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 10, 2021

Finch Therapeutics Group, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40227**	**82-3433558**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

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

On November 10, 2021, Finch Therapeutics Group, Inc. (the "Company") issued a press release announcing its recent business highlights and financial results for the quarterly period ended September 30, 2021. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in Item 2.02 of 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 Securities and 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 7.01. Regulation FD.

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 10, 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 and is furnished as Exhibit 99.2 in this Current Report on Form 8-K.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.2 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of 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	Press Release, dated November 10, 2021
99.2	Corporate Presentation, dated November 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: November 10, 2021

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

Exhibit 99.1

Finch Therapeutics Reports Third Quarter 2021 Financial Results and Provides Business Updates

- *New positive topline data from 132-participant PRISM-EXT Phase 2 open-label trial of CP101 in recurrent C. difficile infection (CDI) show 80.3% sustained clinical cure rate through 8 weeks, with a similar rate maintained through 24 weeks*
- *New data presented at ACG annual meeting from PRISM3 Phase 2 trial of CP101 in recurrent CDI show a statistically significant improvement in sustained clinical cure and a safety profile similar to placebo through 24 weeks*
- *Initiated enrollment in PRISM4 Phase 3 trial of CP101 in recurrent CDI*
- *Continued progress advancing platform and development programs, with construction completed on new manufacturing facility and two programs positioned to enter the clinic in 2022*

SOMERVILLE, Mass., November 10, 2021 (GLOBE NEWSWIRE) -- Finch Therapeutics Group, Inc. (“Finch” or “Finch Therapeutics”) (Nasdaq: FNCH), a clinical-stage microbiome therapeutics company leveraging its *Human-First Discovery*® platform to develop a novel class of orally administered biological drugs, today reported financial results for the third quarter ended September 30, 2021 and provided business updates.

“We are pleased to have recently shared additional positive clinical data supporting our lead candidate CP101 for the prevention of recurrent *C. difficile* infection, including new topline data from our PRISM-EXT Phase 2 open label trial, as well as additional data from our PRISM3 Phase 2 trial that were presented at this year’s ACG meeting. These data highlight the growing evidence and momentum supporting our lead candidate, and more broadly, provide a firm foundation for the development of the next wave of candidates in our growing pipeline,” said Mark Smith, PhD, Chief Executive Officer of Finch Therapeutics. “As we look ahead, Finch is poised to enter a transformational period, with a Phase 3 trial underway for CP101 and our development programs targeting autism and chronic hepatitis B infection scheduled to enter the clinic in 2022. We believe that readouts from these next programs will further demonstrate the potential for microbiome therapeutics to become the next new modality that transforms patient care across multiple therapeutic areas.”

Recent Highlights

- **Reported Positive Topline Results from PRISM-EXT Phase 2 Trial of CP101 in Recurrent CDI:** In November 2021, Finch reported positive topline results from PRISM-EXT, a Phase 2 open-label trial evaluating CP101 for the prevention of recurrent CDI. Of the 132 participants who received CP101 following standard-of-care antibiotics, 80.3% and 78.8% of participants achieved sustained clinical cure through 8 weeks and 24 weeks post-treatment, respectively. There were no treatment-related serious adverse events reported and CP101 exhibited an overall safety profile consistent with the profile observed in PRISM3. The PRISM-EXT results are consistent with and build on the previously reported PRISM3 Phase 2 trial results, which showed that CP101 met its primary efficacy endpoint with a statistically significant improvement in the prevention of recurrent CDI compared to placebo through 8 weeks post-treatment. Across PRISM-EXT and PRISM3, 234 doses of CP101 have been administered to 214 participants, which we believe is the largest clinical dataset reported to date for an orally administered investigational microbiome therapeutic.
- **Initiated Enrollment in PRISM4 Phase 3 Trial of CP101 in Recurrent CDI:** In November 2021, Finch announced the start of enrollment in PRISM4, a Phase 3 randomized,

placebo-controlled trial that is expected to enroll approximately 300 participants with recurrent CDI. PRISM4 is designed to serve as the second pivotal trial of CP101 for the prevention of recurrent CDI.

- **Presented Additional Positive Data from PRISM3 Phase 2 Placebo-Controlled Trial of CP101 in Recurrent CDI at American College of Gastroenterology (ACG) Annual Meeting:** Data presented at ACG in October 2021 from the PRISM3 Phase 2 trial showed that CP101 demonstrated statistically significant improvement in the prevention of recurrent CDI compared to placebo and a safety profile similar to placebo through 24 weeks post-treatment.
- **Completed Construction of New Manufacturing Facility:** Finch recently completed the construction of its new manufacturing facility designed to support the manufacture of its microbiome product candidates for clinical trials and potential commercialization. Commissioning and qualification activities are underway for the newly constructed facility.
- **AUSPIRE Phase 1b Trial of FIN-211 in Children with Autism Spectrum Disorder (ASD) and Gastrointestinal Symptoms Expanded to Include a Second Cohort:** The AUSPIRE Phase 1b trial of FIN-211 in children with ASD and gastrointestinal (GI) symptoms will include a dose escalation portion (Part A) and a recently added expansion cohort (Part B). In Part A, two weeks of a low and high dose of FIN-211 will be evaluated in trial participants. In Part B, eight weeks of the highest tolerated FIN-211 dose from Part A will be evaluated in two groups, one that will receive vancomycin pre-treatment and one without vancomycin pre-treatment.
- **Takeda Accelerated Leadership Role in TAK-524 (formerly FIN-524) Ulcerative Colitis (UC) Development Program**: In August 2021, Finch announced that Takeda elected to accelerate the transition of development responsibility for TAK-524, a targeted consortia microbiome product candidate developed by Finch and Takeda for the treatment of UC. The transition will enable Takeda to leverage its expertise in inflammatory bowel disease throughout the clinical development of TAK-524.

Leadership Updates:

- **Transition of Chief Medical Officer (CMO):** In November 2021, Finch announced that Zain Kassam, MD, MPH elected to step down as CMO in order to return to Canada to attend to a family health matter. Dr. Kassam will continue to support Finch as a special advisor. Debra Silberg, MD, PhD, an accomplished gastroenterologist and pharmaceutical executive with 18 years of experience in clinical development, will serve as Finch's interim CMO and support the company through the transition and search for a new CMO.
- **Expanded Board of Directors:** In October 2021, Finch appointed Samuel Allen (Al) Hamood to its Board of Directors. Mr. Hamood is an accomplished executive with over 30 years of experience in finance, business development, corporate strategy, and M&A across several global industry sectors.
- **Strengthened Executive Leadership Team:** In September 2021, Finch appointed Marc Blaustein as Chief Operating Officer. Mr. Blaustein is a seasoned biopharmaceutical executive with more than 20 years of experience building and leading companies and critical business functions including operations, business development, program management, and manufacturing.

Key Anticipated Milestones

- Initiation of AUSPIRE Phase 1b trial of FIN-211 in children with ASD and GI symptoms anticipated in the first half of 2022, with an interim readout expected from the dose escalation portion of the trial in the second half of 2022 and topline data from the expansion cohort expected in 2023.
- Initiation of RECLAIM Phase 1b trial of CP101 in chronic HBV infection anticipated in early 2022, with topline data from an initial cohort expected in the second half of 2022.
- Topline data readout from PRISM4 Phase 3 trial of CP101 in recurrent CDI expected in the first half of 2023.

Third Quarter 2021 Financial Results

- Finch reported a net loss of $10.0 million for the third quarter of 2021 as compared to a net loss of $10.1 million for the same period in 2020. The net loss was driven by an increase in research and development expenses, as well as increased costs related to the infrastructure needed to support Finch's growth, which was offset by collaboration revenue earned through our agreement with Takeda.
- Research and development expenses for the third quarter of 2021 were $15.5 million compared with $9.0 million for the same period in 2020. The increase was primarily due to an increase in personnel costs, manufacturing related expenses and early asset discovery work. Increases were also due to expansion and development of Finch's chronic HBV and ASD programs.
- General and administrative expenses for the third quarter of 2021 were $5.7 million, as compared with $2.8 million for the same period in 2020. The increase was primarily due to increased headcount to support Finch's operational growth, an increase in business insurance costs and an increase in professional fees to support Finch's transition to a public company.
- Finch's cash and cash equivalents as of September 30, 2021 was $149.2 million compared to $99.7 million as of December 31, 2020. Finch expects that the cash and cash equivalents it had on hand at September 30, 2021 will be sufficient to fund operating expenses and capital expenditures into mid-2023.

About Finch Therapeutics

Finch Therapeutics is a clinical-stage microbiome therapeutics company leveraging its *Human-First Discovery*® platform to develop a novel class of orally administered biological drugs. With the capabilities to develop both complete and targeted microbiome therapeutics, Finch is advancing a rich pipeline of candidates designed to address a wide range of unmet medical needs. Finch's lead candidate, CP101, is in late-stage clinical development for the prevention of recurrent *C. difficile* infection (CDI), and has received Breakthrough Therapy and Fast Track designations from the U.S. Food and Drug Administration. In June 2020, Finch announced that CP101 met its primary efficacy endpoint in PRISM3, the first of two pivotal trials to support the development of CP101 for the prevention of recurrent CDI. PRISM4, a Phase 3 trial, is designed to serve as the second pivotal trial of CP101 for recurrent CDI. Finch is also developing CP101 for the treatment of chronic hepatitis B virus infection, and FIN-211 for the treatment of the gastrointestinal and behavioral symptoms of autism spectrum disorder. Finch has a partnership with Takeda focused on the development of targeted microbiome therapeutics for inflammatory bowel disease.

Forward-Looking Statements

Statements contained in this press release 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 structure and timing of Finch’s clinical trials and the period during which the results of trials will be available, including specifically the total enrollment of PRISM4, Finch’s Phase 3 clinical trial in CDI and the initiation of Phase 1 trials in ASD and chronic HBV, and the release of topline data from each of those trials; Finch’s ability to advance the development of a novel class of therapeutics, including through the manufacture of its product candidates at its newly completed manufacturing facility; and the therapeutic value, development, and commercial potential of microbiome therapeutics. 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: Finch’s limited operating history and historical losses; Finch’s ability to raise additional funding to complete the development and any commercialization of its product candidates; Finch’s dependence on the success of its lead product candidate, CP101; the possibility that Finch 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 Finch’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; Finch’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; Finch’s ability to maintain patent and other intellectual property protection and the possibility that Finch’s intellectual property rights may be infringed, invalid or unenforceable or will be threatened by third parties; Finch’s ability to qualify and scale its manufacturing capabilities in anticipation of commencement of multiple global clinical trials; Finch’s lack of experience in selling, marketing and distributing its product candidates; Finch’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 Finch’s business. These and other risks are described more fully in Finch’s filings with the Securities and Exchange Commission (“SEC”), including the section titled “Risk Factors” in Finch’s Quarterly Report on Form 10-Q filed with the SEC on August 10, 2021, as well as discussions of potential risks, uncertainties, and other important factors in Finch’s other filings with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, Finch 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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Finch Therapeutics Group, Inc.
Condensed Consolidated Statements of Operations (Unaudited)
(in thousands, except share and per share data)

	FOR THE THREE MONTHS ENDED SEPTEMBER 30,		FOR THE NINE MONTHS ENDED SEPTEMBER 30,	
	2021	**2020**	**2021**	**2020**
Revenue:				
Collaboration revenue	$ 11,343	$ 1,733	$ 17,726	$ 5,582
Royalty revenue from related party	—	38	—	330
Total revenue	11,343	1,771	17,726	5,912
Operating expenses:				
Research and development	15,537	9,045	42,476	24,577
General and administrative	5,739	2,807	16,173	7,639
Total operating expenses	21,276	11,852	58,649	32,216
Loss from operations	(9,933)	(10,081)	(40,923)	(26,304)
Other (expense) income	(22)	(9)	1,818	54
Net loss	$ (9,955)	$ (10,090)	$ (39,105)	$ (26,250)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.21)	$ (1.22)	$ (1.07)	$ (3.25)
Weighted-average common stock outstanding—basic and diluted	47,445,195	8,258,537	36,408,506	8,065,730

Finch Therapeutics Group, Inc.
Condensed Consolidated Balance Sheet Data (Unaudited)
(in thousands)

	SEPTEMBER 30, 2021	DECEMBER 31, 2020
Assets:		
Cash and cash equivalents	$ 149,200	$ 99,710
Other assets	83,779	65,628
Total assets	$ 232,979	$ 165,338
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Liabilities	13,178	28,002
Redeemable convertible preferred stock	—	233,054
Stockholders' equity (deficit)	219,801	(95,718)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 232,979	$ 165,338

Exhibit 99.2

FINCH

Harnessing the Genomic Revolution & Machine Learning to Pioneer Microbiome Therapeutics

CORPORATE PRESENTATION | NOVEMBER 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 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; 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 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.

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

Mark Smith, PhD
Chief Executive Officer

OPENBIOME · MIT

Greg Perry
Chief Financial Officer

novelion · immunogen

Debra Silberg, MD, PhD
Interim Chief Medical Officer

Takeda · Shire

Sonia Timberlake, PhD
Senior VP Research

JUNO · AVITRO

Marc Blaustein
Chief Operating Officer

Alkermes · akashi therapeutics

Jim Sigler, MBA
Executive VP CMC

genzyme · ACCELERON

Michelle Rose, PhD
Chief Regulatory Officer

CHIMERIX · EMD SERONO

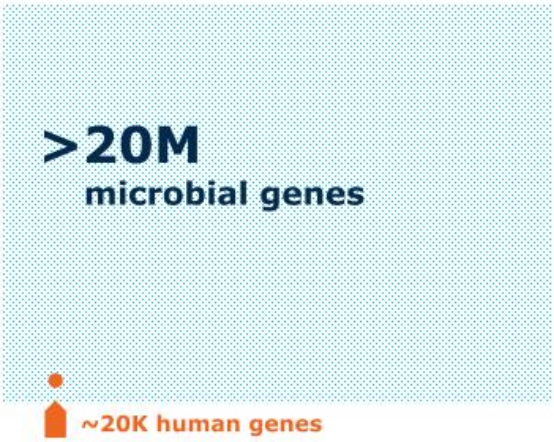
Joe Vittiglio, JD
General Counsel

AVEO · amag

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

- Immune modulation
- Metabolic function
- Neurologic regulation

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

FINCH

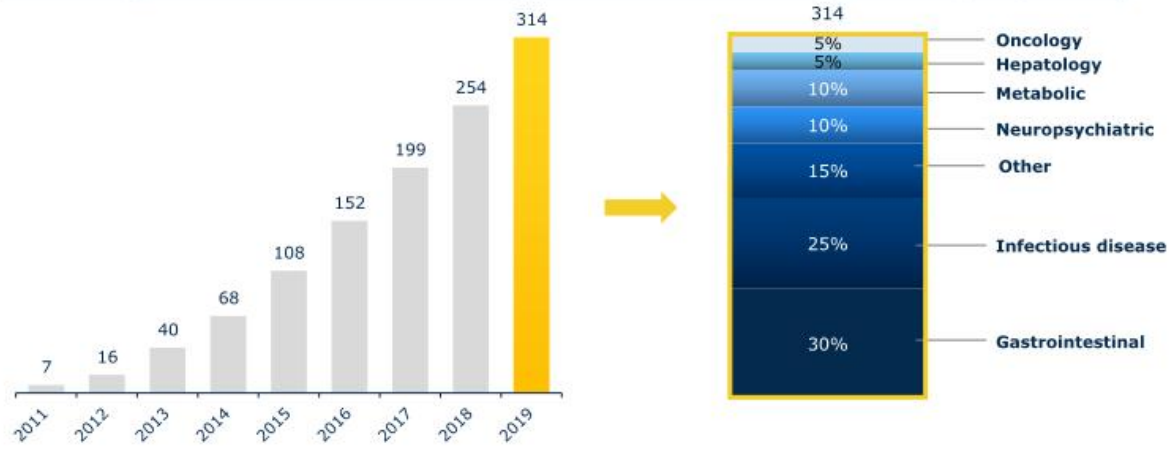
Sources: Tierney Cell Host Microbe 2019

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 fuels our discovery engine and guides product design

Registered clinical trials evaluating Fecal Microbiota Transplantation (FMT)



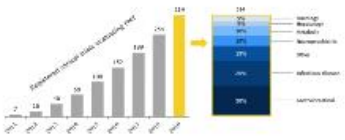
Finch has proprietary access to data through strategic partnerships with leading providers of FMT in the US, China and Australia

FINCH

Source: Clinicaltrials.gov

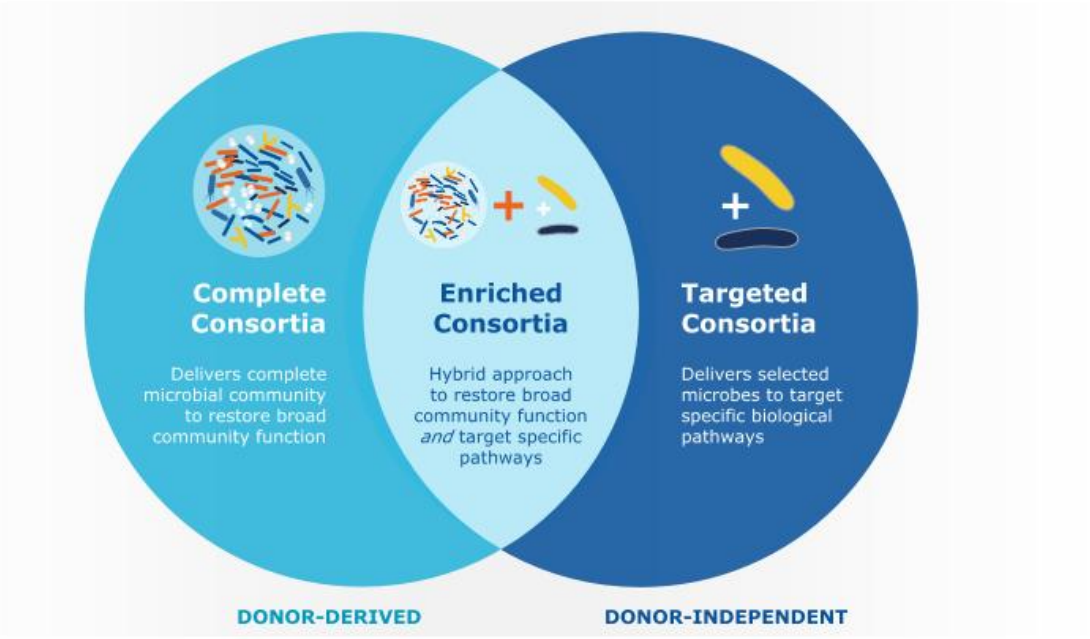
Our *Human-First Discovery* platform enables capital efficient de-risking

Program launch & capital commitment

1. Clinical Proof-of-Concept *(3rd party data)*	2. Data-Mining for Mechanistic Insights	3. Product Development
Enabled by: **Proprietary access to data**	*Enabled by:* **Machine learning engine**	*Enabled by:* **Platform to target full microbiome**
		

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

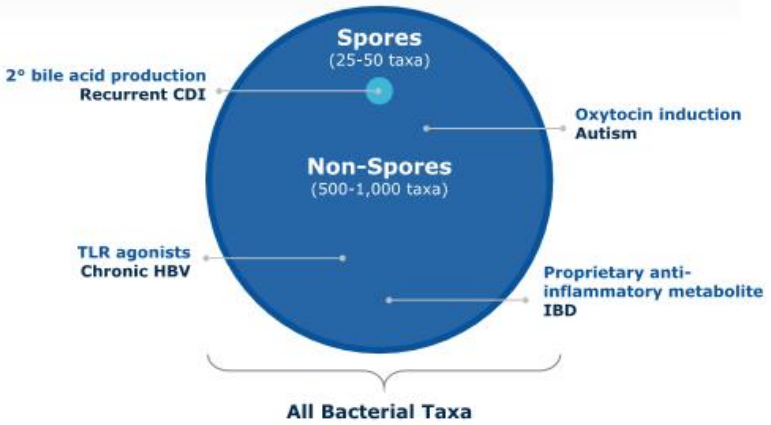


Finch is uniquely positioned to harness the full diversity and potential of the microbiome across diverse therapeutic areas

Complete consortia candidates designed to deliver entire microbial community

1. Healthy Donor Sourcing & Qualification
2. Harvest, Purification, & Preservation
3. Lyophilization & Encapsulation

Ability to harness full diversity provides potential for broad pipeline expansion



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	Anticipated Milestone	Program Rights
GI/Immuno	**CP101**	Recurrent *C. difficile*	Complete	*First pivotal completed*	Topline Phase 3 readout in H1 2023	
GI/Immuno	**TAK-524** (formerly FIN-524)	Ulcerative Colitis	Targeted		Initiate Phase 1 trial	Takeda to lead development
GI/Immuno	**FIN-525**	Crohn's Disease	Targeted		Initiate IND-enabling activities	
Neuro	**FIN-211**	Autism Spectrum Disorder	Enriched		Initiate Phase 1b trial in H1 2022	
Liver	**CP101**	Chronic Hepatitis B	Complete		Initiate Phase 1b trial in early 2022	


FINCH
CP101 for Recurrent C. difficile Infection (CDI)

Recurrent CDI is an enormous human and economic burden

CP101 Complete Consortia
delivers full microbiome community

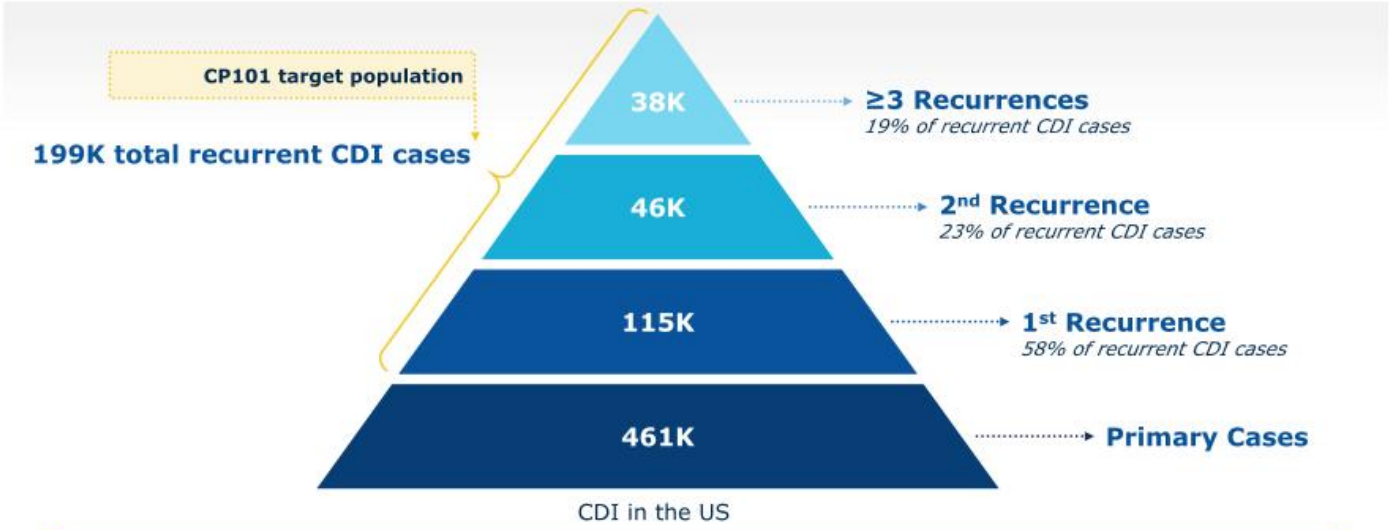
44K	2.4M	$5B	$27K
Annual deaths attributable to CDI in the US	Total inpatient days associated with CDI in the US	Annual direct costs of CDI in the US	Saved per patient by using microbiota transplantation

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

FINCH

Sources: Zhang BMC Infect Dis 2016; Dehlholm-Lambertsen Ther Adv Gastroenter 2019 (1 EUR = 1.1482 USD); Desai BMC Infect Dis 2016; CDC Antibiotic Resistance Threat Report 2019

CP101 is positioned to serve a large population in recurrent CDI



CDI in the US

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

FINCH

Sources: Desai BMC Infect Dis 2016

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

PRISM3 enrolled a broad population including:

Participants experiencing their 1st 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

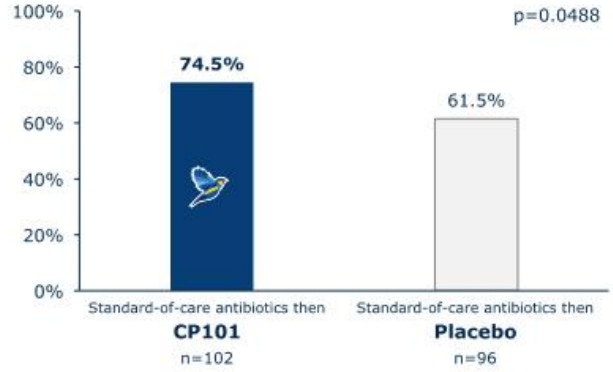
FINCH

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

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

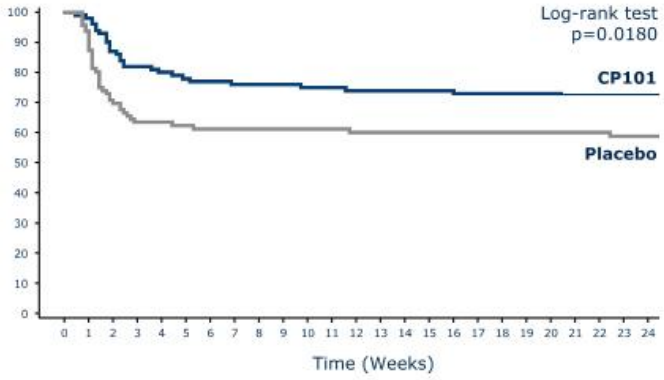
CP101 achieved 33.8% relative risk reduction for CDI recurrence

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

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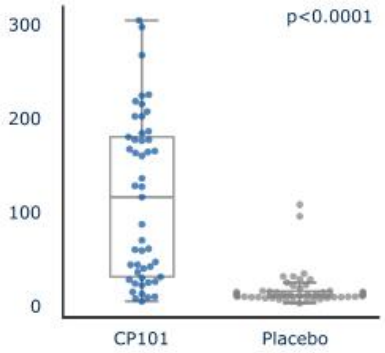
SAEs: Serious adverse events

CDI

Strong relationship between CP101 engraftment and clinical outcomes in PRISM3

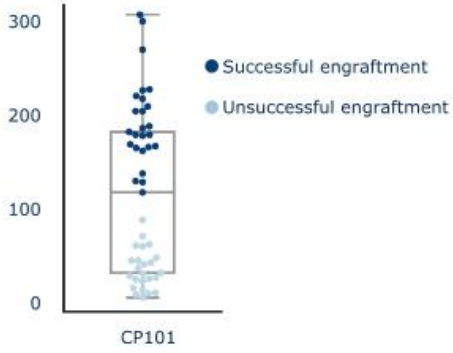
CP101 showed significant engraftment overall

Number of engrafted CP101-associated taxa at Week 1



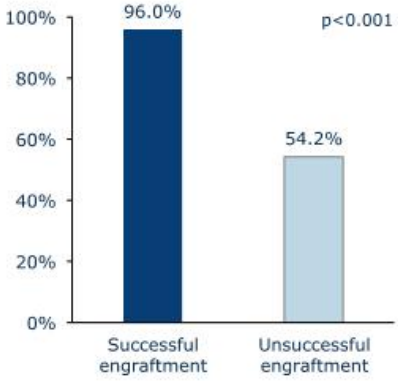
Engraftment showed bimodal distribution

Number of engrafted CP101-associated taxa at Week 1



Engraftment correlated with sustained clinical cure

Sustained clinical cure through Week 8 by engraftment group



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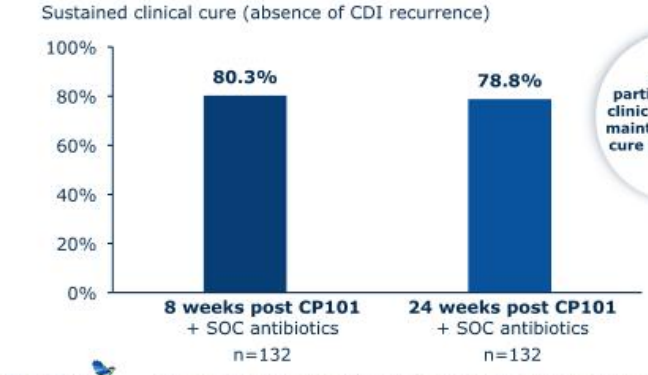
Source: CP101 Phase 2 study (PRISM3)

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



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*

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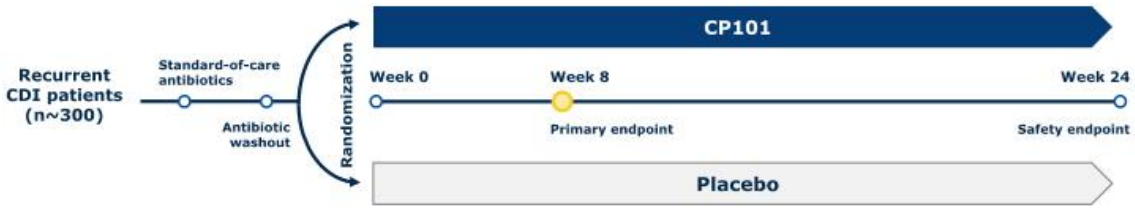
SOC: Standard of care; SAEs: Serious adverse events; *Post-hoc analysis of 102 participants who received either a single dose of CP101 in PRISM3 (n=82) or two doses of CP101 by enrolling in PRISM-EXT (n=20)

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

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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	70,000	20%	$31B+
Affected by IBD in the US alone	Patients diagnosed with IBD per year in US	With ulcerative colitis require colectomy	In attributable costs per year in US

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

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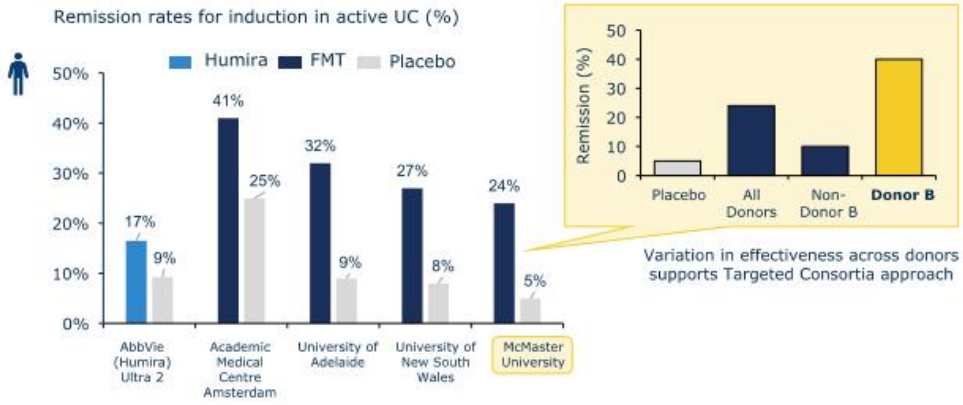
Sources: Dahlhamer MMWR 2016; Crohn's and Colitis Foundation: Facts About IBD 2014; Bernstein Inflamm Bowel Dis 2010

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

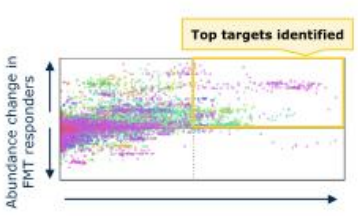


Takeda recently accelerated its leadership role in the development of the TAK-524 ulcerative colitis program

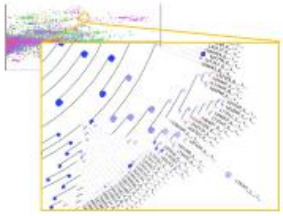
Sources: Rossen Gastroenterology 2015; Moayyedi Gastroenterology 2015; Paramsothy Lancet 2017; Costello JAMA 2017; Sandborn Gastroenterology 2012

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

1. Reverse Translation Narrows Search Space → **2. Proprietary Algorithms Uncover Strain-Level Hits** → **3. Strain Isolation from Effective Donors** → **4. Mechanism of Action Data Generation**

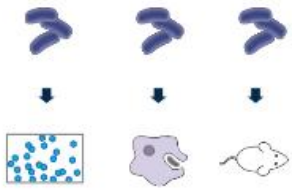


Depletion of microbes in patients with target condition, compared to healthy controls



Phylogenetic analysis to identify strain-level signals

Isolation of specific strains from donor samples that demonstrated promising results in the clinic



High throughput molecular screens | Human cells/tissue | *In vivo* models

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	■	■		✓
Strain 2	■	■		✓
Strain 3	■			✓
Strain 4	■			✓
Strain 5		■		✓
Strain 6		■		✓
Strain 7		■		✓
Strain 8	■	■	■	✓
Strain 9			■	✓

■ Mechanism strongly engaged

■ Mechanism engaged

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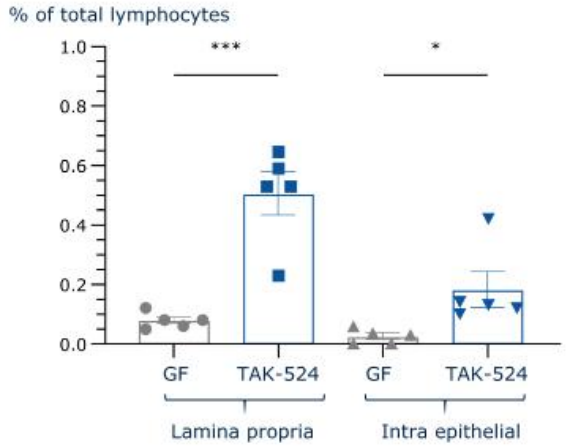
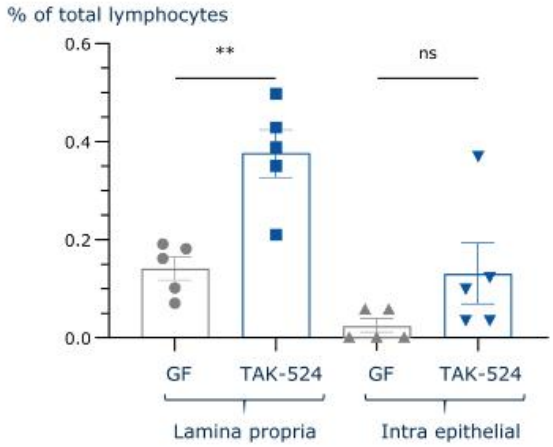
Administration of TAK-524 *in vivo* expands GI regulatory T-cells that are important for immune suppression

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

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Tregs: Regulatory T cells; GF: Germ free

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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

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Sources: Chaidez J Autism Dev Disord 2014; Cao Shanghai Arch Psychiatry 2013; CDC Data and Statistics on ASD 2019; Leigh J Autism Dev Disord 2015

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

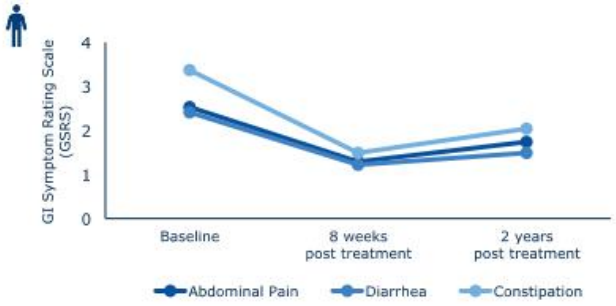
- Multiple FMT studies show improvements in both GI and behavioral endpoints

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**		

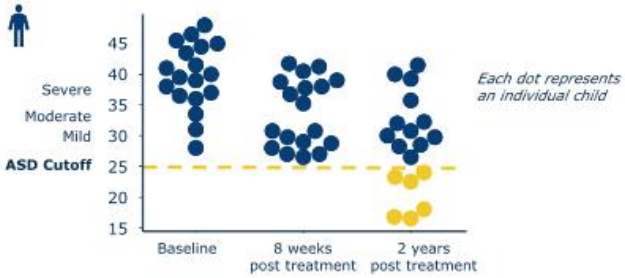
Sources: Ding J Autism Dev 2017; Zhang JAMA Netw Open 2019; Bittker Neuropsychiatr Dis Treat 2018; Modahl Biol Psychiatry 1998; Sgritta Neuron 2019; Needham Biol Psychiatry 2020; Hsiao Cell 2013; Antonini Front Immunol 2019; Kang Microbiome 2017; Kang Sci Rep 2019; Zhao Gastrointest Endosc 2019 (DDW Abstract); Ward Open Forum Infect Dis 2016 (ID Week Abstract); Li Zhonghua Wei Chang Wai Ke Za Zhi 2019

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



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Sources: Kang Microbiome 2017; Kang Sci Rep 2019

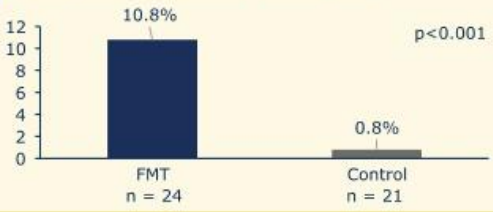
Randomized, independent clinical study showed improvement in both GI and behavioral symptoms following microbiota transplantation

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 (%)



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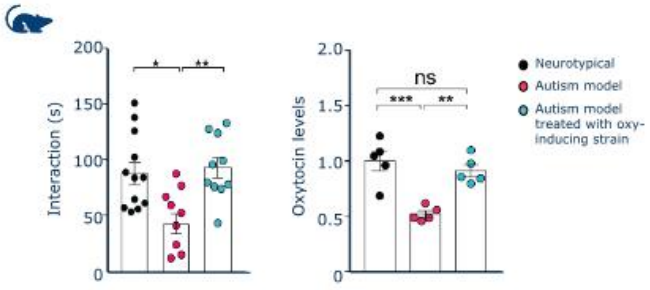
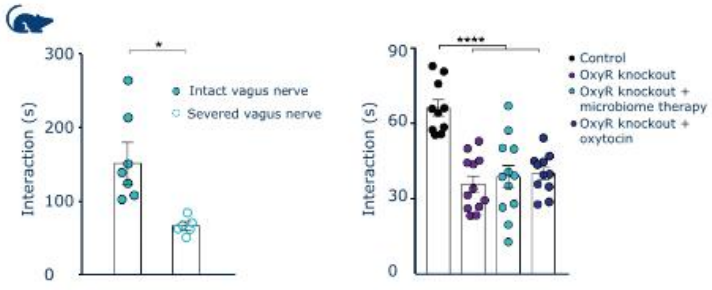
Source: Zhao Gastrointest Endosc 2019 (DDW Abstract)

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



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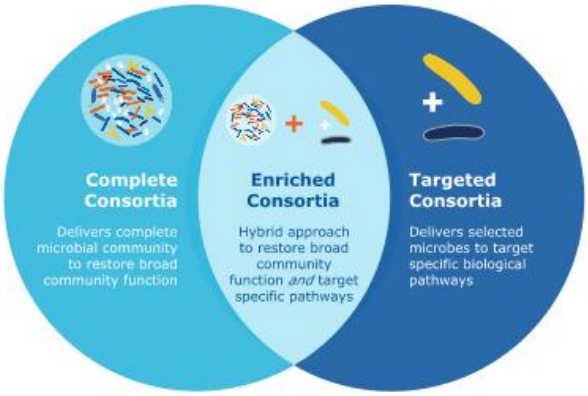
Sources: Sgritta Neuron 2019

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:

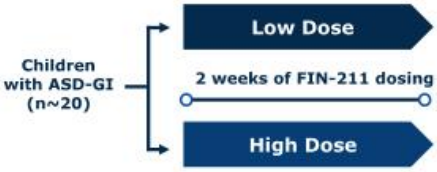
1. FIN-211 may proceed directly to children with ASD
2. Demonstrating benefit for *either* GI or behavioral symptoms could support a BLA

ASD

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 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

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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	900K	25-40%	$160K
Have chronic HBV globally, with 2M affected chronically in the US	Deaths globally from chronic HBV-related complications per year	Lifetime risk of liver cancer in patients with chronic HBV	Cost of liver transplantation

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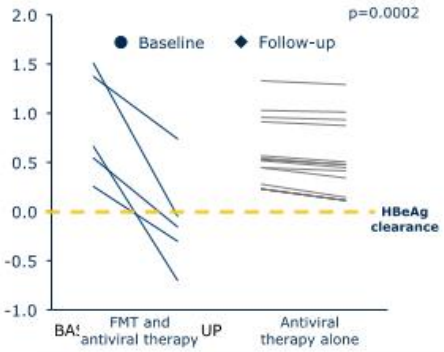
Sources: WHO Global Hepatitis Report 2017; CDC Hepatitis B: The Pink Book; Committee on a National Strategy for the Elimination of Hepatitis B and C; Hepatitis B Foundation; Van der Hilst Med Care Res Rev 2009

Multiple clinical studies with microbiota transplantation show improved HBV pathology

Microbiota transplantation induced HBeAg clearance

Trial 1: HBeAg positive

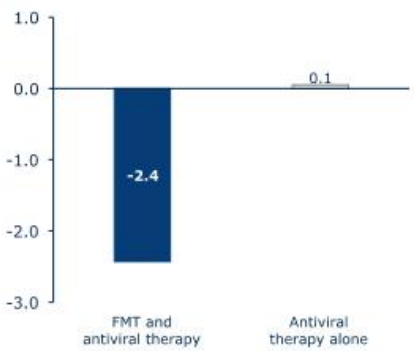
HBeAg titer (log10[S/CO]) **Ren 2017**



Microbiota transplantation induced HBeAg clearance and HBV DNA decrease

Trial 2: HBeAg positive

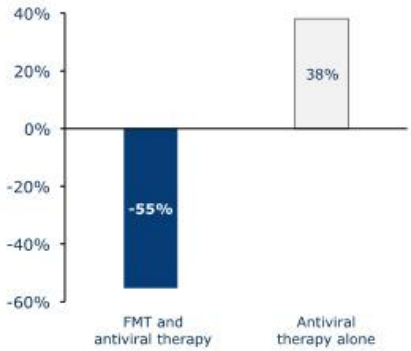
6-month HBV DNA reduction (Log^{10}) **Chauhan 2020**



Microbiota transplantation decreased HBsAg

Trial 3: HBeAg negative

% change in HBsAg titer **Xie 2018**



Addressing community-level dysbiosis led to improvement of HBV endpoints

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Sources: Ren Hepatology 2017; Chauhan Digest Dis Sci 2020; Xie Gut 2018

Anticipated Milestones

Finch positioned to continue momentum

Anticipated milestones

2020	2021	2022
✓ **Positive topline data from PRISM3 trial of CP101 in recurrent CDI**	✓ Completed upsized $130.8M IPO	☐ Initiate Phase 1b trial in chronic HBV
✓ Completed $90M financing	✓ Takeda accelerated leadership role in TAK-524 ulcerative colitis program	☐ Initiate Phase 1b trial in ASD
✓ Completed pre-IND meeting for ASD	✓ Initiated enrollment in PRISM4 Phase 3 trial of CP101 in recurrent CDI	☐ **Initial readout from Phase 1b trial in ASD**
✓ FDA confirmation of pivotal nature of PRISM3 and path to BLA	✓ **Positive topline PRISM-EXT data from CP101 in recurrent CDI**	☐ **Initial readout from Phase 1b trial in chronic HBV**
	✓ Completed construction of commercial manufacturing facility	

Strong balance sheet with anticipated runway into mid -2023*

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*As of 09/30/2021, unaudited cash and cash equivalents of $149 million

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Harnessing the microbiome to transform patients' lives