colorectal diseases.

Quick & Simple:

No Stool Handling





Interpretation

Negative	Positive	Positive

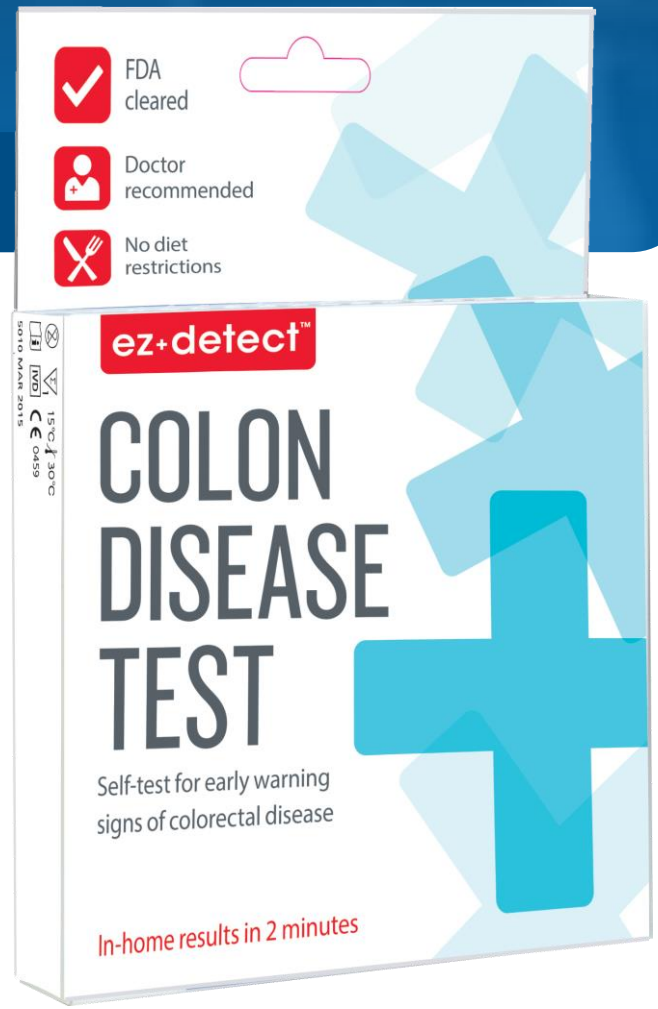
Any color in the test area (no matter how small) should be considered as a positive result

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Key performance metrics for EZ Detect™, Cologuard®, & FITs

Value	EZ Detect™ (1)	Cologuard® (2)	FIT (2)
Price	$14	$649	$22
Accuracy	93.2%	86.6%	94.7%
Positive Likelihood Ratio	91.2	6.9	14.3
Negative Likelihood Ratio	0.27	0.09	0.28
Specificity (vs. all negative findings on colonoscopy/sigmoidoscopy)	99.2% (124/125)	86.6% (7936/9167)	94.9% (8,695/9167)
Sensitivity (vs. all CRC found by colonoscopy/sigmoidoscopy)	72.9% (27/37)	92.3% (60/65)	73.8% (48/65)
Negative Predictive Value	92.5% (124/134)	99.9% (7936/7941)	99.8% (8695/8712)
Positive Predictive Value	96.4% (27/28)	4.6% (60/1291)	9.2% (48/520)



(1)Results of the Study (Screening) Conducted by Renfe's Medical Department. 2000.
(2)Multitarget Stool DNA Testing for Colorectal-Cancer Screening. Imperiale, Thomas F, et al. 2014, The New England Journal of Medicine, Vol. 370, pp. 1287-1297.

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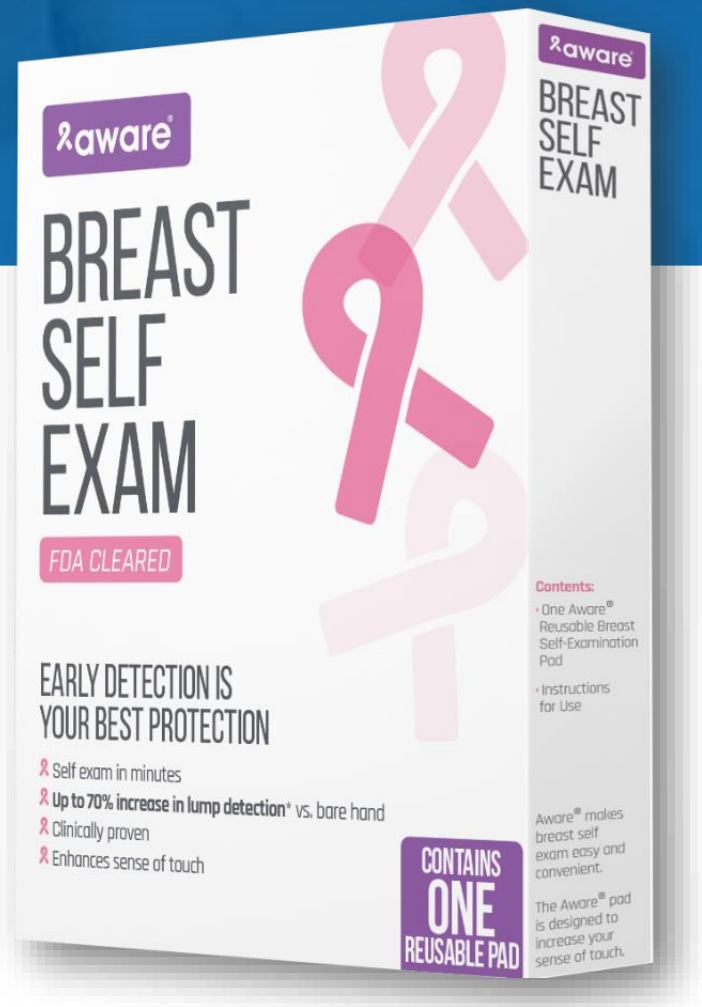
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Aware® Breast Self Exam

- **FDA – Cleared and CE Mark**
- The Aware® Pad is as an aid for performing at-home breast self-examination
- About **80% of breast cancers** are **detected because women themselves notice changes** in their breasts[1]
- Recurrent purchases and several pads for female family members



1. https://www.pinkribbon-deutschland.de/vorsorge-fakten/fakten, accessed 02 AUG 2022

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Aware® Performance

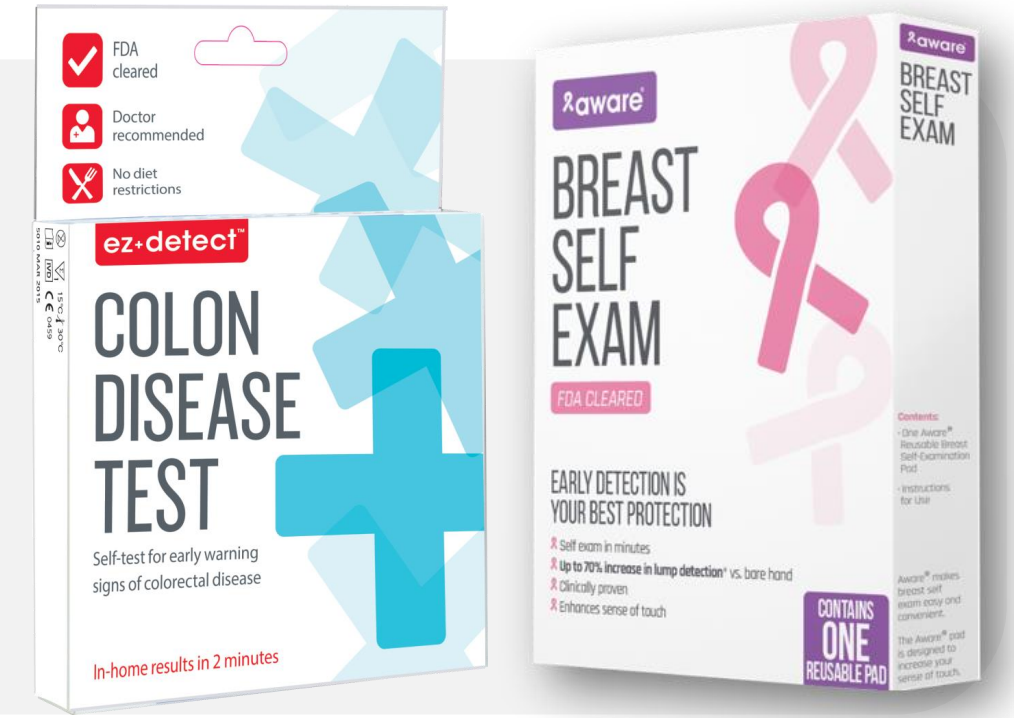
Clinical Study
Kawasaki Medical University Hospital
for Aware FDA approval (N=832 Patients)

- Study concluded that **Aware®** is a highly effective tool for early detection of breast abnormalities
- Regular practice of Breast Self Exam is extremely important for early cancer detection

Detection Ratios				
	Breast Cancer	**Fibroma** Biopsy Case / Non-Biopsy Case	**Mastitis** Biopsy Case / Non-Biopsy Case	**Non-Tumor**
Patient	98.6%	90.9%/87.8%	86.4%/65.2%	9.8%
Nurse	100%	96.0%/92.0%	86.4%/58.2%	4.8%



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ez+detect™ & aware

Available at Walmart

EZ Detect now in over

4,600

Walmart Stores

Aware now in over

2,400

Walmart Stores

Available online at Walmart

Available at amazon.com

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Leveraging Our Unique Technology

Disruptive Patented Platform Technology redefining the GI Market

Addressing the large need for IBS patients and then targeting multiple other diseases

InFoods Model is Unique

Benefits Patient / Physician / Insurer

Broad IP Protection

Robust patent portfolio (11 issued patents; 100+ patents pending)

- 16+ year remaining on patents filed
- Patents cover multiple disease states

Financially Attractive

- Low burn rate
- Clean Cap table - No warrants, no preferred equity and no debt

IBS Key Opinion Leaders set Treatment Guidelines

- SAB Leadership includes US Members of the Rome Foundation
- Clinical studies lead by principal investigators who set GI “treatment guidelines”

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