

BIOMERICA

Investor Presentation • June 2022 / 2022年6月 投资者报告

Forward-Looking Statement / 前瞻性陈述

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 / 诊断指导治疗

Using Science, Diet and Technology to Revolutionize the GI Market / 使用科学、饮食和 技术彻底改变胃肠道市场







Investment Highlights / 投资亮点



Disruptive Patented Platform Technology redefining the GI Market /突破性的专利平台科技重新定义了冒肠道市场

First ever FDA-regulated diagnostic therapy / 有史以来第一个由FDA监管 的诊断疗法



Large Growing Market / 庞大并且不断增长的市场

- \$30+ Billion expansive market opportunity / \$300多亿的广阔市场机会
- Robust patent portfolio (11 issued patents; 100+ patents pending) / 强大的专利组合(11项已颁发的专利:100多项待批准的专利)



Significant Milestones Driving Growth / 推动增长的重大里程碑

- InFoods® IBS clinical trial complete / InFoods® IBS临床试验完成
- H. Pylori antigen test launch / 幽门螺杆菌抗原试剂推出
- ez+detect Colon Disease Test / ez+detect 结肠疾病试剂



Conservative Capital Structure / 保守的资本结构

- ~18% Insider ownership / 内部人士持股约18%
- No warrants, no preferred equity and no debt / 无认股权证、无优先股、 无债务



Depth of Scientific Leadership / 资深的科学领导力

- SAB Leadership includes US Members of the Rome Foundation / SAB 领导层包括罗马基金会的美国成员
- Clinical studies lead by principal investigators who set GI "treatment guidelines" / 由制定胃肠道《治疗指南》的主要研究人员领导临床研究



Leadership, Board & Depth in Science / 领导层、董

事会和深入科研

Management / 管理层

Scientific Advisory Board / 科学顾问委员会



ZACK IRANI

- Chief Executive Officer & Chairman / 首席执行 官兼董事会主席
- Previous CEO & Chairman of Lancer
 Orthodontics Inc. / Lancer Orthodontics Inc. 前 任首席执行官兼董事会主席



ALLEN BARBIERI

- Executive Vice Chairman / 执行董事会副主席
- Previous CEO of numerous public and private companies / 曾任多家上市公司和私营企业的首席执行官
- Board member at CareTrust REIT / CareTrust REIT董事会成员



STEVE SLOAN

- Chief Financial Officer / 首席财务官
- Previously held various roles at General Electric and Medtronic / 曾在通用电气和美敦力 担任多个职务



Cathy Coste, CPA / 注册会计师

lane Emerson, MD, PhD / 医学博士、博士

Mark Sirgo, PharmD / 医药博士



DOUGLAS DROSSMAN, MD/医学博士

- President Emeritus, Rome Foundation / 罗马基金会名誉主席
- Co-Director Emeritus, UNC Center for Functional GI and Motility Disorders / UNC功能 胃肠道和运动障碍中心荣誉联合主任



LIN CHANG, MD / 医学博士

- Professor of Medicine, UCLA, Division of Digestive Diseases / 加州大学洛杉矶分校消化系 统疾病科医学教授
- Rome Board member / 罗马基金会董事会成员
- Served on FDA GI advisory panel / 曾任美国FDA 胃肠道顾问小组成员



WILLIAM CHEY, MD, AGAF, FACG, FACP

- Professor GI & Nutrition Sciences, Univ. of Michigan / 密歇根大学胃肠道和营养科学教授
- Rome Board member / 罗马基金会董事会成员
- Co-Director Michigan Bowel Program / 密歇根 州肠道项目联合主任



WILLIAM WHITEHEAD, PHD

 Director, UNC Center for Functional GI and Motility Disorders / UNC功能性胃肠道和运动障 碍中心主任



ANTHONY LEMBO, MD

- Harvard Medical & Beth Israel Deaconess Medical Center / 哈佛医学和贝斯以色列女执事医疗中心
- Associate Editor of Journal of Clinical Gastroenterology and Digestive Diseases and Science / 《临床胃肠病学和消化道疾病与科学杂志》副编辑

Principal Investigators or Collaborators for: / 主要调査员或合作者:

Linzess[⊭]

Xifaxan



Viberzi

Xifoxon



Linzess✓ Viberzi

InFoods® Principal Investigators / InFoods® 主要研究员

WILLIAM CHEY, MD, AGAF, FACG. FACP

- University of Michigan Ann Arbor / 密歇根大学 -安阿伯分校
- Director of the Digestive
 Diseases Center / 消化系统疾病中心主任
- Co-Author of ACG Guidelines / ACG指南的共同 作者



 Harvard – Beth Israel Deaconess Medical Center / 哈佛大学-贝斯以色列女执事医疗中心

TISHA LUNSFORD. MD / 医学博士

- Mayo Clinic / 梅奥诊所
- Director of the Motility Interest Group / 运动学 兴趣小组主任

BRIAN LACY, MD, PHD

- Mayo Clinic / 梅奥诊所
- Current co-Editor in Chief of the American Journal of Gastroenterology / 現任《美国胃肠病 学杂志》联合主编
- Co-Author of ACG Guidelines / ACG指南的共同 作者

作者 EAMONN OUIGLEY. MD

 Chief, Division of Gastroenterology and Hepatology at Houston Methodist / 休斯顿卫理 公会胃肠病学和肝脏病学部主任

BROOKS CASH, MD, AGAF, FACG, FACP, FASGE

• Chief of Gastroenterology, University of Texas Health Science Center at Houston /德克萨斯大学 休斯顿健康科学中心胃肠病学主任





BIOMERICA

Background & Innovation / 背景与创新

Leveraging diagnostic expertise to transition into diagnostic-guided therapeutics / 利用诊断方面的专业知识,过渡到诊断指导疗法

Specialty diagnostics enabling early disease detection and monitoring / 实现早期疾病检测和监测的专业诊断方法

- Two FDA, CE, CFDA registered manufacturing facilities in California and Mexico / 在加州和墨西哥有两个FDA、CE、CFDA认证的制造工厂
- Commercially launched FDA cleared diagnostic tests / 商业推出 FDA认证的诊断试剂

SinFoodsDisruptive patented technology platform enabling diagnostic therapies / 突破性的专利科技平台*为诊断疗法提供支持*

- Redefining the treatment of GI diseases / 重新定义胃肠道疾病的治疗
- Also applicable for treating non-GI chronic inflammatory diseases / 也适用于治疗非胃肠 道的慢性炎症性疾病
- Gross margin opportunities similar to drugs / 毛利率机会与药物类似



InFoods® – Diagnostic Guided Therapy (DGT) to Treat Chronic Inflammatory Diseases / InFoods®—治疗慢性炎症性疾病的诊断指 导疗法(DGT)





- FDA-regulated diagnostic to be used as therapy /美国食品药品监督管理局(FDA) 监管的诊断,将用作治疗方法
- Measures immunoreactivity for a panel of foods to determine which foods are above normal range and problematic for a specific patient / 测量一组食物的免疫反 应性,以确定哪些食物超出正常范围并且不适合特异性患者
- Allows physicians to identify patient-specific foods which, when removed from diet, may alleviate or improve the patient's gastrointestinal symptoms and suffering / 让医生识别特异性患者食物, 如果从饮食中去除,可能会减轻或改善患者的胃肠道症状和痛苦
- Clinical trial guided by U.S. members of the Rome Foundation, the leading organization that sets IBS treatment guidelines / 临床 试验由罗马基金会的美国成员指导,该基金会是制定肠易激综合征 (IBS)治疗指南的主要组织

Example of Patient-Specific Results / 特异 性患者结果示例

Food / 食物	Result / 结果		
Blueberry / 蓝莓	+ POSITIVE / 阳性		
Chicken / 鸡肉	NEGATIVE / 阴性		
Cabbage / 卷心菜	NEGATIVE / 阴性		
Egg/鸡蛋	+ POSITIVE / 阳性		
Garlic / 大蒜	NEGATIVE / 阴性		
Lemon / 柠檬	NEGATIVE / 阴性		
Mustard / 芥末	NEGATIVE / 阴性		
Pork/猪肉	+ POSITIVE / 阳性		
Potato / 土豆	NEGATIVE / 阴性		
Sugar / 糖	NEGATIVE / 阴性		

Positive for: egg, blueberry, and pork / 阳性:鸡蛋、 蓝莓和猪肉

Irritable Bowel Syndrome (IBS) is Very Common and Costly / 肠易 激综合征 (IBS) 非常常见,而且成 本高昂

IBS is the **#1 most common diagnosis** made by gastroenterologists /肠易激综合征(IBS)是肠胃科医生做出的**第一大最常见诊断**¹

IBS is the **#7** most common diagnosis made by **all physicians /** 肠易激综合征 是所有医生做出的第七大最常见诊断 ¹

IBS patients visit doctors **3x more** than non-IBS patients / IBS患者看医生的次数比非IBS 患者**3倍**

IBS sufferers have **74% more** direct healthcare costs vs. non-IBS sufferers / IBS患者的直接医疗费用比非IBS患者**974%**

The Majority of IBS patients believe **foods trigger** their **symptoms** / 大多数IBS患者认为**食物**会引发他们的症状

¹Recent AGA Survey (American Gastroenterological Association). / 最近的AGA调查(美国胃肠病学协会)。



IBS Market is Significant Today and Growing / IBS市场现在 很重要而且在不断增长 \$30B+/\$300多亿

U.S. TAM / 美国潜在市场规模 1



1/3 IBS-C (Constipation / 便秘)

1/3 IBS-D (Diarrhea/腹泻)

1/3 IBS-M (Mixed: Alternates C+D) (混合: 便秘+腹泻交替)



21(11):1365-75。

US IBS Patients: / 美国IBS患者: seeking consistent physician treatment / 寻求一致 的医生疗法



IBS-M Patients: / IBS-M 患者:

No approved therapy/drug/没有被批准 的疗法/药物2



InFoods[®] IBS: Broad Benefits to Patients, Physicians, and Healthcare Insurers / InFoods® IBS: 对患者、医生和医疗保险公司有广泛益处

Targets 100% of the IBS Market (<u>IBS-M</u>, IBS-C, IBS-D) / 针对100%的IBS市场(IBS-M、IBS-C、IBS-D)¹

Patient Benefits / 患者受益

InFoods® targets underlying causes without causing side effects / InFoods®针对 根本原因,不产生副作用



IBS Drugs – Primarily treat symptoms AND can cause **major side effects** / 肠易激综合征药物-主要是治疗症状, 会引起主要的副作用

Physician Benefits / 医生受益

InFoods®: Recurring revenue potential as problem foods change in patients / InFoods®: 随着患者问题饮食发生变化,而使医生产生潜在的常续性营收



IBS Drugs = \$0 revenue to physician / IBS药物=医生的收入 为\$0

Payer/insurer Benefits / 支付方/保险方受益

InFoods[®] insurer savings

Currently: IBS Patients require 3x doctor visits & monthly drug costs / InFoods® 目前为保险公司节约成本: IBS患者需要三倍的就诊次数以及每月的药物费用

U.S. Healthcare annual costs of IBS ~\$30B/year / 美国每年用于IBS的医疗费用约为\$300亿

¹IBS-M = Mixed: Alternates C+D; IBS-C = Constipation; IBS-D = Diarrhea. / IBS-M = 混合:便秘+腹泻交替; IBS-C=便秘; IBS-D=腹泻。



FDA Approved Therapies are Expensive and have Efficacy and Safety Limitations / 美国食品药品监督管理局批准的治疗方法价格昂贵,并且有疗效和安全方面的限制

Indication / 适应症	Drug / 药物	FDA Approval / FDA批准	Drug Treatment Response / 药物治疗反应	Placebo Response / 安慰剂反应	Drug minus Placebo Response / 药 物减去安慰剂 后的反应	Monthly Cost / 每月花 费	Annualized U.S. Sale / 年 化美国销售额	Limitations / 限制
IBS-C	Linzess	2012	20% - 34%	6% - 27%	7% - 14%	\$467	\$1,963M / \$19.63 亿	• Diarrhea side effect (20%) / 腹泻副作用(20%)
	Amitiza	2008	14%	8%	6%	\$371	\$410M / \$4.1亿	• Indicated for women only; not studied for men / 仅适用于女性;未对男性作研究
IBS-D	Xifaxan	2015	41%	32%	9%	\$2,757 ¹	\$1,905M / \$19.05 亿	• Not for chronic use / 不适合长期使用
	Viberzi	2015	25% - 30%	17% - 16%	8% - 14%	\$1,383	\$266M / \$2.66{Z	• Abdominal pain (secondary) endpoint not met / 腹痛(次要) 终点未达到
	Lotronex	2002	NA / 不适用	NA / 不适用	13% - 20%	\$2,240 ²	\$6M / \$600万	For women only / 仅适用于女性Black box warning / 黑框警告

IBS Drug Side Effects Can Be Dangerous / IBS药物的副作用可能 很危险

Lotronex carries a black box warning related to the risk of potentially serious GI events / Lotronex有一个黑框警告,涉及潜在的严重胃肠道事件风险

Source: IQVIA FY2020 sales and monthly WAC. / 来源: IQVIA 2020财年销售额和月度加权平均费用。

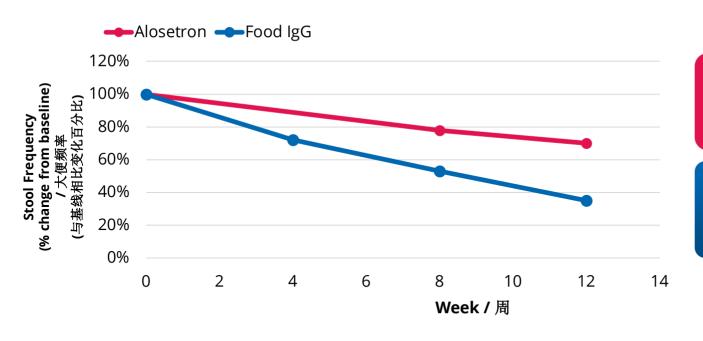


¹Denotes cost for 550mg Xifaxan dose; 200mg dose WAC is \$723. ²Denotes cost for 1mg Lotronex dose; 0.5mg dose WAC is \$1,120. / ¹表示550毫克Xifaxan剂量的费用; 200毫克剂量的加权平均费用为\$723。 ²表示1毫克Lotronex剂量的费用; 0.5毫克剂量的加权平均费用为\$1,120。

Biomerica First-Generation Product vs. Lotronex™ / Biomerica第一代产品与 Lotronex™相比

(Diarrhea Stool Frequency: an FDA endpoint) / (腹泻大便频率: FDA终点)

IBS-Diarrhea / IBS-腹泻



Alosetron (Lotronex™)

Drop from Baseline: / 从基线下降:

30%

Biomerica First-Gen Product Biomerica第一代产品

Drop from Baseline: /从基线下降:

65%

Separate Independent studies: Ther Adv Gastroenterol 2018, Vol. 11: 1–11 J Int Med Res. 2012;40(1):204-10. / 单独的独立研究: Ther Adv Gastroenterol 2018, Vol. 11: 1–11 J Int Med Res. 2012;40(1):204-10。



InFoods® Regulatory Pathway / InFoods®监管途径

IP & Data / 知识产权 和数据

Product Dev. R&D /产品开发研发

FDA Sub O

End Point Trial / 终点 试验

- 1. final patient treatment / 最终 患者治疗
- 2. Top line results / 顶线结果

Pivotal Trial / 关键性 试验

FDA Approval / FDA 批准

12 - 14 months / 12-14个月

- FDA has indicated InFoods® IBS will be evaluated as a therapy / FDA表示 InFoods® IBS将被作为一种疗法进行评估
- 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) / FDA已经确定提议的IBS 临床研究是一项非重大风险,避免了成本更 高、时间更长的PMA临床试验途径(不需要I、 ||或||期)。
- Endpoint Trial is complete: Goal of the trial was identifying the best primary endpoint to use in the final Pivotal Trial / 终点试验已完成: 试验的目标是确定 在最终关键性试验中使用的最佳主要终点

Endpoint and Pivotal Trials Overview / 终点和关键性试验概述

Sites / 场地

Mayo Clinic, Harvard BID, University of Michigan. **Houston Methodist. University of Texas Houston &** others / 梅奥诊所、哈佛大学BID 医学中心、密歇根大学、休斯顿卫 理公会、德克萨斯大学休斯顿分校 及其他机构

Design / 设计

Double-blind randomized placebo controlled trial of true diet for foods with a positive immune response v. sham diet of random foods / 双盲随机 安慰剂对照试验, 对具有 阳性免疫反应的食物的真 实饮食与随机食物的模拟 饮食进行对比

Primary Endpoint / 主要终点

All 9 FDA endpoints OOL, API, BSS, SSS, etc. for Endpoint Trial: one endpoint to be selected for Pivotal Trial (e.g. API) / 所有9个FDA终点QOL、 API、BSS、SSS等用于终点 试验:一个终点用于关键 性试验(如API)

Participants / 参与者

N=180 (Endpoint Trial); N=500-700 (Expected for Pivotal Trial) / N=180(终 点试验): N=500-700 (预计用于关键性试验)

Complete / 已完成

Positive Topline Results from the Endpoint Clinical Trial from InFoods® IBS **Treatment for Patients** with Irritable Bowel Syndrome / InFoods® IBS 治疗肠易激综合征患者的终点临床 试验取得积极的顶线结果



InFoods® IBS: Clinical Trial Design Summary / InFoods® IBS: 临床试验设计摘要

Randomized Double Blinded Placebo controlled / 随机双盲安慰剂对照

Patient is InFoods positive to:

Blueberries & Almonds / 患者对
InFoods呈阳性反应: 蓝莓和杏仁



Treatment Arm / 治 疗组

Eliminates

Blueberries & Almonds / 減
去蓝莓和杏仁

Placebo Arm / 安慰 剂组

Eliminates
Raspberries & Walnuts

(if negative and same consumption)/ 减去**树莓和核桃** (如果是阴性和相同的食用量)



Highlights / 亮点

Statistically meaningful improvements were seen in multiple endpoints (symptoms), this is only a selection of topline results from the InFoods® IBS endpoint trial / 在多个终点(症状)中出现了有统计学意义的改善,这只是InFoods® IBS终点试验顶线结果的一部分

Global Endpoints / 总体终点

, ;

GIS \Rightarrow

InFoods® IBS Top Line - Global Endpoints / 顶 线——总体终点

(nFoods

Treatment Arm / 治疗组 Vs.

Placebo Arm / 安 慰剂组

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) / 所有患者亚型作为一组,**受试者总体缓解评估(SGA)**终点改善的**P值为0.007**(基线与8周相比)

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 / 受试者总体缓解评估(SGA)是一个单一的衡量标准(终点),包括腹痛/不适、肠道功能的改变和整体健康状况。这种测量方法已在IBS人群中得到验证,在过去被认为是IBS试验的标准症状评估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) / 所有患者亚型作为一组,**总体改善量表(GIS)**终点改善的**P值为0.040**(基线与8周相比)

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 / 总体改善量表(GIS)使用患者定义的7点李克特量表评估了多种肠易激综合征(IBS)症状,评估范围从症状严重恶化到显著改善

Highlights / 亮点

Statistically meaningful improvements were seen in multiple endpoints (symptoms), this is only a selection of topline results from the InFoods® IBS endpoint trial / 在多个终点(症状)中出现了有统计学意义的改善,这只是InFoods® IBS终点试验顶线结果的一部分

Pain and Bloating / 疼痛和腹胀

API

 \Rightarrow

Bloating / 腹胀

InFoods® IBS Top Line - Global Endpoints Endpoints / 顶线——总体终点

(inFoods

Treatment Arm / 治疗组 Vs.

Placebo Arm / 安慰剂组

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-混合型和IBS-便秘型患者作为一组,**腹痛强度(API)**终点改善的**P值为0.012**(基线与8周相比)

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 / IBS部分依据疼痛来定义,而疼痛是许多患者IBS疾病经历的基石。腹痛指数(API)是唯一可以作为整体腹痛严重程度的综合测量工具,由疼痛频率、强度和持续时间组成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) / IBS-混合型和IBS-便秘型患者作为一组,**腹胀**终点改善的**P值为0.022**(基线与8周相比)

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 / 高达96%的肠易激综合征(IBS)患者都有腹胀的症状,女性更常见,而且经常被列为最令人烦恼的症状²

InFoods® Commercialization Strategy / InFoods®商业化战略

Multiple Avenues to Drive Adoption / 多渠道推动采用

Inclusion in Guidelines / 纳入指南

- Inclusion in the IBS treatment guidelines will accelerate product adoption / 列入IBS治疗指南将加速产品的采用
- → The Rome Foundation holds significant influence in setting the treatment guidelines / 罗马基金会在制定治疗指南方面有很大的影响力

Reimbursement Awareness and Enhanced Coverage / 报销

- 意识和加强覆盖面
- Help GI physicians monetize their largest patient population: reimbursement code already exists for Medicare patients / 帮助胃肠科医生通过他们最大的患者群体获利: 医疗保险患者已经有了报销代码
- Initiate conversations with payors to enhance access to product at both the point of care and outpatient diagnostic centers / 与付款人进行对话,以便在护理点和门诊诊断中心都能获得产品

Broad Physician Interest / 大量医生感兴趣

- Capitalize on strong physician interest evidenced by market research / 利用市场调查,证明医生有强烈兴趣¹
- GI physician and PCP respondents indicated they would adopt this product for 95% 100% of their patients, depending on the IBS subtype / 胃肠科医生和初级保健医生受访者表示,他们将为95%-100%的患者采用该产品,具体取决于IBS的亚型1

95% GI Physicians and PCPs Would Adopt InFoods® for Their Patients Depending on Subtype / 95%的胃肠科医生和初级保健医生会根据亚型为他们的患者采用InFoods®

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. /市场研究来源: Market Vision。根据在市场研究调查中获得的信息,所示百分比为胃肠科医生和初级保健医生的中位数。



SAB: Rome Foundation-Sets IBS Guidelines Expertise in Clinical Trials / SAB: 罗马基金会-设定IBS指南临床试验专业知识



Rome Foundation / 罗马 基金会 (Leading IBS organization) /(领先的IBS组织)

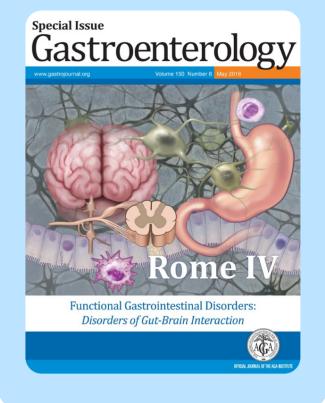
- Leading independent non-profit organization focused on the diagnosis and treatment of functional gastrointestinal disorders, including IBS / 领先的独立非营利组织,专注于功能性胃肠道疾病的诊断和治疗,包括IBS
- Rome creates the diagnostic criteria and guidelines that FDA and physicians use to define an IBS patient, and treat those patients / 罗马基金会创建了诊断标准和指导方针,FDA和医生使用这些标准和指导方针来定义IBS患者并治疗这些患者

Dr. Doug Drossman /博士 (Biomerica SAB Chair) / (Biomerica SAB主席)

- Dr. Doug Drossman (President Emeritus of the Rome Foundation) is one of the foremost opinion leaders in IBS / Doug Drossman博士(罗马基金会名誉主席)是IBS领域最重要的意见领袖之一
 - Participated in 50+ Clinical Studies for IBS / 参与了50多 个IBS的临床研究

Key Expertise on IBS Clinical Trials / 在IBS临床试验方面有重要的专业知识

- SAB members were the PI's on clinical trials for multiple approved GI drugs, including Linzess®, Viberzi®, and Xifaxan® / SAB成员是多个获批胃肠道药物的临床试验的PI,包括Linzess®、Viberzi®和Xifaxan®。
- Members serve on FDA GI advisory panel / 成员在FDA胃肠 道顾问小组任职



Platform Technology: / 平台技术:

Functional Gastrointestinal Disorders / 功能性胃肠道紊 乱

Gastrointestinal Diseases / 胃肠道疾病

Other Chronic Inflammatory Diseases / 其他慢性炎 症性疾病

InFoods® Development Pipeline / 开发管线

IP & Data / 知识产权和数据

Product Dev. R&D / 产品开发 研发

FDA Sub Q / FDA预申请 End Point Trial / 终点试验 Pivotal Trial / 关键性 试验

FDA Approval / FDA批准

Irritable Bowel Syndrome (IBS) / 肠易激综合征 (IBS)

Functional Dyspepsia / 功能性消化不良

GERD disease / 胃食管反流症

Ulcerative Colitis (UC) / 溃疡性结肠炎 (UC)

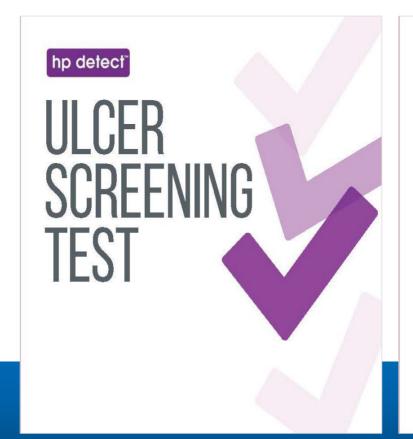
Crohn's / 克罗恩氏病

Migraines / 偏头痛

Dermatology / 皮肤病

Depression / 抑郁症

Specialty Diagnostics /专业诊断





2022 Growth opportunity - H. pylori / 2022年增长机会—幽门螺杆菌

hp detect

Detects H. pylori Antigen / 检测幽门螺杆菌抗原

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. / 幽门螺杆菌是一种细菌,感染了大约35%的美国人口和45%的欧洲五个主要国家的人口。大约20%的幽门螺杆菌感染者会出现一系列问题,包括消化性溃疡病、消化不良和胃癌。

- **Status:** Biomerica has submitted a 510k to FDA 510K submission April 2022. Initial sales planned in 2022. / **状态:** Biomerica已在2022年4月向FDA提交了510K申请。计划在2022年进行初始销售。
- 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. / 胃癌: 胃癌是世界上癌症相关死亡的第三大原因。超过80%的胃癌是由幽门螺杆菌感染引起的。在2017年,世界卫生组织(WHO)将幽门螺杆菌列为对人类健康构成最大威胁的16种耐抗生素细菌之一,并将幽门螺杆菌定为1级致癌物
- 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. / 盈利机会: 一旦获得美国食品药品监督管理局的批准,Bioserica可以以比竞争产品更高的折扣出售幽门螺杆菌产品,并且仍然可以获得80%的毛利率。
- **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. / 客户: 大多数幽门螺杆菌诊断试剂出售给大型实验室,如Quest、LabCorp和ARUP。因此,只需要较少的营销工作就能实现重要市场渗透。

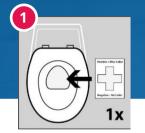


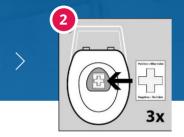
Colorectal Disease Test: EZ DetectTM / 大肠疾病检测: EZ DetectTM

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. / EZ Detect是一项用时2分钟的家用试剂,用于测 定粪便隐血,这是结肠直肠癌(CRC)和其他结肠直肠疾病 的早期预警信号。

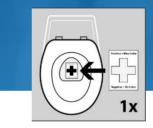


No Stool Handling /无需处理粪便













Negative / 阴性

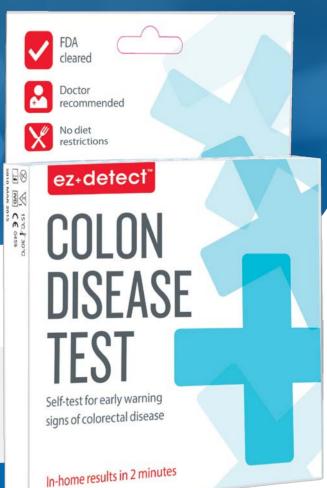


Positive / 阳性



Positive / 阳性

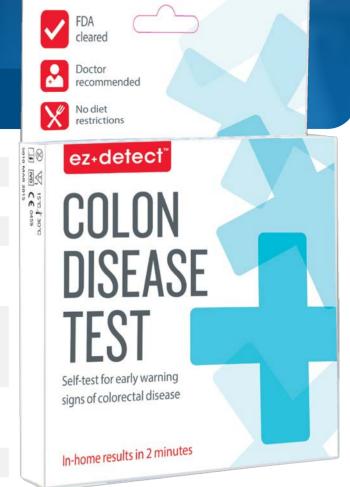
Any color in the test area (no matter how small) should be considered as a positive result / 检测区域的 任何颜色 (无论多小)都应被视为阳性结果





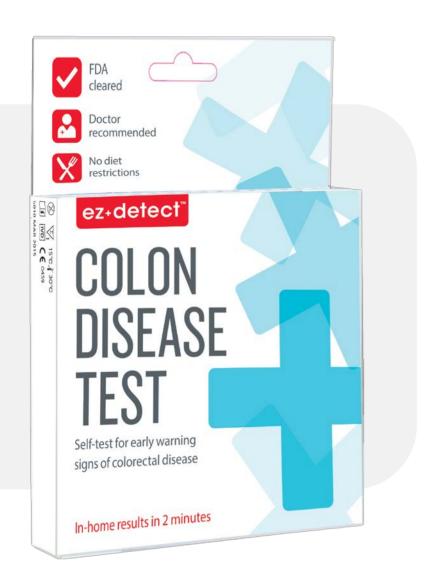
Key performance metrics for EZ DetectTM, Cologuard®, & FITs / EZ DetectTM、Cologuard®和FITs的关键性能 指标

Value / 价值	EZ Detect ^{™ (1)}	Cologuard® (2)	FIT ⁽²⁾
Price / 价格	\$14	\$649	\$22
Accuracy / 准确度	93.2%	86.6%	94.7%
Positive Likelihood Ratio /阳性似然比	91.2	6.9	14.3
Negative Likelihood Ratio /阴性似然比	0.27	0.09	0.28
Specificity (vs. all negative findings on colonoscopy/sigmoidoscopy) / 特异性(与结肠镜/乙状结肠镜检查的所有阴性结果相比)	99.2% (124/125)	86.6% (7936/9167)	94.9% (8,695/9167)
Sensitivity (vs. all CRC found by colonoscopy/sigmoidoscopy) / 灵敏度(与结肠镜/乙状腺镜检查发现的所有结肠直肠癌(CRC)相比)	72.9% (27/37)	92.3% (60/65)	73.8% (48/65)
Negative Predictive Value / 阴性预测值	92.5% (124/134)	99.9% (7936/7941)	99.8% (8695/8712)
Positive Predictive Value / 阳性预测值	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. / 由Renfe医疗部进行的研究(筛选)结果。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. / 用于大肠癌筛查的多目标粪便DNA测试。 Imperiale, Thomas F, et al. 2014, The New England Journal of Medicine, Vol. 370, pp. 1287-1297.



EZ Detect™: **Available at Walmart** / 在沃尔玛有售

Now in over / 现在 超过

4,600

Walmart Stores / 沃尔玛商店





Leveraging **Our Unique** Technology / 利用我们独特



Disruptive Patented Platform Technology redefining the GI Market / 突破性的专利平台技术重新定义了胃肠道市场

Addressing the large need for IBS patients and then targeting multiple other diseases / 解决IBS患者的大量需求, 然后针对其他多种疾病讲行治疗



InFoods Model is Unique / InFoods模式独一无二

Benefits Patient / Physician / Insurer / 使患者/医生/保险公司受益



Broad IP Protection / 广泛的知识产权保护

Robust patent portfolio (11 issued patents; 100+ patents pending) / 强大的专利组合(11项已颁 发的专利: 100多项待申请的专利)

- 16+ year remaining on patents filed / 已申请的专利还有16年以上的有效期
- Patents cover multiple disease states / 专利覆盖多种疾病状态



Financially Attractive / 财务吸引力

- Low burn rate / 资金消耗率低
- Clean Cap table No warrants, no preferred equity and no debt / 清晰的资本表—无认股权证、 无优先股、无债务



IBS Key Opinion Leaders set Treatment Guidelines / IBS关键意 见领袖制定治疗指南

- SAB Leadership includes US Members of the Rome Foundation / SAB领导层包括罗马基金会 的美国成员
- Clinical studies lead by principal investigators who set GI "treatment guidelines" / 由制定胃肠 道《治疗指南》的主要研究人员领导临床研究

