



Investor Presentation • May 2022

Forward-Looking Statement

The Private Securities Litigation Reform Act of 1995 provides a “safe harbor” for forward-looking statements. Certain information included in this presentation (as well as information included in oral statements or other written statements made or to be made by Biomerica) contains statements that are forward-looking, including statements other than statements of historical facts; such as statements relating to intended launch dates, sales potential, significant benefits, market size, number of sufferers with IBS, prospects, new products, favorable outlook, efficacy of competing products, the FDA pathway, expansion, increases in productivity and margins, expected orders, market competition, anticipated future sales, possible future revenues including InFoods® revenue opportunities, possible FDA or other regulatory clearances, insurance reimbursement availability and amounts, physician adoption rates, physician pricing, patent protection of the InFoods® technology, frequency of patient testing, production volume of the Company, the launch or success of current and new product offerings; as well as statements relating to the Company’s tests including; the efficacy of InFoods IBS at treating IBS symptoms in patients, accuracy of the InFoods product at detecting correct foods causing patient IBS symptoms, results of studies testing the efficacy and accuracy, FDA clearance, EUA clearance including CE Mark, the rapidity of testing results, uniqueness of these tests, use and commercial adoption of these tests, pricing of the Company’s test kits, domestic and international demand and orders, the Company’s manufacturing capacity, patent protection, and all regulatory approvals necessary prior to commercialization of these tests; and, resource and other constraints on our suppliers; dependence on our third party manufacturers; dependence on international shipping carriers; governmental import/export regulations; competition from other similar products and from competitors that have significantly more financial and other resources available; governmental virus control regulations that may make it difficult or impossible for the company to maintain current operations; and any other aspect of the Company’s Tests. Such forward-looking information involves important risks and uncertainties that could significantly affect anticipated results in the future, and accordingly, such results may differ materially from those expressed in any forward-looking statements made by or on behalf of Biomerica. Forward looking statements also include the assumptions underlying or relating to such statements. The underlying assumptions could prove to be inaccurate or known or unknown risks or uncertainties could materialize, therefore actual results could vary materially. The potential risks and uncertainties include, among others, fluctuations in the Company’s operating results, downturns in international and or national economies, the Company’s ability to raise additional capital as needed, the competitive environment in which the Company will be competing, and the Company’s dependence on strategic relationships and on regulatory approvals. A further list and description of these risks, uncertainties and other factors can be found in our report on Form 10-K filed with the Securities and Exchange Commission on August 31, 2021. Any forward-looking statements made in this presentation speak only as of the date of the presentation. The Company is under no obligation to update any forward-looking statements after the date of this presentation.

Diagnostic Guided Therapy

Using Science, Diet and Technology
to Revolutionize the GI Market



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
- H. Pylori antigen test launch
- ez+detect – Colon Disease Test



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”

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, FACP, FASCP

- 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, FACP, FASCP

- 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, FACP, FASGE

- Chief of Gastroenterology, University of Texas Health Science Center at Houston





Background & Innovation

Leveraging diagnostic expertise to transition into diagnostic-guided therapeutics

Specialty diagnostics *enabling early disease detection and monitoring*

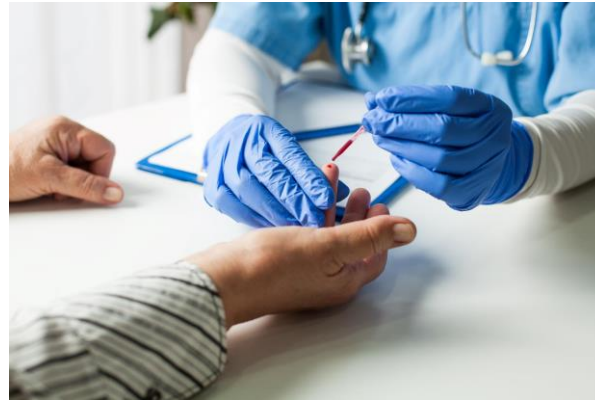
- Two FDA, CE, CFDA registered manufacturing facilities in California and Mexico
- Commercially launched FDA cleared diagnostic tests



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

InFoods® – Diagnostic Guided Therapy (DGT) to Treat Chronic Inflammatory Diseases



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

Irritable Bowel Syndrome (IBS) is Very Common and Costly

IBS is the **#1 most common diagnosis** made by gastroenterologists¹

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

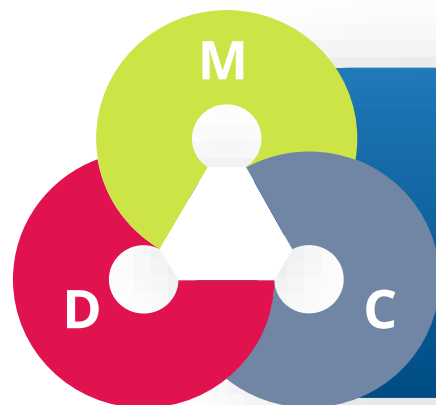
The Majority of IBS patients believe **foods trigger** their **symptoms**

¹Recent AGA Survey (American Gastroenterological Association).

IBS Market is Significant Today and Growing

\$30B+

U.S. TAM¹



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

M I L L I O N

US IBS Patients:
seeking consistent
physician treatment

~13

M I L L I O N

IBS-M Patients:
No approved
therapy/drug²

¹Global prevalence of and risk factors for irritable bowel syndrome: a meta-analysis. *Clinical gastroenterology and hepatology*. 2012 Jul 1;10(7):712-21.

²Irritable bowel syndrome in the United States: prevalence, symptom patterns and impact. *Alimentary pharmacology & therapeutics*. 2005 Jun;21(11):1365-75.

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

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

FDA Approved Therapies are Expensive and have Efficacy and Safety Limitations

Indication	Drug	FDA Approval	Drug Treatment Response	Placebo Response	Drug minus Placebo Response	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 Drug Side Effects Can Be Dangerous

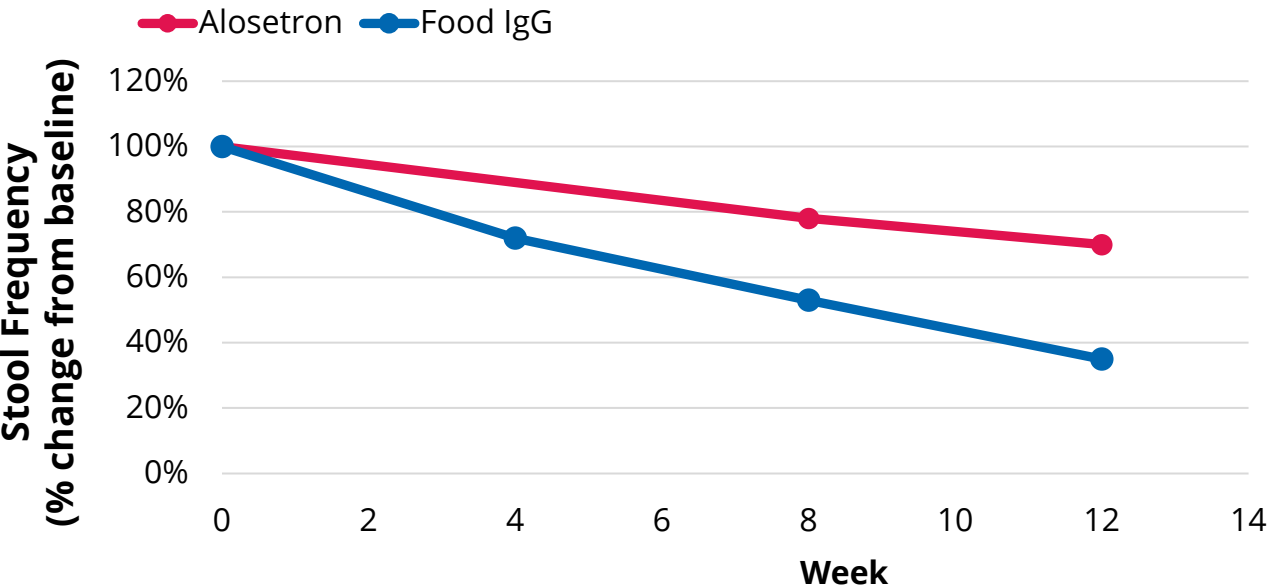
Lotronex carries a black box warning related to the risk of potentially serious GI events

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

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.

InFoods® Regulatory Pathway



⇒ FDA has indicated InFoods® IBS will be **evaluated as a therapy**

⇒ FDA has determined proposed IBS clinical study is a **non-significant risk** → avoids much costlier and more time-consuming PMA clinical trial route (No Phase I, II or III required)

⇒ Endpoint Trial is complete: Goal of the trial was **identifying the best primary endpoint to use in the final Pivotal Trial**

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)

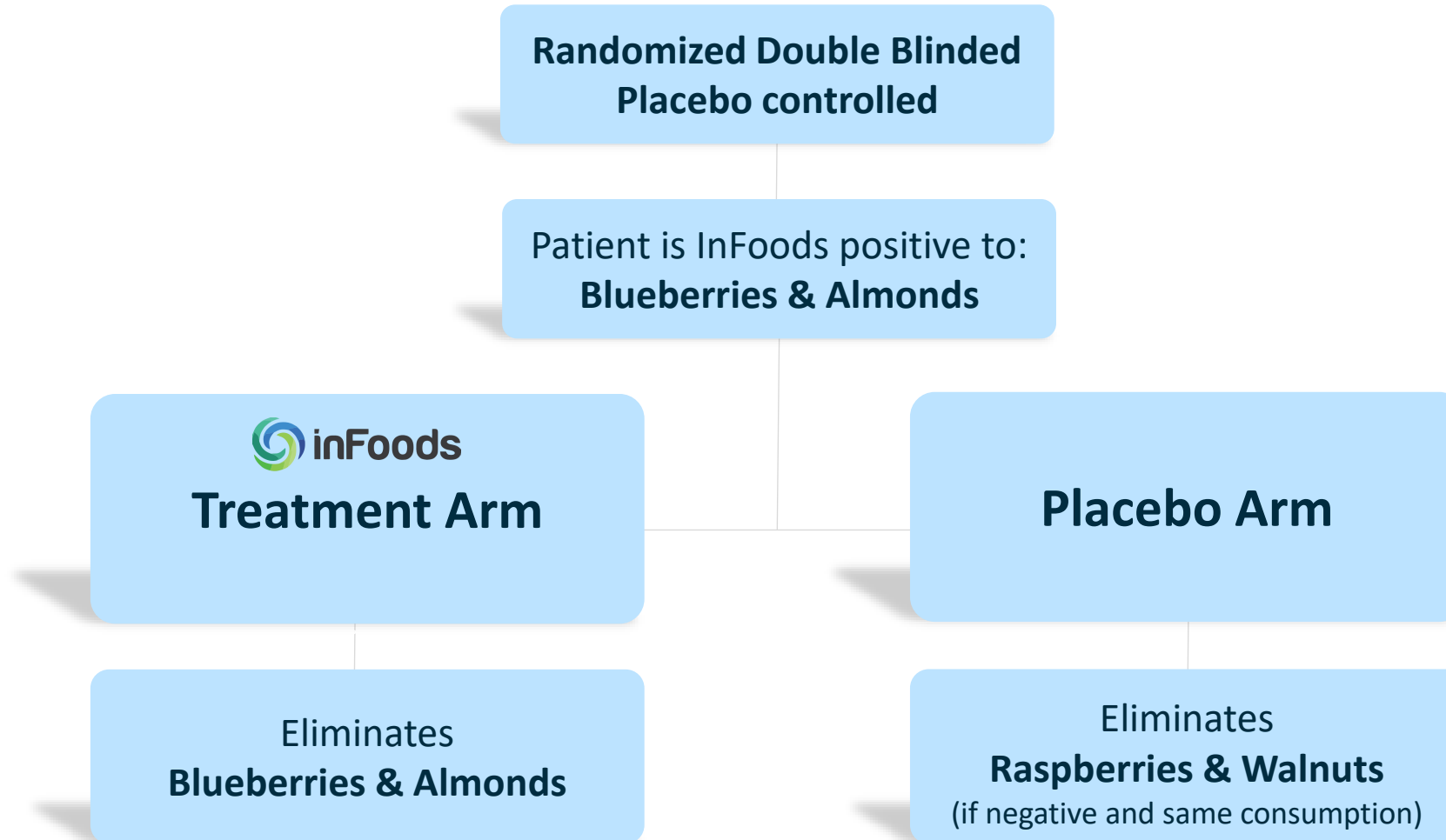
Participants

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

Complete

Positive Topline Results from the Endpoint Clinical Trial from InFoods® IBS Treatment for Patients with Irritable Bowel Syndrome

InFoods® IBS: Clinical Trial Design Summary



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


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 past¹

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

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


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 duration¹

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 symptom²

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

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 research¹
- GI physician and PCP respondents indicated they would adopt this product for 95% - 100% of their patients, depending on the IBS subtype¹

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

¹Market 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.

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



Rome Foundation (Leading IBS organization)

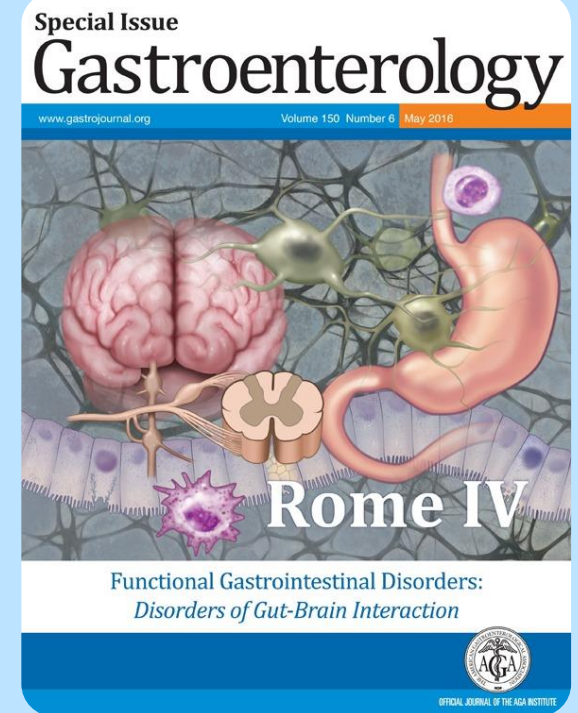
- ➔ Leading independent non-profit organization focused on the diagnosis and treatment of functional gastrointestinal disorders, including IBS
- ➔ Rome creates the diagnostic criteria and guidelines that FDA and physicians use to define an IBS patient, and treat those patients

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



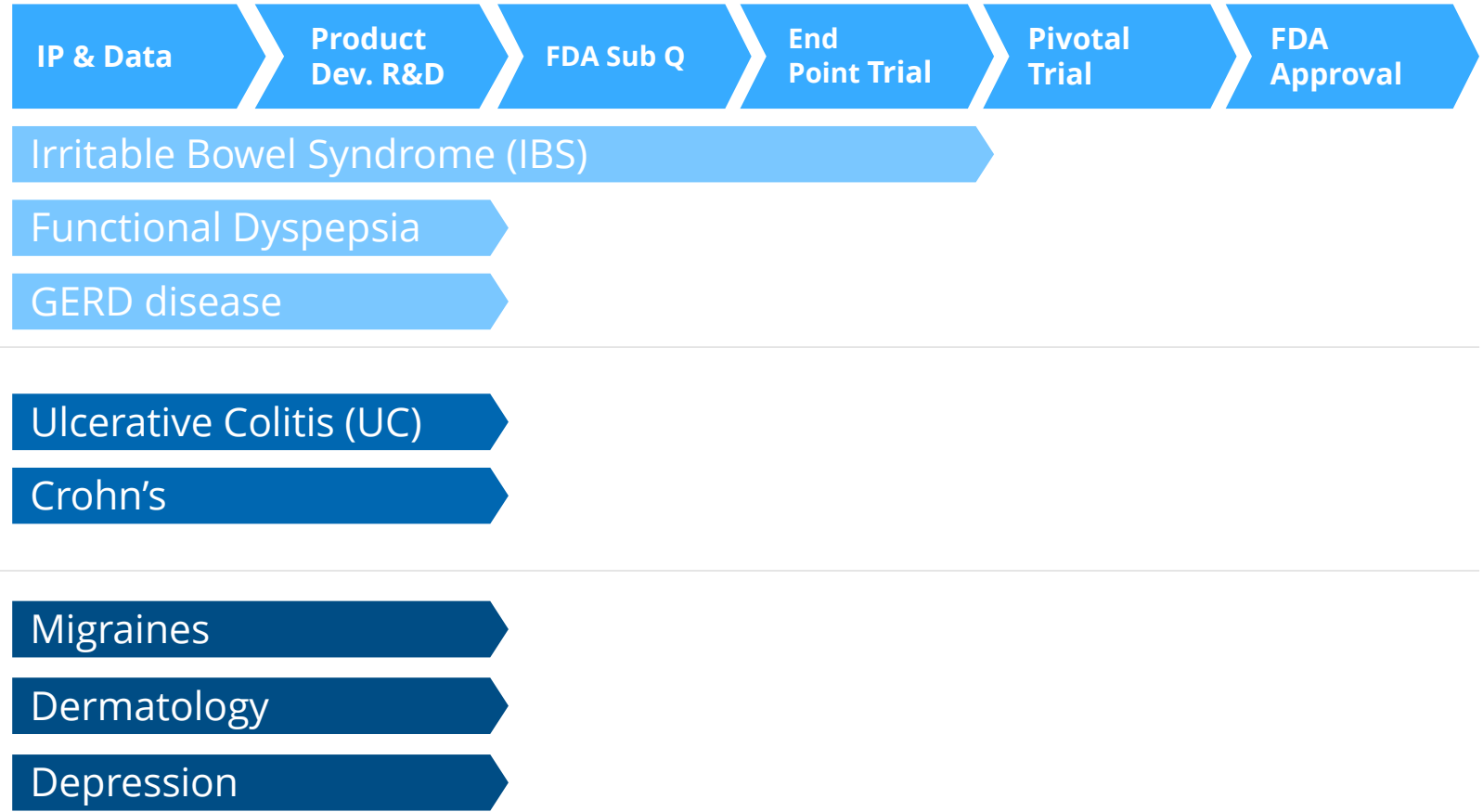
Platform Technology:

Functional
Gastrointestinal
Disorders

Gastrointestinal
Diseases

Other Chronic
Inflammatory
Diseases

InFoods® Development Pipeline



Specialty Diagnostics

hp detect™

ULCER SCREENING TEST

ez+detect™

COLON DISEASE TEST

Self-test for early warning
signs of colorectal disease

In-home results in 2 minutes

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.

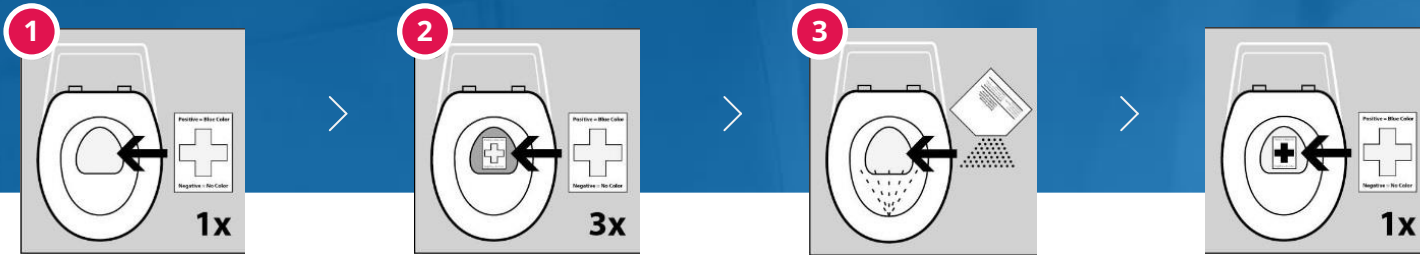
- ➞ **Status:** Biomerica has submitted a 510k to FDA 510K submission April 2022. Initial sales planned in 2022.
- ➞ **Gastric Cancer:** Gastric cancer is the 3rd most common cause of cancer related death in the world. Over 80% of gastric cancers are attributed to *H. pylori* infection. In 2017, the 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.

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

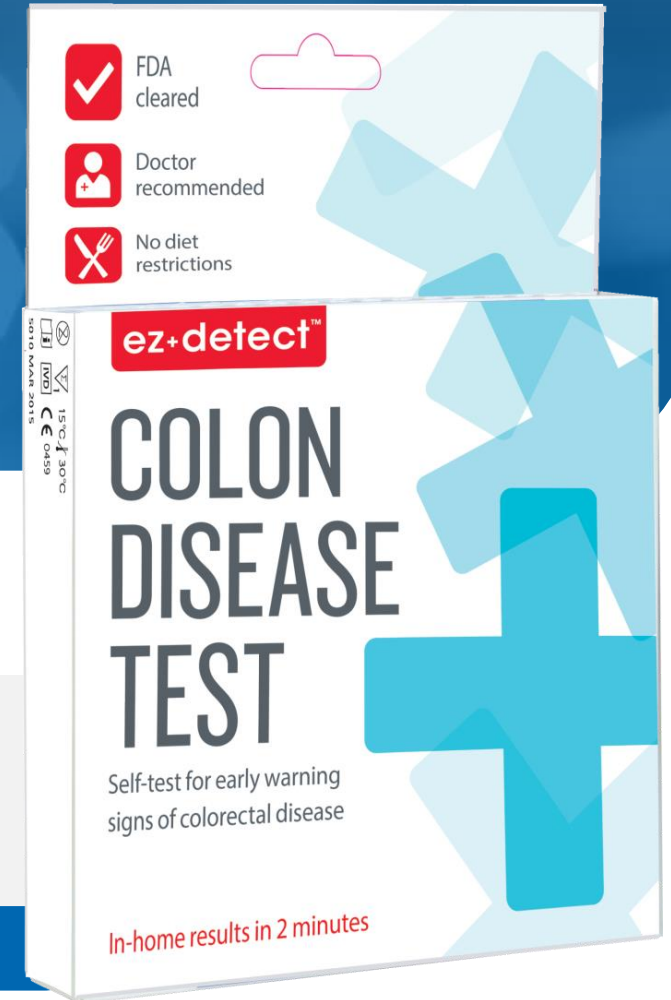


Positive



Positive

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

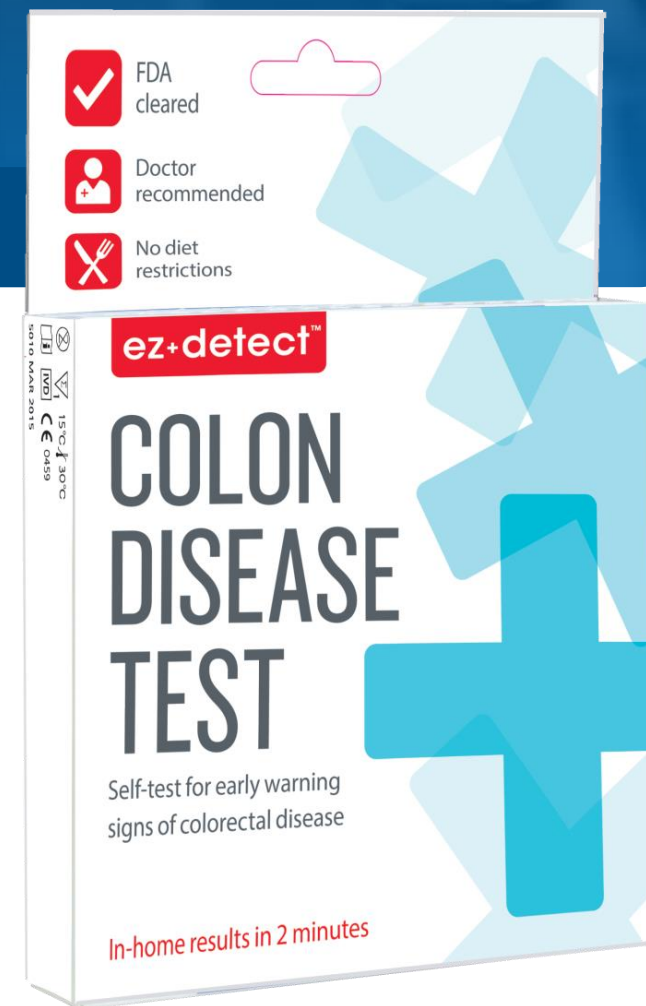


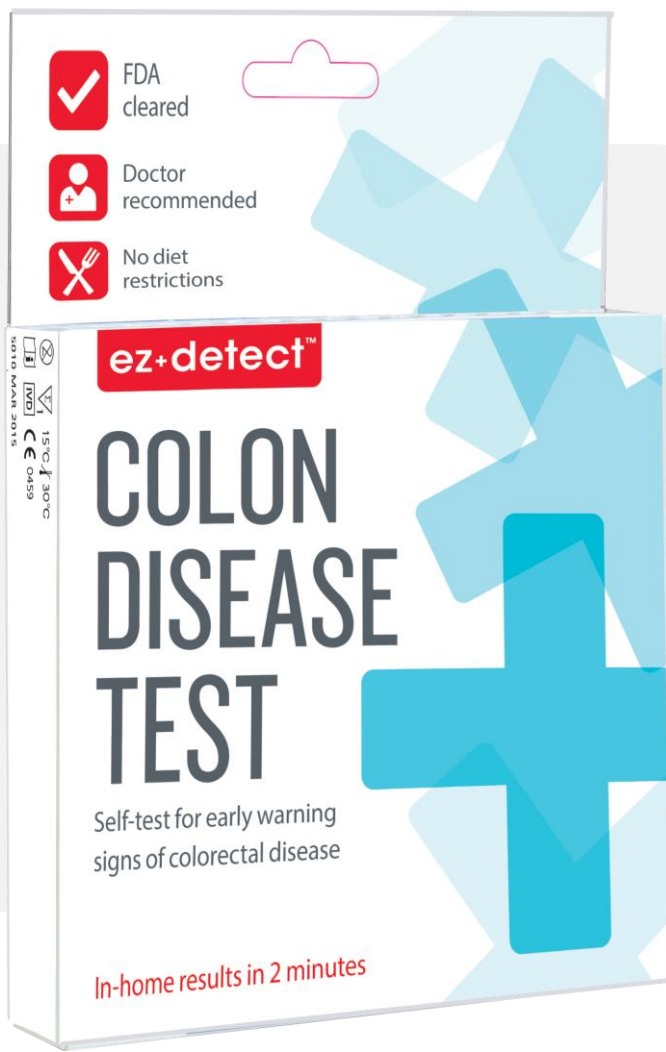
Key performance metrics for EZ Detect™, Cologuard®, & FITs

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.





EZ Detect™: **Available at Walmart**

Now in over

4,600

Walmart Stores

Available online at
Walmart 

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”