



*Pioneering Development
in the Gut Microbiome*
(NASDAQ: RTTR)

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Financial Snapshot: RTTR

Stock Information*	
Exchange	NASDAQ
Symbol	RTTR
Recent Price	\$2.10
52 Week Range	\$0.18 - \$4.00
Market Cap	\$11.3 Million
Com. Shares Outstanding	5.3 Million
50 Day Avg. Daily Vol.	108K Shares

*As of August 29, 2018

Ritter Pharmaceuticals Overview

Microbiome Therapeutics Improving Human Health

- Developing novel therapeutics that **modulate the gut microbiome** to treat gastrointestinal diseases
- RP-G28, potentially the **first FDA-approved drug for lactose intolerance (LI)**
 - Phase 3 pivotal study underway
- Robust intellectual property portfolio and NCE status
- **Experienced executive leadership team** and world-renowned scientific advisors

Highlights

Product	<ul style="list-style-type: none">• RP-G28, potentially the first FDA-approved drug for lactose intolerance (LI)
Large, Growing & Unsatisfied Market	<ul style="list-style-type: none">• \$2.5B over-the-counter (OTC) U.S. market• 40M U.S. sufferers with a target market of 9M moderate/severe individuals & millions more suffering globally
Clinical and Regulatory Pathway	<ul style="list-style-type: none">• Pivotal Phase 3 trial of RP-G28 initiated in Q2 2018• Approx. 12 month study, data readout expect in 2H 2019
Several Other Anticipated Initiatives	<ul style="list-style-type: none">• Product development of additional indications• Commercialization strategy and reimbursement analysis
Expanding Executive Team	<ul style="list-style-type: none">• Seasoned late-stage clinical development and capital markets focus
Compelling Valuation	<ul style="list-style-type: none">• Phase 3 asset with proof of efficacy/safety in large underserved market

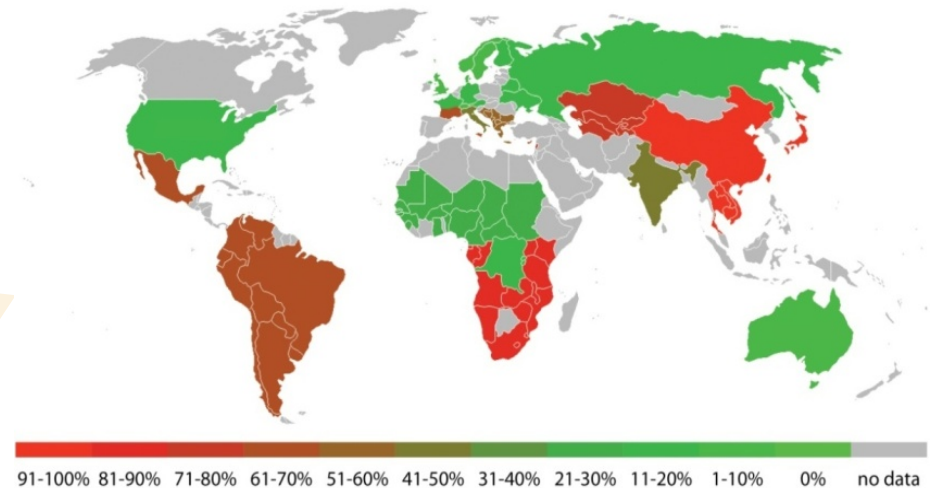
Lactose Intolerance Market Summary

Significant Market Opportunity

No prescription drug currently available for LI despite patient **desire and need** for a prescription treatment

- **40 million** U.S. lactose intolerant population¹
 - **9 million** are moderate/severe patients
- **>1 billion** global lactose intolerant population¹
 - **65 million** in Europe
 - **90 million** in Japan

Global Penetration Rates of Lactose Intolerance²



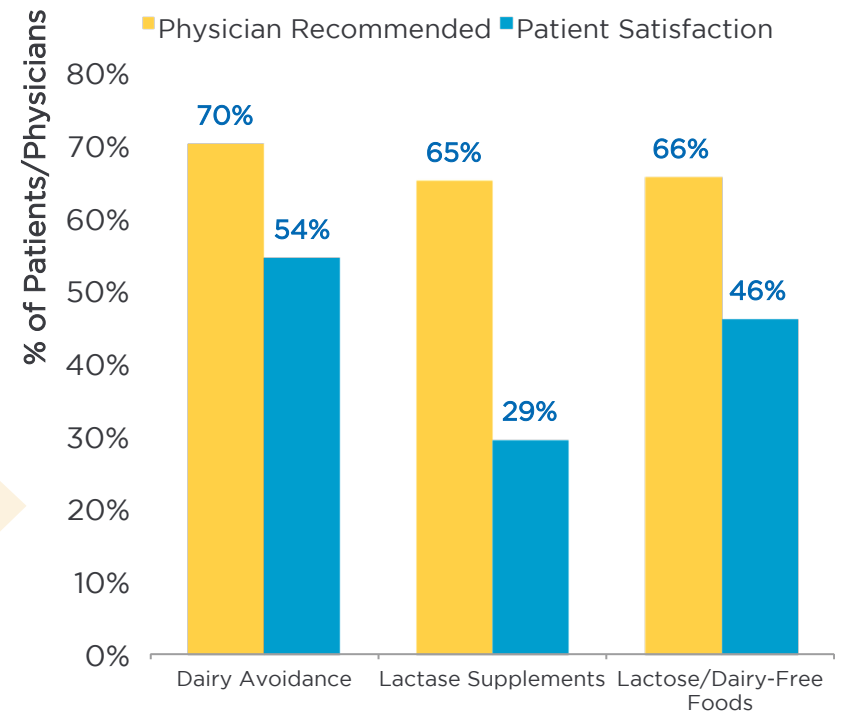
1. Objective Insights, "Market Research Analysis and Forecasts on Lactose Intolerance and RP-G28." June, 2012.
2. Bouwma A., Crawford D., Malladi S., Mirabito P., Oleksiak M., Osborn J., & Seawell P. (2010). Worldwide Distribution of Lactose Intolerance. Case Study.

Unsatisfactory Treatment Options

Significant \$ Spend on OTC Products

- **60% of patients seek a better solution**
- **Unsatisfactory treatment options²:**
 - Challenging to avoid all dairy and “hidden” lactose can cause unexpected symptoms
 - Lactase supplements are unreliable and modestly effective
 - \$400/person current annual spend on LI management options³

Patients Dissatisfied with Current Physician Recommended LI Management Options²



1. Lactose Intolerance Market Analysis Report - 2012.

2. Objective Insights, "Market Research Analysis and Forecasts on Lactose Intolerance and RP-G28." June, 2012.

3. Internal Formula - Lactaid Purchase 3x Month x 12 Months.

Symptoms Driving Strong Consumer Demand

- **82% experience symptoms weekly or more frequently**
 - >50% report symptoms moderately or severely impacts their daily activities¹
 - Long-term health concerns (such as osteoporosis, hypertension)
- **78% are interested in consuming dairy products without discomfort**
 - >70% are “extremely interested” or “interested” in an FDA-approved treatment
 - GI physicians report seeing 29 LI patients/month
 - Physicians likely to recommend RP-G28 to 44% of their patients as a first management option



- Engage Health Inc., “Market Potential for an Rx and Nutritional Supplement Product for Lactose Intolerance in the US.” June, 2008.
- Mary Bordeaux Consulting, “Managed Markets Research, RP-G28, Treatment for Lactose Intolerance.” March, 2012.

RP-G28

Novel Lactose Intolerance Treatment

- **Novel, non-digestible oligosaccharide**
 - Modulates the gut microbiome
 - Designed to stimulate growth of lactose-metabolizing colonic bacteria
- **Single, 30-day course of treatment**
 - Early results suggest 1 course of treatment may provide long-lasting, durable relief
 - Patients likely can be safely re-treated (study planned)
- **Provided in single dose packets as a powder to be mixed with water**



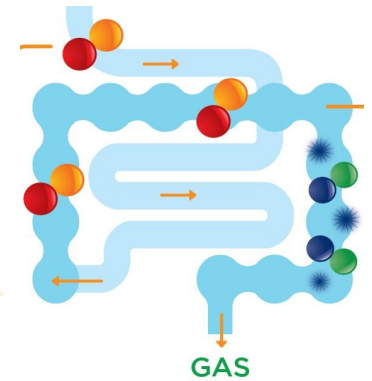
Target claim:
For the
treatment
of lactose
intolerance

Mechanism of Action

Microbiome Modulation

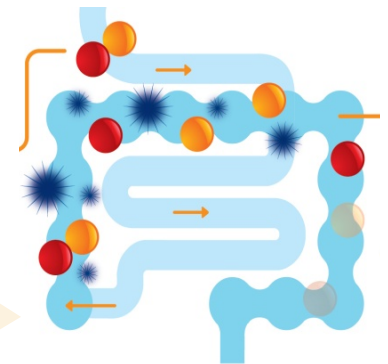
- **Lactose Intolerance:**

- Inadequate lactase activity in small intestine results in undigested lactose
- LI symptoms from undigested lactose are the result of:
 - Bacteria in gut ferments lactose that produces: **abdominal pain, flatulence and cramping**
 - Osmotically active lactose causes water retention in the gut: **bloating and diarrhea**



- **RP-G28 Promotes Colonic Adaptation:**

- Preferentially **stimulates growth of lactose-metabolizing** bacteria in the GI tract
 - Lactose-metabolizing bacteria compensate for the lack of endogenous lactase activity
 - Decrease proportion of gas-producing bacteria
- Lactose is broken down, reducing gas production and water retention, thus reducing gastric symptoms



RP-G28 Development

- RP-G28 is **one of the most advanced therapeutics** in microbiome research & development
- Clinical development program in Phase 3
- Strong safety profile demonstrated

PHASE TRIAL

1

- N=14
- Evaluated the pharmacokinetic (PK) profile of RP-G28

PHASE TRIAL

2a

- N=62
- Established mode of action (colonic adaptation), identified appropriate endpoints and clarified dosing regimen
- Safety and tolerability supported continued development
- No SAEs reported, AEs similar between placebo and treatment

Publications

- *Nutrition Journal* 2016¹
- *PNAS* 2017²
- DDW 2016, 2017

PHASE TRIAL

2b

- N=377
- Established efficacy and selected optimal dose
- Validated well-defined patient-reported outcomes tools providing meaningful treatment benefit assessment
- Established safety profile: SAEs and AEs similar between placebo and treatment
- Completed End of Phase 2 Meeting with the FDA

Publications

- *Publication pending submission*
- DDW 2018

PHASE PROGRAM

3

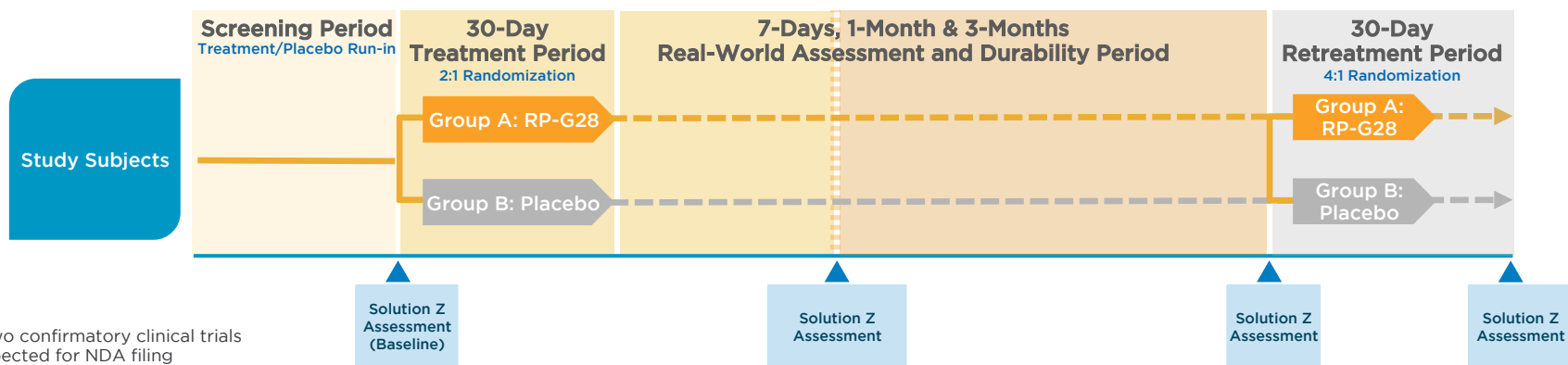
- Two confirmatory clinical trials expected for NDA filing
- First Phase 3 trial underway

1. Savaiano et al.: "Improving lactose digestion and symptoms of lactose intolerance with a novel galacto-oligosaccharide (RP-G28): a randomized, double-blind clinical trial." *Nutrition Journal*, 2013. 12:160.

2. M. Azcarate-Peril et al.: "Impact of short-chain galactooligosaccharides on the gut microbiome of lactose-intolerant individuals." *PNAS*, 2017. 114 (3) E367-E375.

Phase 3: Clinical Trial Protocol Design

- Double-blind, placebo-controlled, multi-center (approx. 28 sites): N=approx. 525
- Designed with input from an End of Phase 2 Meeting with the FDA*
 - Well-defined patient population with improved screening criteria
 - Electronic data capture of patient's symptoms and dairy intake
 - Validated symptom assessment measures to capture appropriate clinical outcome endpoints
 - 90-Day study assessment period to allow for claims of durability of effect
- **Primary endpoint: Mean change in LI symptom composite score 30-days post-treatment**
 - Secondary endpoints will evaluate LI signs and symptoms and global assessment outcomes to evaluate and assess a patient's continued treatment benefit
 - Analysis of primary and secondary endpoints at various time points will assess treatment benefit and durability of treatment in addition to retreatment benefit



Endpoints:

Designed to Demonstrate Compelling Treatment Benefit

Patient Symptoms and Experiences

Symptom Improvement

- Evaluation of patients' symptoms of lactose intolerance
- Captured by a validated lactose intolerance assessment tool

Dairy/Milk Intake

- Quantifying how much milk/dairy patients consume
- Collected at-home via ePRO

Global Impression

- Assessment of overall patient experiences, signs and symptoms of treatment benefit
- Treatment satisfaction and relief from bothersome symptoms

Time points of Analysis

Treatment Benefit

- Evaluation of treatment benefits collected in-clinic after a challenge as well as at-home in "real world" assessments captured via ePRO

Durability of Treatment

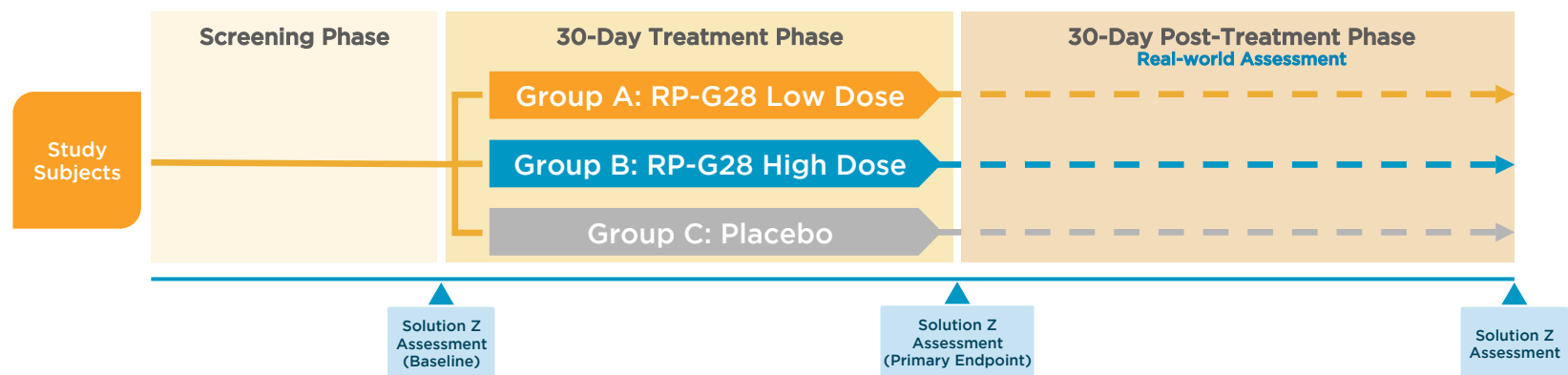
- Evaluation of treatment benefit 30-days and 90-days post-treatment
- Assess length of treatment benefit

Retreatment

- Assessment of safety and efficacy of patients administered a second course of treatment
- Provides potential profile of patients that may experience therapeutic benefit from a retreatment

Phase 2b: Clinical Trial Protocol Design

- Double-blind, placebo-controlled, multi-center, dose ranging study conducted at 15 U.S. clinical sites, n=377
- Inclusion/Exclusion
 - Minimum severity of LI assessed by blinded lactose challenge and lactase deficiency confirmed by standard hydrogen breath test
- Endpoints
 - Employed a patient-reported outcomes tool validated by outcomes experts
 - Primary endpoint: Proportion of subjects who report a clinically meaningful reduction in lactose intolerance symptoms, comprised of a composite score of reported GI symptoms (abdominal pain, cramping, bloating and gas)
 - Endpoints incorporated FDA's recommendations prior to un-blinding the data



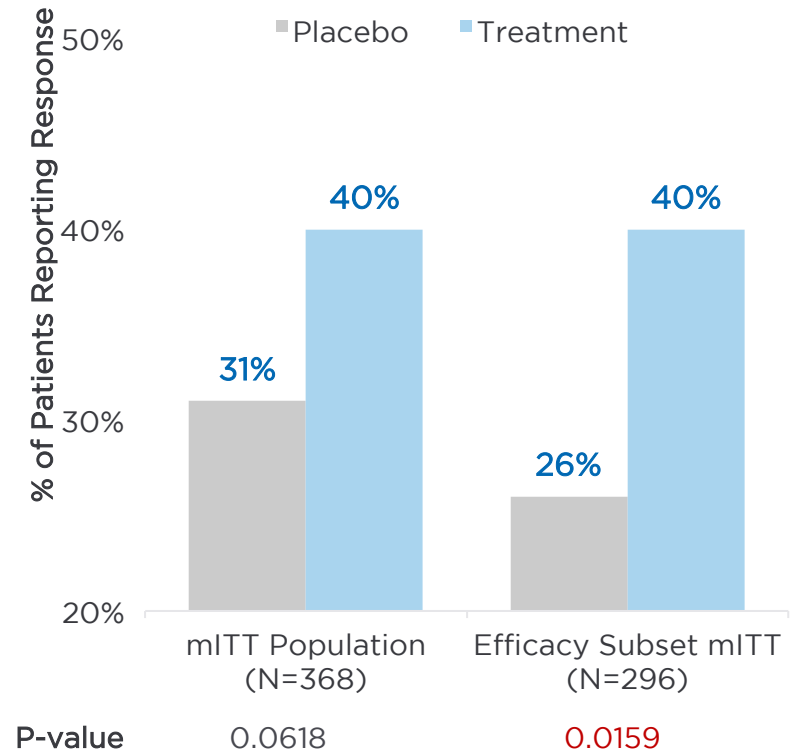
Phase 2b: Primary Endpoint Analysis

Lactose Intolerance Symptom Composite

Clinically Meaningful Benefit

- **Significant reduction of lactose intolerance symptoms** after a 30-day course of treatment
- Primary endpoint met statistical significance in efficacy subset analysis²
 - A statistically significant difference from placebo was reported with both doses²: low dose: p=0.0434; high dose: p=0.0294
- 14-percentage point difference between RP-G28 & placebo, comparable with recently FDA-approved GI drugs that averaged 11-percentage point difference³

Proportion of Patients Reporting Meaningful Improvement in Lactose Intolerance Symptoms^{1,2}



1. Primary endpoint defined as patients reporting a ≥ 4 -point change in LI Symptom Composite Score post-treatment compared to baseline or a zero LI Symptom Composite Score post-treatment.
2. Efficacy Subset modified intent to treat (mITT) population excludes from analysis inconsistent data from one study center (mITT population represents full data set).
3. Comparable endpoint delta analysis includes Amitiza, Entyvio, Viberzi, Linzess.

Phase 2b: Secondary Endpoints

Compelling Treatment Outcomes¹

Significant percent of treated patients reported elimination of symptoms

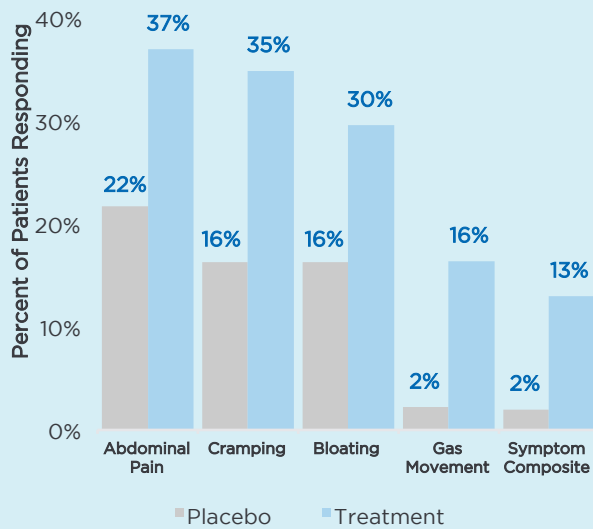
Lactose Intolerance Symptoms

Treatment patients consumed nearly 2x more milk

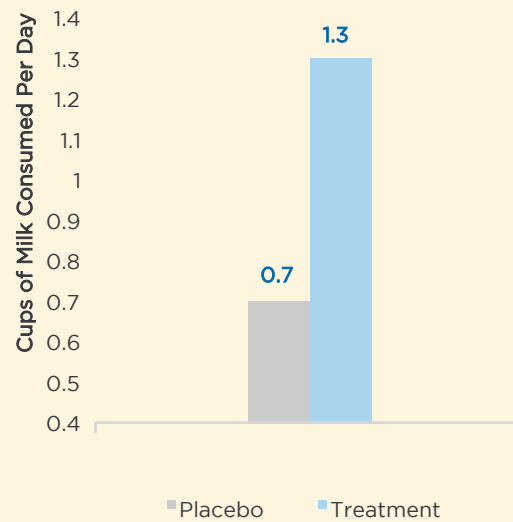
Milk Consumption

Patients consistently report symptom relief

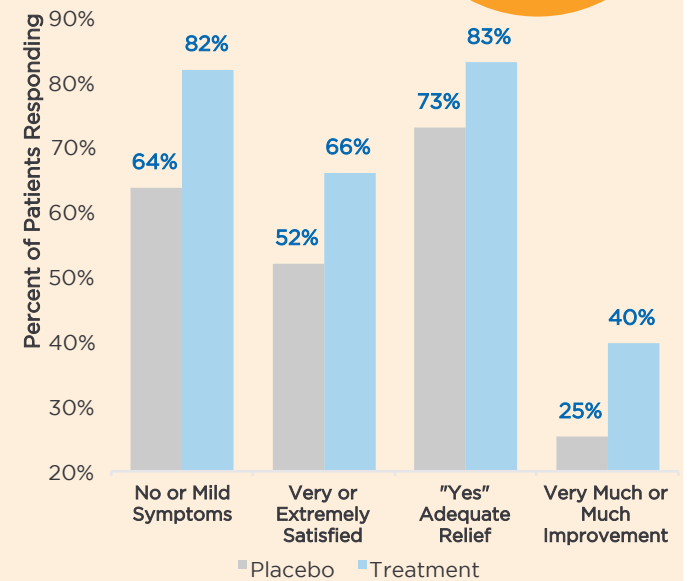
Global Assessments



P-value (vs. baseline)
 Abdominal Pain: 0.0144
 Cramping: 0.0020
 Bloating: 0.0150
 Gas Movement: 0.0005
 Symptom Composite: 0.004



P-value (vs. placebo)
 0.0144



P-value (vs. baseline)
 No or Mild Symptoms: 0.0013
 Very or Extremely Satisfied: 0.0302
 "Yes" Adequate Relief: 0.042
 Very Much or Much Improvement: 0.0343

1. Efficacy Subset PP, observed inconsistent data from one study center was excluded from analysis.

Strong Intellectual Property

30 Issued Patents Worldwide

- **Formulation: 11 issued patents** - US, AU, DE, ES, FR, GB, IT & NL
- **Methods of Use: 13 issued patents** - US, AU, DE, ES, FR, GB, IT, NL & ZA
- **Manufacturing Processes: 11 issued patents** - US, CH, CN, JP, KR, DE, FR, GB, IE, IT & NL
- **NCE Market Exclusivity**
 - From date of approval, 5 years in the United States and 10 years in Europe
- **Additional Information**
 - Most patents expiring in 2030, with a potential Patent Term Extension in the United States to 2035 and 2028 in Europe (SPC in Europe)
 - 25 pending patent applications in the United States and other key international markets

Formulation Patents: US9,579,340; US9,775,860; US9,808,481; US9,592,248; AU2017200343; DE602010036226.4; ES10746529; FR2400839; GB2400839; IT502016000104943; NL2400839
Method of Use Patents: US8,492,124; US9,370,532; US9,775,860; US8,486,668; US8,785,160; AU2017200343; DE602010036226.4; ES10746529; FR2400839; GB2400839; GB2480042; IT502016000104943; NL2400839; ZA2011/06066
Manufacturing Process Patents: US9,200,303; CH2462234; CN201080035013.2; JP6105680; KR10-1776164; DE60 2010 013 526.8; FR2462234; GB2462234; IE2462234; IT1395068; NL2462234
IP Counsel: Knobbe, Martens Olson & Bear LLP

Leadership and Management

Andrew J. Ritter
Co-founder and
Chief Executive Officer

15+ years of research in gastrointestinal diseases

- Founder of Ritter Pharmaceuticals. Former President of Ritter Natural Sciences, developed and marketed digestive healthcare products. Wharton MBA

John W. Beck
Chief Financial Officer

25+ years of experience in finance, fundraising, and accounting in the pharmaceutical industry

- Former CFO of Ardea Biosciences (acquired by AstraZeneca in 2012); former CFO of Metabasis Therapeutics.

Robin Schmidt
Director, Clinical Operations

20+ years of clinical operations experience

- Extensive global Phase 1-4 clinical trial experience at inVentiv Health Clinical, Aastrom Biosciences, Metabasis and Pfizer

Jennifer Timmerman
Senior Director,
Regulatory Affairs

13+ years of US and International regulatory strategy

- Most recent experience at Medpace, Kedrion Biopharma, Reckitt Benckiser

Ira E. Ritter
Chairman, Co-Founder,
Chief Strategic Officer

40+ years serving on Executive Boards; Rockwood, Oak Media, RG Publishing

- President and Chairman of Rockwood, produced over 200 private label HBA products for major national retailers including GNC and K-Mart

Board of Directors

- **Ira E. Ritter**
Chairman
- **Matthew W. Foehr**
President & COO, Ligand Pharmaceuticals
- **Paul V. Maier**
Former CFO, Sequenom, Inc.
- **Michael D. Step**
Former Sr. VP Corporate Development, Santarus, Inc.
- **Andrew J. Ritter**
Co-founder and Chief Executive Officer
- **Noah J. Doyle**
Managing Director, Javelin Ventures
- **William M. Merino, Ph.D.**
Former Sr. VP Worldwide Regulatory Affairs at Warner Lambert Pharmaceuticals

Medical Advisory Board



Dennis Savaiano, Ph.D.

Virginia C. Meredith Professor, Department of Nutrition Science, Purdue University
Considered one of the foremost experts on lactose intolerance in the world



William J. Sandborn, M.D.

Chief, Division of Gastroenterology and Director, University of California San Diego Inflammatory Bowel Disease Center



William Chey, M.D.

Director of the GI Physiology Laboratory, Michigan
Co-Director of the Michigan Bowel Control Program, Michigan Medicine



W. Allan Walker, M.D.

Director Nutrition at Harvard Medical School



Todd Klaenhammer, Ph.D.

Professor of Food Science, Microbiology & Genetics at North Carolina State University
National Academy of Science Member



Byron L. Cryer, M.D.

Professor of Digestive & Liver Diseases
Associate Dean at the University of Texas Southwestern Medical Center at Dallas



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Phase 2b: Microbiome Data

- **Post-treatment (Day 31), a clear and significant increase in the relative abundance of:**
 - Phylum Actinobacteria
 - Family Bifidobacteriaceae
 - Genus Bifidobacterium
- **78% of treatment patients compared to 52% of placebo patients increased Bifidobacteria ($p < .001$)**
 - Sequencing data showed that 5 Bifidobacterium taxa were clearly increased by both low and high dose treatments of RP-G28
- **Phase 2b findings are consistent with the Phase 2a microbiome clinical data**

