



**SYNTHETIC**

B I O L O G I C S

**NYSE MKT: SYN**

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## **FBR & Co. 2<sup>nd</sup> Annual Healthcare Conference**

Boston, MA  
September 9, 2015



# Forward-Looking Statements

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*This presentation includes forward-looking statements on Synthetic Biologics' current expectations and projections about future events. In some cases forward-looking statements can be identified by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," "indicates," and similar expressions. These statements are based upon current beliefs, expectations and assumptions and are subject to a number of risks and uncertainties, many of which are difficult to predict and include statements regarding our clinical trials, our establishment of collaborations and our execution of our growth strategy. The forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those set forth or implied by any forward-looking statements. Important factors that could cause actual results to differ materially from those reflected in Synthetic Biologics' forward-looking statements include, among others, a failure of our product candidates to be demonstrably safe and effective, a failure to initiate clinical trials and if initiated, a failure to achieve the desired results, a failure to obtain regulatory approval for our product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to our ability to promote or commercialize our product candidates for the specific indications, a lack of acceptance of our product candidates in the marketplace, a failure of us to become or remain profitable, a failure to establish collaborations, our inability to obtain or maintain the capital or grants necessary to fund our research and development activities, a loss of any of our key scientists or management personnel, and other factors described in Synthetic Biologics' annual report on Form 10-K for the year ended December 31, 2014, subsequent quarterly reports on Form 10-Qs and any other filings we make with the SEC. The information in this presentation is provided only as of the date presented, and Synthetic Biologics undertakes no obligation to update any forward-looking statements contained in this presentation on account of new information, future events, or otherwise, except as required by law.*

# Investment Considerations

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- Microbiome-focused, clinical-stage therapeutics to protect the microbiome while targeting pathogen-specific diseases
  - Innovative, first-in-class product candidates for prevention and treatment
  - Large markets addressing significant unmet medical needs
- Clinical-stage
  - Prevention of *C. difficile* infections and antibiotic-associated diarrhea (AAD) – First Phase 2a trial initiated March 2015; second Phase 2a initiated June 2015; Phase 2b proof-of-concept trial expected to commence 3Q 2015
  - Irritable bowel syndrome with constipation (IBS-C) – First Phase 2 trial initiated June 2015; second Phase 2 trial expected to commence 2H 2015
  - MS – Ongoing strategic partnering efforts supported by demonstrated therapeutic potential and safety profile of oral estriol; topline MRI data expected 30 days following receipt from UCLA
- Strategic collaboration with Intrexon Corporation (NYSE: XON)
  - Pertussis (whooping cough) – Positive preclinical findings reported at ECCMID in March 2015
  - *Acinetobacter* infections (potentially lethal infection increasing in ICUs and military injuries)
  - Phenylketonuria (PKU) – New discovery program; August 2015
- Experienced management team with extensive clinical and commercial track record

# Management Team

- **Jeffrey Riley, CEO**  
*Pfizer, Nichols Institute (Quest), SmithKline Beecham, QIC*
- **Steven Shallcross, CFO**  
*Vanda Pharmaceuticals, Inc., Empire Petroleum Partners, LLC, Innocoll AG (formerly privately held Innocoll Holdings, Inc.)*
- **John Monahan, Ph.D., EVP R&D**  
*Avigen, Somatix, Triton Biosciences, Hoffman-LaRoche*
- **Joseph Sliman, M.D., MPH, SVP Clinical/Regulatory**  
*Vanda Pharmaceuticals, Inc., MedImmune, Inc., DynPort Vaccine*
- **Klaus Gottlieb, M.D., FACG, VP Clinical/Regulatory**  
*Quintiles, U.S. Food & Drug Administration*
- **Maureen Early, M.B.A., VP Commercial**  
*Rhone Poulenc Rorer/Aventis, Upside Endeavors*
- **Amy Sloan, R.A.C., VP Regulatory**  
*MedImmune, Inc., DynPort Vaccine*



# Product Pipeline

Therapeutic Area	Product Candidate	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
<i>C. difficile</i> infection/ Antibiotic-associated diarrhea (AAD)	SYN-004					
Irritable bowel syndrome with constipation (IBS-C)	SYN-010 <sup>C</sup>					
Relapsing-remitting multiple sclerosis	Trimesta <sup>TM</sup>					
Cognitive dysfunction in multiple sclerosis	Trimesta <sup>TM</sup>					
Pertussis (whooping cough)	SYN-005 <sup>I,T</sup>					

C - Cedars-Sinai Medical Center collaboration  
 I - Intrexon Corporation collaboration  
 T - The University of Texas at Austin collaboration

 Completed     Planned – 2015

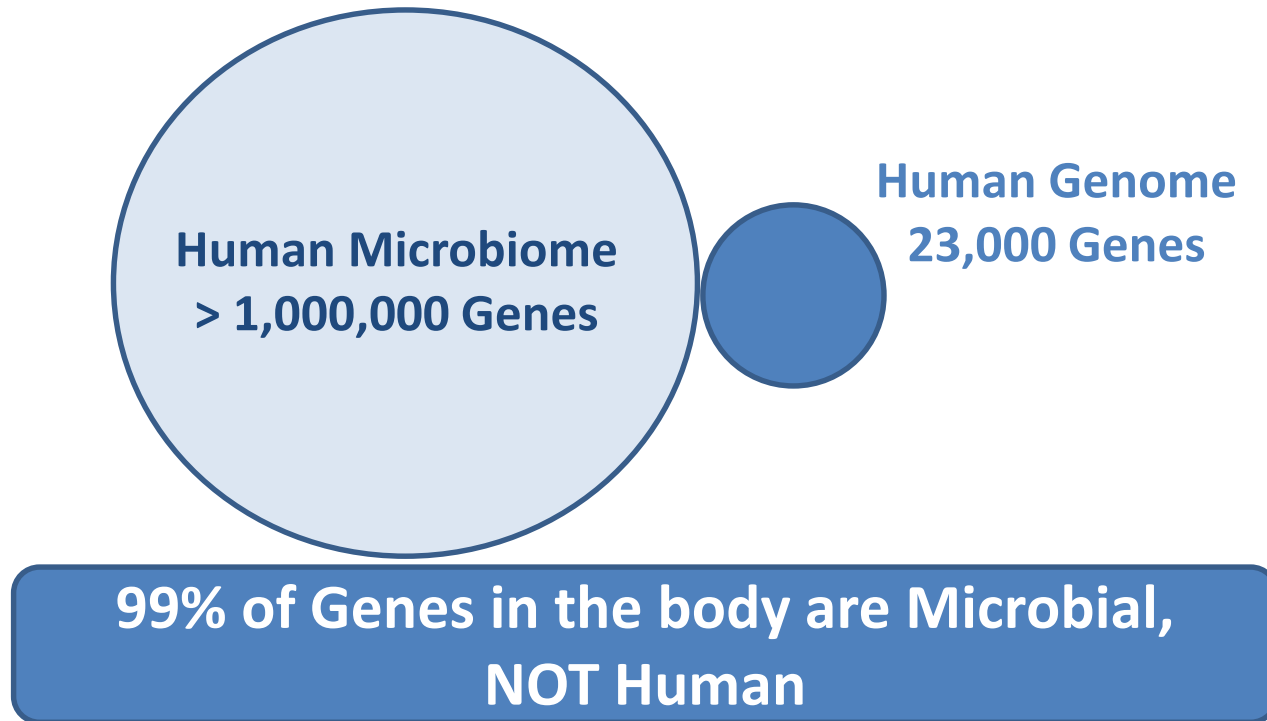
# Milestones: Achieved & Upcoming

Therapeutic Area/ Product Candidate	Timeline
<b><i>C. difficile</i>/AAD – SYN-004:</b>	
Phase 1a/1b	<ul style="list-style-type: none"> <li>✓ 1Q 2015 – Positive topline Phase 1b results</li> <li>✓ 1Q 2015 – Positive Phase 1a/1b PK data</li> </ul>
Phase 2a (1 <sup>st</sup> ileostomy study; ceftriaxone)	<ul style="list-style-type: none"> <li>✓ 1Q 2015 – Initiated Phase 2a</li> <li>✓ 3Q 2015 – Supportive Phase 2a data from initial 4 of 12 expected participants</li> <li>3Q 2015 – Report Phase 2a topline data</li> </ul>
Phase 2a (2 <sup>nd</sup> ileostomy study; ceftriaxone+PPI)	<ul style="list-style-type: none"> <li>✓ 2Q 2015 – Initiated Phase 2a</li> <li>2H 2015 – Report Phase 2a topline data</li> </ul>
Phase 2b proof-of concept	<ul style="list-style-type: none"> <li>3Q 2015 – Initiate Phase 2b trial</li> <li>2H 2015 – Interim analysis of blinded data</li> </ul>
Pivotal Phase 3 trial(s)	2016 – Initiate Phase 3 trial(s)
<b>IBS-C – SYN-010:</b>	<ul style="list-style-type: none"> <li>✓ 1Q 2015 – SYN-010 modified-release formulation of lovastatin</li> </ul>
Phase 2 (1 <sup>st</sup> study; acute, placebo-controlled)	<ul style="list-style-type: none"> <li>✓ 2Q 2015 – Initiated Phase 2</li> <li>2H 2015 – Report Phase 2 topline data</li> </ul>
Phase 2 (2 <sup>nd</sup> study; extension, SYN-010 only)	<ul style="list-style-type: none"> <li>2H 2015 – Initiate Phase 2</li> <li>1H 2016 – Report Phase 2 topline data</li> </ul>
Pivotal Phase 3 trial(s)	2016 – Initiate Phase 3 trial(s)

# Human Microbiome

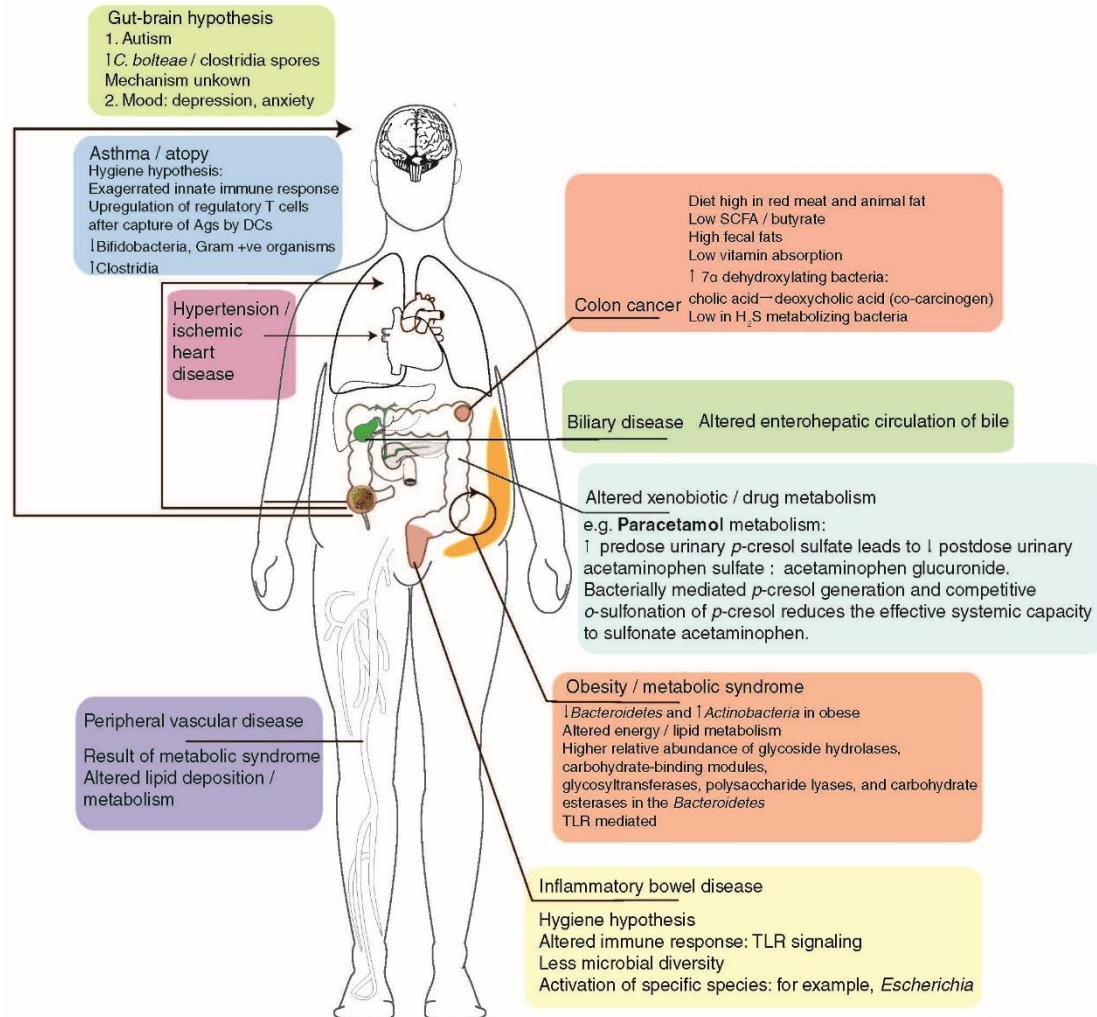
The body has 10 times as many microbe cells as human cells

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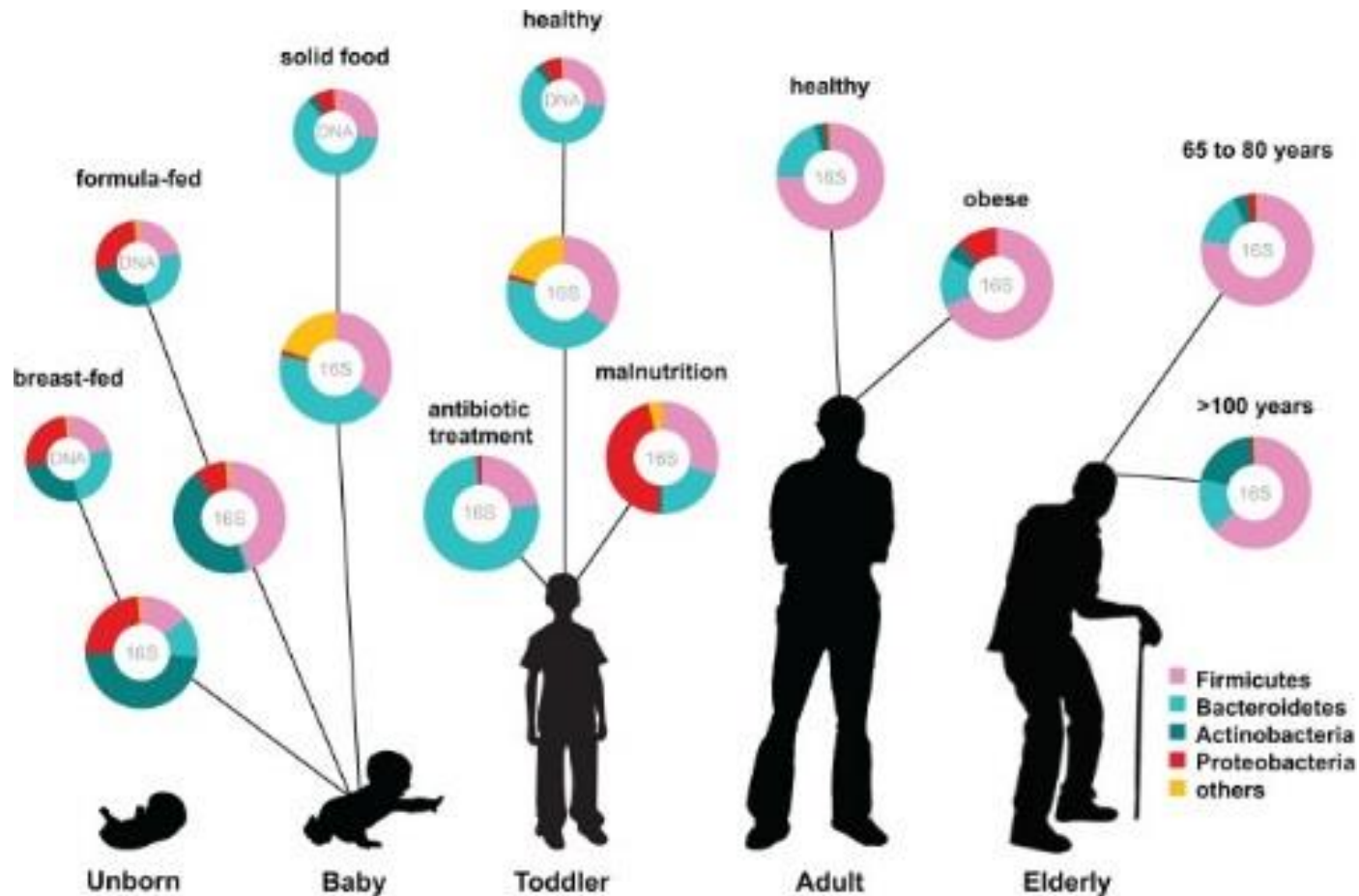
**Leveraging the microbiome  
could significantly change medicine**

# Diseases Directly Influenced by the Gut Microbiome



# Human Microbiome Over Time

## Response to Environmental Conditions and Life Stages



Source: US National Library of Medicine. Image source: Ottman N, et al. (2012) The function of our microbiota: who is out there and what do they do? Front. Cell. Inf. Microbio. 2:104.

# Collateral Damage Caused by Antibiotic Use

## Imbalance of the gut microbiome

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- Antibiotics
  - Prevent/treat primary infections
  - Carried to liver, transported to bile and excreted via large intestine
  - May unintentionally upset natural balance of gut microbiome by killing off good bacteria
- A microbial imbalance in the gut microbiome provides an opportunity for overgrowth of harmful pathogenic organisms (e.g., *C. difficile*) which may cause severe diarrhea, damage to the colon and in some cases death

**24 million patients are administered  
IV antibiotics annually in the U.S.<sup>1</sup>**

<sup>1</sup>This information is an estimate derived from the use of information under license from the following IMS Health Incorporated information service: CDM Hospital database for full year 2012. IMS expressly reserves all rights, including rights of copying, distribution and republication.

# *C. difficile* Infections (CDI)

## Preventing *C. difficile* is now a national priority



- National Action Plan to combat antibiotic resistance issued by White House in March '15<sup>1</sup>
- CDI is currently the most prevalent hospital-acquired infection in the U.S., according to the CDC
  - Surpassed methicillin-resistant *Staphylococcus aureus* (MRSA)
- CDI has been identified as an “urgent public health threat” by the CDC, FDA and EU health authorities
- CDI in the U.S.:
  - 1.1 million patients infected with *C. difficile* annually<sup>2</sup>
  - Patients with *C. difficile* hospitalized approximately 4-7 extra days<sup>3</sup>
  - \$8.2 billion in costs associated with *C. difficile*-related stays in hospital<sup>4</sup>
  - Up to ~25% of CDI patients have a recurrence within 1-3 months<sup>5-7</sup>
  - >30,000 *C. difficile*-related deaths annually<sup>8</sup>

<sup>1</sup> [https://www.whitehouse.gov/sites/default/files/docs/national\\_action\\_plan\\_for\\_combating\\_antibiotic-resistant\\_bacteria.pdf](https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf)

<sup>2</sup> This information is an estimate derived from the use of information under license from the following IMS Health Incorporated information service: CDM Hospital database for full year 2012. IMS expressly reserves all rights, including rights of copying, distribution and republication.

<sup>3</sup> (APIC) National Prevalence Study of *Clostridium difficile* in U.S. Healthcare Facilities. November 11, 2008.

<sup>4</sup> Agency for Healthcare Research and Quality. Healthcare and Cost Utilization Project. Statistical Brief #124. *Clostridium difficile* Infections (CDI) in Hospital Stays, 2009. January 2012.

<sup>5</sup> Louie TJ, et al. N Engl J Med 2011;364:422–31.

<sup>6</sup> Cornely OA, et al. Lancet Infect Dis 2012;12:281–9.

<sup>7</sup> Vardakas KZ, et al. Int J Antimicrob Agents 2012;40:1–8.

<sup>8</sup> U.S. Department of Health & Human Services. Agency for Healthcare Research and Quality. January 25, 2012.

# Paradigm Shift

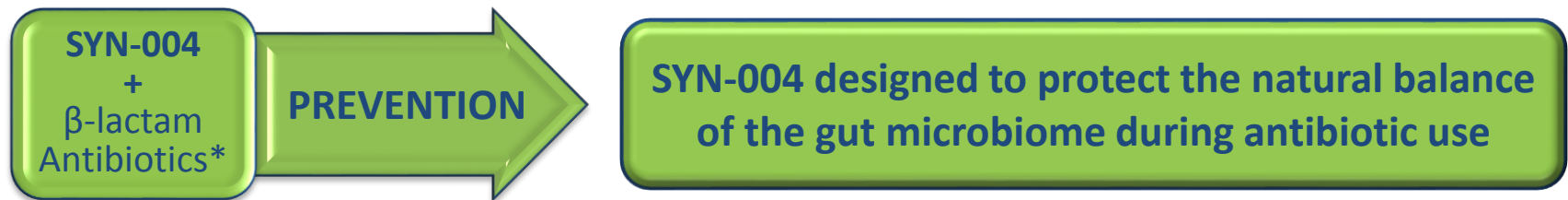
Fewer CDIs expected with co-administration of SYN-004

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## Current Paradigm



## SYN-004 Paradigm



\* Intended to include penicillins plus cephalosporins

# First Generation Candidate Validates Concept

## Proof of concept data demonstrated from Phase 1 and 2 studies

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- Original technology developed by Finnish biotechnology company, Ipsat Therapies Oy
- First generation candidate, P1A, was evaluated in four Phase 1 and one Phase 2 clinical trials conducted in Europe
  - In total, 112 patients and 143 healthy normal subjects participated in the studies
- Well tolerated with no safety concerns identified
- Prevented the occurrence of AAD
- Preserved the normal intestinal microflora when co-administered with IV ampicillin or piperacillin
- Did not alter the PK profile of IV piperacillin or ampicillin nor the efficacy of ampicillin in patients with respiratory infection requiring hospitalization

# Second Generation Enzyme SYN-004

## Activity against a broader spectrum of beta-lactam antibiotics

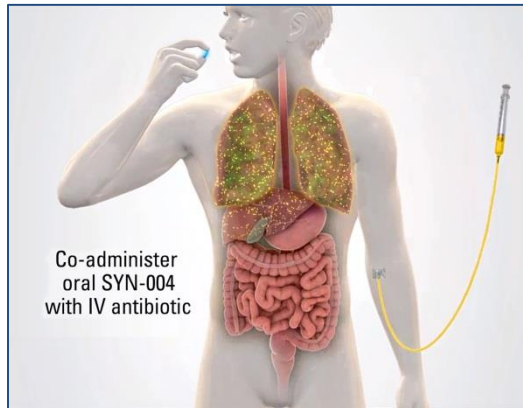
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- SYN-004 represents next generation beta-lactamase enzyme
  - Based on single amino acid change
- Expected to have activity against both penicillins and certain cephalosporins
- Due to the structural similarities between P1A and SYN-004, IND leveraged certain preclinical data collected on P1A in support of an IND for SYN-004
- Patents and pending patents
  - Composition of matter claims and pharmaceutical compositions of beta-lactamases, including SYN-004, was issued in November 2014 (U.S. Patent 8,894,994)
    - Carries a term to at least 2031
  - An extensive portfolio of granted use patents and pending patent applications for SYN-004-related technology
  - Additional patent filings covering composition of matter claims could extend patent protection of SYN-004 to 2035

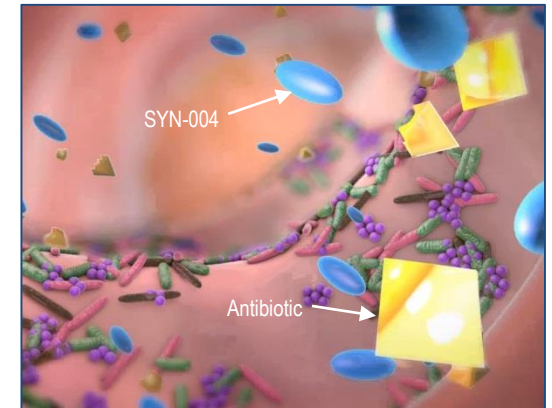
# SYN-004 Co-Administered with IV Antibiotics

Designed to neutralize  $\beta$ -lactam antibiotics in GI tract

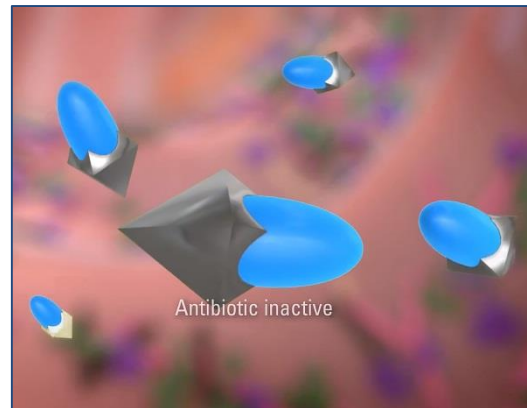
1. SYN-004 is an oral enzyme tablet (blue) to be co-administered with IV antibiotics (yellow).



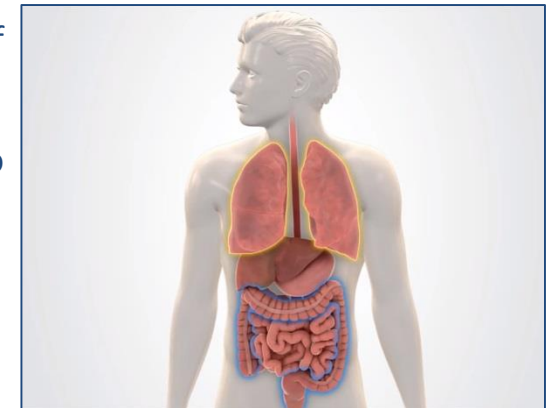
2. IV antibiotics can upset the natural balance of the gut microbiome, killing “good” bacteria, allowing for the overgrowth of *C. difficile*.



3. SYN-004 is intended to remain in the GI tract and neutralize IV antibiotics (black), protecting the natural balance of the gut microbiome.



4. Co-administration of SYN-004 is intended to allow the IV antibiotic (yellow) to treat the primary infection while protecting the gut microbiome (blue), and preventing CDI.



# SYN-004

## Clinical trial development

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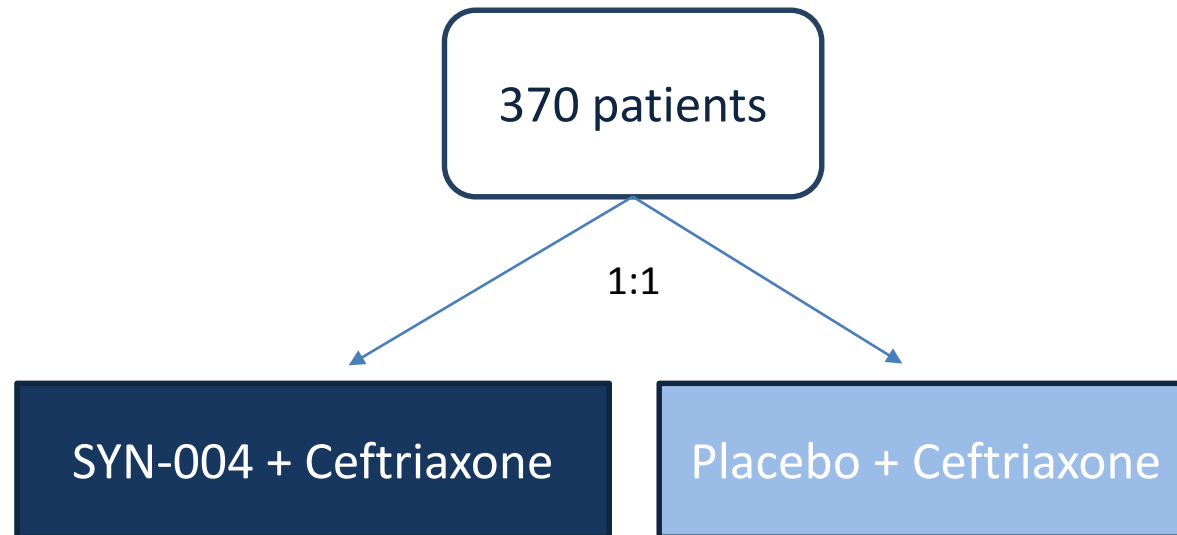
- Completed Phase 1a (40 participants) and 1b (24 participants) trials
  - PK data supports that SYN-004 should have no effect on the IV antibiotic in the bloodstream
  - No clinically significant safety events were observed; well tolerated by participants
- Initiated first Phase 2a trial (March 2015)
  - Characterize SYN-004 activity on ceftriaxone in the small intestine
  - Demonstrate SYN-004 has no activity on ceftriaxone in the bloodstream
  - SYN-004 degraded ceftriaxone in the chyme of initial four of 12 expected healthy participants with functioning ileostomies without affecting ceftriaxone in the bloodstream (July 2015)
- Initiated second Phase 2a trial (June 2015)
  - Characterize SYN-004 activity on ceftriaxone in the small intestine in the presence of esomeprazole, an approved, over-the-counter proton pump inhibitor
- Phase 2b (Proof-of-Concept) trial objectives (initiation expected 3Q 2015)
- FDA Type C meeting requested (trial design and endpoints)
- Phase 3 trial vision
  - Prevention of CDI and AAD among hospitalized patients receiving IV ceftriaxone and other beta-lactam antibiotics
  - Global study; multiple indications for IV beta-lactam therapy
  - Demonstrate no effect on blood levels of antibiotic or primary diagnosis cure rates

# SYN-004

## Phase 2b trial design for CDI prevention

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~75 Global Clinical Sites



**Primary Endpoint:**

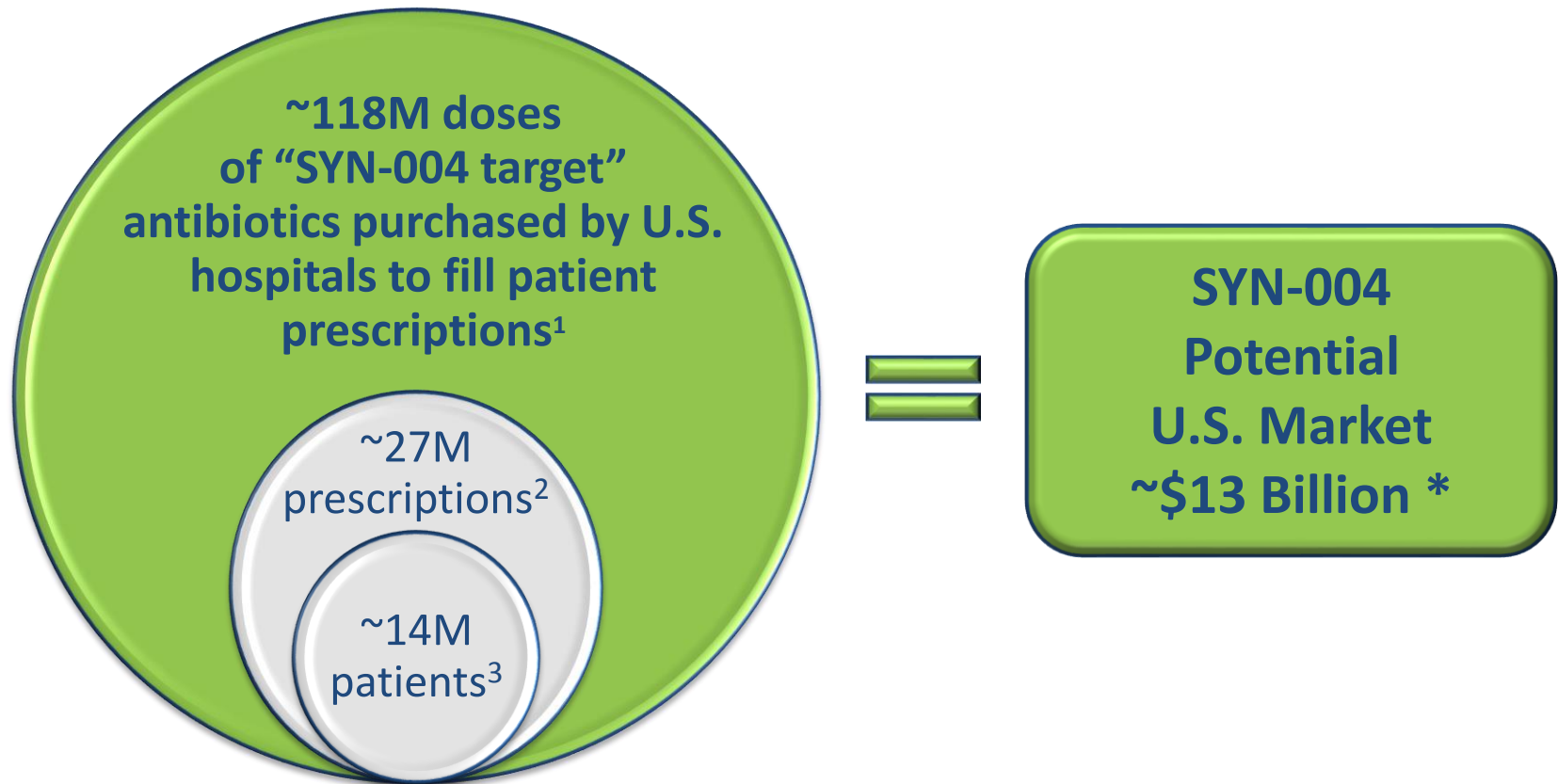
- Prevention of CDI

**Secondary Endpoints:**

- Prevention of AAD
- Limiting disruption of gut microbiome diversity

# SYN-004: Market Potential

Intended to target certain IV  $\beta$ -lactam antibiotics



\* Estimate based on the following assumptions: 5 day prescription x 4 “SYN-004 tablets”/day x \$25/“SYN-004 tablet” x 26.5M prescriptions of “SYN-004 target”  $\beta$ -lactam antibiotics in 2012

<sup>1-3</sup> This information is an estimate derived from the use of information under license from the following IMS Health Incorporated information service: CDM Hospital database for full year 2012. IMS expressly reserves all rights, including rights of copying, distribution and republication. Based on U.S. market data in 2012.

# C. difficile Market Overview<sup>1</sup>

SYN-004 is a prophylactic approach versus treatment

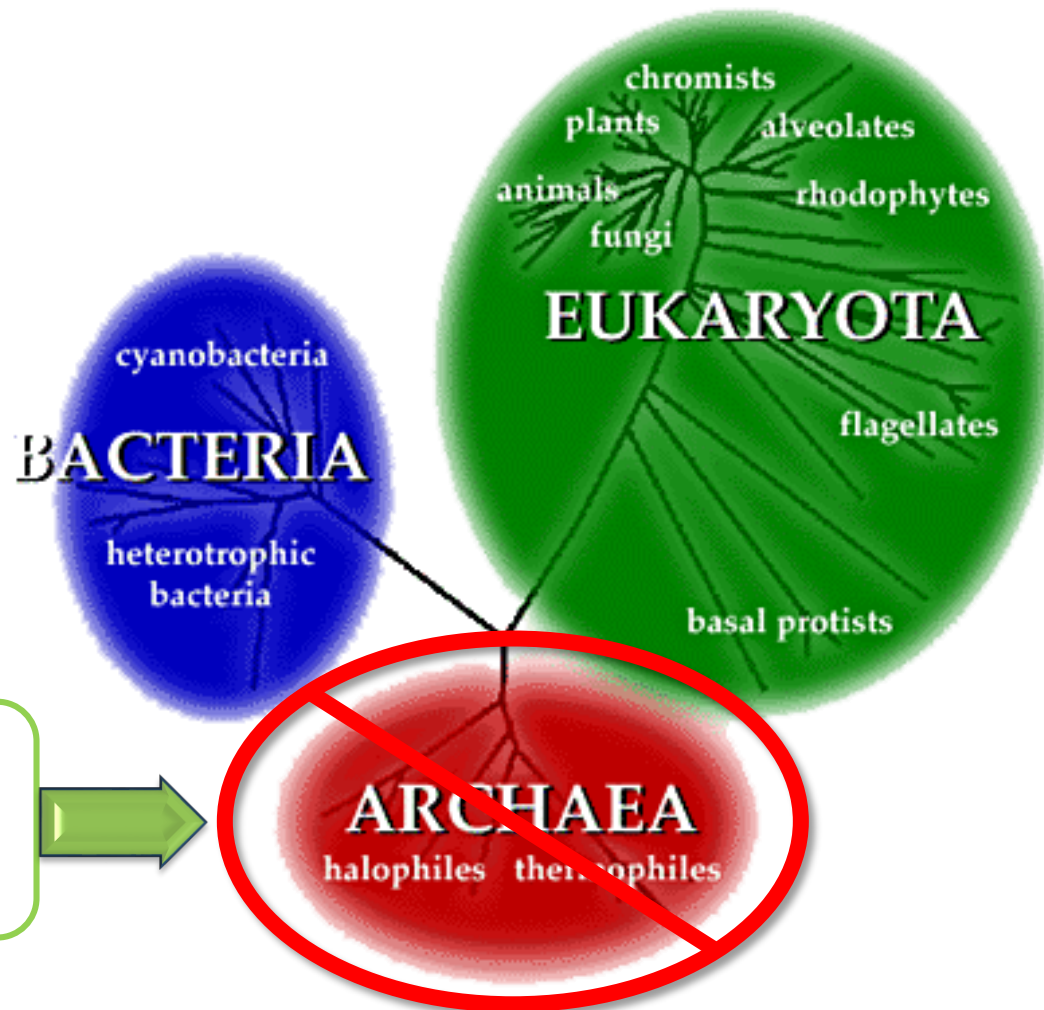
Product Candidate	SYN-004 *	Dificid	MK-3451A	SER-109	ACAM-CDIFF™
Company	Synthetic	Merck	Merck	Seres	Sanofi
Compound	Enzyme to protect microbiome	Macrocyclic antibiotic	Monoclonal antibody	Microbiome therapeutic	Vaccine
Phase/Status	Phase 2	Marketed	Phase 3	Phase 2	Phase 2
Prophylactic/ Primary prevention	●	○	○	○	●
Treatment	N/A	●	○	○	●
Prevention of recurrence	N/A	●	●	●	N/A
Route of administration	Oral	Oral	Infusion	Oral	Injections (3X over 30 days)

\*Based on preclinical & Phase 1 data and Company expectations

Currently the only methods for preventing primary *C. difficile* infection are through antibiotic stewardship and infection control

# Pathogen-Specific Microbiome Therapeutic

Treating the underlying cause not symptoms



**SYN APPROACH:**  
Anti-Archaea  
specific therapeutic

# Irritable Bowel Syndrome

## IBS Prevalence

- IBS is a chronic GI disorder characterized as a group of symptoms
  - Diarrhea/constipation
  - Abdominal discomfort
  - Bloating
- Severely impacts and reduces quality of life
- Statistics
  - 10-15% of the global population
- Who is affected?
  - Women = 66.1%; Men = 33.9%
  - IBS-D = 53%; IBS-M = 27%; IBS-C = 20%
- SYN focused on the treatment of IBS-C

### IBS Prevalence (age > 10)\*

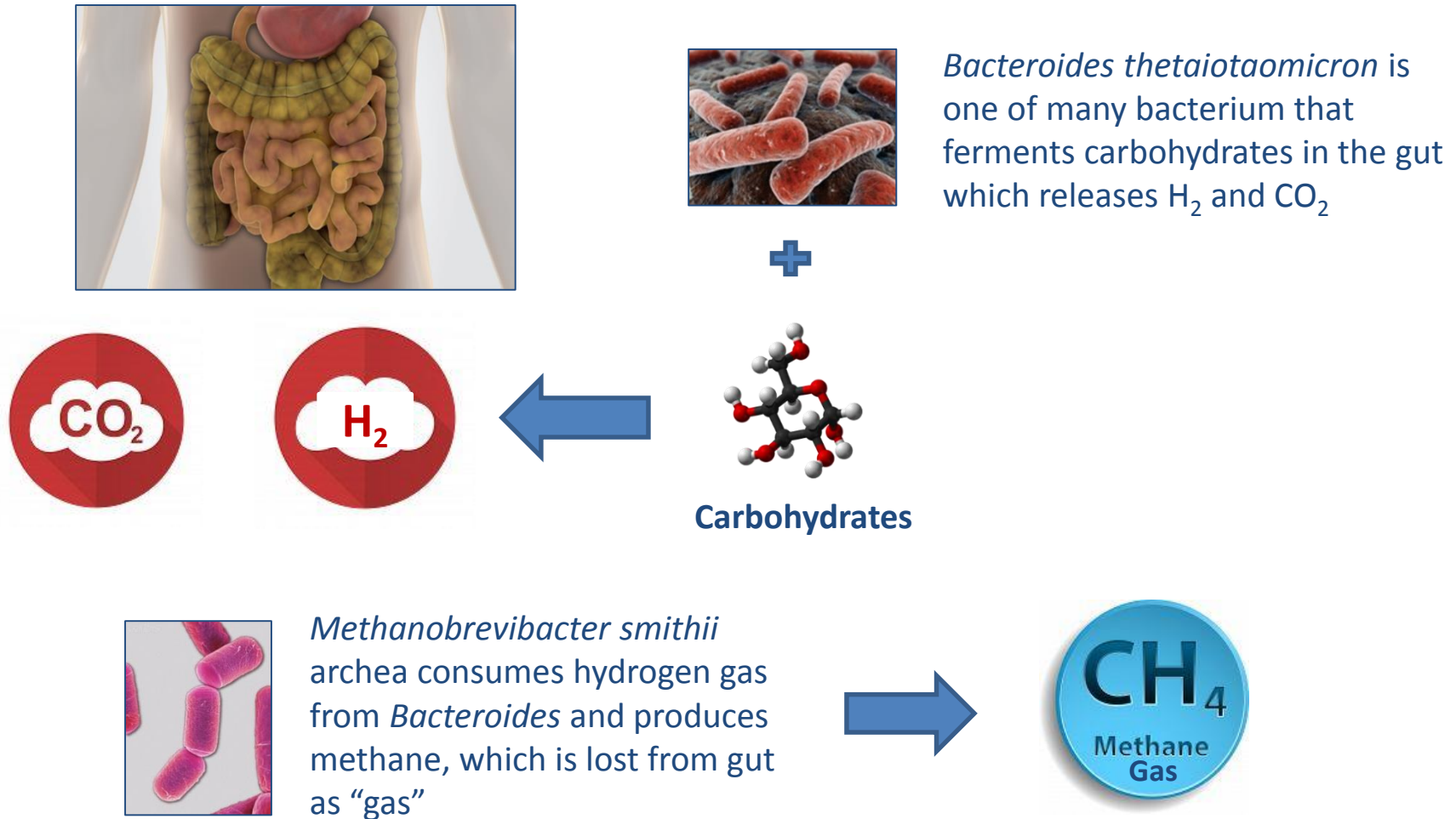
US	17.2M
EU5	16.5M
Japan	7.0M
Total	40.7M

\* Forecast uses stringent disease diagnosis criteria (ROME II) to ensure market relevance and a population most likely to receive a diagnosis and prescription drug treatment.

Source: GlobalData Publication Irritable Bowel Syndrome Global Drug Forecast and Market Analysis 2014.

# SYN-010: Modified-Release Lovastatin

Designed to reduce methane production by *M. smithii* in the intestine

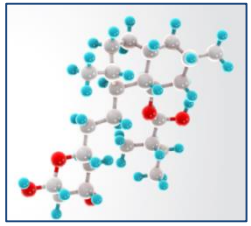


# Methane Production: Underlying Cause of IBS-C

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- Intestinal methane production is an underlying cause of constipation
  - Critical discovery by Mark Pimentel, MD, and collaborators at Cedars-Sinai
    - Extensive clinical evidence in IBS-C and now chronic idiopathic constipation (CIC)
- Reduction of intestinal methane has been shown to reverse constipation and improve IBS-C symptoms
- Significant opportunity for a therapy for chronic use in IBS-C
  - Treat the underlying cause of constipation
    - Not just stool mass transit
    - No diarrhea
  - Targeted to the intestine
    - Minimized systemic drug levels
  - Not antimicrobial
    - Suitable for chronic use
    - Minimal disruption of the microbiome

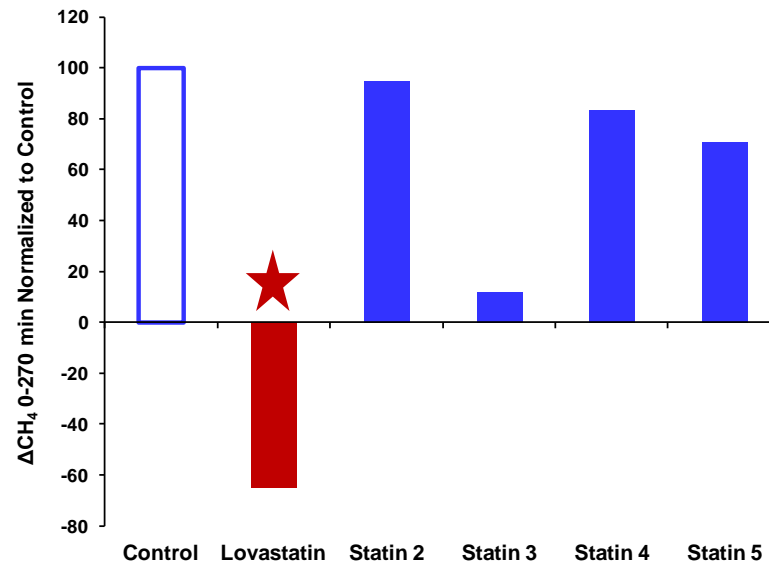
# Anti-Methanogenic Therapy for IBS-C



Lovastatin demonstrated significant reduction in methane gas

- Studies demonstrated that statins in animal feed reduced methane gas in ruminant animals (4-chambered stomach)
- Dr. Pimentel translated the use of statins to reduce methane in humans (single-chamber stomach) by evaluating commercial lovastatin formulations in select IBS-C patients in his practice
- Dr. Pimentel further demonstrated that lovastatin is uniquely effective in reducing methane compared to other statins

## *In vitro* methane production analysis with human IBS-C stool samples

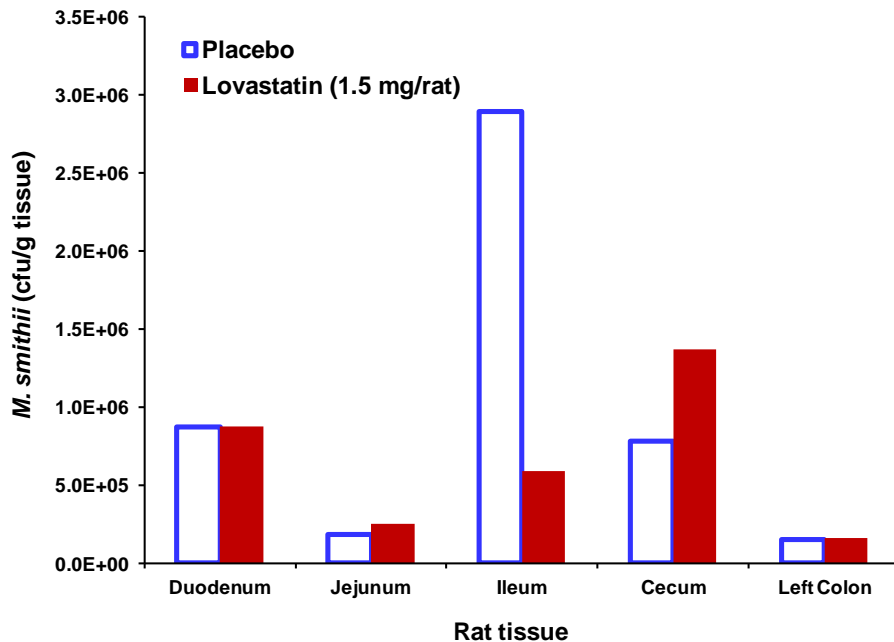


# Lovastatin: Targeting Production of Methane Gas

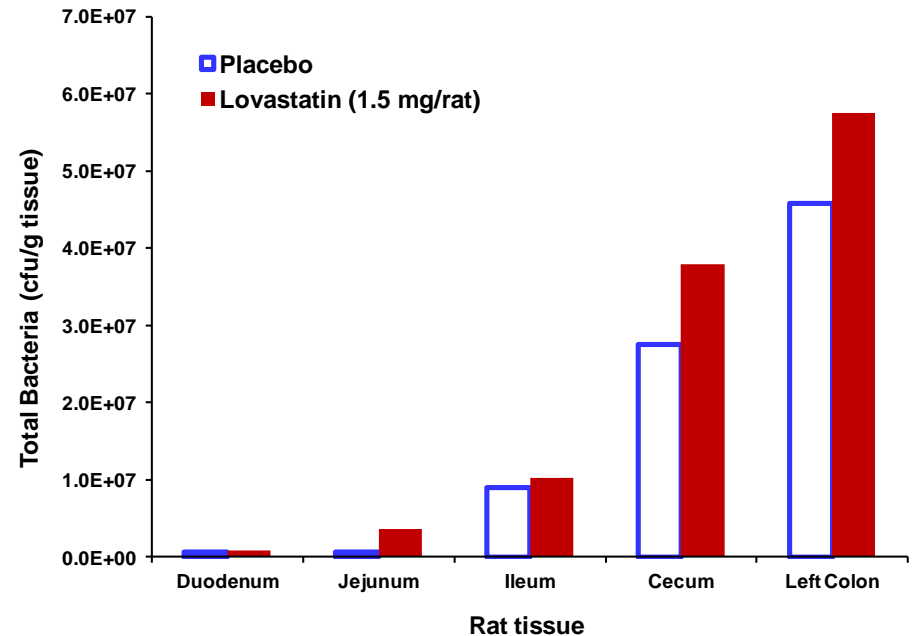
## Minimal impact on microbiome

Effect of lovastatin on levels of *M. smithii* and total bacteria in rat GI tract after 10 days oral gavage dosing

*M. smithii*



Total bacteria



Source: Morales, W. et al. (2015) Gastroenterology 148(4):S779-80.

# SYN-010: Differentiators

## Proprietary, modified-release lovastatin

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- Modified-release lovastatin formulation targeting intestinal methane production
  - Leveraging detailed pharmacokinetic and safety profiles from decades of prior clinical use
- Designed to treat the underlying cause of constipation
- Patents and pending patents licensed through Cedars-Sinai
  - An extensive portfolio of granted use patents and pending patent applications for SYN-010
  - Additional worldwide patent filings covering composition of matter claims could extend patent protection of SYN-010 to 2035
- Anticipate 505(b)(2) development pathway

# SYN-010 for IBS-C

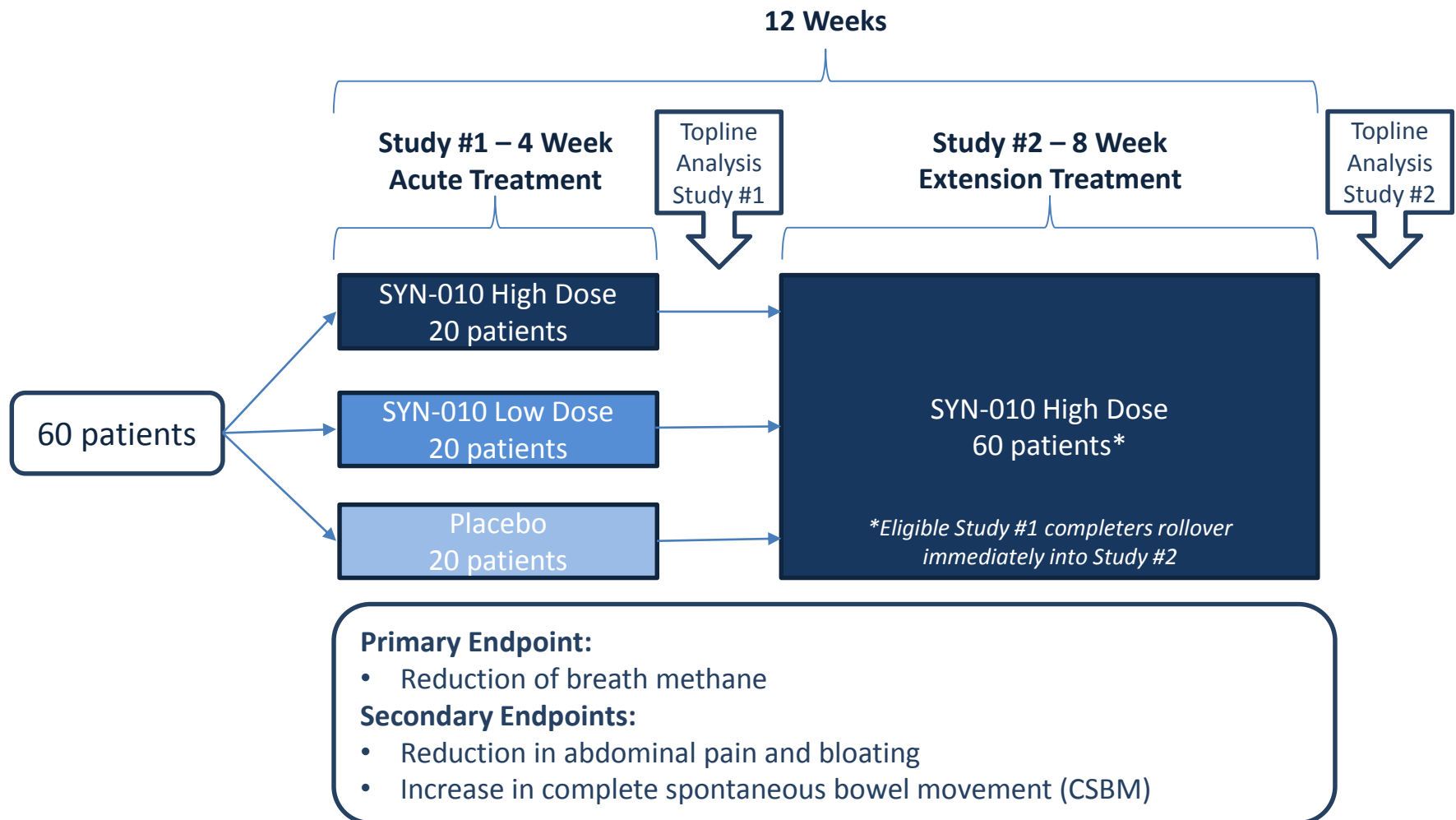
## Clinical development

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- Preclinical data
  - Lovastatin prevented proliferation of methanogens in rat ileum with minimal impact on remaining microbiome
- *Ex vivo* clinical data
  - Lovastatin prevented methane production by methanogens in human stool
- Initiated first SYN-010 Phase 2 placebo-controlled, acute clinical trial (June 2015)
  - Multiple sites in U.S.
- Second SYN-010 Phase 2 high-dose extension clinical trial (initiation expected 2H 2015)
- Pursue SYN-010 Phase 3 clinical trials – Estimated to begin in 2016

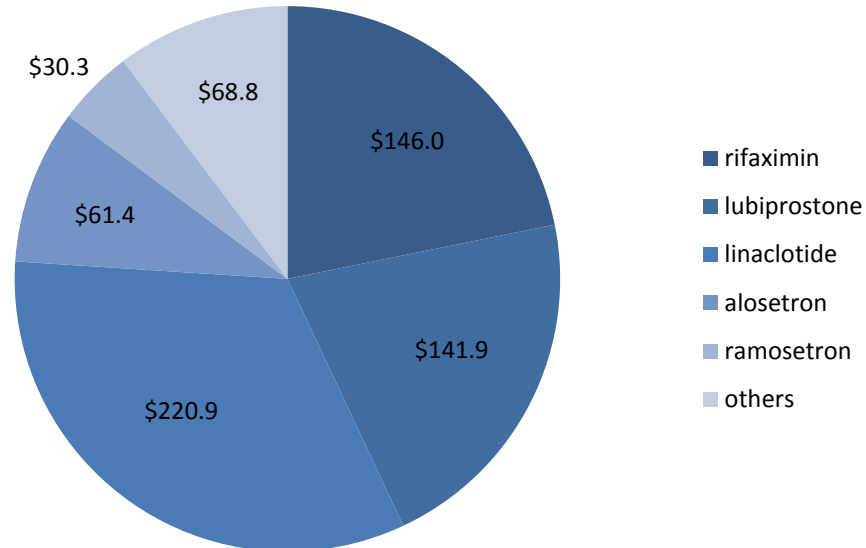
# SYN-010

## Phase 2 trial design for IBS-C – multiple sites in U.S



# IBS Market Overview

## 2015 IBS Global Therapeutic Sales Forecast ~\$669.3M

































**Global IBS Sales in 2023 are expected to be greater than \$1.5B**

### Market growth attributed to:

- Increased uptake of Linzess® and label expansion of Xifaxan®
- Launch of 4 late-stage pipeline products including 2 late-stage for IBS-C:
  - Plecanatide - Synergy
  - Tenapanor - Ardelyx

# IBS-C Market Overview<sup>1</sup>

## SYN-010 targets underlying cause versus competition

Product Candidate	SYN-010 *	Linzess	Amitiza	OTC Laxatives	Plecanatide
Company	Synthetic	Ironwood	Takeda	Various	Synergy
Phase/Status	Phase 2	Marketed	Marketed	Marketed	Phase 3
Treat underlying cause of IBS-C					
Treat symptoms					
Relieves constipation					
Relieves pain					
Causes more regular bowel movements					
Does not cause severe diarrhea					

\*Based on preclinical data and Company expectations

<sup>1</sup> Not a comprehensive list of pipeline products; representative of compounds that are the farthest along in clinical development  
Source: [www.clinicaltrials.gov](http://www.clinicaltrials.gov); GlobalData; Corporate pipeline websites

# Trimesta™

## Phase 2 relapsing-remitting MS clinical data



- UCLA-led Phase 2 trial<sup>1</sup> with data available from lead investigator for relapse-remitting MS, including annualized relapse rate, and cognitive and physical improvement
  - 158 women randomized 1:1 into 16-center, investigator-initiated, double-blind, placebo-controlled U.S. trial<sup>15</sup>
- Annualized relapse rate declined relative to standard of care, Copaxone®
  - Statistically significant 47% decrease in annualized MS relapse rate at 12 months with Trimesta™ + Copaxone® compared to placebo + Copaxone® (p=0.02 / powered for significance level 0.05)
  - Sustained decrease (32%) in annualized relapse rate at 24 months with Trimesta™ + Copaxone® compared to placebo + Copaxone® (p=0.11 / powered for significance level 0.10)
  - Per study protocol, investigators anticipated a 29% decrease in relapse rate at both 12 and 24 months
- Data supports potential treatment for cognitive dysfunction
  - Patients in the Trimesta™ arm with Paced Auditory Serial Addition Test (PASAT) scores lower than 55 before treatment experienced an ~12%, or 6 point, improvement in cognitive scores within 12 months (p<0.05)
  - Improvement from baseline was sustained throughout 24 month study
- Trimesta™ + Copaxone® demonstrated a strong safety profile and was well tolerated
- Planned next steps for Trimesta™ include:
  - Ongoing strategic partnering efforts supported by demonstrated therapeutic potential and safety profile of oral estriol
  - MRI analyses ongoing by UCLA to evaluate changes in the brain that correlate with improvements seen in clinical outcomes; topline data expected 30 days following receipt from UCLA
  - Phase 3 clinical trials protocol meeting with FDA following MRI results

<sup>1</sup> \$8 million+ grant funding supporting trial, predominantly National MS Society & NIH

Source: Presented at 2014 ACTRIMS-ECTRIMS by lead investigator, Rhonda Voskuhl, M.D., Professor of Neurology, Director of UCLA MS Program

# SYN-005: Whooping Cough (Pertussis)

mAb combination designed to target and neutralize pertussis toxin

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- Pertussis toxin is a major cause of disease virulence
- Antibiotic use does not have a major effect on the disease course
  - While antibiotics can eliminate the bacteria, they do not neutralize pertussis toxin
- U.S. Orphan Drug designation granted September 2014 for the treatment of Pertussis
- Patents and pending patents:
  - Patents pending on compositions and uses of SYN-005
  - Issued U.S. patent on compositions and uses of other pertussis mAbs licensed through The University of Texas at Austin
- Collaborations increase available resources for pipeline development
  - Exclusive Channel Collaboration (ECC) with Intrexon Corporation (NYSE: XON)
  - Academic researchers at The University of Texas at Austin
- Planned next steps for SYN-005
  - Seeking non-dilutive funding to support program (Gates Foundation, Wellcome Trust, NGOs, etc.)
    - Initiate non-human primate program to explore prophylactic effects
    - File IND to support initiation of Phase 1 clinical trial
    - Initiate Phase 1 clinical trial

# Financial Snapshot

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- Cash balance (as of 6/30/15): ~\$4.8 million
- Net proceeds from capital raise (7/21/15): ~\$42.6 million
- Current Price: \$2.51 (as of 9/8/15)
- 52 Week Range: \$1.34 - \$4.32
- Average Volume (3 months): 2,033,320
- Shares Outstanding: ~88.5 million (as of 8/6/15)
- Options Outstanding: ~7.5 million\*
- Warrants Outstanding: ~7.9 million\*\*
- Market Capitalization: ~\$222 million
- Office in Rockville, Maryland

\* As of 8/6/15 weighted average exercise price is \$2.01

\*\* As of 8/6/15 weighted average exercise price is \$1.79

# Investment Considerations

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- Microbiome-focused, clinical-stage therapeutics to protect the microbiome while targeting pathogen-specific diseases
  - Innovative, first-in-class product candidates for prevention and treatment
  - Large markets addressing significant unmet medical needs
- Clinical-stage
  - Prevention of *C. difficile* infections and AAD – First Phase 2a trial initiated March 2015; second Phase 2a initiated June 2015; Phase 2b trial expected 3Q 2015
  - IBS-C – First Phase 2 trial initiated June 2015; second Phase 2 trial expected 2H 2015
  - MS – Ongoing strategic partnering efforts supported by demonstrated therapeutic potential and safety profile of oral estriol; topline MRI data expected 30 days following receipt from UCLA
- Strategic collaboration with Intrexon Corporation (NYSE: XON)
  - Pertussis (whooping cough) – Positive preclinical findings reported at ECCMID in March 2015
  - *Acinetobacter* infections (potentially lethal infection increasing in ICUs and military injuries)
- Experienced management team with extensive clinical and commercial track record



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## **FBR & Co. 2<sup>nd</sup> Annual Healthcare Conference**

Boston, MA  
September 9, 2015



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