



# **Harnessing the Genomic Revolution & Machine Learning to Pioneer Microbiome Therapeutics**

**CORPORATE PRESENTATION | JUNE 2021**



# Forward-Looking Statements

Statements contained in this presentation regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Words such as “anticipates,” “believes,” “expects,” “intends,” “plans,” “potential,” “projects,” “would” and “future” or similar expressions are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding: the growth, strategy, initiation, timing, progress and results of the Company’s current and future research and development programs, preclinical studies and clinical trials and related preparatory work and the period during which the results of such trials will become available, including specifically the initiation and conduct of a Phase 3 trial in recurrent *C. difficile* and Phase 1 trials in ulcerative colitis, autism and chronic hepatitis B; the Company’s ability to obtain regulatory approval of CP101, FIN-211, FIN-524, FIN-525 and any other current and future product candidates that it develops; the Company’s ability to develop additional product candidates; its expectations regarding the potential market size and the rate and degree of market acceptance for any product candidates that it develops; the therapeutic value and commercial potential of candidates developed using its *Human-First Discovery* platform; the completion of its commercial manufacturing facility; and the Company’s expected cash runway. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, among others: the Company’s limited operating history and historical losses; the Company’s ability to raise additional funding to complete the development and any commercialization of its product candidates; the Company’s dependence on the success of its lead product candidate, CP101; the possibility that the Company may be delayed in initiating, enrolling or completing any clinical trials; results of clinical trials may not be sufficient to satisfy regulatory authorities to approve the Company’s product candidates in their targeted or other indications (or such authorities may request additional trials or additional information); results of clinical trials may not be indicative of final or future results from later stage or larger clinical trials (or in broader patient populations once the product is approved for use by regulatory agencies) or may not be favorable or may not support further development; the Company’s product candidates, including CP101, may not generate the benefits to patients that are anticipated; anticipated regulatory approvals may be delayed or refused; competition from third parties that are developing products for similar uses; the Company’s ability to maintain patent and other intellectual property protection and the possibility that the Company’s intellectual property rights may be infringed, invalid or unenforceable or will be threatened by third parties; the Company’s ability to qualify and scale its manufacturing capabilities in anticipation of commencement of multiple global clinical trials; the Company’s lack of experience in selling, marketing and distributing its product candidates; the Company’s dependence on third parties in connection with manufacturing, clinical trials and preclinical studies; and risks relating to the impact and duration of the COVID-19 pandemic on the Company’s business. These and other risks are described more fully in the Company’s filings with the Securities and Exchange Commission (“SEC”), including the section titled “Risk Factors” in the Company’s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 13, 2021, as well as discussions of potential risks, uncertainties, and other important factors in the Company’s other filings with the SEC. All forward-looking statements contained in this presentation speak only as of the date on which they were made. Except to the extent required by law, the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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*Human-First Discovery*® is a registered trademark of the Company.

# Accomplished leadership team with experience in innovation, development, and commercial execution



**Mark Smith, PhD**  
Chief Executive Officer



**Greg Perry**  
Chief Financial Officer



**Zain Kassam, MD, MPH**  
Chief Medical Officer



**Sonia Timberlake, PhD**  
Senior VP Research



**Jim Sigler, MBA**  
Executive VP CMC



**Michelle Rose, PhD**  
Chief Regulatory Officer



**Joe Vittiglio, JD**  
General Counsel



**Management team has collectively developed >40 approved therapeutics**

# The microbiome is an untapped target for therapeutic intervention

Humans carry 1000-fold more microbial genes than host genes

**>20M**  
microbial genes

 **~20K human genes**

The microbiome is an organ system fundamental to human health

Immune modulation



Metabolic function



Neurologic regulation



Enabled by genomics and data science, Finch is pioneering microbiome therapeutics

# Investment Highlights



## **Differentiated discovery process leveraging clinical data de-risks development**

*Leading machine learning capability recognized by Takeda partnership*

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## **Positive pivotal data with lead asset**

*Provides clinical validation of Finch's approach*

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## **Broad microbiome platform enables applications across diverse therapeutic areas**

*Novel class of orally administered biological drugs, with both complete and targeted capabilities*

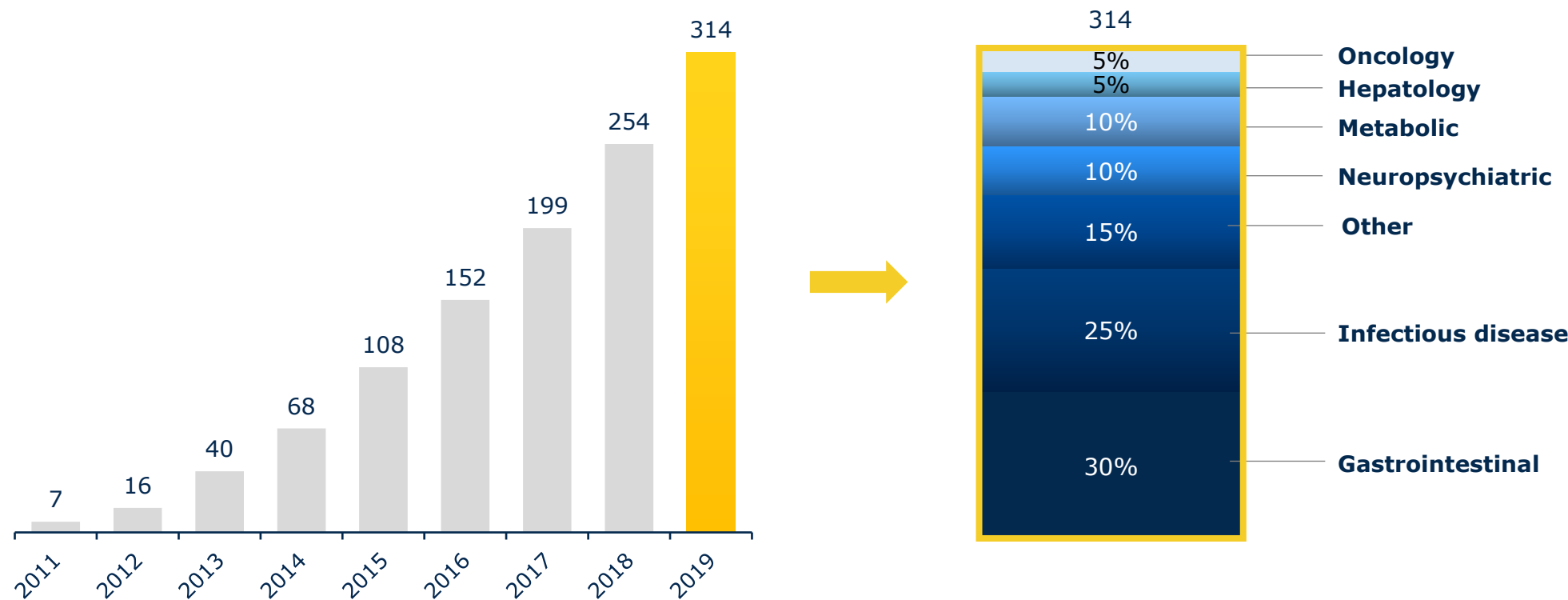
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## **Pioneers in microbiome research**

*Extensive database and partnerships enable Finch to capitalize on advances in the field*

# Growing body of clinical evidence across diverse therapeutic areas

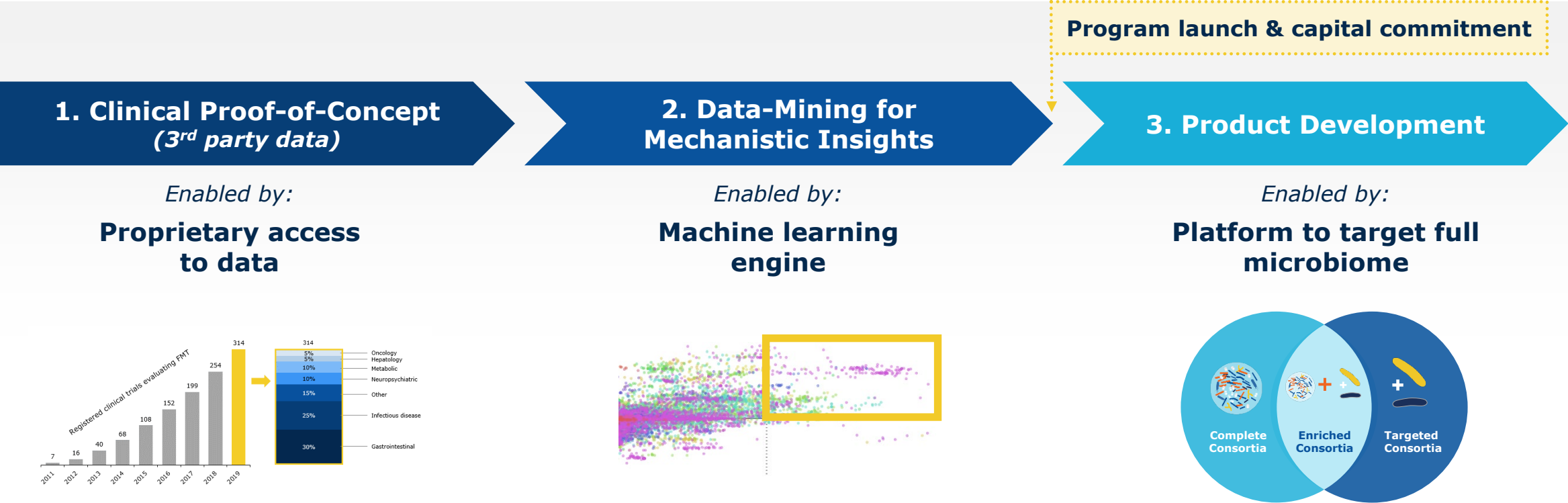
Registered clinical trials evaluating Fecal Microbiota Transplantation (FMT)



**Finch has proprietary access to data through strategic partnerships with leading providers of FMT in the US, China and Australia**

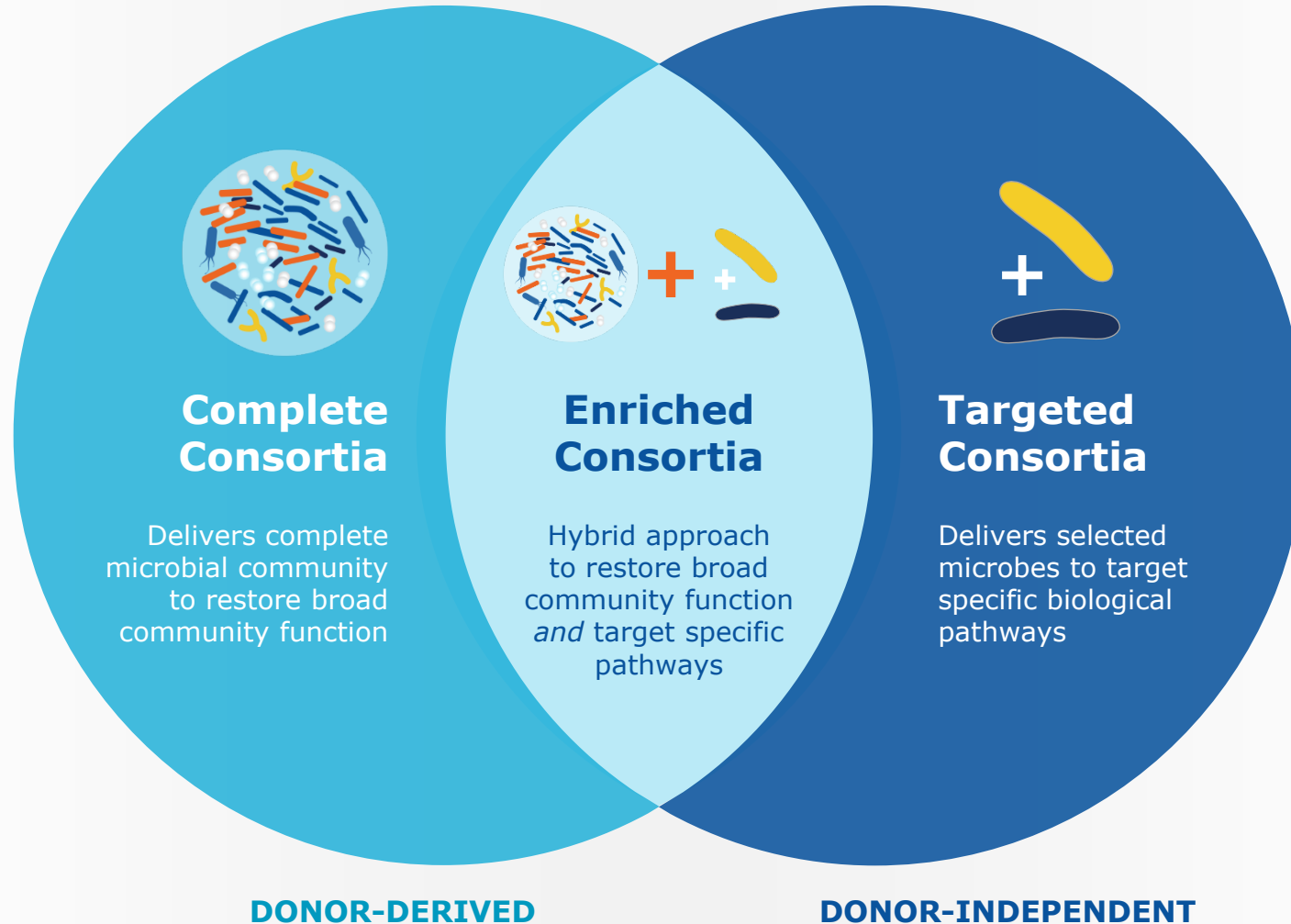


# Our *Human-First Discovery* platform enables capital efficient de-risking








**Starting discovery with proof-of-concept human data reduces risk early**

# Finch is the only company with both complete and targeted approaches for developing microbiome therapeutics





# Finch is advancing a diverse portfolio

	Candidate	Indication	Consortia Type	Preclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestone	Program Rights
GI/Immuno	CP101	Recurrent <i>C. difficile</i>	Complete	First pivotal completed				Initiate Phase 3 trial in mid-2021	
	FIN-524	Ulcerative Colitis	Targeted					Initiate Phase 1 trial in H1 2022	
	FIN-525	Crohn's Disease	Targeted					Initiate IND-enabling activities in 2021	
Neuro	FIN-211	Autism Spectrum Disorder	Enriched					Initiate Phase 1b trial in H2 2021	
Liver	CP101	Chronic Hepatitis B	Complete					Initiate Phase 1b trial in mid-2021	

# CP101 for Recurrent *C. difficile* Infection (CDI)



# CP101 delivers a complete microbiome in orally administered capsules

*Lyophilization technology optimized to preserve entire community, enabling use across multiple indications*

**Efficient, scalable manufacturing enabled by molecular screening of donors**

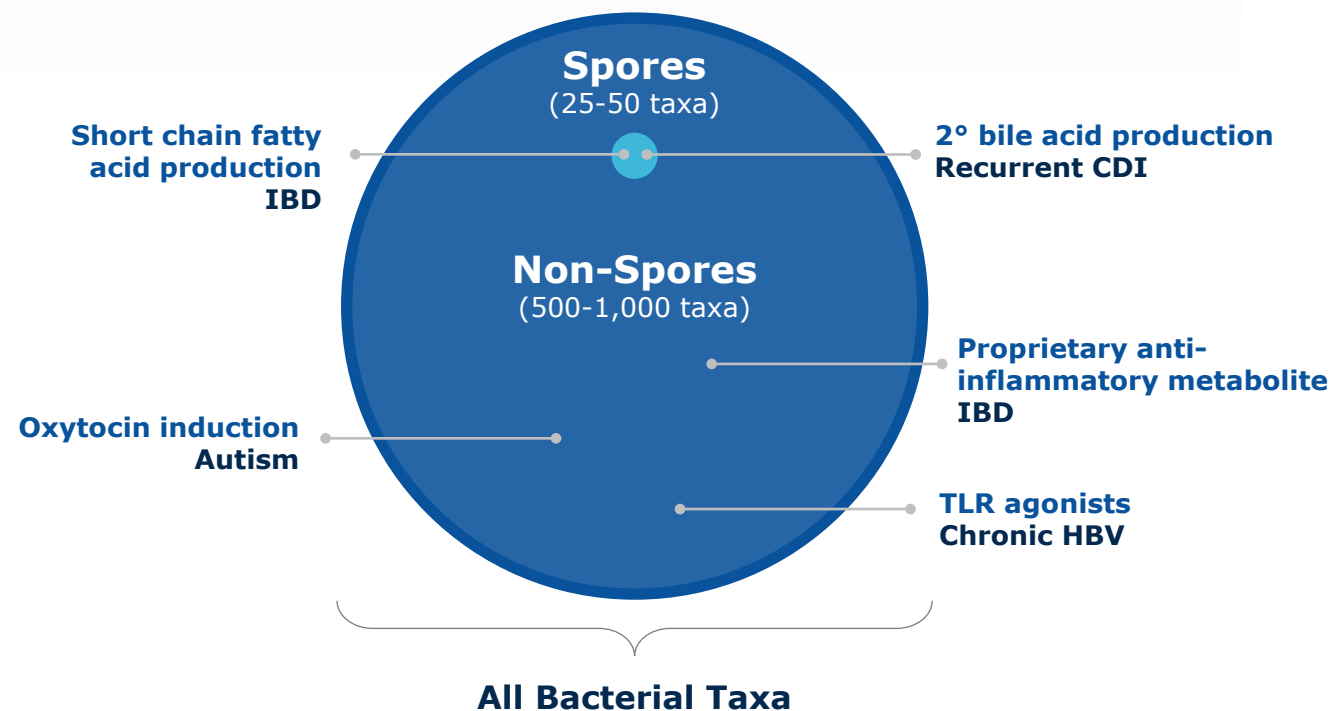
**1. Healthy Donor Sourcing & Qualification**

**2. Harvest, Purification, & Preservation**

**3. Lyophilization & Encapsulation**

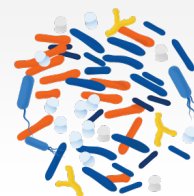


**Complete consortia composition provides potential for broad label expansion**



## Recurrent CDI is an enormous human and economic burden

**CP101 Complete Consortia**  
delivers full microbiome community



**44K**

Annual deaths  
attributable to CDI  
in the US



**2.4M**

Total inpatient days  
associated with CDI  
in the US



**\$5B**

Annual direct costs  
of CDI in the US

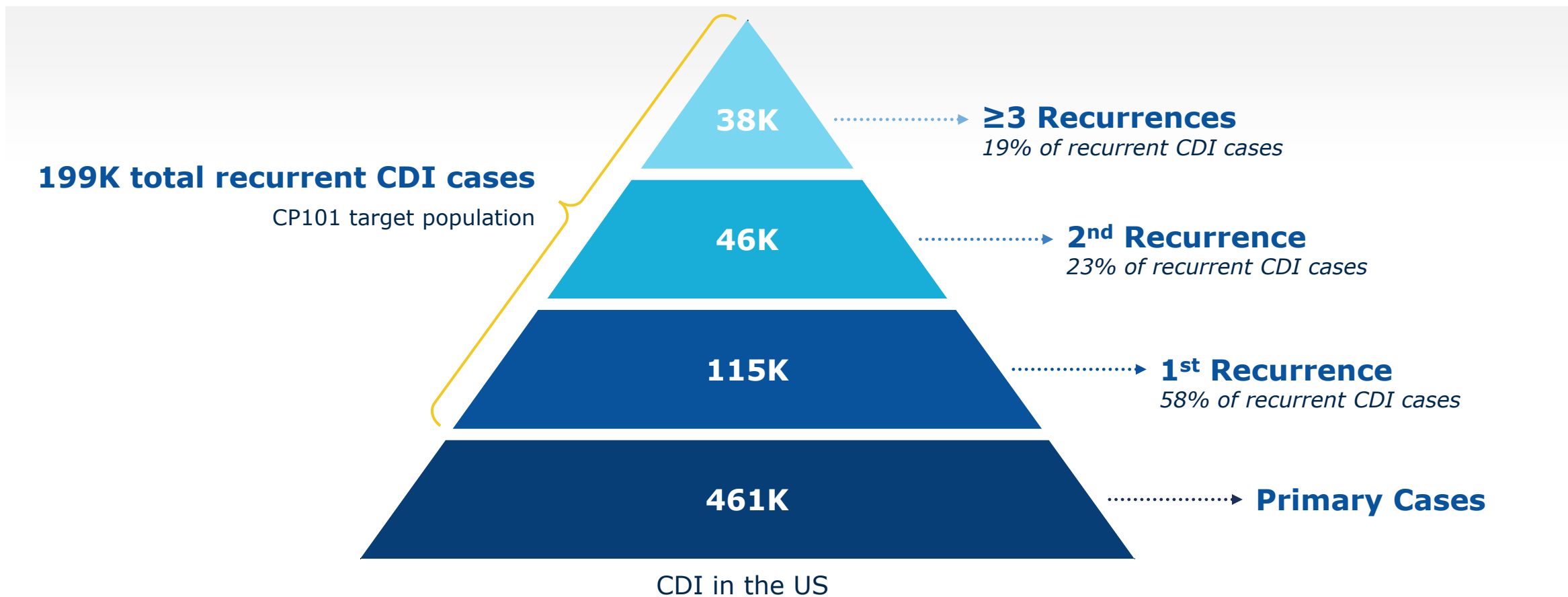


**\$27K**

Saved per patient by  
using microbiota  
transplantation

**CDC has declared *C. difficile* a top antibiotic resistant threat**

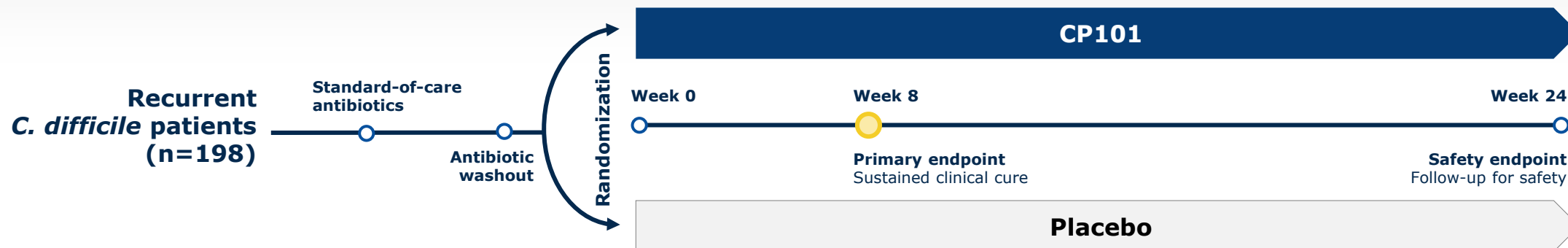
## CP101 is positioned to serve a large population in recurrent CDI



**Standard-of-care antibiotics often result in costly CDI recurrences**

# PRISM3 designed to demonstrate superiority over SOC antibiotics alone

*CP101 evaluated in a broad population to support labeling and market access*



## PRISM3 enrolled a broad population including:



**Patients experiencing their 1<sup>st</sup> CDI recurrence**

*Relevance: 58% of all recurrent CDI cases are 1st recurrence*



**Patients diagnosed with CDI via PCR testing**

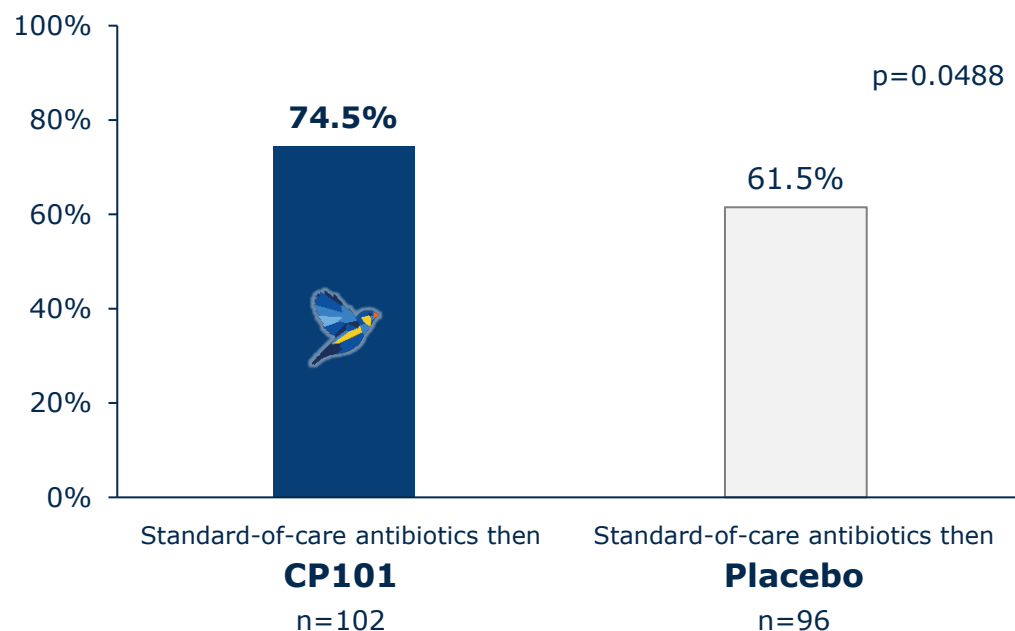
*Relevance: >80% of all CDI cases are diagnosed via PCR*



# CP101 achieved its primary efficacy endpoint and demonstrated a favorable tolerability profile in PRISM3

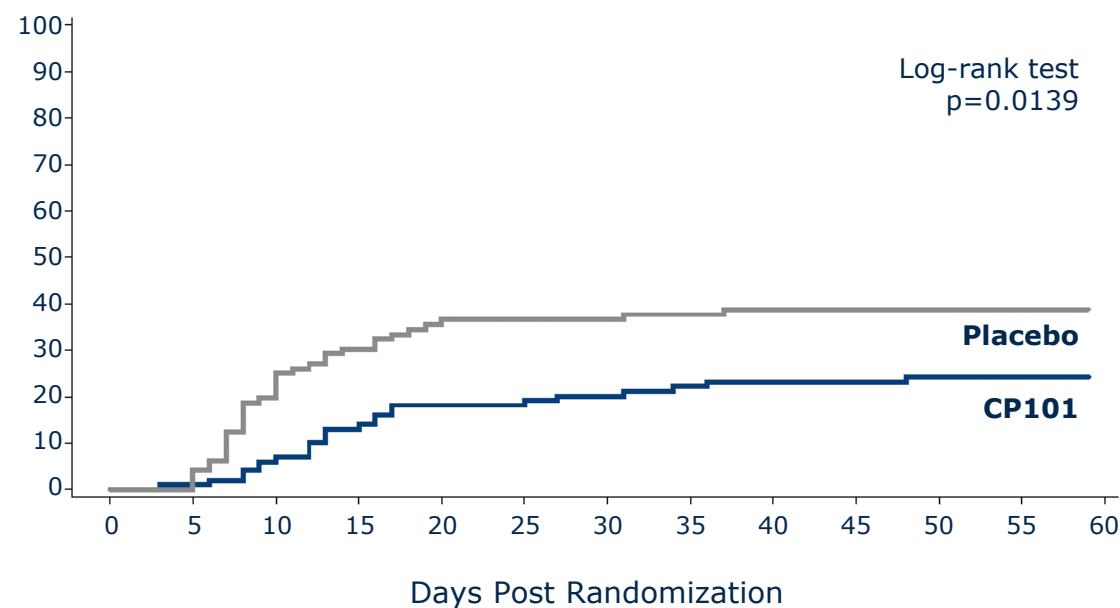
## CP101 achieved 33.8% relative risk reduction for CDI recurrence

**Primary efficacy analysis: Sustained clinical cure through Week 8**  
Recurrence determined by blinded adjudication board



## CP101's effect was durable over time compared to placebo

**Percentage of participants with CDI recurrence (%)**  
Recurrence determined by blinded adjudication board

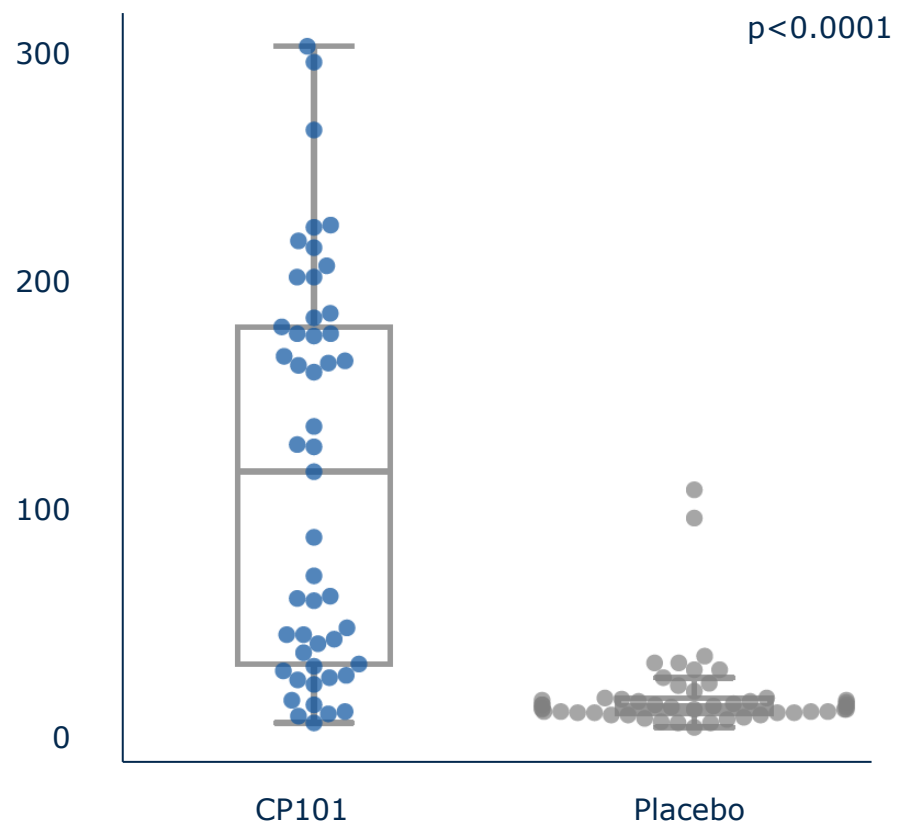


**CP101 met its primary efficacy endpoint in a broad population, with no treatment-related SAEs in the CP101 arm**

# CP101 engrafts new species, altering the structure of the microbiome

## CP101 shows significant engraftment overall

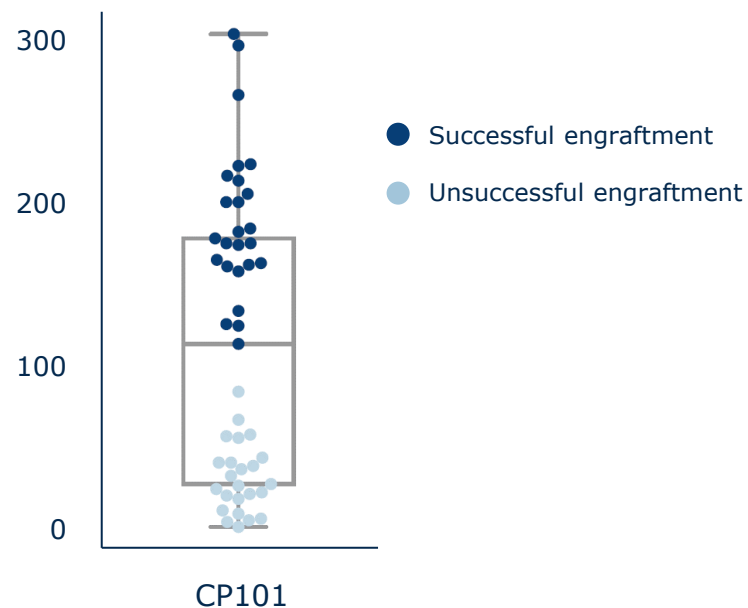
Number of engrafted CP101-associated taxa



# Strong relationship between CP101 engraftment and clinical outcomes in PRISM3

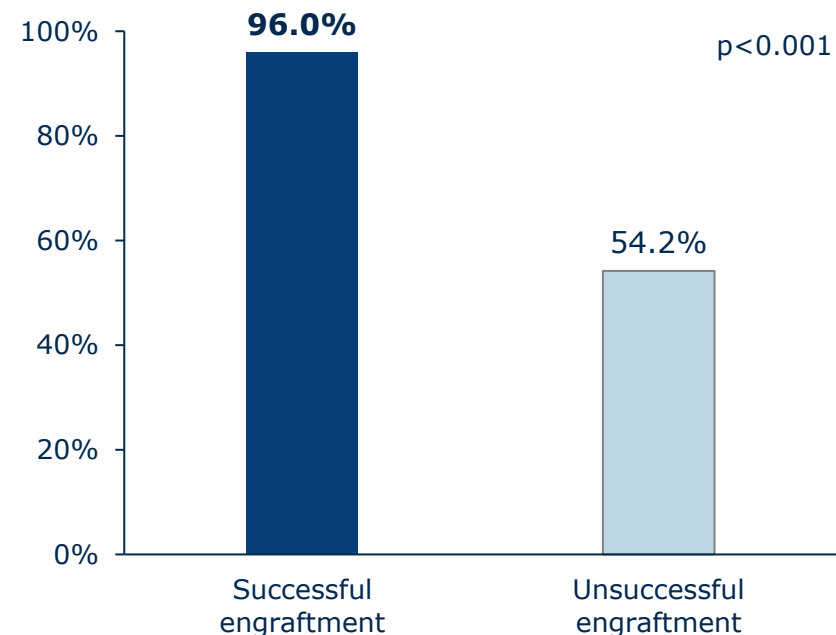
## Engraftment shows a bimodal distribution

Number of engrafted CP101-associated taxa



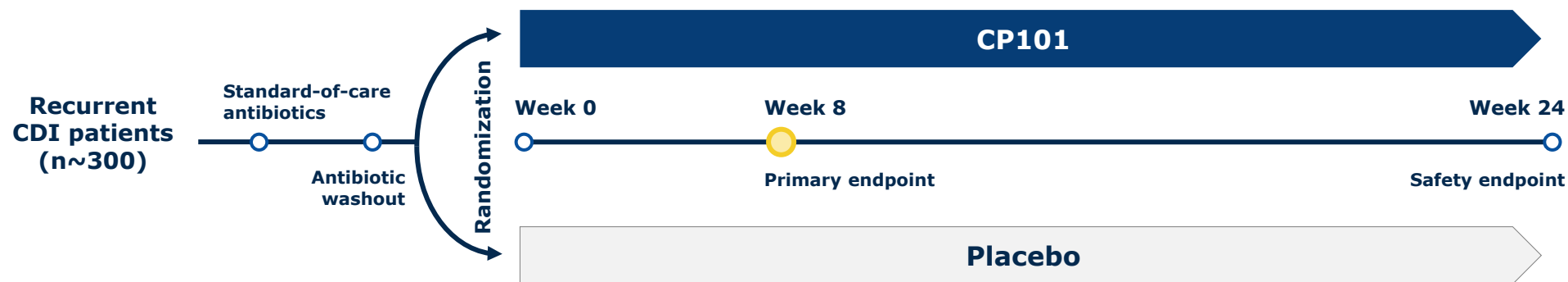
## Engraftment correlates with sustained clinical cure

Sustained clinical cure by engraftment group



## Phase 3 trial of CP101 in recurrent CDI is initiating in mid-2021

**PRISM4 is designed to serve as a second pivotal trial to support a BLA for CP101**



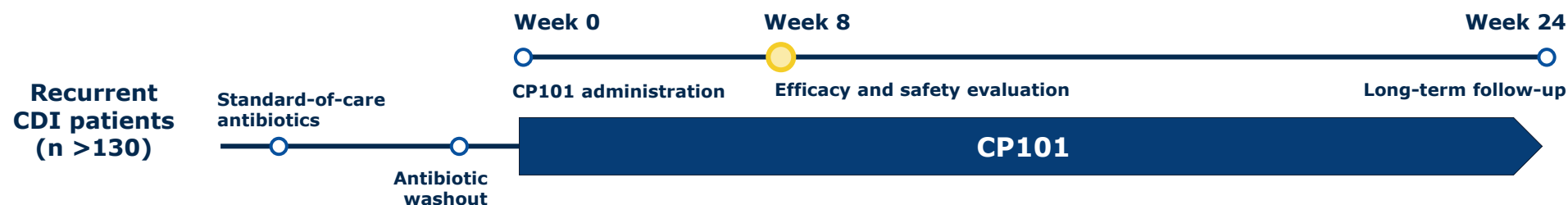
### Key Features

1. Extension of antibiotic washout period to enhance engraftment
2. Sample size increased to enhance power
3. Global study to support marketing authorizations outside the US

**Topline PRISM4 data readout  
expected in H1 2023**

## Additional CP101 data reading out in 2021

**PRISM-EXT is an open-label study providing safety and efficacy data in recurrent CDI**



**Additional clinical data with CP101 will contribute to overall safety database**

## CP101 positioned to be market leader in recurrent CDI



**Convenient, one-time oral capsule delivery**



**Achieved primary endpoint in a broad population:**

- All stages of recurrent CDI
- All test methods for CDI diagnosis



**Fast Track and Breakthrough Therapy designations for prevention of recurrent CDI**



**Efficient, scalable manufacturing enabled by molecular rather than chemical pathogen exclusion**



**Complete consortia composition provides potential for broad label expansion**



## **FIN-524 & FIN-525 for Inflammatory Bowel Disease (IBD)**

## Finch & Takeda working together to develop new therapeutics for IBD



**FIN-524 & FIN-525**  
**Targeted Consortia**



**3.1M**

Affected by IBD in  
the US alone



**70,000**

Patients diagnosed  
with IBD per year  
in US



**20%**

With ulcerative colitis  
require colectomy



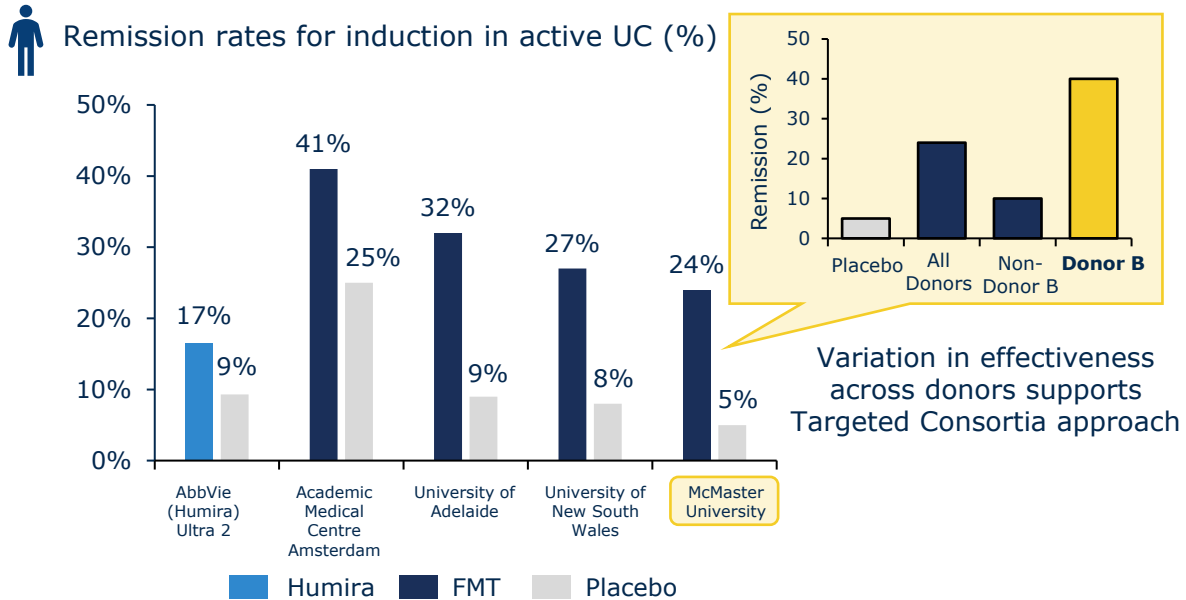
**\$31B+**

In attributable  
costs per year  
in US

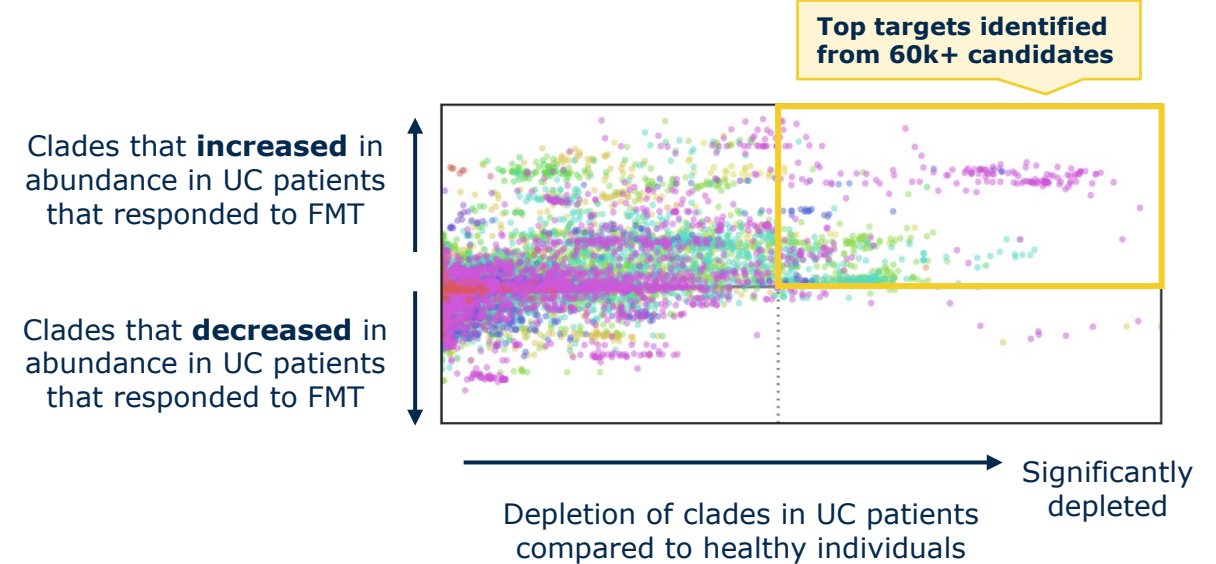
**Large unmet need for well-tolerated, effective therapeutics administered orally**

# Finch's machine learning platform enables identification and isolation of promising targets from clinical data

## Four placebo-controlled FMT trials show compelling results compared to current standard of care

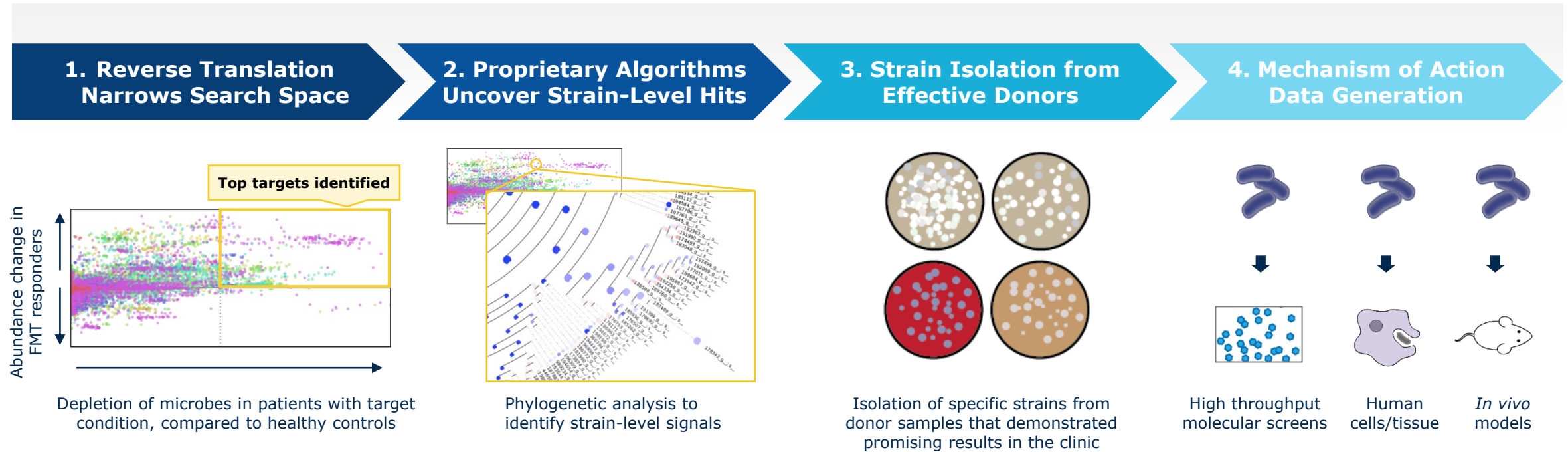


## Platform used to identify "super donor" strains as potential therapeutic candidates



**FIN-524 and FIN-525 illustrate the power of Finch's platform for the development of Targeted Consortia**

# Finch's combination of proprietary data and machine learning capabilities enable differentiated Targeted Consortia



**Finch's platform brings the power of AI to microbiome therapeutic development**



# **FIN-211 for Autism Spectrum Disorder (ASD)**



# ASD is a significant unmet need linked to the gut-brain axis

Finch plans to initially focus on the subset of the ASD population suffering from significant GI symptoms

**Complete Consortia** addresses community level dysbiosis



**FIN-211**  
**Enriched Consortia**



**Targeted Consortia** ensure key mechanisms are consistently engaged



**4.6M**

Children and adults in the US with ASD



**>30%**

Report significant GI symptoms (diarrhea/constipation)



**0**

FDA-approved therapeutics for core symptoms of ASD



**\$100B**

Annual cost to care for individuals with ASD in the US

**Autism is a large unmet need with no FDA-approved therapeutics for core symptoms**



# Multiple lines of evidence point to the role of the microbiome in ASD

## 1. Dysbiosis

- Distinct microbiome composition among individuals with ASD
- Early life events that impact the microbiome are associated with increased risk of ASD
  - Cesarean section: 33% higher ASD risk
  - Reduced breast feeding: 93% - 107% higher ASD risk
  - Antibiotics: 144% - 264% higher ASD risk

## 2. Mechanistic insights

### Oxytocin:

- Depleted levels of oxytocin in those with ASD
- Key, non-spore microbes induce oxytocin production

### Gut barrier:

- Impaired gut barrier integrity and translocation of behavior-influencing metabolites (e.g. 4-EPS)
- Microbiome enhances gut barrier integrity

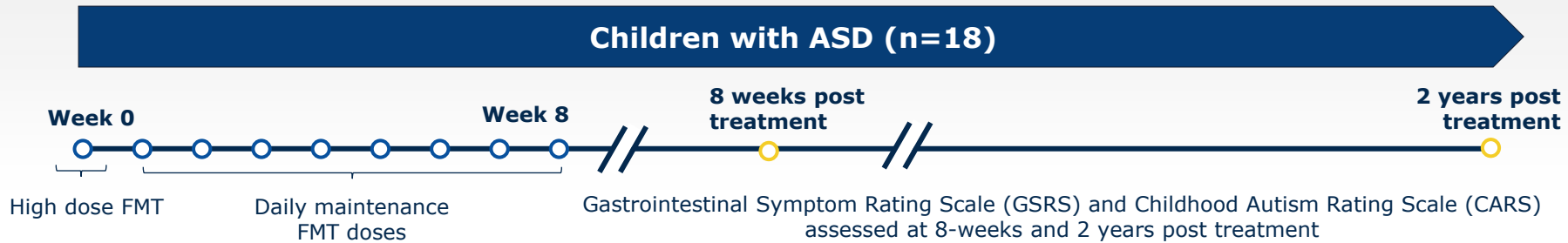
## 3. PoC FMT clinical studies

- Multiple FMT studies show improvements in both GI and behavioral endpoints

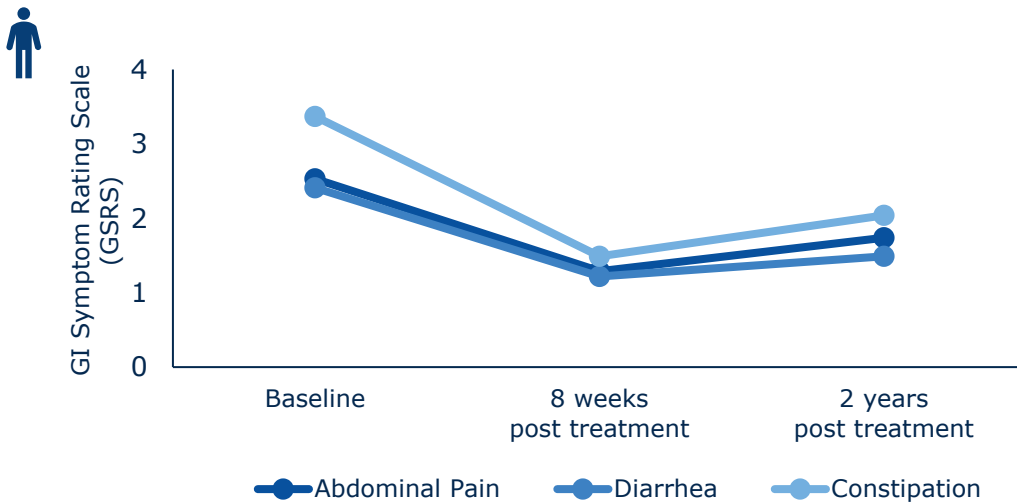


Study	Number of participants	GI improvement	Behavioral improvement
Ward (2016)	9	N/A	✓
Kang (2017)	18	✓	✓
Zhao (2019)	48	✓	✓
Li (2019)	85	✓	✓
Huanlong (unpublished)	31	✓	✓
<b>Total</b>	<b>191</b>		

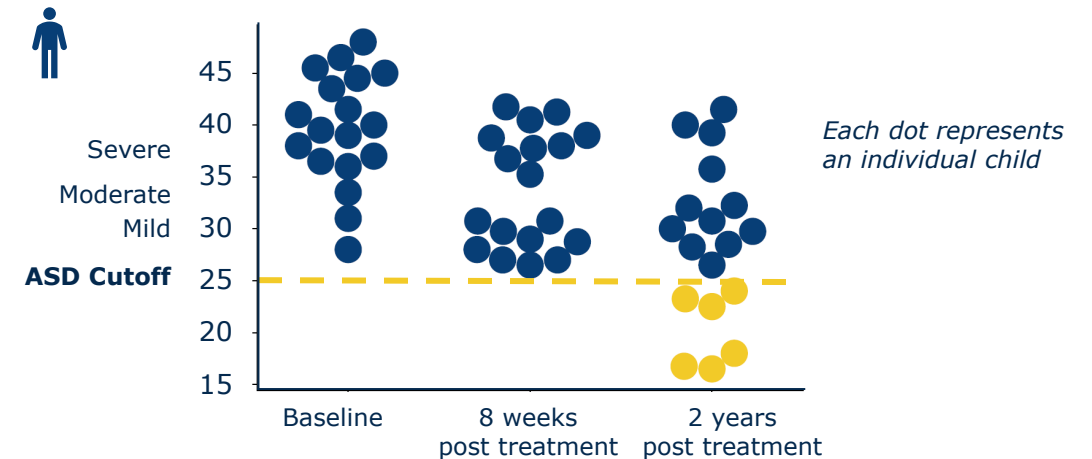
# Open label data shows improvements in both GI and behavioral symptoms following microbiota transplantation



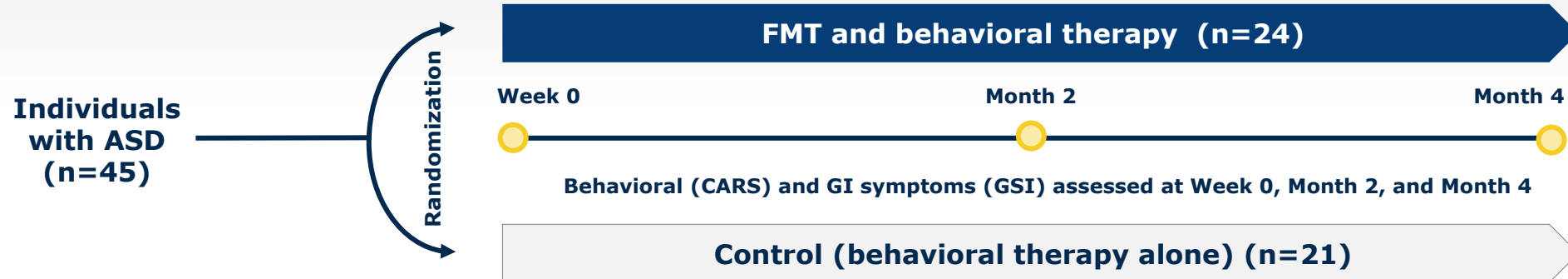
**58% reduction in GI symptoms** at 2 years post treatment compared to baseline



**33% of children below the cutoff for ASD diagnosis** at 2 years post treatment



# Randomized, independent clinical study showed improvement in both GI and behavioral symptoms following microbiota transplantation



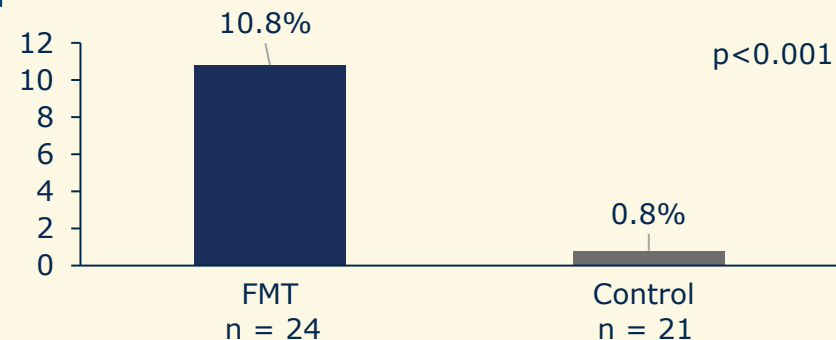
## Results at 2 months post FMT

- GI severity index (GSI) significantly improved
- Behavioral (CARS) scores significantly improved
- Microbiome shifted towards a healthy composition

### Behavioral scores significantly improved at 2 months post FMT

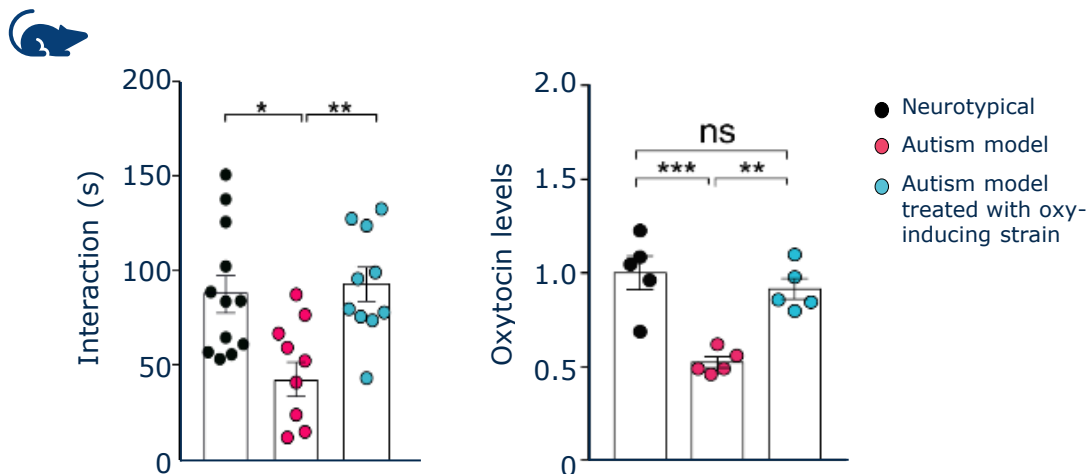


CARS score improvements at Month 2 (%)

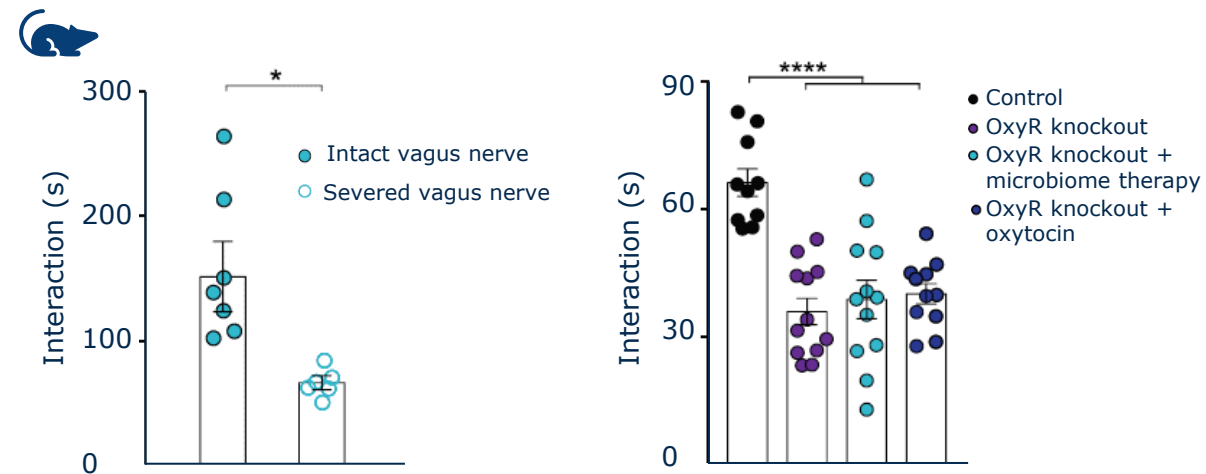


# Preclinical data show oxytocin-dependent behavioral improvements with microbiome therapy

## Microbiome therapy restores neurotypical behavior and oxytocin production



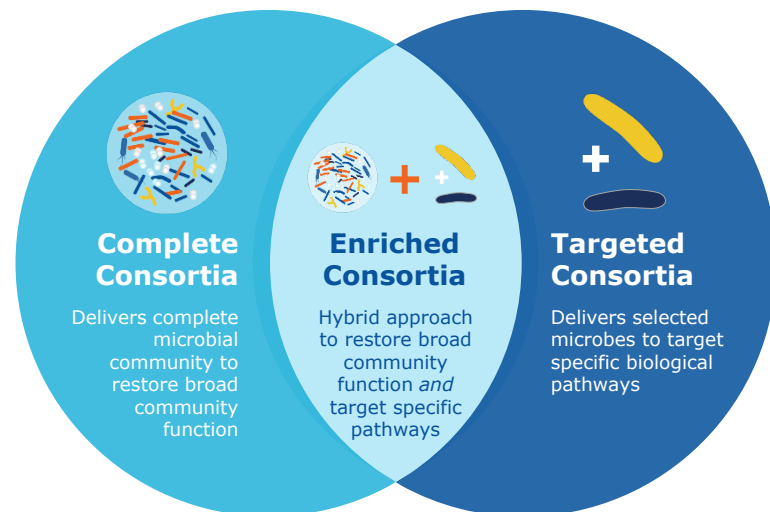
## Therapeutic benefit is eliminated when vagus nerve is severed or oxytocin receptor knocked out



# FIN-211 is positioned to address a tremendous unmet need

## Enriched Consortia product strategy

Designed to address both community-level and species-level dysbiosis in pediatric friendly formulation



## Pre-IND FDA feedback yielded two key insights

1. FIN-211 may proceed directly to children with ASD
2. Demonstrating benefit for *either* GI or behavioral symptoms could support a BLA

## Phase 1b will evaluate multiple dosing regimens



### Ph1b Endpoints

Primary endpoints	Safety & tolerability
Secondary endpoints	Pharmacokinetics (engraftment)
Exploratory endpoints	Behavioral endpoints including CARS scores GI endpoints including spontaneous bowel movements

# CP101 for Chronic Hepatitis B Virus (HBV)

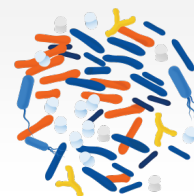




# Chronic HBV is the first label expansion opportunity for CP101

*Clinical data support the role of microbiome in chronic HBV*

**CP101 Complete Consortia**  
delivers full microbiome community



**290M**

Have chronic HBV globally,  
with 2M affected  
chronically in the US



**900K**

Deaths globally from  
chronic HBV-related  
complications per year



**25-40%**

Lifetime risk of liver  
cancer in patients with  
chronic HBV



**\$160K**

Cost of liver  
transplantation

# Microbiome mediated immune activation presents a novel mechanism for chronic HBV

## Current therapeutic strategies aim to disrupt viral activity or activate an immune response

### Strategy #1: Disrupt viral activity

- Nucleos(t)ide analogs
- siRNA

### Strategy #2: Activate immune response

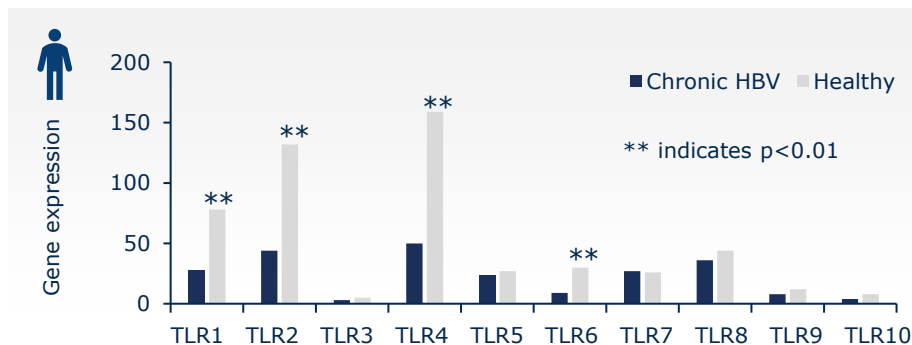
- Interferon
- Checkpoint inhibitors
- Toll-like receptor (TLR)-agonists

## 1. Dysbiosis

- Distinct microbiome composition among chronic HBV patients
- Epidemiological and murine data link the microbiome to the deficient immune response that leads to chronic HBV

## 2. Mechanistic insights

- TLR pathways broadly downregulated in chronic HBV, but plays critical role in immune clearance of HBV



- Microbiome upregulates multiple TLR pathways, a mechanism that has been shown to inhibit replication and facilitate HBV clearance

## 3. PoC FMT clinical studies

- 3 FMT trials demonstrate significant anti-viral activity in chronic HBV patients

# Studies show that a functional microbiome enables HBV clearance

*Mechanism tied to immune activation*

## Epidemiological data shows that risk of chronic HBV is correlated with age



Age (years)	Susceptibility to Chronic HBV
Adults (18+)	<1 – 12%
Infant (<1)	90%

## Murine data shows age-dependent susceptibility can be reversed through microbiome manipulation



Age	Microbiome Status	Susceptibility to Chronic HBV
Adult	Mature <i>(no intervention)</i>	No
	Disrupted <i>(antibiotic treated)</i>	Yes
Pup	Immature <i>(no intervention)</i>	Yes
	Mature <i>(microbiota transplantation from adult mouse)</i>	No

# CP101 is positioned to address two important clinical objectives

20%  
HBeAg  
positive

**Objective #1:** Achieve HBeAg clearance among HBeAg positive patients

80%  
HBeAg  
negative

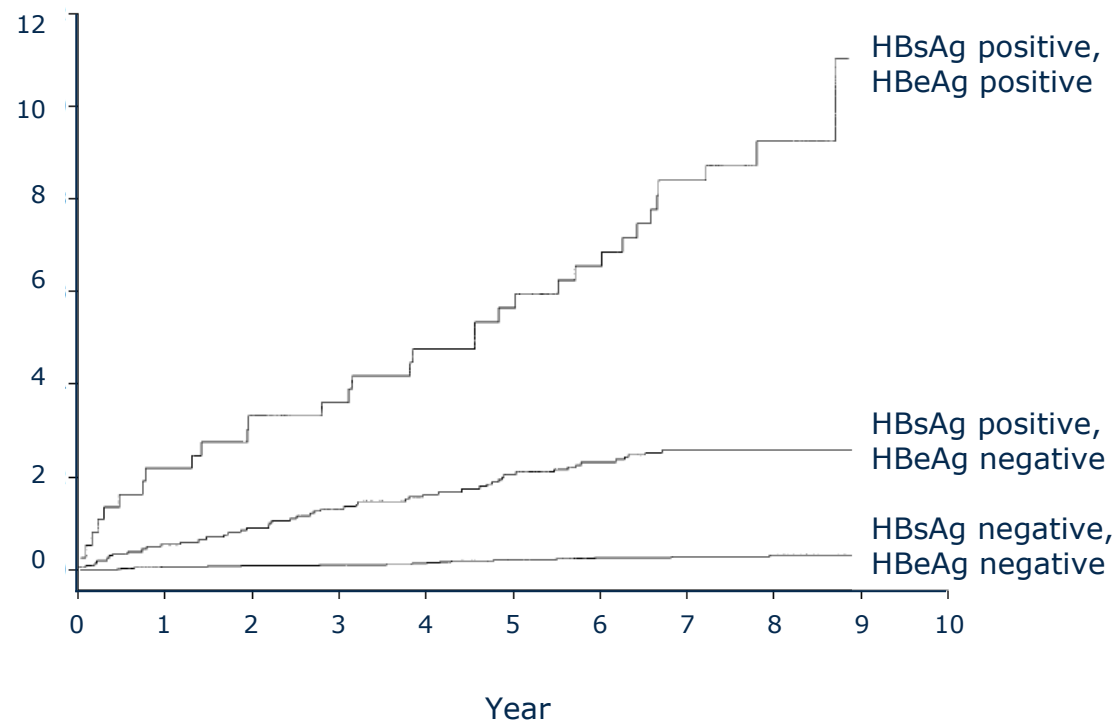
**Objective #2:** Reduce HBsAg in HBeAg negative patients

Chronic HBV  
population

**HBeAg positive patients are at significantly increased risk of liver cancer**



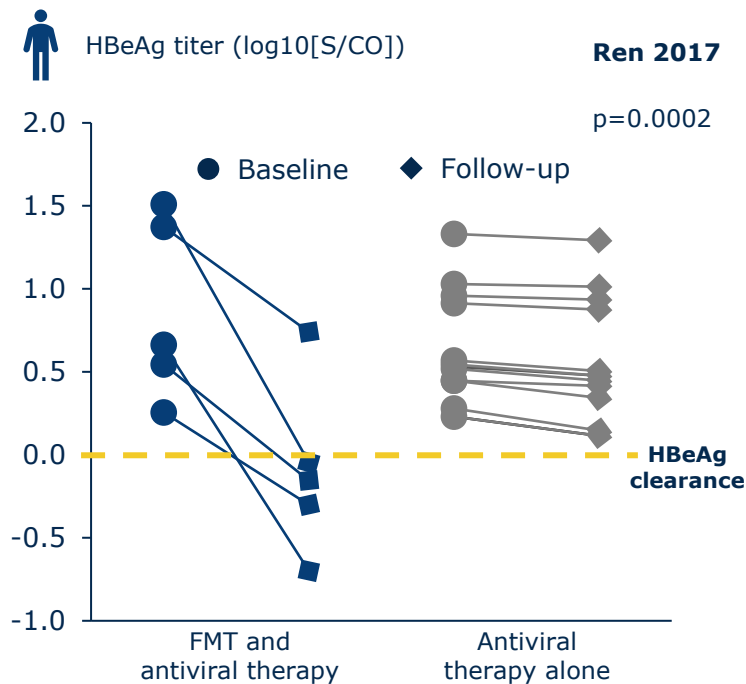
Cumulative incidence of liver cancer (%)



# Multiple clinical studies with microbiota transplantation show improved HBV clearance

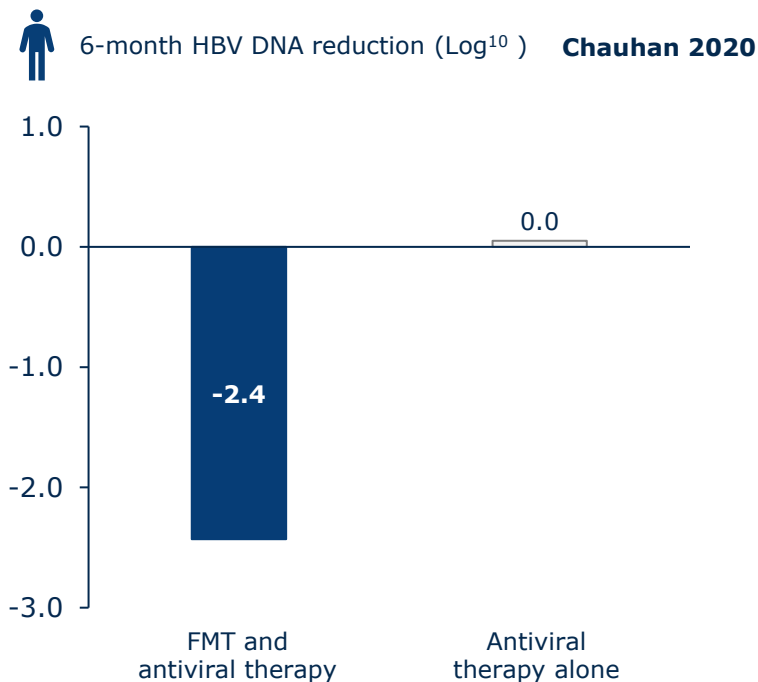
## Microbiota transplantation induced HBeAg clearance

### Trial 1: HBeAg positive



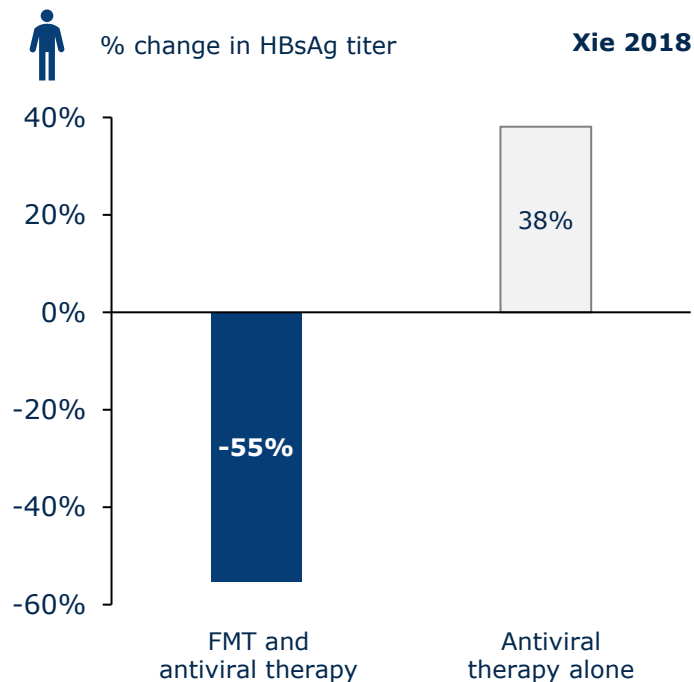
## Microbiota transplantation induced HBeAg clearance and HBV DNA decrease

### Trial 2: HBeAg positive



## Microbiota transplantation decreased HBsAg


### Trial 3: HBeAg negative



**Addressing community-level dysbiosis led to improvement of HBV endpoints**

# Finch plans to start a Phase 1b study of CP101 in chronic HBV in 2021

*Trial will evaluate outcomes in two key subpopulations*

  
**Chronic HBV  
patients  
(n~45)**



**HBeAg positive**

**HBeAg negative**

## Ph 1b Endpoints

### Primary endpoints

Safety & tolerability

### Secondary endpoints

Pharmacokinetics (engraftment)

### Exploratory endpoints

Hepatitis B viral endpoints including HBsAg, HBeAg, HBV DNA  
Mechanistic biomarkers including immune and metabolic markers

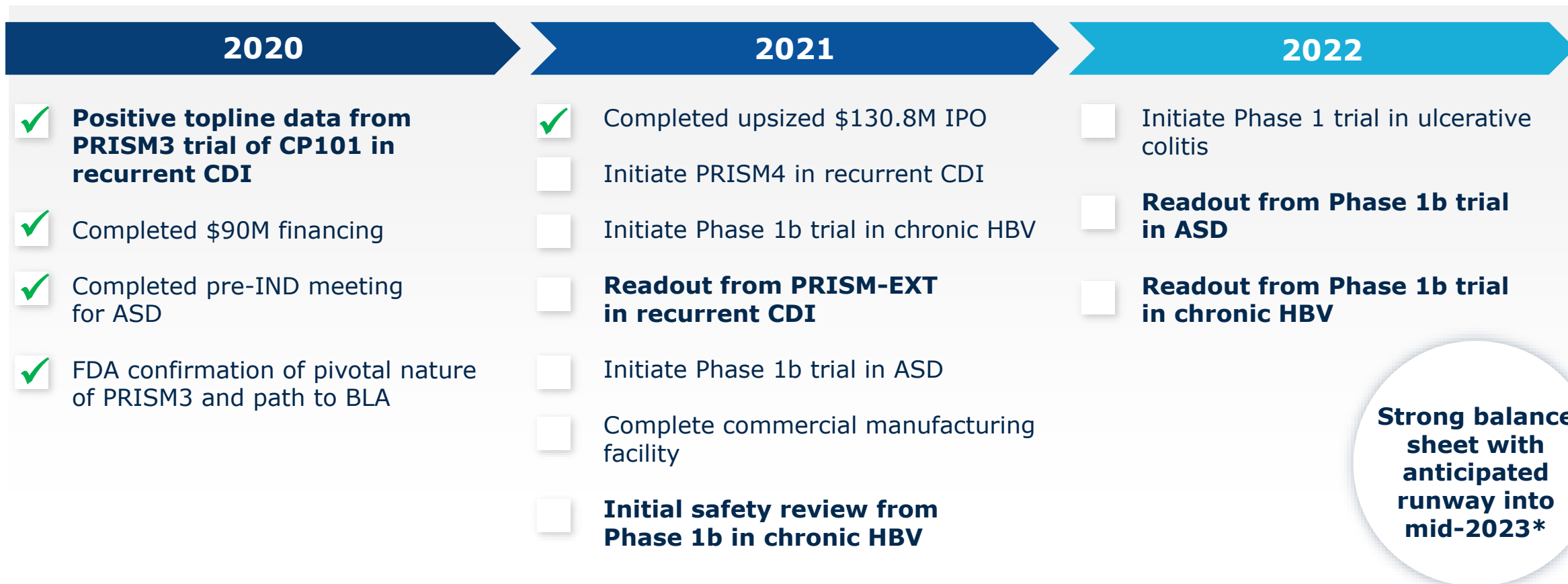


## Anticipated Milestones



# Finch positioned to continue momentum

*Anticipated milestones*





**Harnessing the microbiome  
to transform patients' lives**

