

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): November 14, 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 7.01 Regulation FD Disclosure.

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 November 14, 2022, 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 contained in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Corporate Presentation, dated November 2022.
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: November 14, 2022

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



Harnessing the Microbiome to Transform Lives

CORPORATE PRESENTATION | NOVEMBER 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 "will," "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 therapeutic potential of Finch's product candidates to have the potential to be a transformative new class of medicines, including the potential of CP101 to fulfill the need for a convenient, one-time oral therapy for the prevention of recurrent CDI; the anticipated timing for topline data for PRISM4; the ability for CP101 to function as a Complete Consortia product candidate that delivers a diverse, donor-derived microbial community to restore broad community function; the safety profile of CP101 and its potential to serve a large population in recurrent CDI; potential label expansion opportunities for CP101; the Company's ability to execute upon its mission and strategic priorities; potential strategic partnerships to advance Finch's product candidates; opportunities to leverage clinical data generated by third party studies to inform Finch's ASD program strategy; possible alternative clinical development strategies for CP101 and Finch's other 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 anticipated 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, those related to: 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 and the potential impact of termination of the Company's collaboration with Takeda on such funding requirements and the Company's ability to obtain funding; 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, including PRISM4; unexpected regulatory actions or delays, such as requests for additional safety and/or efficacy data or analysis of data, and including with respect to the FDA's planned review of the validation package for one of the Company's release tests, which is utilized for CP101; 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; the Company's ability to comply with regulatory requirements and continued regulatory review, which may result in significant additional expense and with respect to which the Company may be subject to penalties for failure to comply; 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; 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 Annual Report on Form 10-K filed with the SEC on March 31, 2022, as supplemented by the Company's Quarterly Reports on Form 10-Q filed with the SEC on May 16, 2022 and August 11, 2022, 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.

Management team composed of accomplished biopharma executives and leading microbiome experts



Mark Smith, PhD
Chief Executive Officer



Marc Blaustein
Chief Operating Officer



Alka Batycky, PhD
Chief Development Officer



Howard Franklin, MD
Chief Medical Officer



Joe Vittiglio, JD
Chief Business & Legal Officer



Bryan Gillis, MBA
Chief Technology Officer



Sonia Timberlake, PhD
Senior Vice President, Research



Leadership team has collectively developed more than a dozen approved therapeutics

Microbiome therapeutics have the potential to be a transformative new class of medicines

Multi-decade trends have disrupted the microbiome and the important role it plays in maintaining human health

Humans carry 1,000-fold more microbial genes than human genes¹



~20K
human genes
vs.
>20M
microbial genes

The microbiome is hypothesized to play many critical roles in human health

Protection from
pathogens



Influencing
response to drugs



Production of
neurotransmitters



Immune
modulation



Metabolism
of nutrients



Finch is a leading microbiome company with a differentiated, late-stage candidate for the prevention of recurrent CDI

Convenient, one-time oral administration of CP101 provides differentiation in CDI

CP101 supported by positive Ph 2 placebo-controlled and open-label data in recurrent CDI

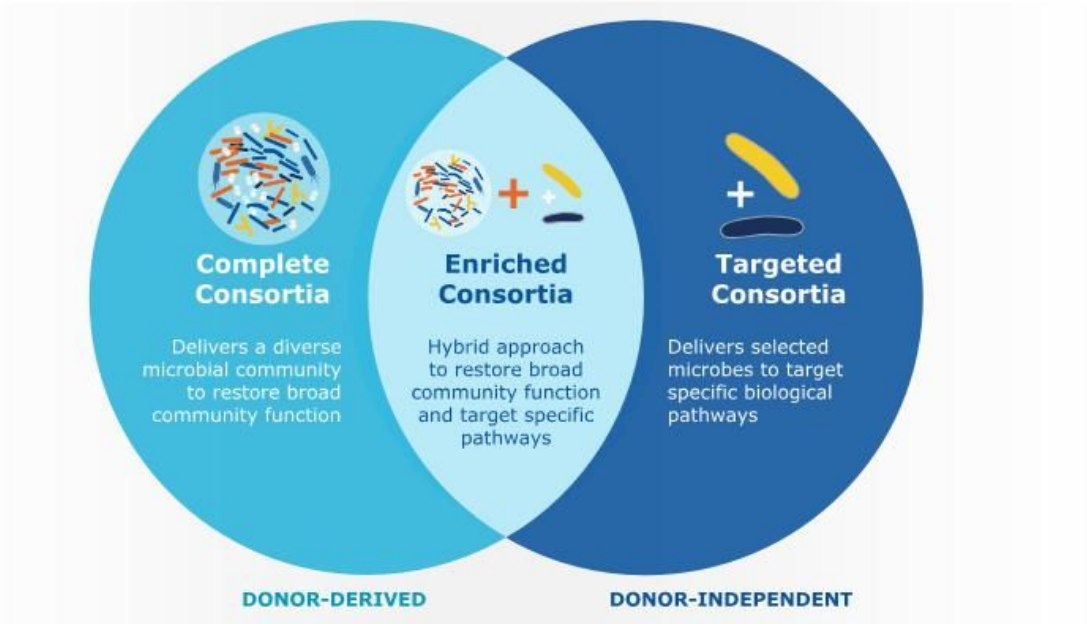
Ongoing Ph 3 trial of CP101 in recurrent CDI with topline data expected in H1 2024

Leading patent portfolio with broad relevance for the industry and robust protection for lead candidate through 2036

Finch aims to harness full diversity and potential of the microbiome, with additional assets targeting autism and IBD

CP101 is a Complete Consortia product candidate that delivers a diverse, donor-derived microbial community to restore broad community function

Finch is uniquely positioned with Complete Consortia, Enriched, and Targeted Consortia assets



Recurrent *C. difficile* Infection (CDI)



***C. difficile* infection is a debilitating, potentially life-threatening disease with an enormous health and economic impact**

“Six months and four rounds of the strongest antibiotics did not stop the infection. My only choice to avoid sepsis was a microbiota transplant, which saved my life. **Fighting *C. diff* was the most horrific experience of my life.**”

— *C. diff* survivor

44K Annual deaths attributable to CDI in the U.S.¹

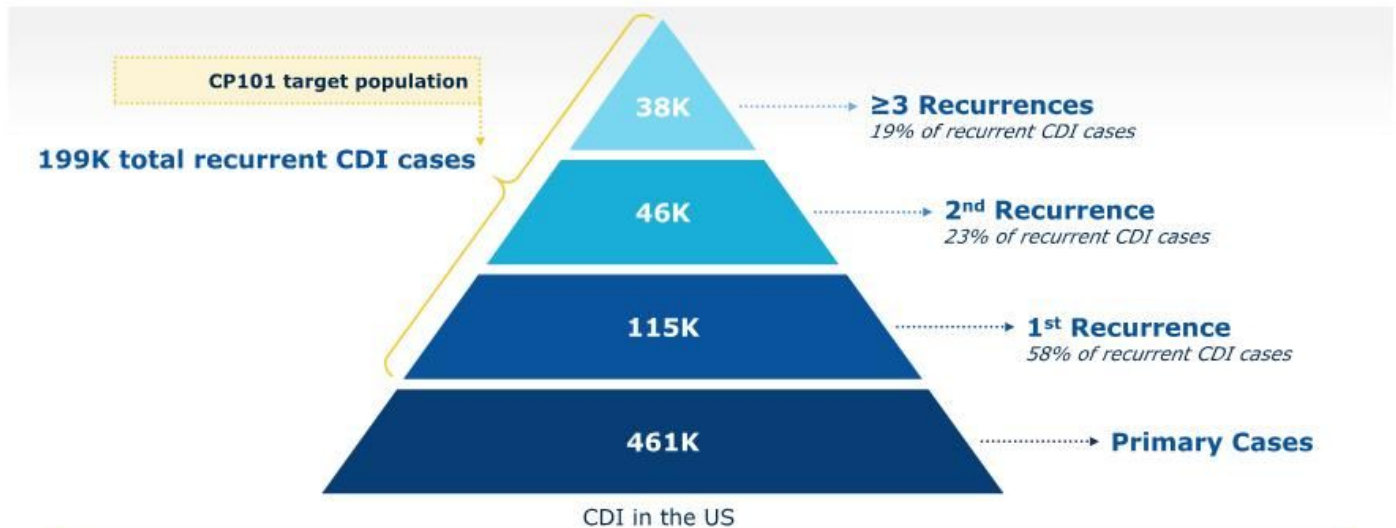
2.4M Inpatient days associated with CDI in the U.S.²

\$5B+ Annual direct costs of CDI in the U.S.²

\$27K Per patient healthcare costs averted after microbiota transplantation³

1 of 5 Top threats due to antibiotic resistance as designated by the CDC⁴

CP101 has the potential to serve a large population in recurrent CDI



CP101 is designed to enable early intervention in the management of CDI

PRISM3, a Phase 2, randomized, placebo-controlled trial of CP101 for the prevention of recurrent *C. difficile* infection

First randomized study of CP101 in recurrent CDI



PRISM3 enrolled a population including:



Participants experiencing one or more CDI recurrences*

Relevance: 58% of all recurrent CDI cases are 1st recurrence¹



Participants diagnosed with CDI via **PCR** or toxin-based testing

Relevance: >80% of all CDI cases are diagnosed via PCR²

PRISM3 included all stages of recurrence and any guideline recommended CDI diagnostic method to support labeling and market access

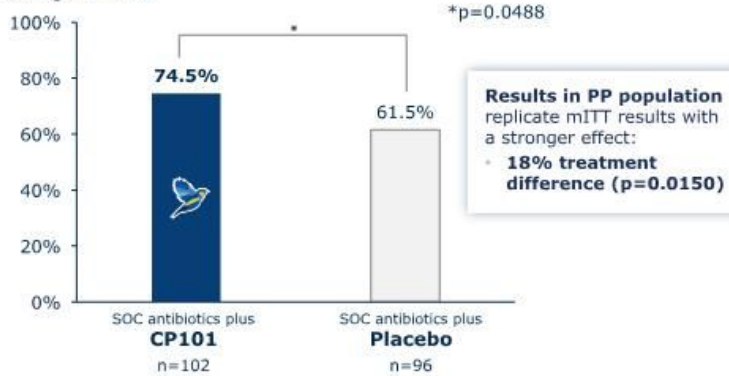


*Participants entering study on 1st recurrence were required to be ≥ 65 years of age; Sources: 1. Desai BMC Infect Dis 2016; 2. Guh N Engl J Med 2020; SOC: standard of care

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

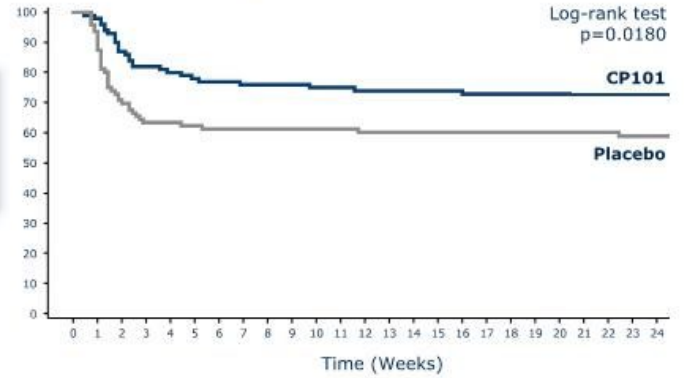
CP101 achieved 33.8% relative risk reduction for CDI recurrence through Week 8

Primary efficacy endpoint: Proportion without CDI recurrence through Week 8



Participants treated with CP101 had a lower risk of CDI recurrence through Week 24

Recurrence-free (%) through Week 24



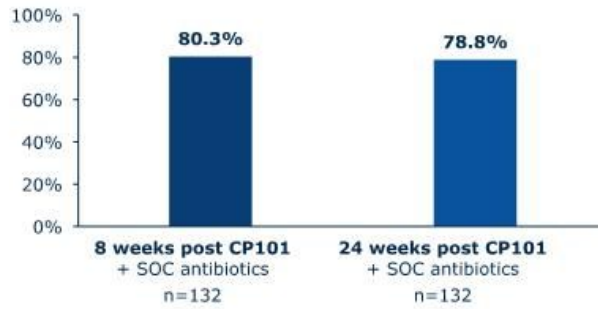
CP101 met its primary efficacy endpoint in PRISM3, with no treatment-related SAEs in the CP101 arm

PRISM-EXT, a Phase 2, open-label trial of CP101, also demonstrated positive efficacy and safety results



PRISM-EXT efficacy through Week 8 and Week 24

Proportion without CDI recurrence



Aggregated 88.2% of participants without CDI recurrence 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*

Clinical safety data for CP101 are promising and consistent with the favorable safety profile of microbial therapies as a class

- **No treatment-related serious adverse events (SAEs) from CP101**
- All treatment-related adverse events from CP101 were mild (Grade 1) or moderate (Grade 2)
- Adverse events were primarily gastrointestinal in nature
- These safety data build upon other results reported for the class of microbial therapeutics

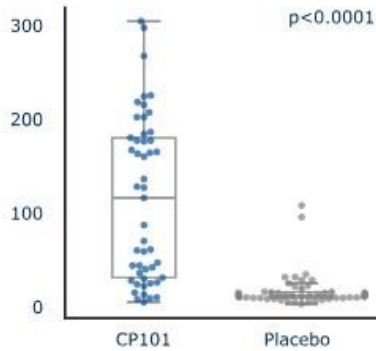
		PRISM3		PRISM-EXT	
		CP101 (n=104)	Placebo (n=99)	CP101 (n=132)	
Treatment-related serious adverse events		0	1	0	
Treatment-related adverse events		17 (16.3%)	19 (19.2%)	13 (9.8%)	
Most frequent treatment-related adverse events	Diarrhea	7.7%	10.1%	Defecation urgency	4.5%
	Abdominal distension	7.7%	6.1%	Abdominal pain	3.8%
	Abdominal pain	3.8%	10.1%	Diarrhea	3.8%
	Nausea	6.7%	4.0%	Nausea	2.3%
	Defecation urgency	2.9%	5.1%	Decreased appetite	2.3%

PRISM3 biomarker data indicate a strong relationship between CP101 engraftment and clinical outcomes

Persistence of residual vancomycin may have reduced engraftment among some PRISM3 participants

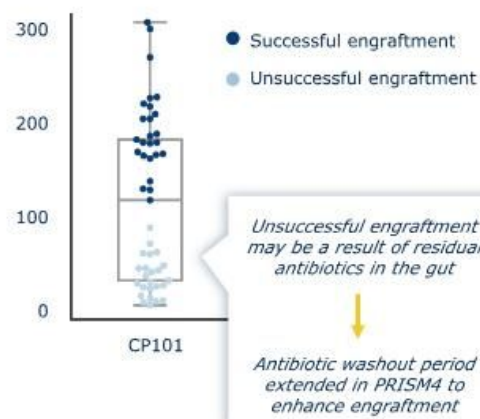
CP101 showed significant engraftment overall

Number of engrafted CP101-associated taxa at Week 1



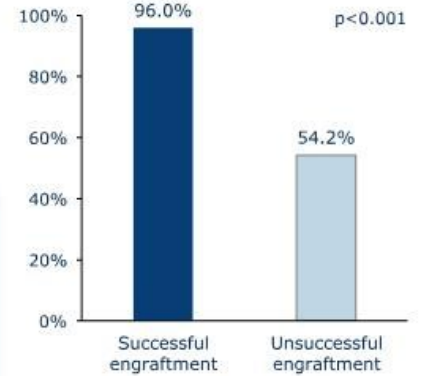
Engraftment showed bimodal distribution

Number of engrafted CP101-associated taxa at Week 1

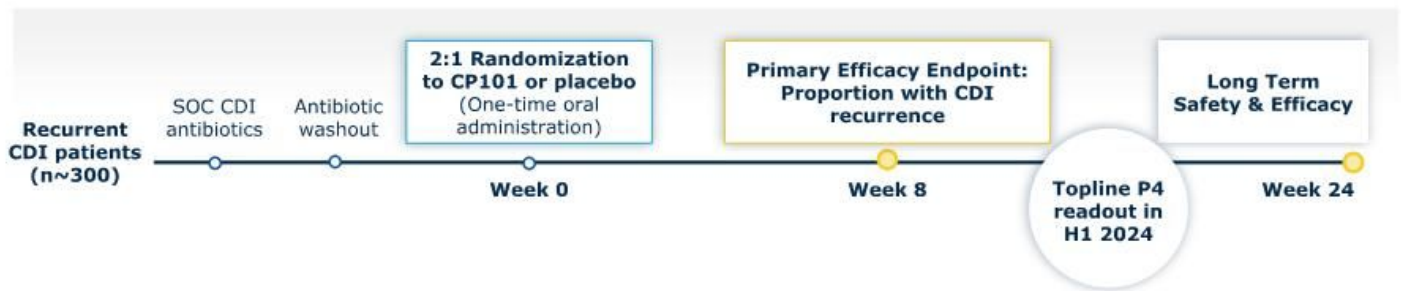


Engraftment correlated with prevention of CDI recurrence

Proportion without CDI recurrence through Week 8 by engraftment group



PRISM4, a Phase 3 trial of CP101 in recurrent CDI is designed to serve as a second pivotal trial to support a potential BLA for CP101



Key PRISM4 Features:

- Antibiotic washout period extended to potentially enhance engraftment and efficacy
- 2:1 randomization to CP101 or placebo
- Open-label option for eligible participants who experience a recurrence during the trial
- Global study sites

CP101's composition enables multiple potential label expansion opportunities

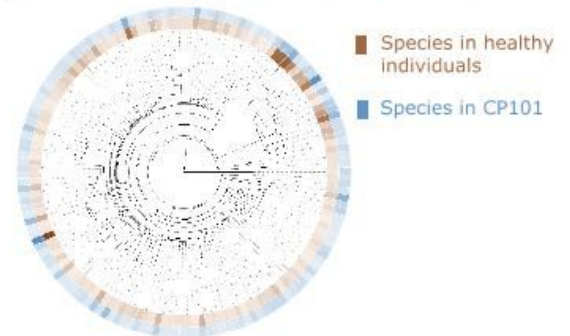
A rapidly growing body of FMT data provides opportunity to advance CP101 into new areas

Number of registered clinical trials studying fecal microbiota transplantation (FMT)¹



CP101 recapitulates the biology and activity of FMT in an oral, standardized and scalable formulation

Heat map: Abundance of key species in human microbiome²



CP101 — the only late-stage, oral product candidate that delivers a diverse microbiome — provides opportunities in multiple areas beyond CDI

With proprietary data and IP from partnerships with large microbiota transplant providers, Finch is positioned to identify attractive opportunities

Finch's development of CP101 in recurrent CDI illustrates a possible path for targeting new therapeutic areas

UMN reports positive Ph 1 results in rCDI for an oral, lyophilized candidate ✓

In-license of UMN assets (CP101) ✓

CP101 receives Breakthrough Designation ✓

Positive Ph 2 CP101 trial ✓

Ph 3 CP101 trial underway

Beyond recurrent CDI, there is compelling third-party proof-of-principle evidence in a range of therapeutic areas, including:

Ulcerative Colitis

Seven RCTs show that microbiota transplantation may be effective for inducing remission in ulcerative colitis¹⁻⁷

Autism Spectrum Disorder

Multiple open-label studies find improvement in GI and behavioral symptoms following microbiota transplantation⁸⁻¹⁴

Advanced Melanoma

Three open-label studies find that microbiota transplantation may improve response to anti-PD-1 therapy in advanced melanoma¹⁵⁻¹⁷



Sources: 1. Rossen Gastroenterology 2015; 2. Costello JAMA 2017; 3. Paramsothy Lancet 2017; 4. Kedia Gut 2022; 5. Hafler Lancet Gastroenterol Hepatol 2022; 6. Crothers BMC Gastroenterol 2021; 7. Moayyedi Gastroenterology 2015; 8. Ward Open Forum Infect Dis 2016 (ID Week Abstract); 9. Kang Microbiome 2017; 10. Kang Sci Rep 2019; 11. Zhao Gastrointest Endosc 2019 (DDW Abstract); 12. Li Zhonghua Wei Chang Wai Ke Za Zhi 2019; 13. Li Front Cell Infect Microbiol 2021; 14. Pan Front Pediatr 2022; 15. Banuch Science 2023; 16. Davar Science 2021; 17. Miller J Clin Oncol 2022 (ASCO abstract); rCDI: Recurrent C. difficile infection

CP101 has a compelling
value proposition and
significant commercial
franchise potential



1. Positive safety & efficacy data in recurrent CDI

Achieved primary efficacy endpoint in first pivotal trial; zero treatment-related SAEs across all completed studies



2. Potential best-in-class experience for recurrent CDI patients

Oral capsules, one-time administration, no bowel prep



3. Established & efficient CMC platform

CP101 manufacturing facility is built to support potential commercial launch in recurrent CDI



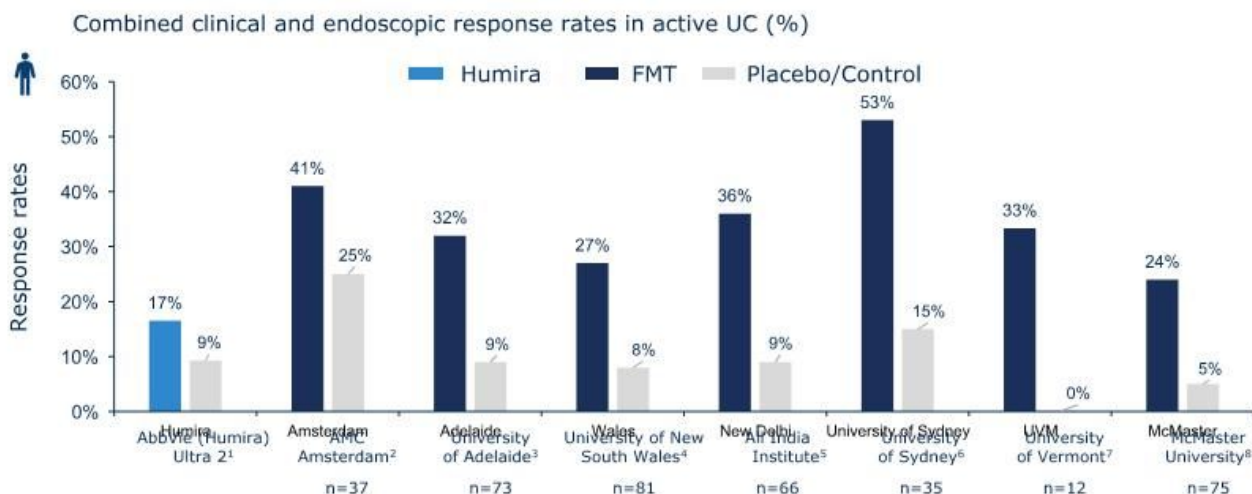
4. Multiple label expansion opportunities

Delivery of a diverse microbial community provides potential for expansion into other therapeutic areas

Inflammatory Bowel Disease (IBD)



Seven microbiota transplantation studies have demonstrated promising outcomes in ulcerative colitis (UC)



Insights from compelling proof-of-principle clinical data informed the development of FIN-524 for UC and FIN-525 for Crohn's disease

Finch leveraged promising clinical data to select strains for FIN-524, a Targeted Consortia product candidate for UC

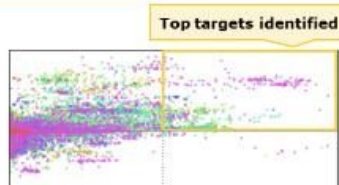
A similar approach was leveraged in the development of FIN-525 for Crohn's disease

1. Data from >2000 patients



Extensive clinical data underlie the design of FIN-524, including observational and interventional microbiome datasets

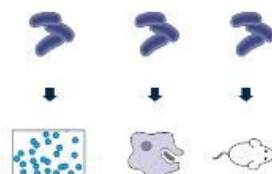
2. Discovery of multiple MoA and design criteria



Computational and molecular analysis of these large clinical datasets were used to:

- Prioritize MoA to screen drug candidates
- Pick candidate strains from a proprietary library of thousands of strains isolated from successful microbiota transplantation donors

3. Consortium optimized through *in vitro* screening



Screening of Finch's strain library for the most clinically supported mechanisms yielded the final FIN-524 composition

Finch is exploring opportunities to further the development of FIN-524 for UC and FIN-525 for Crohn's disease through a potential strategic partnership



FIN-524 is composed of 9 strains that each target multiple MoAs relevant in UC

- FIN-524 strains were isolated directly from donors whose samples induced a response in clinical studies of microbiota transplantation for UC

- Consortium includes 3 phyla (spore and non-spore-forming organisms)

- FIN-524's composition was driven by 3 selection strategies identified through analysis of clinical datasets:

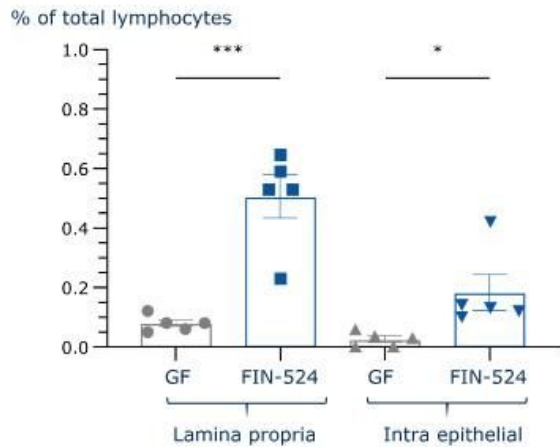
- 1: Strains that grow to a high abundance to produce a metabolite which modulates inflammatory responses and promotes intestinal epithelial barrier repair
 - 2: Strains statistically associated with positive clinical phenotype
 - 3: Strains that engage a receptor which modulates inflammatory responses and promotes intestinal epithelial barrier function

FIN-524 strains	Selection Strategy			Supported by human FMT engraftment data
	1	2	3	
Strain 1				✓
Strain 2				✓
Strain 3				✓
Strain 4				✓
Strain 5				✓
Strain 6				✓
Strain 7				✓
Strain 8				✓
Strain 9				✓

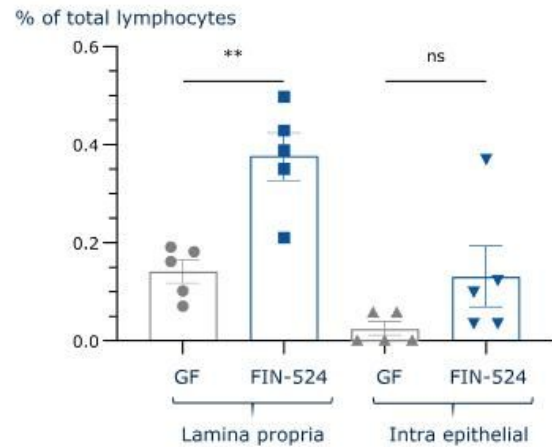
 Mechanism strongly engaged
 Mechanism engaged

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

FIN-524 expands GI-resident Tregs



FIN-524 expands GI-induced Tregs



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

Autism Spectrum Disorder (ASD)



Multiple microbiota transplantation studies have shown compelling results in children with ASD and GI symptoms

Third-party, open-label studies show improvements in GI and behavioral symptoms of ASD

	Study	Number of participants	GI improvement	Behavioral improvement
	1. Ward (2016)	9	N/A	✓
	2. Kang (2017/2019)	18	✓	✓
	3. Zhao (2019)	24	✓	✓
	4. Li (2019)	85	✓	✓
	5. Huanlong (unpublished)	31	✓	✓
	6. Li (2021)	40	✓	✓
	7. Pan (2022)	42	✓	✓
	Total	249		

Finch is exploring opportunities to leverage clinical data generated by ongoing third-party studies to inform its autism strategy going forward

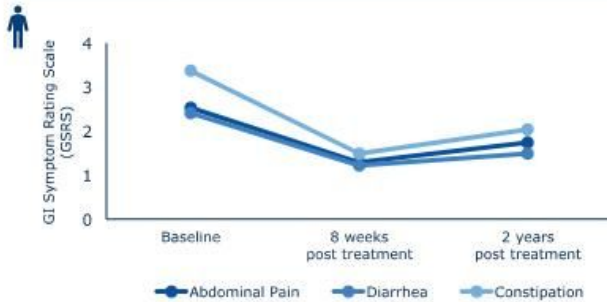
Note: In September 2022, Finch announced the decision to suspend efforts to initiate the Phase 1 trial of FIN-211 while the Company explores opportunities to leverage clinical data generated by ongoing third-party studies to inform its autism strategy.

Open label data shows improvements in both GI and behavioral symptoms following microbiota transplantation (n=18)

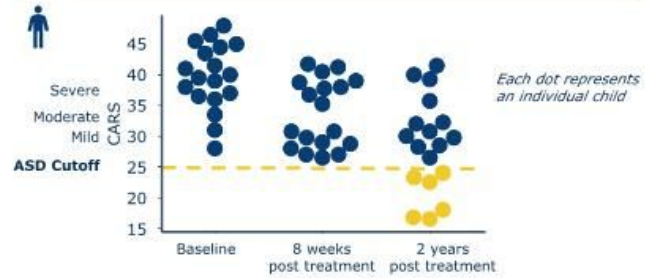
Kang 2019



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 clinical study showed improvement in both GI and behavioral symptoms following microbiota transplantation (n=45)

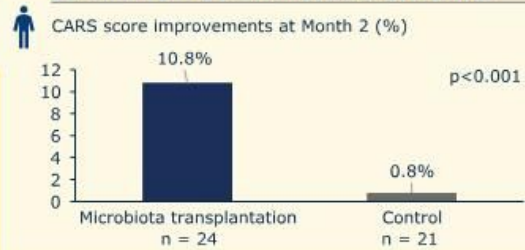
Zhao 2019



Results at 2 months post microbiota transplantation

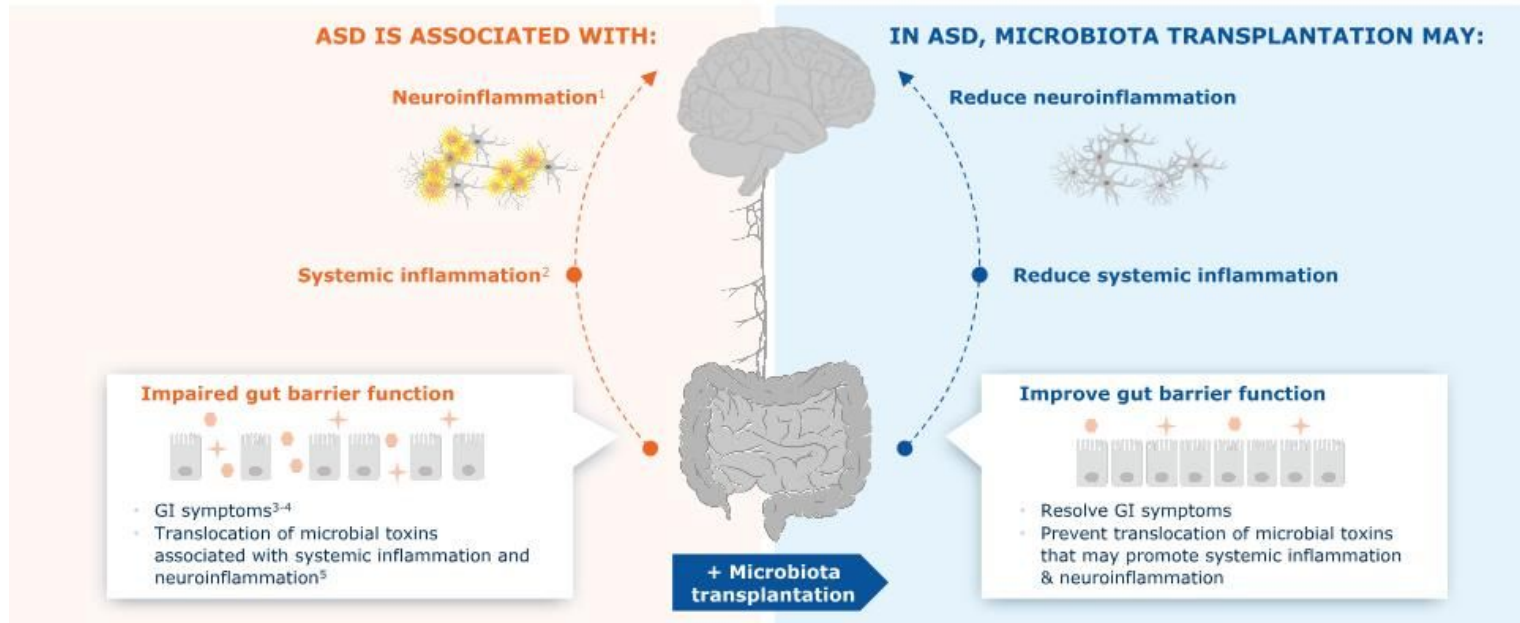
- GI severity index (GSI) significantly improved
- Behavioral (CARS) scores significantly improved

Behavioral scores significantly improved at 2 months post microbiota transplantation



Microbiota transplantation may improve gut barrier function, potentially reducing GI symptoms, systemic inflammation and neuroinflammation

In-vivo and clinical data provide insights into mechanistic targets



Finch is a leading microbiome company with a differentiated, late-stage candidate for the prevention of recurrent CDI

Convenient, one-time oral administration of CP101 provides differentiation in CDI

CP101 supported by positive Ph 2 placebo-controlled and open-label data in recurrent CDI

Ongoing Ph 3 trial of CP101 in recurrent CDI with topline data expected in H1 2024

Leading patent portfolio with broad relevance for the industry and robust protection for lead candidate through 2036

Finch aims to harness full diversity and potential of the microbiome, with additional assets targeting autism and IBD

**Expected
runway into
Q2 2024***



*Expected runway includes cash and cash equivalents on hand as of September 30, 2022, together with anticipated cash inflows from executed subleases for one of the Company's office and lab facilities.



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 >140 patent applications pending
- Robust protection for lead candidate through 2036

Foundational patents in the field

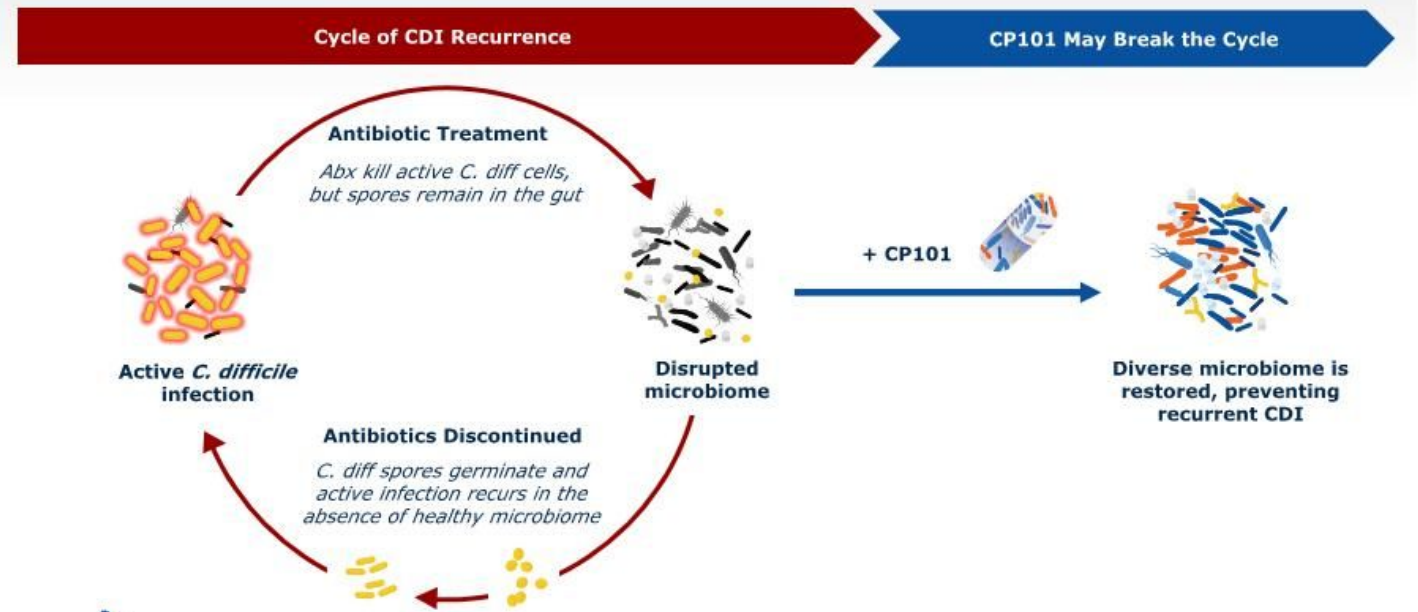
- Priority dates of foundational patent family predate the industry, enabling broad protection for composition of matter, methods of use, manufacture, and formulation claims through 2031

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 potentially prevent recurrent CDI by restoring the microbiome and its function after it has been disrupted by antibiotics

Antibiotics stop active infection, but leave patients with a disrupted microbiome that puts them at risk for CDI recurrence



CP101 is designed to potentially restore the microbiome's ability to produce protective secondary bile acids, breaking the cycle of CDI recurrence

Bile acid concentrations play a critical role in modulating the pathogenic activity of C. difficile

