

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 13, 2021

Finch Therapeutics Group, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40227
(Commission File Number)

82-3433558
(IRS Employer
Identification No.)

**200 Inner Belt Road, Suite 400
Somerville, Massachusetts 02143**
(Address of Principal Executive Offices)

02143
(Zip Code)

Registrant's Telephone Number, Including Area Code: (617) 229-6499

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	FNCH	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD.

Finch Therapeutics Group, Inc. (the “Company”) from time to time presents and/or distributes to the investment community, at various industry and other conferences, slide presentations to provide updates and summaries of its business. On September 13, 2021, the Company posted an updated corporate presentation to its website. The corporate presentation is available under the “Events & Presentations” tab in the “Investors & News” section of the Company’s website, located at www.finchtherapeutics.com.

The information in this Item 7.01 of this Current Report on Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section, nor shall such information be deemed incorporated by reference in any other filing with the Securities and Exchange Commission made by the Company, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Corporate Presentation, dated September 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

FINCH THERAPEUTICS GROUP, INC.

Date: September 13, 2021

By: /s/ Mark Smith
Mark Smith, Ph.D.
Chief Executive Officer

Harnessing the Genomic Revolution & Machine Learning to Pioneer Microbiome Therapeutics

CORPORATE PRESENTATION | SEPTEMBER 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 autism and chronic hepatitis B and the timing of data readouts from those trials; the Company's and its collaborators' ability to obtain regulatory approval of CP101, FIN-211, TAK-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 August 10, 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.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company's own internal estimates and research. While the Company believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. Finally, while the Company believes its own internal research is reliable, such research has not been verified by any independent source.

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



Marc Blaustein
Chief Operating Officer



Jim Sigler, MBA
Executive VP CMC



Michelle Rose, PhD
Chief Regulatory Officer



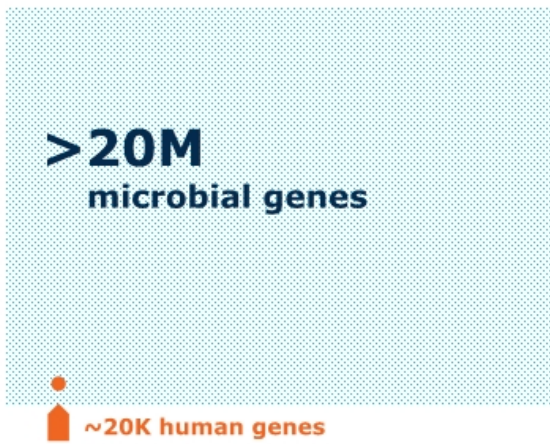
Joe Vittiglio, JD
General Counsel



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



The microbiome is an organ system fundamental to human health



Investment Highlights

Positive pivotal data with lead asset provides foundation for future growth

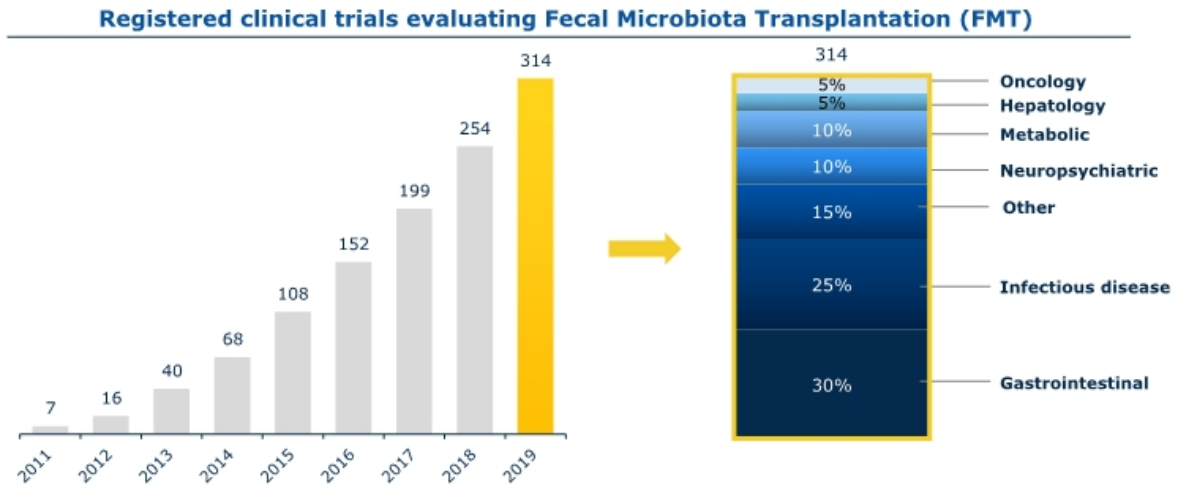
Differentiated discovery process, with proof-of-concept clinical data leveraged to guide product design and de-risk development

Uniquely positioned to harness full diversity and potential of the microbiome across diverse therapeutic areas

Leading machine learning-based platform recognized by Takeda partnership

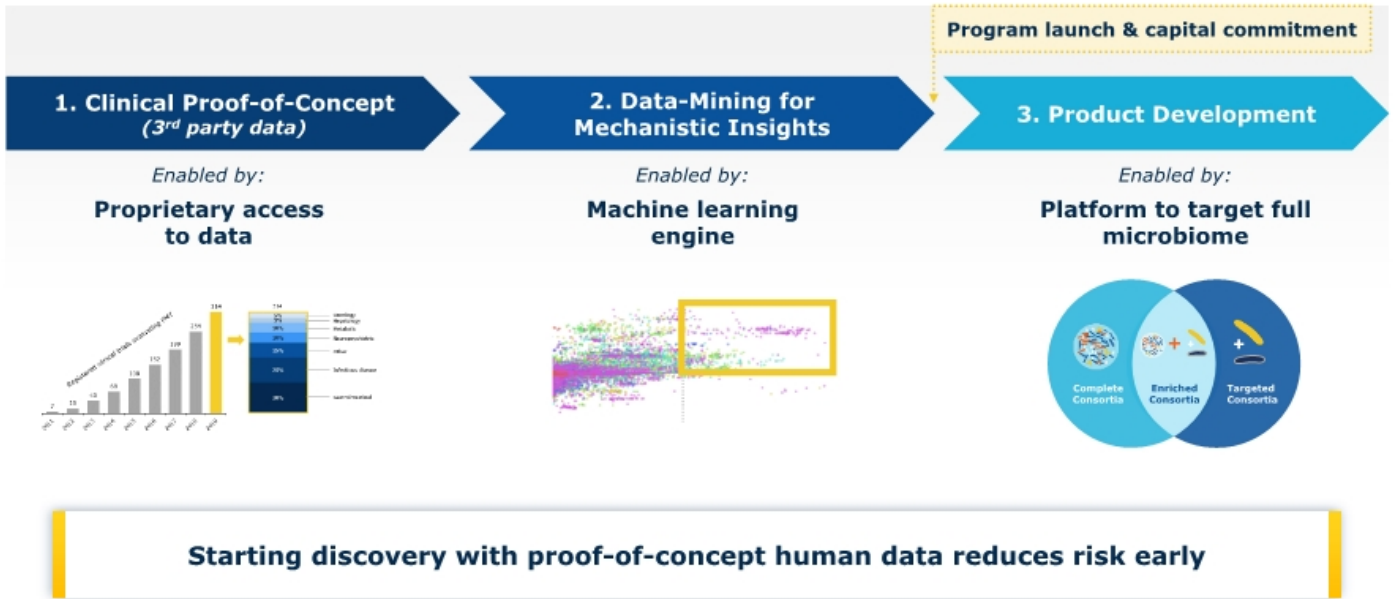
Data-rich period ahead, with multiple programs advancing towards the clinic

Growing body of clinical evidence across diverse therapeutic areas

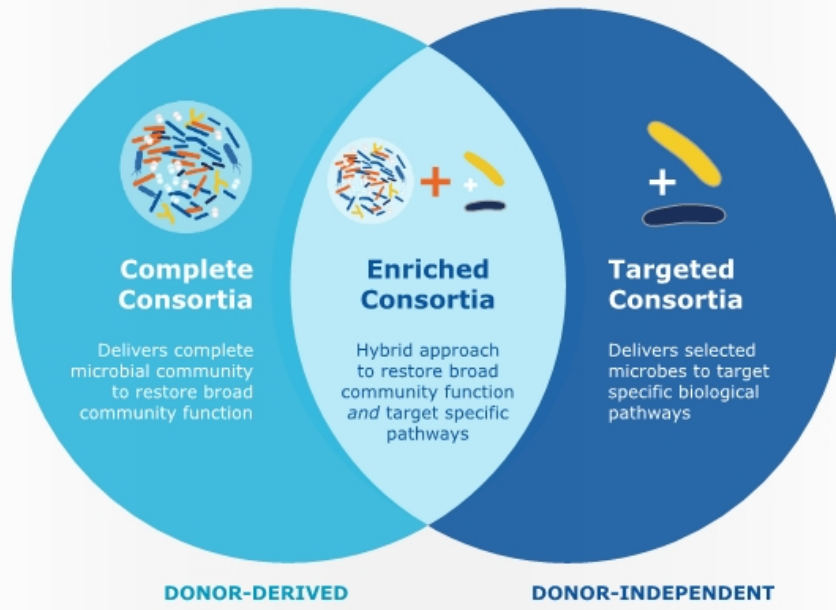


Finch has proprietary access to data through strategic partnerships with leading providers of FMT in the US, China and Australia






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



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				Topline Phase 3 readout in H1 2023	
	TAK-524 (formerly FIN-524)	Ulcerative Colitis	Targeted					Initiate Phase 1 trial	Takeda to lead development 
	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 early 2022	

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



CP101, an orally administered, purified microbiome product candidate delivers a complete microbial community

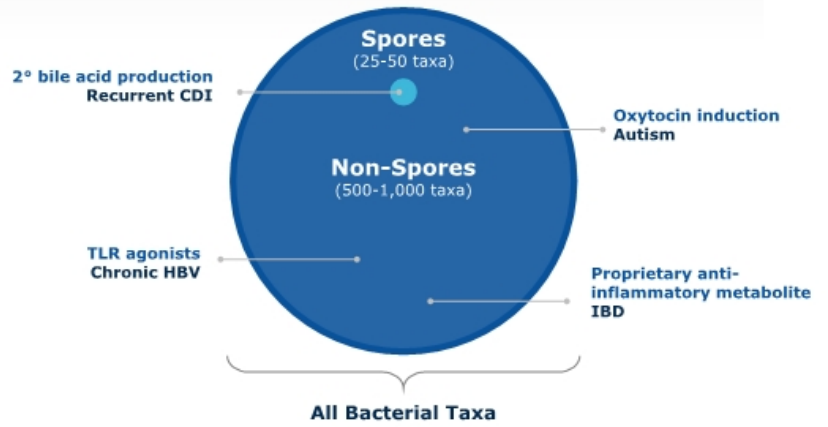
Lyophilization technology optimized to preserve entire community, enabling use across multiple indications



Efficient, scalable manufacturing enabled by molecular screening of donors



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

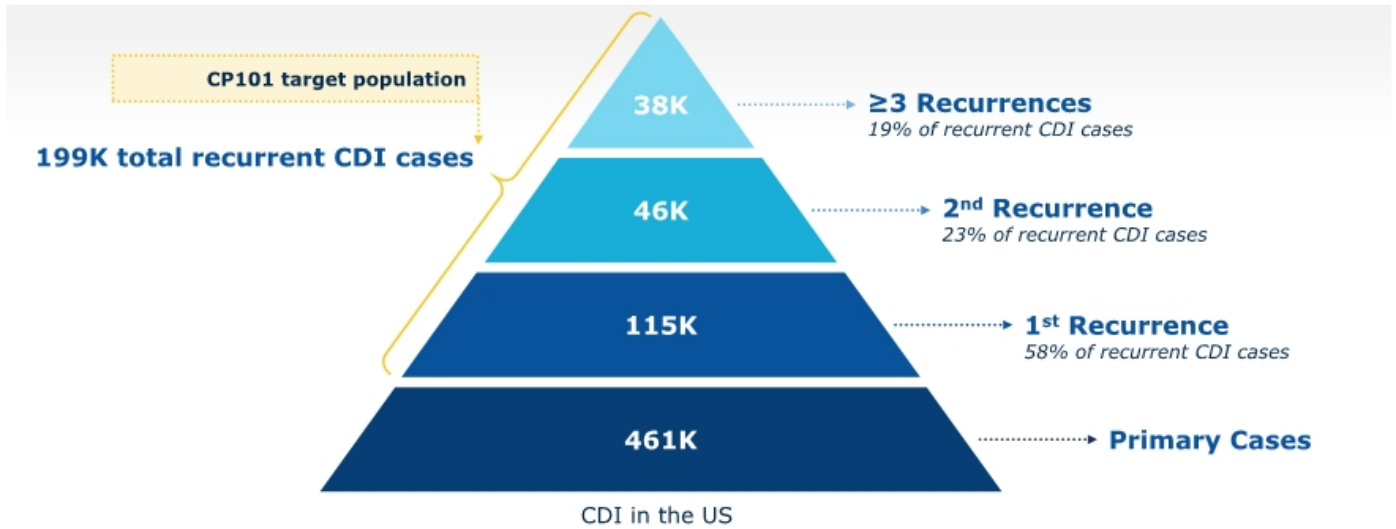


\$27K

Saved per patient by using microbiota transplantation

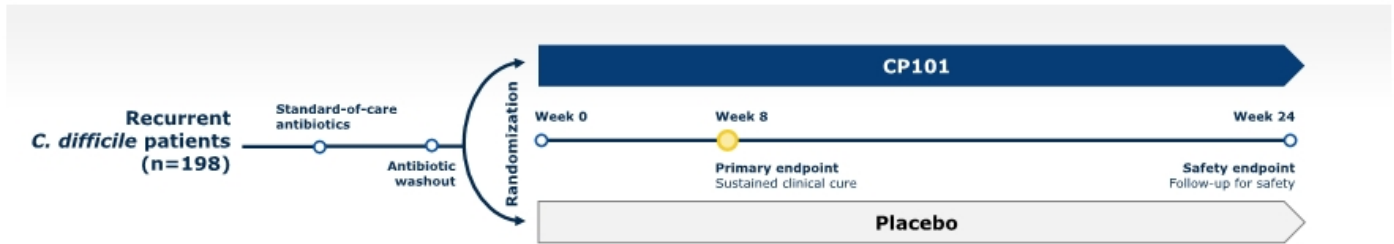
CDC has declared *C. difficile* a top antibiotic resistance threat

CP101 is positioned to serve a large population in recurrent CDI



CP101 uniquely positioned to enable early intervention in the management of CDI

PRISM3 designed to demonstrate superiority over SOC antibiotics alone



PRISM3 enrolled a broad population including:



Patients experiencing their 1st 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 evaluated in a broad population to support labeling and market access

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

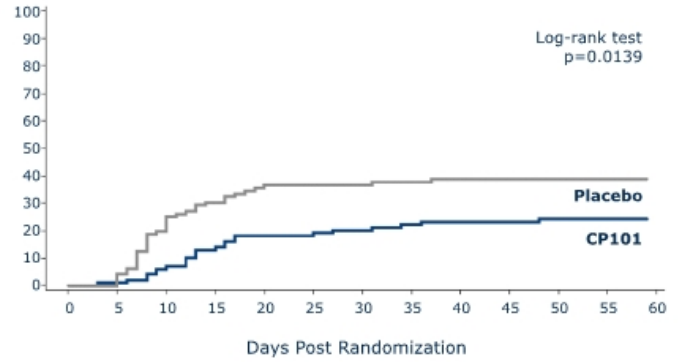
CP101 achieved 33.8% relative risk reduction for CDI recurrence

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

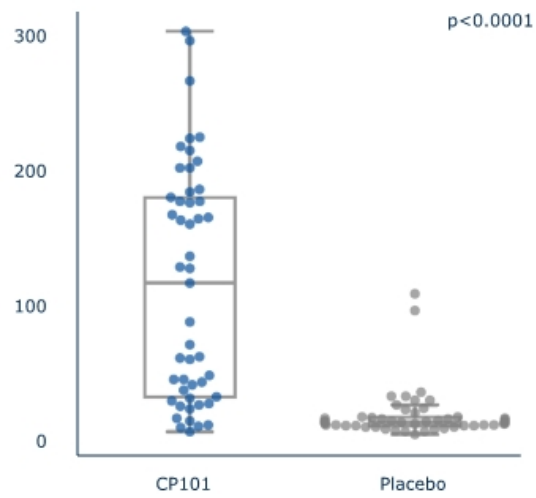


CP101 met its primary efficacy endpoint in a broad population, with no treatment-related SAEs in the CP101 arm

CP101 engrafts new species, altering the structure of the microbiome

CP101 shows significant engraftment overall

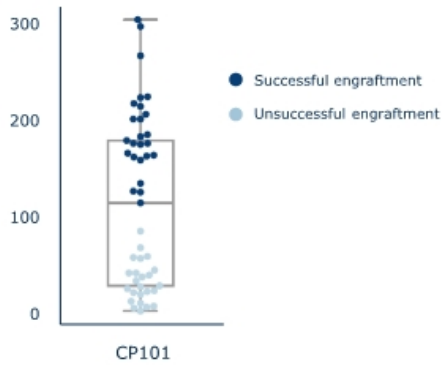
Number of engrafted CP101-associated taxa



Strong relationship between CP101 engraftment and clinical outcomes in PRISM3

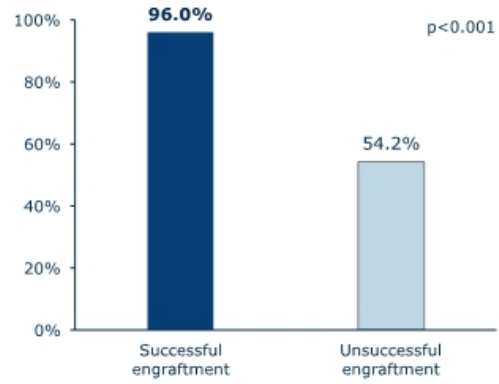
Engraftment shows a bimodal distribution

Number of engrafted CP101-associated taxa



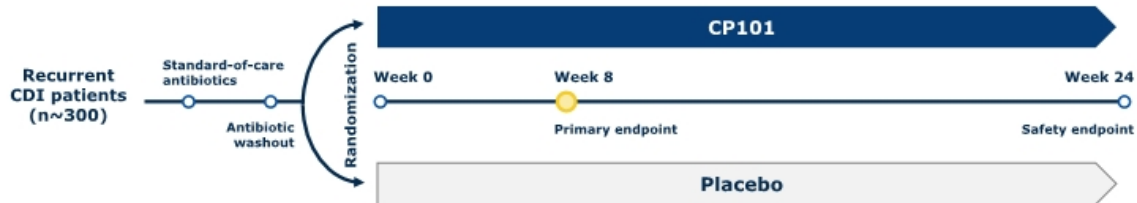
Engraftment correlates with sustained clinical cure

Sustained clinical cure by engraftment group



Topline readout from Phase 3 trial of CP101 in recurrent CDI expected in H1 2023

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

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 administration



Achieved primary endpoint in a broad population, positioning CP101 to serve a significant patient 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

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



Finch & Takeda working together to develop new therapeutics for IBD



TAK-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+

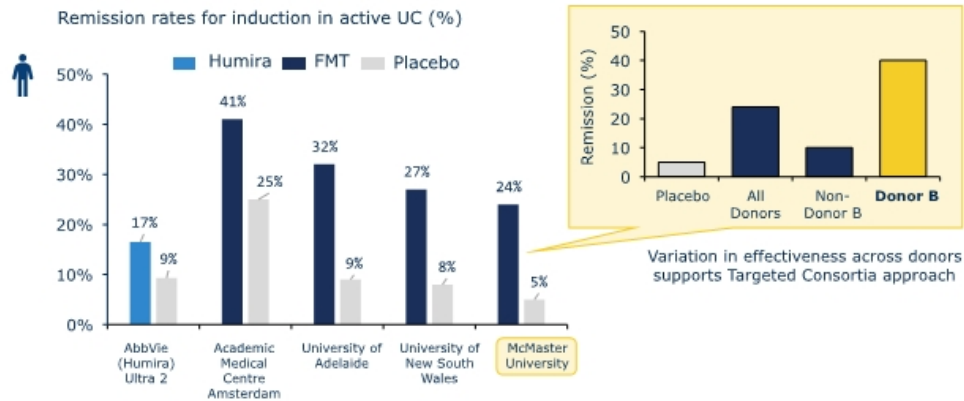
In attributable
costs per year
in US

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

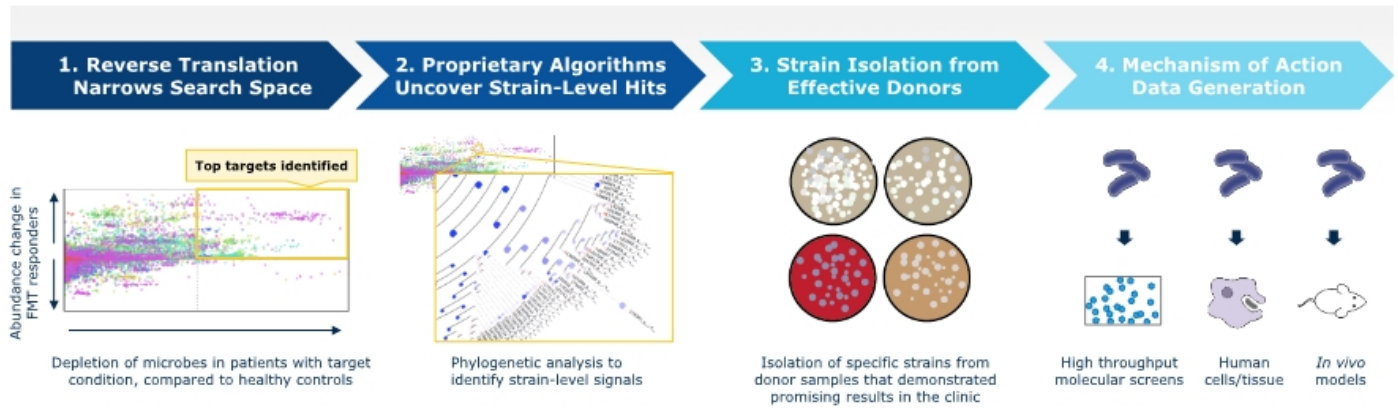
TAK-524 illustrates the power of Finch's platform for the development of Targeted Consortia

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



Takeda recently accelerated its leadership role in the development of the TAK-524 ulcerative colitis program

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

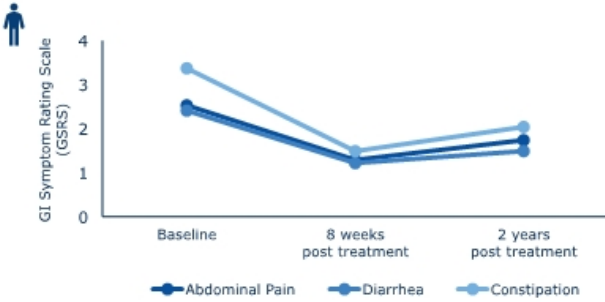


Study	Number of participants	GI improvement	Behavioral improvement
Ward (2016)	9	N/A	✓
Kang (2017)	18	✓	✓
Zhao (2019)	48	✓	✓
Li (2019)	85	✓	✓
Huanlong (unpublished)	31	✓	✓
Total	191		

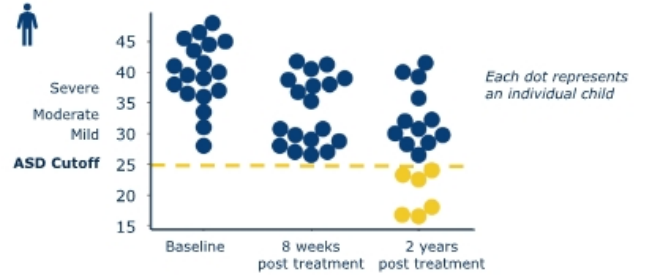
Open label data shows improvements in both GI and behavioral symptoms following microbiota transplantation



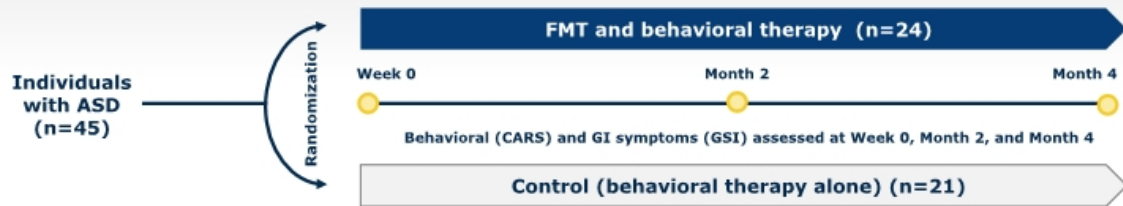
58% reduction in GI symptoms at 2 years post treatment compared to baseline



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



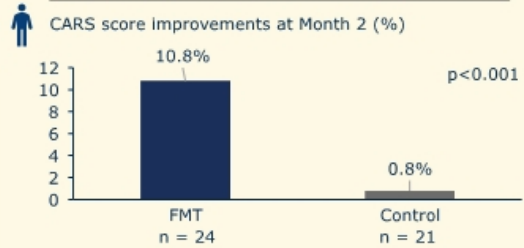
Randomized, independent clinical study showed improvement in both GI and behavioral symptoms following microbiota transplantation



Results at 2 months post FMT

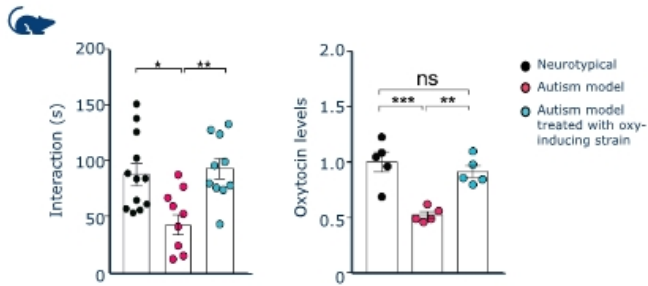
- GI severity index (GSI) significantly improved
- Behavioral (CARS) scores significantly improved
- Microbiome shifted towards a healthy composition

Behavioral scores significantly improved at 2 months post FMT

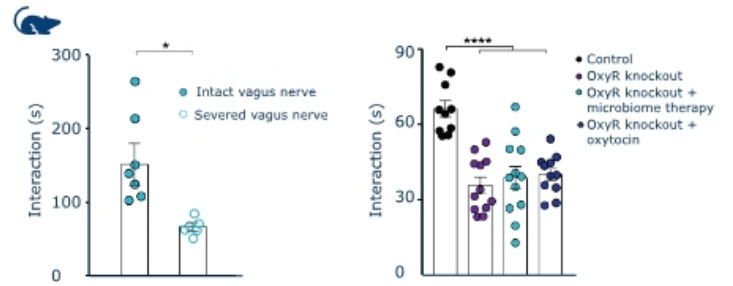


Preclinical data show oxytocin-dependent behavioral improvements with microbiome therapy

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 designed to address both the gastrointestinal (GI) and behavioral symptoms of ASD

Enriched Consortia product strategy

Designed to address both community-level and species-level dysbiosis in an oral formulation



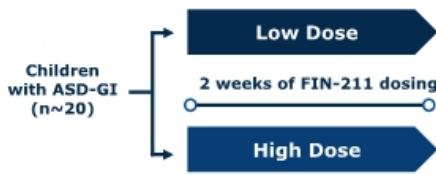
Pre-IND FDA feedback yielded two key insights:

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 AUSPIRE trial will evaluate multiple dosing regimens of FIN-211 in children with ASD and GI symptoms

AUSPIRE Part A: Dose Escalation

Readout expected in H2 2022



AUSPIRE Part B: Expansion Cohort

NEW

Readout expected in 2023



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

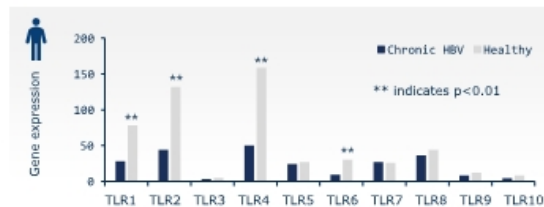
- Interferon
- Checkpoint inhibitors
- Toll-like receptor (TLR)-agonists

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 (no intervention)	No
	Disrupted (antibiotic treated)	Yes
Pup	Immature (no intervention)	Yes
	Mature (microbiota transplantation from adult mouse)	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

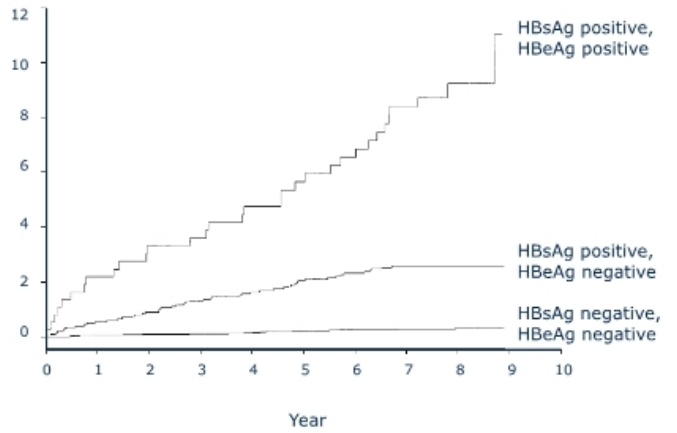


Sources: Ott. BMC Infect Dis 2012; Yang N Engl J Med 2002

HBeAg positive patients are at significantly increased risk of liver cancer

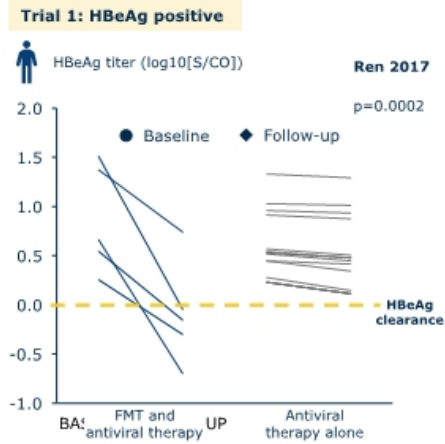


Cumulative incidence of liver cancer (%)

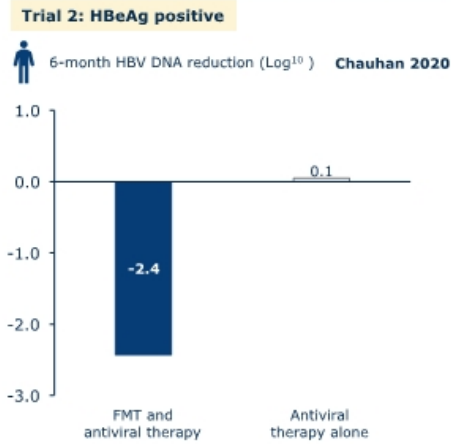


Multiple clinical studies with microbiota transplantation show improved HBV pathology

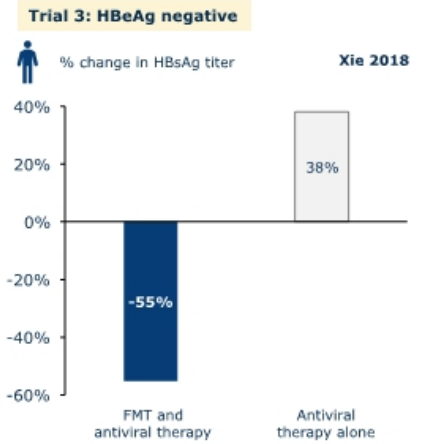
Microbiota transplantation induced HBeAg clearance



Microbiota transplantation induced HBeAg clearance and HBV DNA decrease



Microbiota transplantation decreased HBsAg



Addressing community-level dysbiosis led to improvement of HBV endpoints

Finch plans to start RECLAIM, a Phase 1b trial of CP101 in chronic HBV in early 2022

Trial will evaluate outcomes in four key subpopulations



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

2020	2021	2022
<ul style="list-style-type: none">✓ Positive topline data from PRISM3 trial of CP101 in recurrent CDI✓ Completed \$90M financing✓ Completed pre-IND meeting for ASD✓ FDA confirmation of pivotal nature of PRISM3 and path to BLA	<ul style="list-style-type: none">✓ Completed upsized \$130.8M IPO✓ Takeda accelerated leadership role in TAK-524 ulcerative colitis program☐ Initiate PRISM4 in recurrent CDI☐ Readout from PRISM-EXT in recurrent CDI☐ Initiate Phase 1b trial in ASD☐ Complete commercial manufacturing facility	<ul style="list-style-type: none">☐ Initiate Phase 1b trial in chronic HBV☐ Initial safety review from Phase 1b in chronic HBV☐ Readout from Phase 1b trial in ASD☐ Readout from Phase 1b trial in chronic HBV

Strong balance sheet with anticipated runway into mid-2023*



*As of 6/30/2021, unaudited cash and cash equivalents of \$168 million



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



