

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): January 10, 2022

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  
Somerville, Massachusetts  
(Address of Principal Executive Offices)

02143  
(Zip Code)

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

(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 2.02 Results of Operations and Financial Condition.**

Finch Therapeutics Group, Inc. (the “Company”) intends to share with investors the amount of cash and cash equivalents it had on hand as of December 31, 2021. Although the Company has not finalized its financial results for the twelve months ended December 31, 2021, the Company preliminarily estimates that its cash and cash equivalents as of December 31, 2021 was approximately \$133.5 million.

The information in this Item 2.02 is unaudited and preliminary, and does not present all information necessary for an understanding of the Company’s financial condition as of December 31, 2021 and its results of operations for the three months and year ended December 31, 2021. The audit of the Company’s financial statements for the year ended December 31, 2021 is ongoing. The Company’s actual consolidated cash and cash equivalents as of December 31, 2021 may differ from these estimates due to the completion of the Company’s year-end closing and auditing procedures.

The information in this Item 2.02 shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 7.01 Regulation FD Disclosure.**

Mark Smith, PhD, the Company’s Chief Executive Officer, will present at the upcoming 40th Annual J.P. Morgan Healthcare Conference on Thursday, January 13, 2022 at 9:45 a.m. ET. The presentation will be webcast live and will be available under the “Events & Presentations” tab in the “Investors & News” section of the Company’s website, located at [www.finchtherapeutics.com](http://www.finchtherapeutics.com).

On January 10, 2022, the Company posted an updated corporate presentation dated January 2022 providing a general corporate update to the business and disclosure regarding the Company’s cash and cash equivalents as of December 31, 2021. 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](http://www.finchtherapeutics.com). The Company intends to use this presentation in meetings with analysts, investors and others from time to time.

The information contained in this Item 7.01 is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

Exhibit No.	Description
99.1	<a href="#">Corporate Presentation, dated January 2022.</a>
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: January 10, 2022

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

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Exhibit 99.1



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

**CORPORATE PRESENTATION | JANUARY 2022**



## 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 conduct of a Phase 3 trial in recurrent *C. difficile* and the initiation and conduct of 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 expand on its pipeline and 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 strength of the Company's patent portfolio; 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 and FIN-211, 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 November 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*<sup>®</sup> is a registered trademark of the Company.

# Management team composed of accomplished biopharma executives and leading microbiome and machine learning experts



**Mark Smith, PhD**  
Chief Executive Officer



**Greg Perry**  
Chief Financial Officer



**Debra Silberg, MD, PhD**  
Interim 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**  
Chief Business & Legal Officer



**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; platform supported by leading patent portfolio**

**Leading machine learning-based platform recognized by Takeda partnership**

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



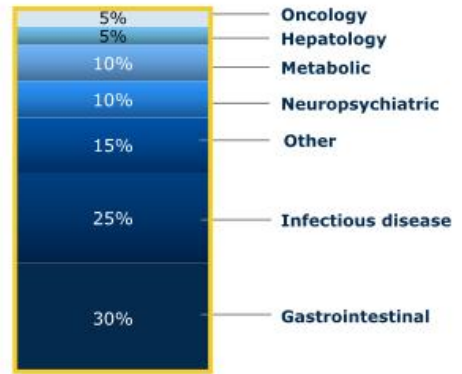
# Growing body of clinical evidence across diverse therapeutic areas fuels our discovery engine and guides product design



## >300 registered clinical trials evaluating Fecal Microbiota Transplantation (FMT)

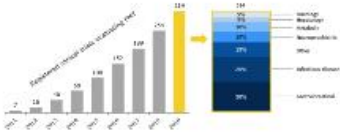


## Recent FMT research spans diverse therapeutic areas with significant unmet needs



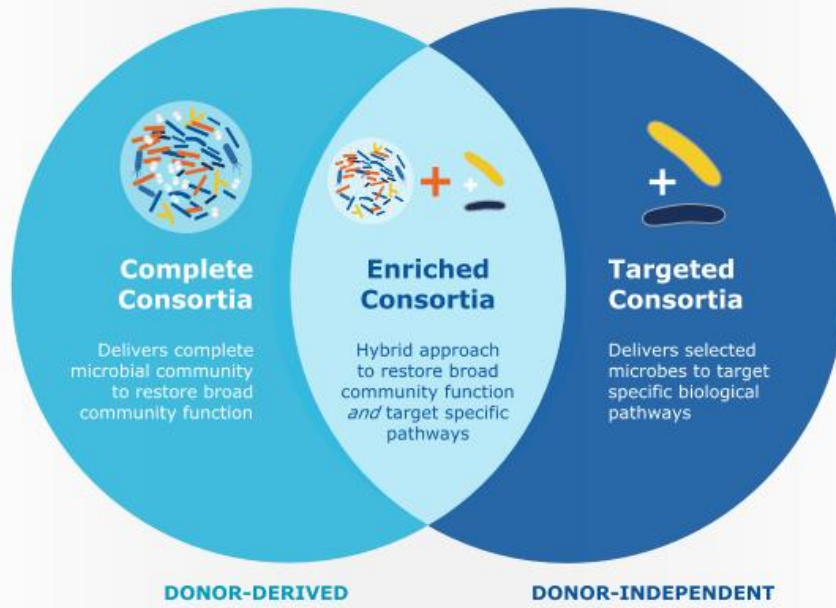
**Finch has proprietary access to data through strategic partnerships with leading providers of FMT in the US, China and Australia**

# 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 designed to establish entry points into new therapeutic areas

	Candidate	Indication	Consortia Type	Preclinical	Phase 1	Phase 2	Phase 3	Program Rights
GI/Immuno	CP101	Recurrent <i>C. difficile</i>	Complete					
	TAK-524 (formerly FIN-524)	Ulcerative Colitis	Targeted					Takeda to lead development 
	FIN-525	Crohn's Disease	Targeted					
Neuro	FIN-211	Autism Spectrum Disorder	Enriched					
Liver	CP101	Chronic Hepatitis B	Complete					

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



## 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 designed to deliver a complete microbiome in orally administered capsules

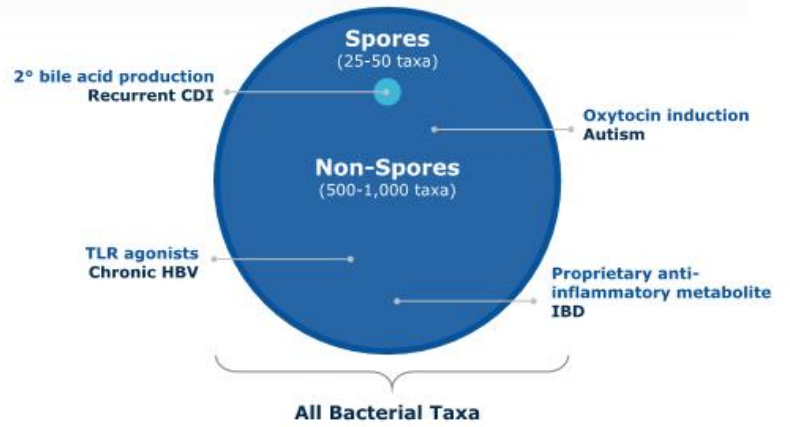
*Lyophilization technology optimized to preserve entire community, enabling use across multiple indications*



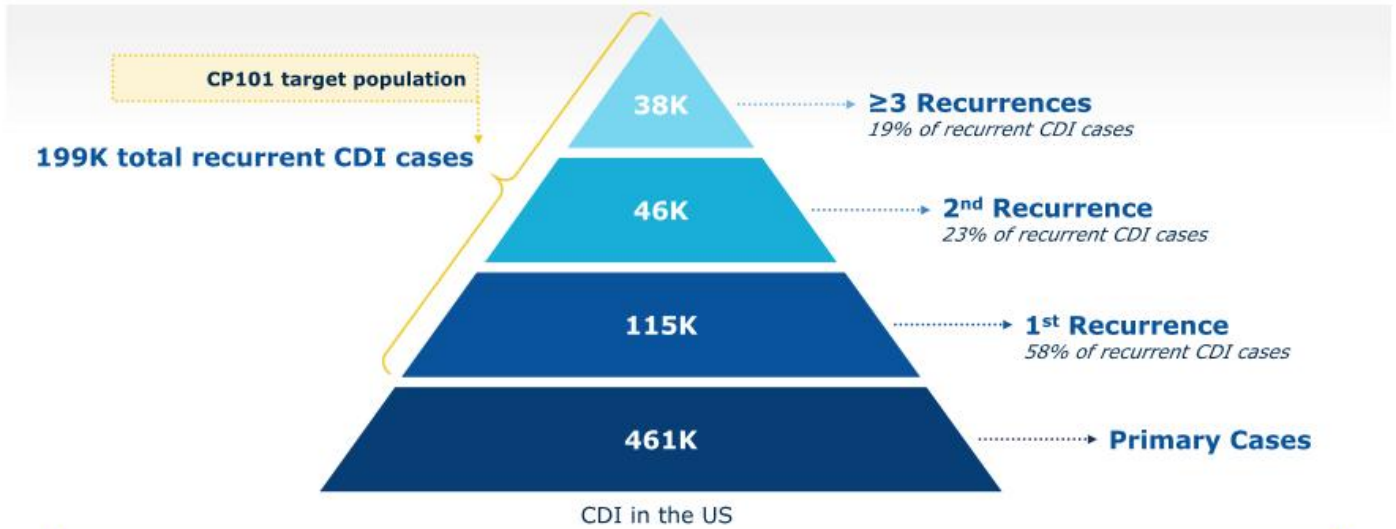
## Efficient, scalable manufacturing enabled by molecular screening of donors



## Complete consortia composition provides potential for broad pipeline expansion



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



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



# PRISM3 Phase 2 trial designed to demonstrate superiority over SOC antibiotics alone



## PRISM3 enrolled a broad population including:



**Participants experiencing their 1<sup>st</sup> CDI recurrence**  
 Relevance: 58% of all recurrent CDI cases are 1st recurrence



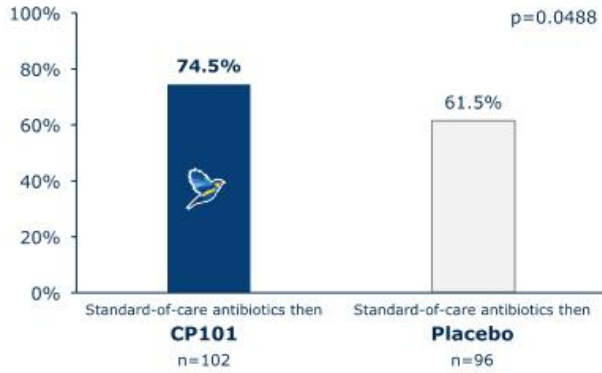
**Participants diagnosed with CDI via PCR testing**  
 Relevance: >80% of all CDI cases are diagnosed via PCR

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

# CP101 achieved its primary efficacy endpoint and demonstrated a safety profile similar to placebo in PRISM3

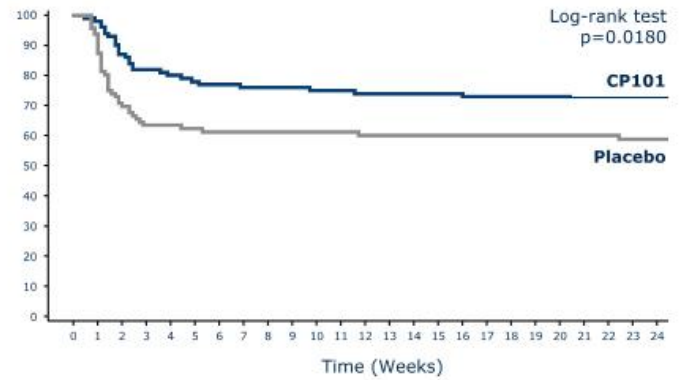
## CP101 achieved 33.8% relative risk reduction for CDI recurrence

Primary efficacy analysis: Sustained clinical cure (absence of CDI recurrence) through Week 8



## Sustained clinical cure at week 8 maintained through week 24

Rate (%) sustained clinical cure (absence of CDI recurrence) through Week 24



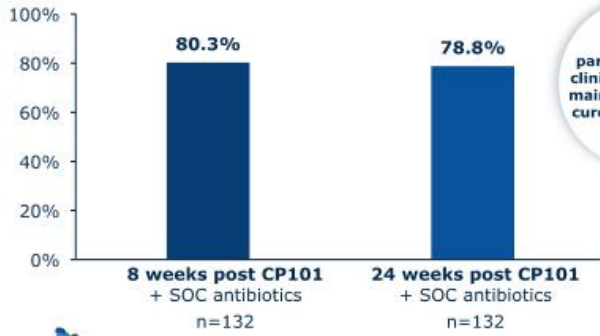
**CP101 met its primary efficacy endpoint, with no treatment-related SAEs in the CP101 arm**

# Positive topline results from PRISM-EXT Phase 2 open-label trial of CP101 in recurrent CDI



## Robust sustained clinical cure in PRISM-EXT with no treatment-related SAEs through 24 weeks

Sustained clinical cure (absence of CDI recurrence)



98% of participants with clinical cure at W8 maintained clinical cure through W24

**Aggregated 88.2% sustained clinical cure rate** shown through 8 weeks following last dose in a post-hoc analysis of participants that received up to two doses of CP101 in PRISM3 and PRISM-EXT\*

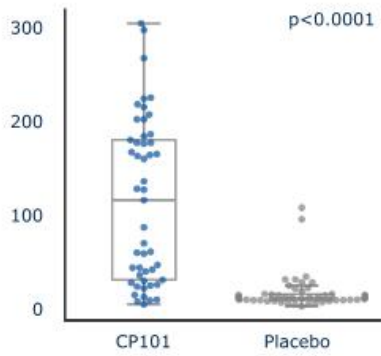


SOC: Standard of care; SAEs: Serious adverse events; \*Post-hoc analysis of 102 participants who received either a single dose of CP101 in PRISM3 (n=82) or two doses of CP101 by enrolling in PRISM-EXT (n=20)

# Strong relationship between CP101 engraftment and clinical outcomes in PRISM3

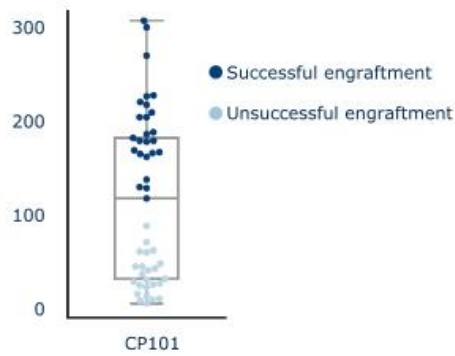
## CP101 showed significant engraftment overall

Number of engrafted CP101-associated taxa at Week 1



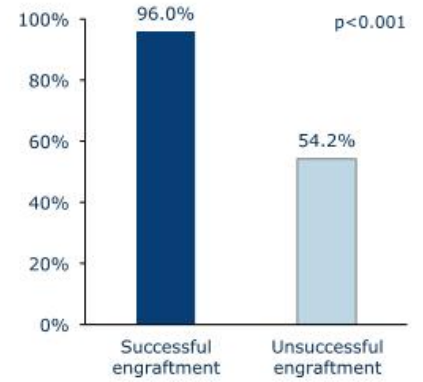
## Engraftment showed bimodal distribution

Number of engrafted CP101-associated taxa at Week 1



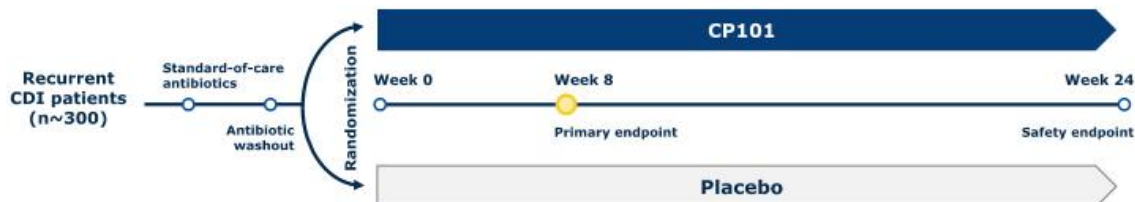
## Engraftment correlated with sustained clinical cure

Sustained clinical cure through Week 8 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

## CP101 positioned to be market leader in recurrent CDI



**Convenient, one-time oral administration**



**Achieved primary endpoint, positioning CP101 to potentially 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 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

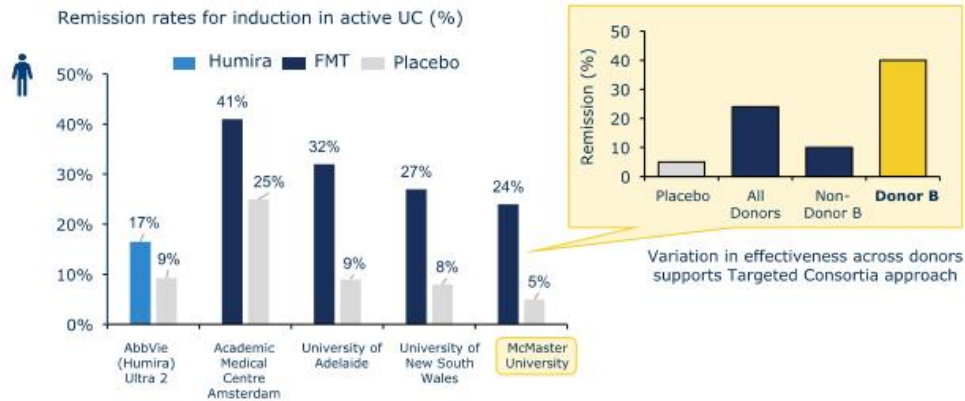
**Large unmet need for well-tolerated, effective therapeutics administered orally**



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

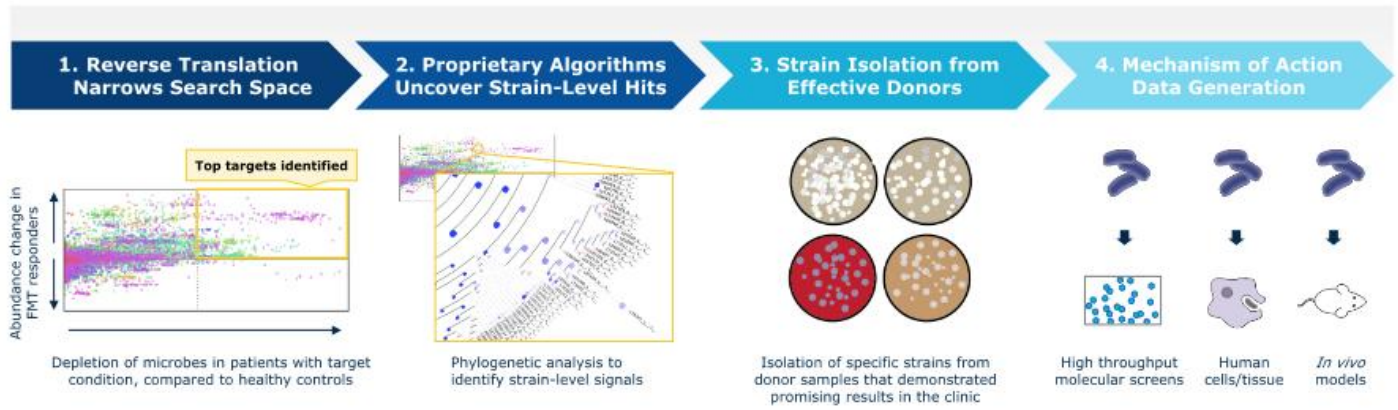
TAK-524 illustrates the power of Finch's platform for the development of Targeted Consortia

### 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**

# TAK-524 is designed to engage multiple mechanisms that are important to ulcerative colitis



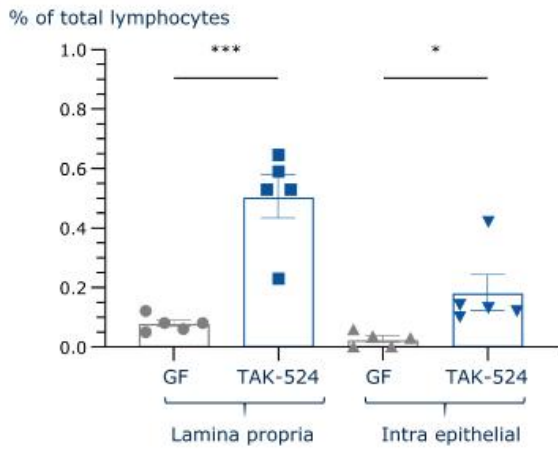
- TAK-524 contains 9 strains isolated directly from donors whose samples induced a response in clinical studies of FMT for UC
  - Consortia includes multiple phyla (spore and non-spore-forming organisms)
- TAK-524 is designed to include multiple strains targeting three key mechanisms and strategies:
  - 1: Production of immunoregulatory microbial metabolite class #1
  - 2: Empirical association with clinical efficacy in UC FMT studies
  - 3: Production of immunoregulatory microbial metabolite class #2

TAK-524 strains	Target mechanisms			Supported by human FMT engraftment data
	1	2	3	
Strain 1	Mechanism strongly engaged	Mechanism engaged		✓
Strain 2	Mechanism strongly engaged	Mechanism engaged		✓
Strain 3	Mechanism strongly engaged			✓
Strain 4	Mechanism strongly engaged			✓
Strain 5		Mechanism strongly engaged		✓
Strain 6		Mechanism strongly engaged		✓
Strain 7		Mechanism strongly engaged		✓
Strain 8	Mechanism engaged	Mechanism engaged	Mechanism strongly engaged	✓
Strain 9			Mechanism strongly engaged	✓

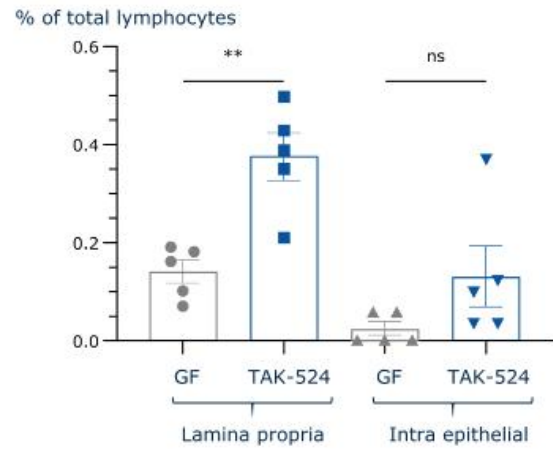
Mechanism strongly engaged  
 Mechanism engaged

# Administration of TAK-524 *in vivo* expands GI regulatory T-cells that are important for immune suppression

## TAK-524 expands GI-resident Tregs



## TAK-524 expands GI-induced Tregs



**TAK-524 contains strains selected for their potential to provide targeted regulation of the immune system**

**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 a potential role of the microbiome in ASD

## 1. Epidemiology

- 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:

- Findings of 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

### Neuroinflammation:

- Higher activation of microglia in those with ASD, which may impact neurological function and development

## 3. PoC FMT clinical studies

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

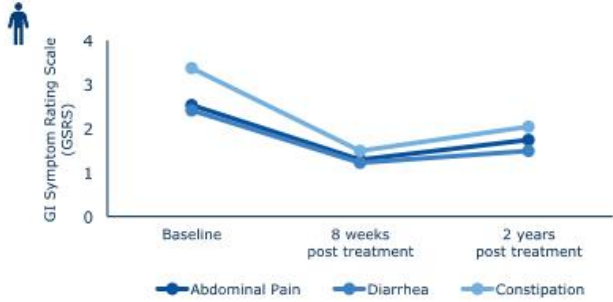
Study	Number of participants	GI Improvement	Behavioral Improvement
Ward (2016)	9	N/A	✓
Kang (2017)	18	✓	✓
Zhao (2019)	24	✓	✓
Li (2019)	85	✓	✓
Huanlong (unpublished)	31	✓	✓
Li (2021)	40	✓	✓
<b>Total</b>	<b>207</b>		

**Recent Cell paper highlights the limitations of cross-sectional data and the value of interventional FMT evidence**

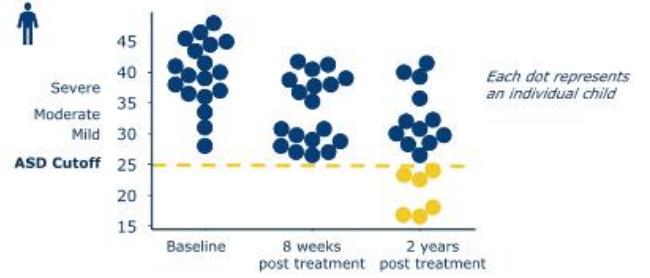
# Open label data shows improvements in both GI and behavioral symptoms following microbiota transplantation



## 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

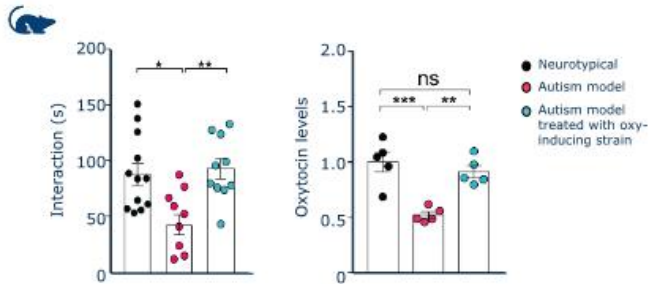
- GI severity index (GSI) significantly improved
- Behavioral (CARS) scores significantly improved
- Microbiome shifted towards a healthy composition

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

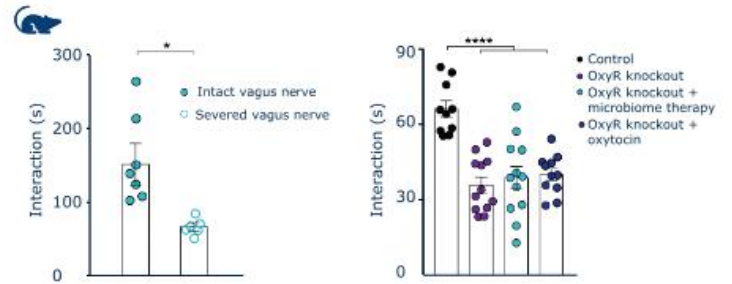


# Preclinical data show oxytocin-dependent behavioral improvements with microbiome therapy

## Microbiome therapy restores neurotypical behavior and oxytocin production



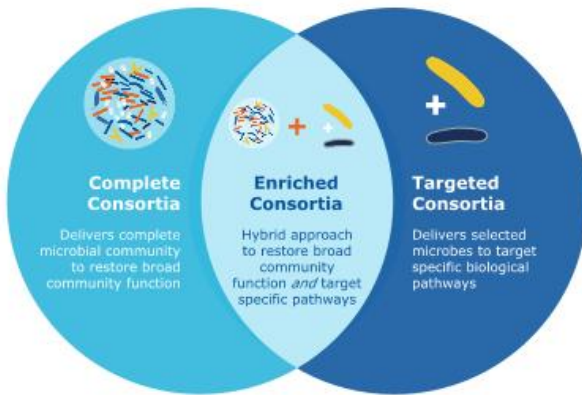
## Therapeutic benefit is eliminated when vagus nerve is severed or oxytocin receptor knocked out



## 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



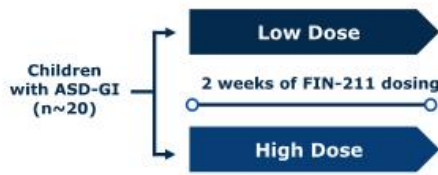
#### Pre-IND FDA feedback yielded two key insights:

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

Interim readout expected in H2 2022



### AUSPIRE Part B: Expansion Cohort

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

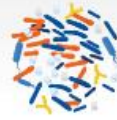
**CP101 for Chronic Hepatitis B  
Virus (HBV) Infection**



## Chronic HBV is a significant unmet need linked to the gut-liver axis

*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



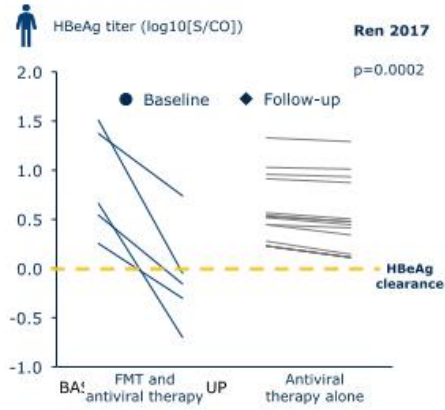
**\$160K**

Cost of liver  
transplantation

# Multiple clinical studies with microbiota transplantation show improved HBV pathology

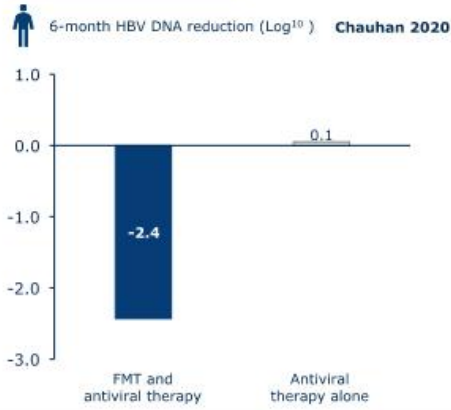
## Microbiota transplantation induced HBeAg clearance

### Trial 1: HBeAg positive



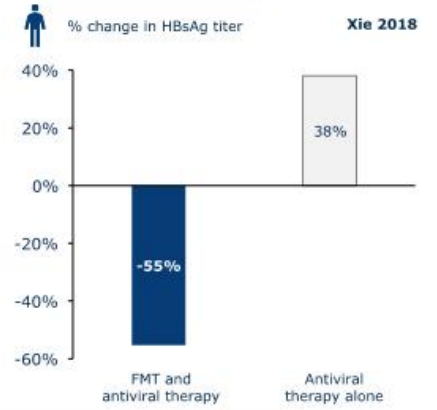
## Microbiota transplantation induced HBeAg clearance and HBV DNA decrease

### Trial 2: HBeAg positive



## Microbiota transplantation decreased HBsAg

### Trial 3: HBeAg negative



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

## Anticipated Milestones





# Finch positioned to continue momentum

Anticipated milestones



\*As of 12/31/2021, unaudited cash and cash equivalents of \$133.5 million



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



**Appendix**



# Finch's platform and pipeline is protected by a leading patent portfolio with significant longevity and broad relevance for the industry

## Extensive, multi-layered patent protection

- >50 issued U.S. and foreign patents and >130 patent applications pending
- Robust protection for lead candidate through 2036

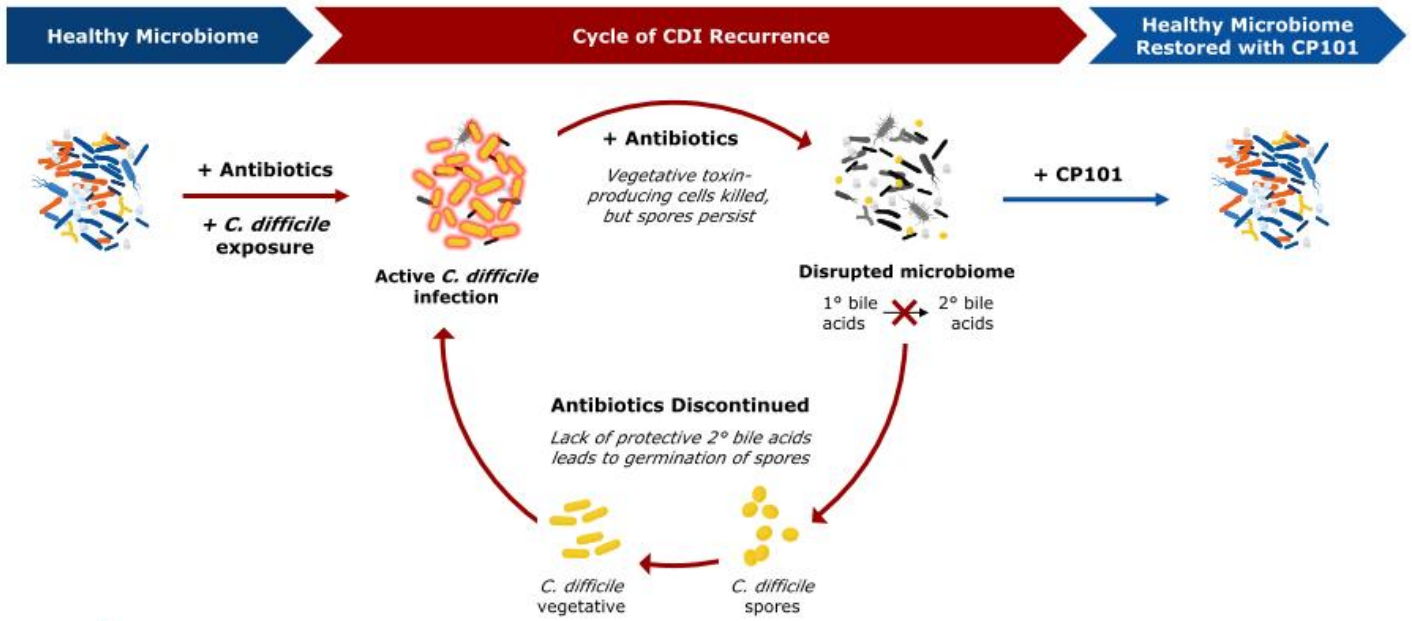
## Foundational patents in the field

- Priority dates of foundational patent family predate the industry, enabling broad protection for composition of matter, methods of use, manufacture, and formulation claims through 2031

## Broad & diverse patent protection

- Protection for multiple microbiome product strategies, including donor-derived and donor-independent product strategies
- Diverse therapeutic coverage, with protection for a wide range of indications of interest

# CP101 is designed to break the cycle of CDI recurrence



# CP101 restores the ability of the microbiome to produce protective secondary bile acids, breaking the cycle of CDI recurrence

