



# Investor Presentation

June 2019



# Forward looking statements

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, prospects, new products, favorable outlook, FDA pathway, expansion, increases in productivity and margins, expected orders, leading market positions, anticipated future sales, hypothetical revenues opportunities, possible InFoods<sup>®</sup> revenue opportunities, possible FDA or other regulatory clearances, insurance reimbursement availability and amounts, physician adoption rates, physician pricing, frequency of patient testing or production volume of the Company, the launch or success of product and new product offerings. 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 due to its business model and expansion plans, downturns in international and or national economies, the Company’s ability to raise additional capital, the competitive environment in which the Company will be competing, and the Company’s dependence on strategic relationships. 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 29, 2018. 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.



# Who We Are



Biomerica (Nasdaq: BMRA) \$23 million market capitalization

## Major customers

*Walgreens*

**CVS/pharmacy**  
Expect something extra

 Quest Diagnostics™

 MAYO CLINIC

## Specialty Diagnostics Company

New technology platform has the potential to disrupt and revolutionize a multiple billion dollar markets

- › Revenue generating manufacturer with FDA cleared products
- › Two FDA, CE, CFDA registered manufacturing facilities in California and Mexico. Regulatory experience taking 8 products through FDA Clearance



Diagnostic Guided Therapy (DGT) Approach to Treat GI Diseases

- › Multi billion dollar potential
- › Patented technology platform



# Investment Highlights

## Opportunity for Investors



Expecting several significant milestones over next 12 months



Milestones

1. Colorectal
2. H. Pylori
3. InFoods IBS



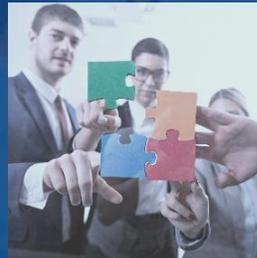
Short time horizon for possible licensing and FDA approvals



Disciplined Share Structure: Approximately 9.5 million shares outstanding (no warrants)\*



Management and Board owned: insiders own approx. 24% of the company. Insider buying



US Members of the ROME foundation are the SAB



# New technology - potential to disrupt & revolutionize a multi billion dollar market



## There Is a Large and Growing Need for New Gastrointestinal Therapies

- > Designed to allow physicians to identify patient specific foods (e.g. eggs, milk, wheat, sugar, corn, etc.), that when removed, may alleviate or improve an individual's IBS
- > FDA – Regulated diagnostic to be used as therapy. Clinical Trial to show efficacy in symptom reduction
- > Clinical Protocol Guided by the US members of the Rome Foundation

## Diagnostic Guided Therapy (DGT) to Treat GI Diseases

### Patents allowed

Foods change (according to researchers): Retest 2 to 3 times per year (recurring revenue)



Food	Result
A	+ POSITIVE
B	NEGATIVE
C	NEGATIVE
D	+ POSITIVE
E	NEGATIVE
F	NEGATIVE
G	NEGATIVE
H	+ POSITIVE
I	NEGATIVE
J	NEGATIVE
<b>Total # Foods Positive</b>	<b>3</b>
<b>Foods are specific</b>	<b>Egg   + Positive (Blueberry)   - Negative</b>



# Our Pipeline

## Functional Gastrointestinal Disorders

1. IBS Irritable Bowel Syndrome
2. Functional Dyspepsia
3. GERD Gastroesophageal reflux disease



## Gastrointestinal Diseases

4. Ulcerative Colitis
5. Crohn's





# InFoods® IBS Product - Irritable Bowel Syndrome

## InFoods® IBS: A Multi-Billion Dollar Market Opportunity in Clinical studies

First ever diagnostic guided therapy for Irritable Bowel Syndrome (IBS) - Simple blood test to identify patient specific foods that alleviate IBS symptoms



InFoods® therapy helps address the problem not just the symptoms



45 Million IBS patients in the U.S.\*



2 patents allowed and 15 patents filed for IBS and other indications



Current Standard of Care is Drug Therapy



Short and inexpensive pathway to commercialization (licensing) compared to drugs

### InFoods® IBS Therapy



### InFoods® Results

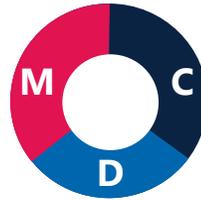
Food	Result
Egg	+ POSITIVE
Blackberries	NEGATIVE
Pork	+ POSITIVE

\*Irritable bowel syndrome in the United States: prevalence, symptom patterns and impact , A. P. S. Hungin, June 2005, Alimentary Pharma & Thera



# IBS Market: > 45 Million in US

3 types of IBS



IBS - C (**Constipation**)

IBS - D (**Diarrhea**)

IBS - M (**Mixed**) alternates C & D

Market

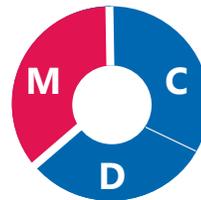


Approximately  
**33% C, D, M**



No approved  
therapy/drug for  
**IBS-M**

A drug can only focus on  
1/3 of the IBS market



- > Drugs can only work on IBS-C or IBS-D
- > They can't do both (IBS-M)
- > **No therapy approved for IBS-M**



# IBS Patients



## IBS patients visit doctors 3x more than normal patients

- > IBS cost is estimated at \$30 billion annually in direct and indirect
- > IBS sufferers incur 74% more direct healthcare costs than non-IBS sufferers



## Majority of IBS patients believe that foods trigger their symptoms

- > Patients desperate to know what foods are causing/exacerbating IBS pain & symptoms



## Recent AGA Survey (American Gastroenterological Association)

- > IBS patients would give up caffeine, their cell phone, internet access, or even sex for one month for the chance to obtain a month's relief from IBS symptoms.
- > **7th most common diagnosis** made by all physicians and the **most common diagnosis made by gastroenterologists**



# Irritable Bowel Syndrome (IBS) Market

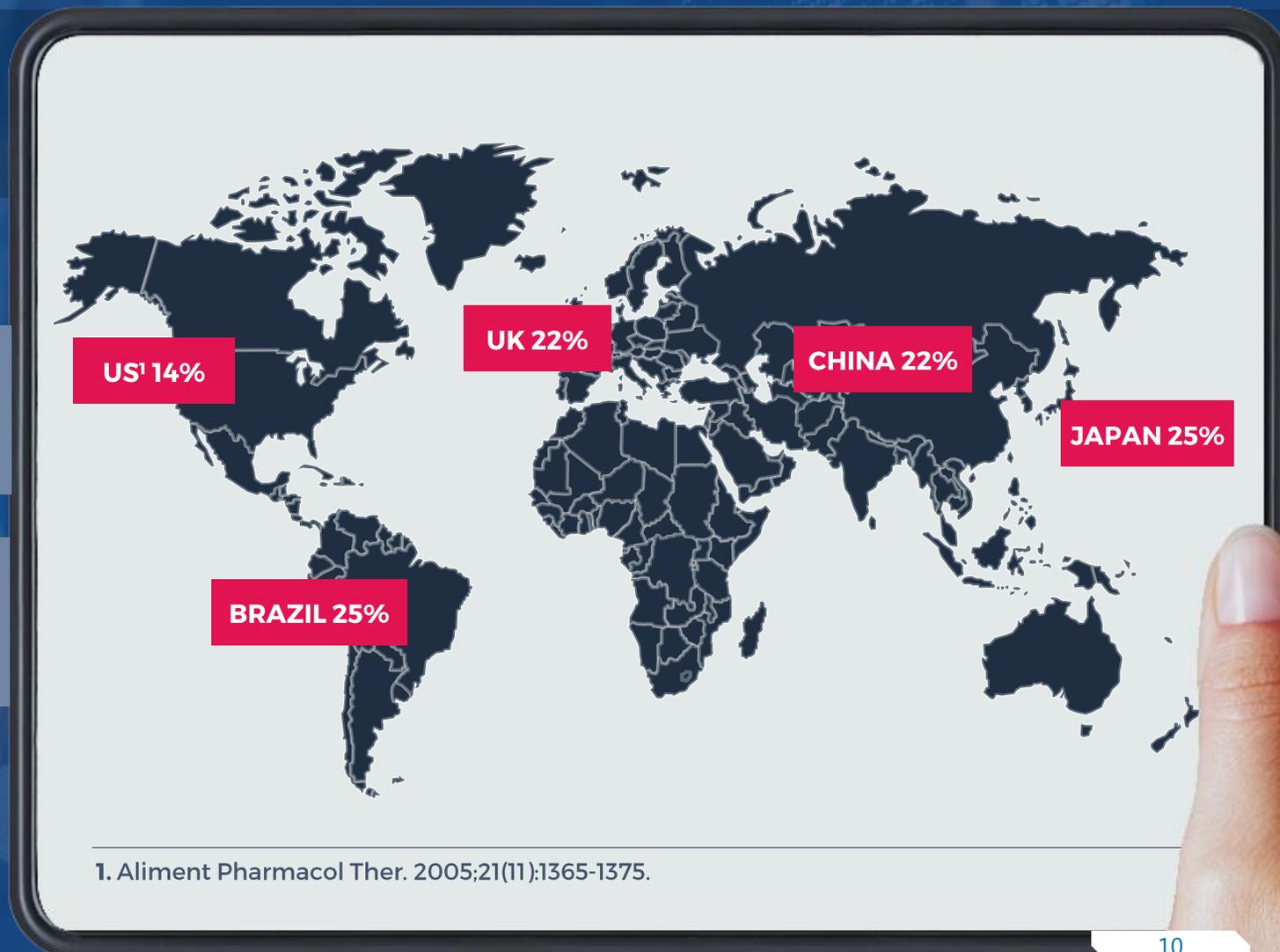
## Worldwide Prevalence Of Disease



**OVER 45 MILLION** IBS Sufferers in US  
at 14% of population



**OVER 825 MILLION** Sufferers Globally  
(at est. 11% of population)



1. Aliment Pharmacol Ther. 2005;21(11):1365-1375.



# Food, the Microbiome, and GI Illness

**Microbial environment in the intestines and diet play a role in the etiology & predisposition to development of GI illness such as IBS; similar inflammatory pathways activated in IBD, but with less severe symptoms**

## Success in IBS-D2 (using Biomerica 1st Gen Product)

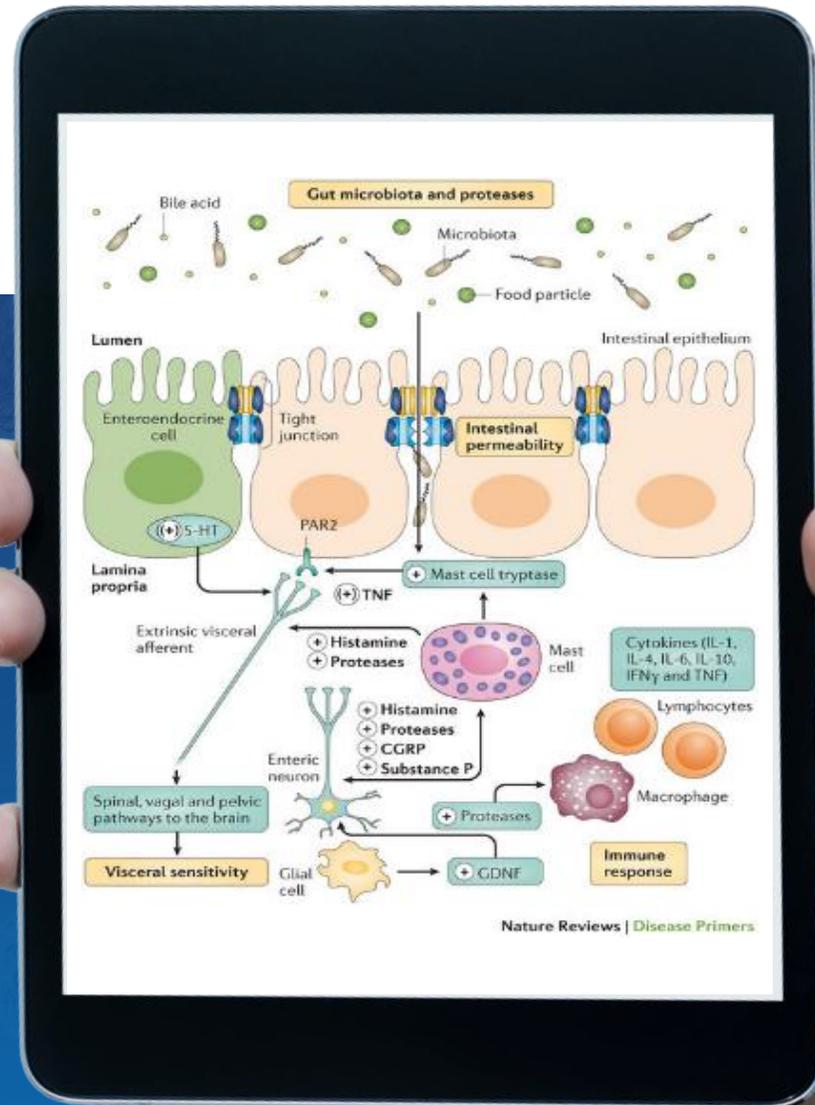
- > 77 patients with 12-week specific-food exclusion diets resulting in significant improvements in abdominal pain, diarrhea frequency, abdominal distension, stool shape, general feelings of distress and total symptom score ( $9.06 \pm 2.06$  to  $3.60 \pm 2.58$  after 12 weeks  $P < 0.01$ ).

## Success in IBD-UC3 (using Biomerica 1st Gen Product)

- > First generation product with UC patients in a clinical trial and found both significant Symptom Improvement (Mayo Score) and Quality of Life (QoL - a validated instrument used in FDA drug studies) improvement.

## Success in IBD (Diet studies)

- > IBD Example Suskind, et.al. 2016: Final follow-up mean pediatric CD disease activity index decreased from  $28.1 \pm 8.8$  to  $4.6 \pm 10.3$ , while the mean UC disease activity index dropped from  $28.3 \pm 23.1$  to  $6.7 \pm 11.6$ . C-reactive protein level dropped from  $24.1 \pm 22.3$  to  $7.1 \pm 0.4$  mg/L at 12 weeks in patients at one site and decreased from  $20.7 \pm 10.9$  to  $4.8 \pm 4.5$  mg/L at the other.

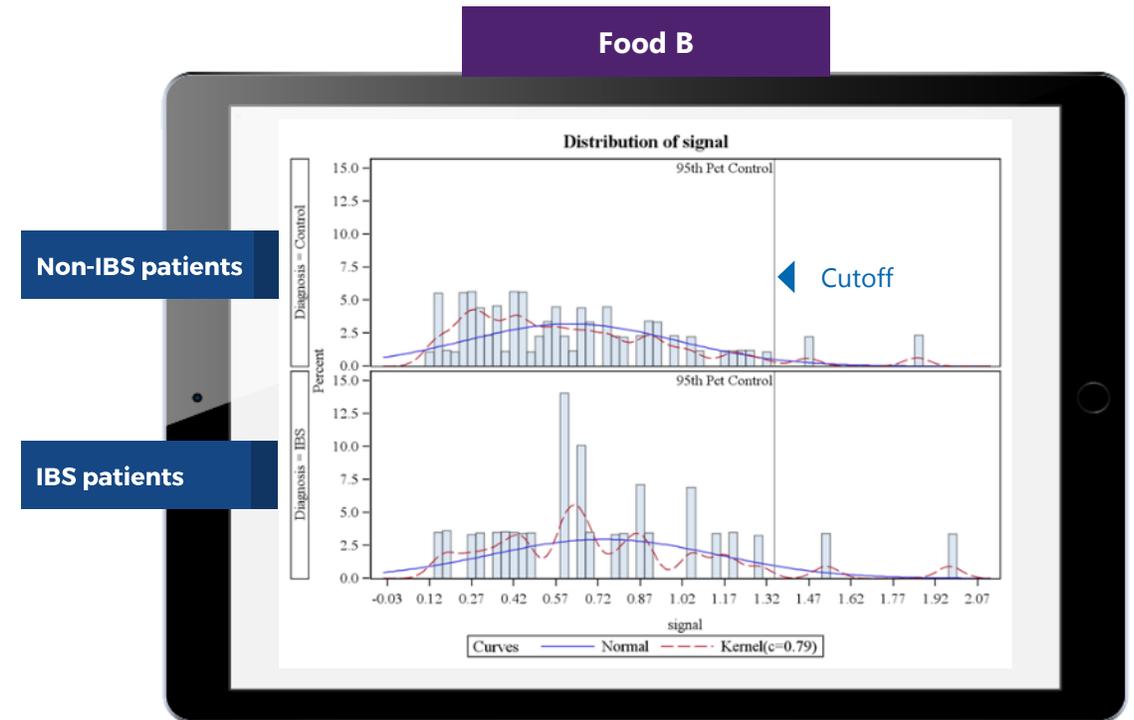
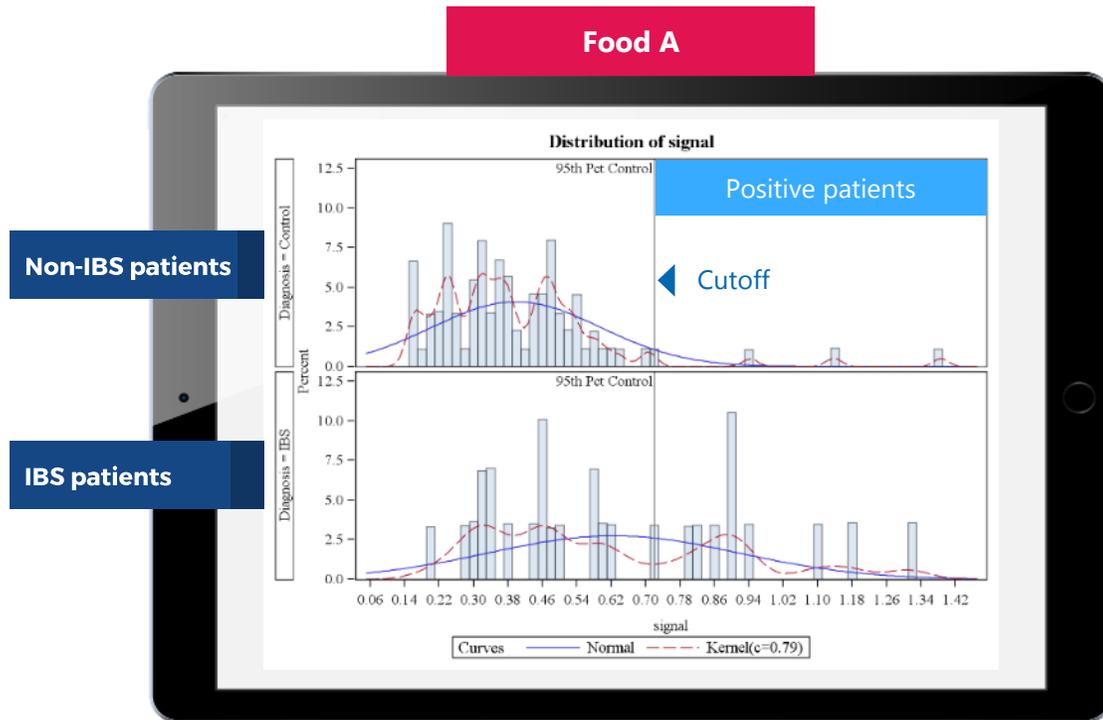


1. Irritable Bowel Syndrome. **Enck, Paul et al.** 2016. Nature Reviews Disease Primers, 2 (16014)
2. Value of Eliminating Foods According to Food-specific Immunoglobulin G Antibodies in Irritable Bowel Syndrome with Diarrhoea. **Hong, Guo, et al.** 2012 The Journal of International Medical Research
3. Inflamm Bowel Dis • Volume 24, Number 9, September 2018



# Technology

- > Histograms show ELISA results for two foods (A&B); top half is non-IBS group, bottom half is IBS subjects
- > Food A shows clear elevation of a percentage of IBS subjects to this food above the normal range; Food B does not
- > Cutoff would be set to call elevated patients positive, rest negative
- > Note: we would not expect all IBS subjects to be positive to every food



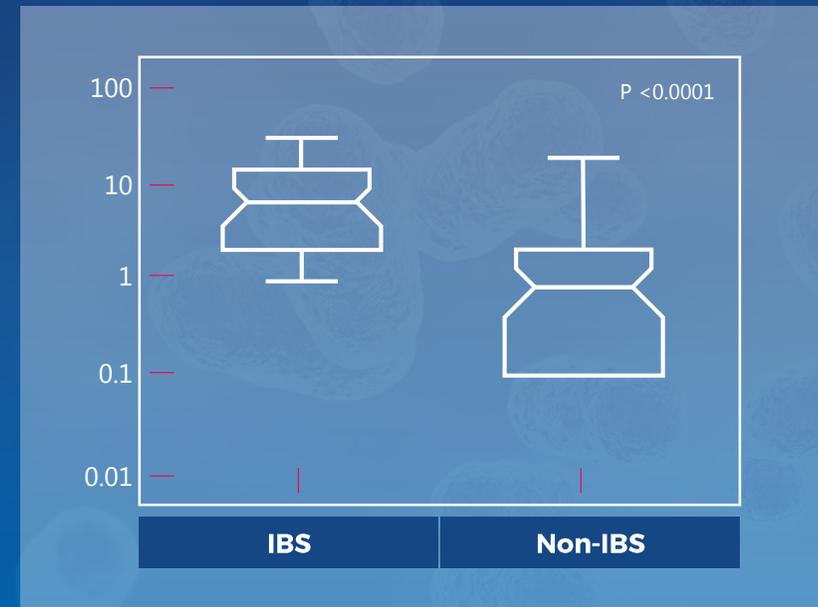


# Technology: IBS Patients vs. non-IBS Controls: # of Positive Foods

## Median # of Positive Foods

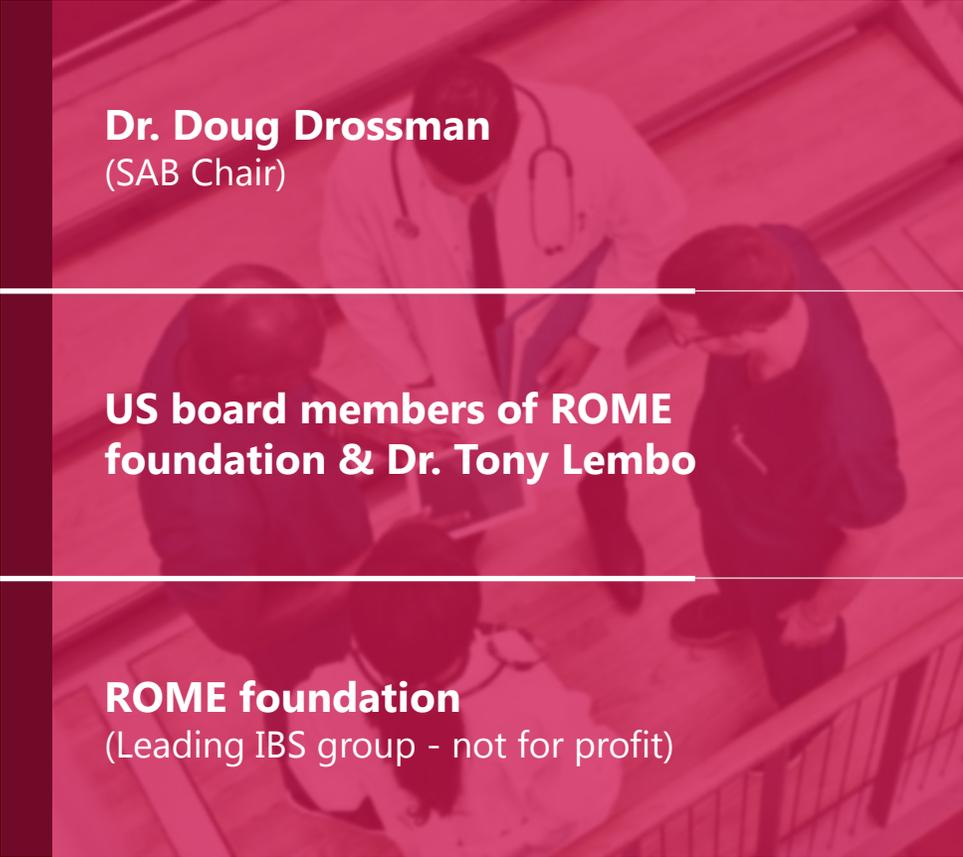
Group	Median #Foods Positive	95% CI for the Median
IBS	5	4-8
Non-IBS	1	1-1

## Box and Whisker Plot IBS vs. non-IBS





# Scientific Advisory Board & ROME Foundation



**Dr. Doug Drossman**  
(SAB Chair)

- > Dr. Doug Drossman (President of the ROME foundation) leading opinion leader in IBS
  - Chair of ROME since 1989
  - Participated in 50+ Clinical Studies for IBS
  - Has been PI for major IBS drugs
- > Recruited the other 3 US members of the ROME foundation
- > Smallest market cap of public company he is involved with is over \$500m

**US board members of ROME foundation & Dr. Tony Lembo**

- > 2 of our SAB members were the PI's for Linzess (Allergan/Ironwood drug)
- > Joined our team to help guide and drive FDA clinical process
- > Member serves on FDA GI advisory panel
- > Tony Lembo, M.D.: Dir of GI at Beth Israel Deaconess Med Center & Professor of medicine at Harvard

**ROME foundation**  
(Leading IBS group - not for profit)

- > Viewed as the leader in functional GI diseases and IBS
- > ROME IV introduced
- > Rome is the criteria that FDA and physicians use to define an IBS patient
- > Mission is to improve the lives of people with functional GI disorders



# Strategic Advisory Board & Dr. Mark Sirgo

## **Ned Barnholt**

Chairman of KLA-Tencor; Former CEO and Chairman of Agilent Technologies

- > Chairman KLA-Tencor (Nasdaq: KLAC market cap: ~\$17 billion)
- > Board of directors of eBay and Adobe
- > Former Chairman/CEO of Agilent Technologies (leading company in life sciences & diagnostics)
- > Led the Agilent spin-out of Hewlett-Packard Company
- > largest IPO in Silicon Valley history at the time of the IPO

## **Dr. Harry Leider**

Former Chief Medical Officer of Walgreens

- > Led a cross-functional department of over 40 professionals that conducted over 60 health outcomes studies
- > Lead a team that evaluated over 200 healthcare technologies, M & A and partnership opportunities
- > Directed the clinical design for a digital health programs
- > Held C-suite positions in several leading health and payor companies

## **Dr. Mark Sirgo**

Former Board of Directors member & Chairman of the Compensation Committee of Salix Pharmaceuticals

- > Assisted in the sale of Salix to Valeant for over \$11.1 billion in cash.
- > 16 years in clinical development and marketing at Glaxo, including Vice President of International OTC Development and Vice President of New Product Marketing
- > >30 years of experience in the pharmaceutical industry, including clinical drug development, marketing & BD
- > Board of Directors of Biomerica



# Competing therapies in the IBS market

## Ironwood Pharmaceuticals (NASDAQ: IRWD)

**Market Cap\*: \$1.75B**

**Product: Linzess®**  
Ironwood owns 50% of Linzess

- > IBS-C
- > PI's: Two members of ROME foundation
- > Side effects: Diarrhea, Abdominal Pain, Flatulence, Headaches, Viral gastroenteritis & Distension
- > US sales of Linzess \$560m

The cost for Linzess 72 mcg capsule is around **\$412 for 30** capsules, depending on the pharmacy you visit  
<https://www.drugs.com/price-guide>

## Salix Pharmaceuticals

**Acq. for \$11Bil by Bausch Health Cos**

**Product: Xifaxan® (Rifaximin)**

- > IBS-D only
- > Side effect: Nausea, Dizziness, Fatigue, Peripheral edema, Ascites (build up of fluid in in abdomen)
- > Xifaxan global sales \$1.1 bil

The cost for Xifaxan 200 mg capsule is around **\$609 for 30** capsules, depending on the pharmacy you visit  
<https://www.drugs.com/price-guide>

## Biomerica (NASDAQ: BMRA)

**Market Cap\*: \$23MM**

**Product: InFoods® IBS**

- > Intended use is entire IBS market (IBS-C, IBS-D, and IBS-M)
- > Diagnostic therapy – Identifies foods to avoid to alleviate IBS symptoms
- > Side effects: NONE

InFoods price based on reimbursement to existing CPT code, one to three times per year.

\*Approximate; as of 5/21/2019



# FDA Approval - Thresholds

Indication	Drug	FDA Appr	Treatment Response	Placebo Response	Delta vs placebo	Cost*	Annualized U.S. Sales (M)	Comments
IBS-C	Linzess	2012	20% - 34%	6% - 27%	<b>7% - 14%</b>	\$382	\$761**	> Diarrhea side effect (20%)
	Amitiza	2008	14%	8%	<b>6%</b>	\$380	\$450**	> Indicated for women only; not studied for men
IBS-D	Xifaxan	2015	41%	32%	<b>9%</b>	\$550	\$1,200***	> Not for chronic use
	Viberzi	2015	25% - 30%	17%-16%	<b>8% - 14%</b>	\$1,000	\$177	> Abdominal pain (secondary) endpoint not met
	Lotronex	2002	NA	NA	<b>13% - 20%</b>	\$940	\$60	> For women only. > Back box warning

\*Cost – per Drugs.com. Based on retail price of 30-day supply of lowest dose

\*\*Includes CIC and IBS-C

\*\*\*Includes overt HE and IBS-D

Side effects which are unpleasant even be dangerous - Lotronex carries a black box warning related to the risk of potentially serious GI events while Viberzi may cause pancreatitis in people w/o a gallbladder.



# Regulatory Pathway IBS



Enrolling patients at Beth Israel (Harvard); Univ. of Michigan.  
New GI Group added May 2019

FDA has determined that our proposed IBS clinical study is a nonsignificant risk (NSR)

> Avoids the much costlier and time-consuming PMA route (No Phase I, II or III)

IP & Data

Product Dev.  
R&D

FDA Sub Q

End Point  
Trial

6 - 9 months

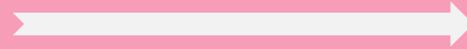
Pivotal Trial

12 - 14 months

Approval

## End Point Trial

- > **Primary Endpoint:** All 9 FDA endpoints QOL, API, BSS, SSS, etc
- > Expected number of Patients: **180**
- > IBS subtypes: **D, C & M**
- > Patient records: **programed EDC**
- > Sites: **Harvard BID, Michigan, GI Groups**



Everything else is same  
except more GI group  
participation

## Pivotal Trial

- > **One Primary Endpoint: Selected from Endpoint trial – e.g. API**
- > Expected number of Patients: **500-700**
- > IBS subtypes: **D, C & M**
- > Patient records: **programed EDC**
- > Sites: **Harvard BID, Michigan, GI Groups**

FDA has indicated that the product will be evaluated as a therapy



# IP & Technology



## Patents

2 patents allowed and 15 patents pending – Key International Patent Application was reviewed by the ISA and all claims were deemed novel and non-obvious.



## First Patents Allowed

- › **Korean Patent** No. 10-1887545 August 6, 2018. Title: Compositions, Devices & Methods of IBS Testing
- › **USA Patent** Allowance April 2019: broadly covers a product that enables physicians to identify patient specific foods that when removed, may alleviate or improve an individual's IBS symptoms.



## Platform Technology

- › First product is specific for IBS indication
- › Lab product - First to be submitted
- › Doctor office product under development - Post FDA approval of lab product
- › Other GI diseases applied for patents



# InFoods® Advantages



**Rx Drugs only treat  
symptoms  
not the underlying cause**

## The InFoods® Key differences

InFoods® focuses on underlying cause of IBS

### Reimbursement to Doctor

- > Drugs = \$0
- > Diagnostic = Large revenue potential
  - ⊙ CPT insurance reimbursement code already exists

### Ability to use on all 3 types of IBS

- > Targets 100% of the IBS market (not just 1/3)
- > Would be the only solution for IBS-M

### Will be used as combination therapy with drugs

- > Key pharma makers could combine InFoods® with their drugs for best practice treatment, locking in their drug in the combined therapy

**Problem food change in patients which could require testing 2-3 times per year**



# Revenue Drivers for InFoods®



## US Market Only

- > 45 million<sup>1</sup> treatable IBS patients in the US
- > 12.7 million<sup>2</sup> Americans, (28.7%) of IBS patients in the US, seek physician treatment consistently
- > Physicians could perform the InFoods test in-office, and generate revenue for their office
- > In a recent survey<sup>3</sup>, the average primary care physician estimated using InFoods therapy on over 90% of their IBS patients
- > Revenues shared by Biomerica, distribution partner and physician's office or lab (win-win-win)



## Global Market

- > Over 825 million<sup>4</sup> estimated IBS sufferers Globally (based on 11% of global population)
- > InFoods will be a fraction of the annual cost of many IBS drugs (key in Gov.-pay countries)

1. Aliment Pharmacol Ther. 2005;21(11):1365-1375

2. Irritable bowel syndrome in the United States: prevalence, symptom patterns and impact , A. P. S. Hungin, June 2005, Alimentary Pharma & Thera.

3. Independent marketing research company

4. Clin Epidemiol. 2014; 6: 71-80. Published online 2014 Feb 4. doi: 10.2147/CLEP.S40245



# Specialty diagnostic company with potential to disrupt and revolutionize a multi billion dollar market



## Specialty Diagnostics Business

2019 growth opportunity

**ez+detect™**

2020 growth opportunity

**hp detect™**

With only \$5.6 million of revenues in 2018, relatively small sales from new products or new distribution partners will have a large impact on sales and profitability. We believe we have significant potential up-side



**Lowers burn rate, creates growth opportunity - limits downside**



# 2019 Growth Opportunity Colorectal Disease Test



## Specialty Diagnostics Business

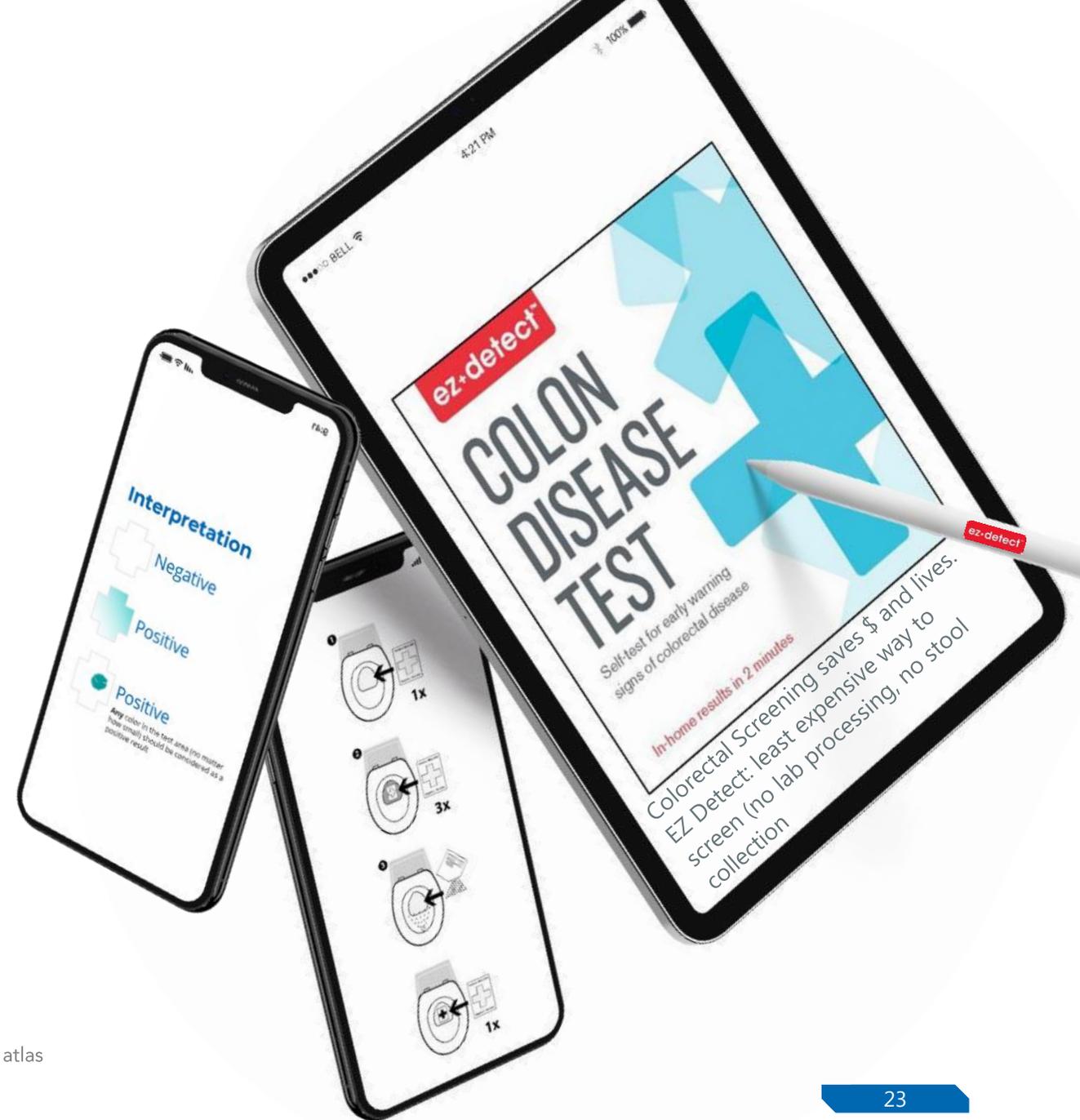
ez+detect™

Colorectal Disease Test

EZ Detect is a 2-minute, at-home test which shows possible early warning sign of colorectal cancer and other colorectal diseases.

- › Discussions with potential distributors ongoing
- › China and Mexico have recently cleared product for sale through their FDA equivalent agencies
- › China Opportunity: Cancer is the leading cause of death in China and is a major public health problem<sup>1</sup>. Over 400 million people are over the age of 50 in China<sup>2</sup>.
- › Particularly attractive in countries where government funds all healthcare

<sup>1</sup> Chen et al., Cancer statistics in China, CA CANCER J CLIN 2016;66:115–132    <sup>2</sup> Knoema world data atlas





# 2020 Growth opportunity - H. pylori in Clinical Trials



## Specialty Diagnostics Business

hp detect™

*Detects H. pylori Ag*

Biomerica is targeting to have clinical trials completed in 2019, and hopes to have FDA clearance and sales in 2020.

- > **MARKET:** Approx. 1/3 of adults in the United States are infected with H. pylori. Infection rate is higher in Southern and Eastern Europe, South America and Asia.



- > **GASTRIC CANCER:** Alarming rate of growth in gastric cancer in US, particularly among immigrant populations in Southern California. Cancer caused by undetected and untreated H. pylori infection.
- > **MEDICAL PROFESSION:** “More accurate and reasonably priced diagnostic tests are needed to detect H. pylori and direct therapy before it causes injury and cancer” James Buxbaum, M.D., Associate Professor of Clinical Medicine at Keck School of Medicine of USC.
- > **COMPETITION:** Meridian Bioscience is largest distributor in the US of H. pylori antigen diagnostic test.
- > **REVENUE OPPORTUNITY:** Meridian H. pylori sales in US alone during 2018 were approximately \$37 million.
- > **PROFIT OPPORTUNITY:** Once approved by the FDA, Biomerica could sell it’s H. pylori product at a significant discount to the Meridian product and still earn 90% 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 needed to achieve material market penetration.



# Summary



## New InFoods<sup>®</sup> IBS therapy – identify foods that can alleviate IBS

- > **Key differentiation**
- > Reimbursement to Physician
- > A therapy that could replace or be combined with drug treatment
- > Treats the cause not the symptom
- > No side effects
- > Access to entire IBS market, not just a subset - Only option for IBS-M

## Expecting significant milestones over next 12 months

1. Colorectal
2. H. Pylori
3. InFoods<sup>®</sup> IBS



## Leading Opinion Leaders in IBS on SAB guiding clinical studies

Rome Foundation Members, Dr. Mark Sirgo & Ned Barnholt

45+ million in US and 1 billion globally suffer from IBS

**IBS market is a multi billion dollar potential opportunity**



**Legacy business provides growth opportunities & floor for valuation**

