

**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): May 16, 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.

On May 16, 2022, Finch Therapeutics Group, Inc. (the “Company”) issued a press release announcing its recent business highlights and financial results for the quarter ended March 31, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 7.01 Regulation FD Disclosure.

On May 16, 2022, the Company will host a conference call and live webcast to discuss updates to its development programs and other business highlights. The Company will post the presentation used during the webcast to its website. A copy of the presentation is furnished as Exhibit 99.2 in this Current Report on Form 8-K.

The information contained in this Current Report on Form 8-K, including Exhibit 99.1 and Exhibit 99.2 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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated May 16, 2022.
99.2	Corporate Presentation, dated May 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: May 16, 2022

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

Finch Therapeutics Provides Corporate Update and Reports First Quarter 2022 Financial Results

- *FDA lifted clinical hold on IND for CP101*
- *Enrollment in PRISM4 Phase 3 trial of CP101 in recurrent CDI expected to proceed in H2 2022*
- *\$15 million drawn from new \$55 million term debt facility*
- *Anticipated cash runway into Q2 2024*
- *Corporate update call today at 8am ET*

SOMERVILLE, Mass., May 16, 2022 (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 provided a corporate update and reported financial results for the first quarter ended March 31, 2022.

"Finch made several important strides this quarter, including the resolution of the FDA clinical hold previously placed on our IND for CP101. We are pleased to have addressed the FDA's questions related to our SARS-CoV-2 screening procedures and look forward to completing the additional activities that we believe will enable us to proceed with enrollment in PRISM4, our Phase 3 trial of CP101 in recurrent *C. difficile* infection," said Mark Smith, PhD, Chief Executive Officer of Finch Therapeutics. "We are also preparing to advance FIN-211 into the clinic, which is our investigational microbiome therapeutic in development for children with autism and significant GI symptoms. We recently made several modifications to the design of AUSPIRE, our Phase 1b trial of FIN-211, such as the addition of a placebo arm which we believe will enable us to draw more meaningful insights into the potential impact of FIN-211 on behavioral and GI symptoms."

Dr. Smith continued, "With our recent decision to prioritize our *C. difficile* and autism programs, in addition to our Takeda-partnered work in inflammatory bowel disease, and the recent debt financing with Hercules Capital, we believe that we are well positioned to execute upon our mission and strategic priorities, with expected cash runway through key clinical milestones, including topline data from PRISM4 and initial safety data from AUSPIRE."

Recent Program Highlights**CP101 for the Prevention of Recurrent *C. difficile* Infection (CDI):**

- **FDA Removed Clinical Hold on CP101 IND:** In April 2022, Finch announced that the U.S. Food and Drug Administration (FDA) removed the clinical hold on its investigational new drug (IND) application for CP101 following a review of information Finch provided related to its SARS-CoV-2 screening procedures and associated informed consent language.

As previously announced, Finch expects to proceed with enrollment in PRISM4 after the Company completes certain manufacturing activities and quality system updates related to the recently resolved clinical hold, and submits for the FDA's review and agreement the validation package for one of its release tests and a PRISM4 protocol amendment. The protocol amendment will implement changes to the algorithm used to diagnose suspected CDI recurrences and revisions to the planned statistical analysis.

- **Updated Timeline for PRISM4 Phase 3 Trial of CP101 in Recurrent CDI:** Finch expects to proceed with enrollment in PRISM4 in H2 2022 and plans to provide further guidance on the expected timing of a topline PRISM4 data readout in the future.
- **Clinical Data from PRISM-EXT and PRISM3 Phase 2 Trials Accepted for Presentation at Digestive Disease Week (DDW) 2022:** In March 2022, Finch announced that data from its PRISM-EXT Phase 2 open-label trial and its PRISM3 Phase 2 placebo-controlled trial will be presented in May at DDW 2022. The topline data presented at DDW will be available in the “Publications” section of the Finch website after the meeting.

FIN-211 for Autism Spectrum Disorder (ASD) with Significant Gastrointestinal (GI) Symptoms:

- **Update on FIN-211 Development Timeline:** Finch anticipates submitting the IND for FIN-211 in Q4 2022. The IND submission is expected to reflect recent enhancements to the design of the AUSPIRE Phase 1b trial of FIN-211 and manufacturing updates related to the recently resolved clinical hold on the IND for CP101. Finch plans to provide guidance in the future on the expected timing of a topline AUSPIRE data readout.
- **Enhanced AUSPIRE Phase 1b Trial Design, Including the Addition of a Placebo Arm:** In the new AUSPIRE trial design, Finch plans to randomize approximately 36 participants to receive FIN-211 or placebo daily for 8 weeks, with the addition of a placebo arm expected to provide greater insights into the therapeutic potential of FIN-211. The primary endpoint of the trial will be safety and tolerability, with secondary endpoints including behavioral and GI symptom assessment. Exploratory endpoints will include additional behavioral and GI endpoints, as well as pharmacokinetic and pharmacodynamic assessments.

Recent Corporate Updates

- **Secured \$55 Million Term Debt Facility from Hercules Capital, Inc. (NYSE: HTGC):** Under the terms of the debt facility with Hercules Capital, \$15 million was drawn at closing, two tranches of \$10 million are each available at Finch’s discretion, and an additional \$20 million is available upon achievement of a milestone linked to topline data from PRISM4.
 - **Appointed Susan E. Graf as Chair of Board of Directors (Board):** In April 2022, Finch announced that Susan E. Graf, who joined Finch’s Board in April 2021, will serve as Chair of its Board of Directors. Ms. Graf brings more than 25 years of leadership experience in the life sciences industry, including previously serving as the Chief Executive Officer of Akamara Therapeutics, Inc. and the Chief Business Officer and Principal Financial Officer at Epizyme, Inc.
 - **Appointed Howard Franklin, MD, as Interim Chief Medical Officer (CMO):** Finch has appointed Howard Franklin, MD, as Interim CMO. Dr. Franklin, who served as CMO at Salix Pharmaceuticals, Inc. prior to joining Finch, has more than 20 years of experience as a general surgeon and biopharmaceutical executive, with deep expertise spanning clinical development, regulatory strategy, medical affairs, and product commercialization.
 - **Restructured Workforce to Focus Resources on Key Development Programs:** In April 2022, Finch announced plans to reduce its workforce by approximately 20%. This workforce reduction is intended to allow the company to focus its financial resources on its recurrent CDI and ASD
-

development programs, two wholly-owned programs that Finch is prioritizing, along with its Takeda-partnered work in inflammatory bowel disease (IBD).

Corporate Update Conference Call and Webcast

Finch management will host a conference call and live webcast on Monday, May 16, 2022, at 8:00 am ET to discuss updates to its development programs and other business highlights. The conference call can be accessed by dialing (833) 649-1186 (domestic) or (270) 823-1080 (international) and entering conference ID 8451806. The live webcast can be accessed by visiting the “Investors & News” section of the Finch website and selecting “Events & Presentations.” The webcast will be archived on the website for approximately 30 days following the event.

First Quarter 2022 Financial Results

- Finch reported a net loss of \$24.6 million for the first quarter of 2022, compared to a net loss of \$14.0 million for the same period in 2021. The net loss was driven by an increase in operating expenses of \$7.4 million compared to the first quarter of 2021, in addition to a decrease in revenue of \$3.2 million, primarily due to the November 2021 amendment to the agreement with Takeda, pursuant to which we transitioned primary responsibilities for TAK-524 to Takeda in the third quarter of 2021, resulting in a decrease in collaboration revenue in the current quarter.
- Research and development expenses were \$15.5 million for the first quarter of 2022, compared to \$13.0 million for the same period in 2021. The increase was primarily due to an increase in personnel costs, manufacturing related expenses and platform related costs, as Finch continues to build its platform and prepare for the future development of commercial supply needs. The increase was partially offset by a decrease in IBD program expenses due to the transition of primary responsibilities for TAK-524 from Finch to Takeda in the third quarter of 2021.
- General and administrative expenses were \$9.4 million for the first quarter of 2022, compared to \$4.6 million for the same period in 2021. The increase was primarily due to an increase in personnel costs including stock-based compensation, an increase in directors and officers insurance expense, and an increase in legal and professional costs, including costs associated with being a public company.
- Finch’s cash and cash equivalents as of March 31, 2022 was \$106.9 million, compared to \$133.5 million as of December 31, 2021. Finch believes its cash and cash equivalents on hand as of March 31, 2022, together with anticipated, non-dilutive sources of additional cash, will fund its operations into Q2 2024. These anticipated sources of cash include \$15 million of funding that has now been drawn under the recent debt facility with Hercules Capital, a \$10 million tranche of funding that is available at Finch’s discretion under this debt facility, expected near term milestones from the Takeda partnership, and the expected subletting of one of Finch’s office and lab facilities.

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 and has received Breakthrough Therapy and Fast Track designations from the U.S. Food and Drug Administration. Finch is also developing FIN-211 for children with autism spectrum disorder and significant gastrointestinal symptoms. Finch has a partnership with Takeda focused on the development of targeted microbiome therapeutics for inflammatory bowel disease. We routinely post information that may be important to our investors on our website at www.finchtherapeutics.com. The Company encourages investors to consult the "Investors & News" section of its website regularly.

Human-First Discovery[®] is a registered trademark of Finch Therapeutics Group, Inc.

Forward-Looking Statements

This press release includes "forward-looking statements." 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: Finch's ability to execute upon its mission and strategic priorities; Finch's ability to complete additional activities that it believes will enable it to proceed with enrollment in PRISM4 and the anticipated timeline for results from the trial; the design of Finch's AUSPIRE trial, Finch's plans to advance FIN-211 into the clinic and the anticipated timeline for submitting an IND for FIN-211; the potential for the modifications to the AUSPIRE trial design to enable the company to draw more meaningful insights into the potential impact of FIN-211 on behavioral and GI symptoms; the workforce reduction and Finch's ability to focus its financial resources on its existing development programs; Finch's ability to build its platform and plan for its future development of commercial supply needs; and Finch's anticipated runway, including accessing additional sources of capital. 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 risk that correspondence from the FDA may require Finch to collect additional data or information beyond what it currently expects, as well as unexpected regulatory actions or delays, including requests for additional safety and/or efficacy data or analysis of data, or government regulation generally; uncertainties relating to regulatory applications and related filing and approval timelines; 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 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; 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); Finch's ability to comply with regulatory requirements; ongoing regulatory obligations and continued regulatory review may result in significant additional expense to Finch and Finch may be subject to penalties for failure to comply; 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 Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 31, 2022, 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 MARCH 31,	
	2022	2021
Revenue:		
Collaboration revenue	\$ 354	\$ 3,553
Total revenue	354	3,553
Operating expenses:		
Research and development	15,530	12,975
General and administrative	9,404	4,552
Total operating expenses	24,934	17,527
Loss from operations	(24,580)	(13,974)
Other income (expense)	13	(7)
Net loss	\$ (24,567)	\$ (13,981)
Net loss per share attributable to common stockholders—basic and diluted	\$ (0.52)	\$ (1.00)
Weighted-average common stock outstanding—basic and diluted	47,528,948	14,033,273

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

	MARCH 31, 2022	DECEMBER 31, 2021
	Assets:	
Cash and cash equivalents	\$ 106,931	\$ 133,481
Other assets	97,702	91,888
Total assets	\$ 204,633	\$ 225,369
Liabilities, redeemable convertible preferred stock and stockholders' equity		
Liabilities	24,842	23,145
Stockholders' equity	179,791	202,224
Total liabilities, redeemable convertible preferred stock and stockholders' equity	\$ 204,633	\$ 225,369

Harnessing the Genomic Revolution & Machine Learning to Pioneer Microbiome Therapeutics

CORPORATE UPDATE | MAY 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: Finch's ability to execute upon its mission and strategic priorities; Finch's ability to complete additional activities that it believes will enable it to proceed with enrollment in PRISM4 and the anticipated timeline for results from the trial; the design of Finch's AUSPIRE trial, Finch's plans to advance FIN-211 into the clinic and the anticipated timeline for submitting an IND for FIN-211; the potential for the modifications to the AUSPIRE trial design to enable the company to draw more meaningful insights into the potential impact of FIN-211 on behavioral and GI symptoms; the workforce reduction and Finch's ability to focus its financial resources on its existing development programs; Finch's ability to build its platform and plan for its future development of commercial supply needs; and Finch'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: the risk that correspondence from the FDA may require Finch to collect additional data or information beyond what it currently expects, as well as unexpected regulatory actions or delays, including 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 Finch's release tests, which is utilized for both CP101 and FIN-211, or government regulation generally; uncertainties relating to regulatory applications and related filing and approval timelines; 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 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; 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); Finch's ability to comply with regulatory requirements; ongoing regulatory obligations and continued regulatory review may result in significant additional expense to Finch and Finch may be subject to penalties for failure to comply; 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 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 Securities and Exchange Commission on March 31, 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.

Agenda

Opening Remarks

Overview of Our Strategy

Recurrent *C. difficile* Infection Program Update

Autism Spectrum Disorder Program Update

Closing Remarks

Q&A



Mark Smith, PhD
Chief Executive Officer



Howard Franklin, MD
Interim Chief Medical Officer



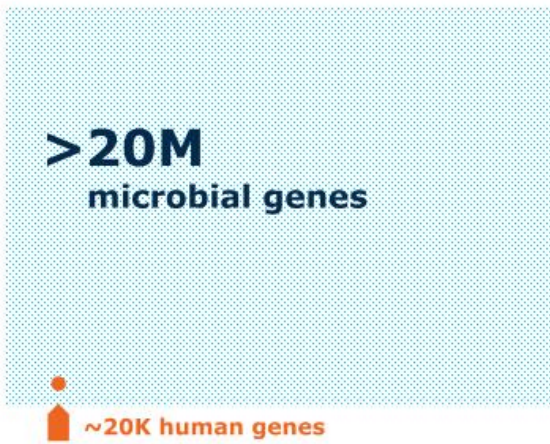
Joe Vittiglio, JD
Chief Business & Legal Officer



Marc Blaustein
Chief Operating Officer &
Principal Financial Officer

The microbiome is an attractive target for therapeutic intervention

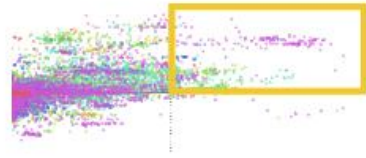
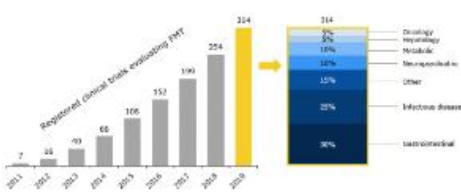
Humans carry 1000-fold more microbial genes than host genes



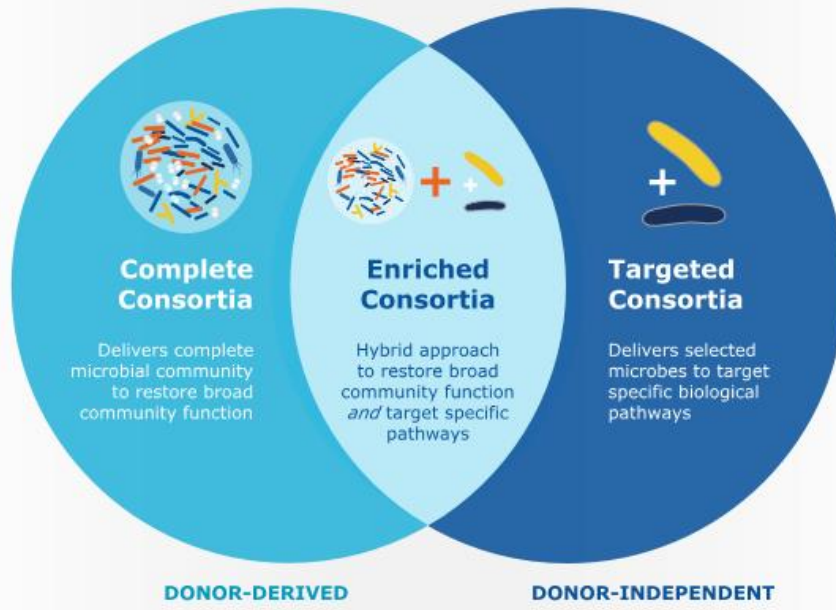
The microbiome is an organ system fundamental to human health



Our *Human-First Discovery* platform is designed to enable capital efficient data generation to support our development programs



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



Finch is advancing a portfolio of product candidates to address significant unmet needs



	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					
	FIN-525	Crohn's Disease	Targeted					
Neuro	FIN-211	Autism Spectrum Disorder	Enriched					

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



Recurrent CDI is an enormous human and economic burden

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



199K

Recurrent CDI cases per year in the U.S.



44K

Annual deaths attributable to CDI in the U.S.



\$5B

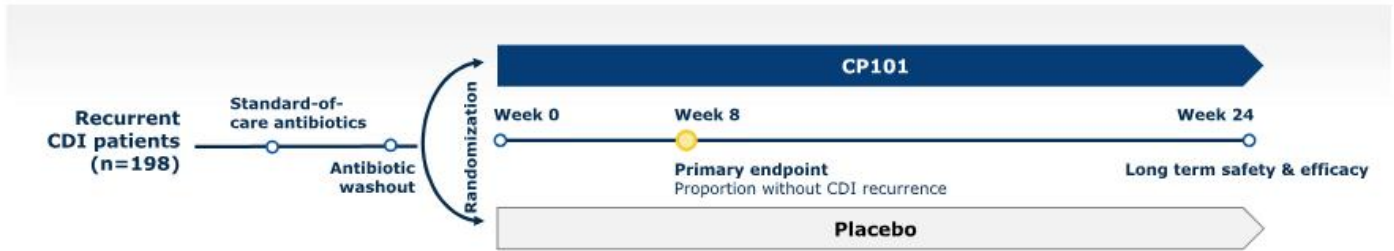
Annual direct costs of CDI in the U.S.



\$27K

Estimated savings per patient with microbiota transplantation

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



PRISM3 enrolled a broad population including:



Participants experiencing one or more CDI recurrences*
Relevance: 58% of all recurrent CDI cases are 1st recurrence



Participants diagnosed with CDI via PCR or toxin-based testing
Relevance: >80% of all CDI cases are diagnosed via PCR

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

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

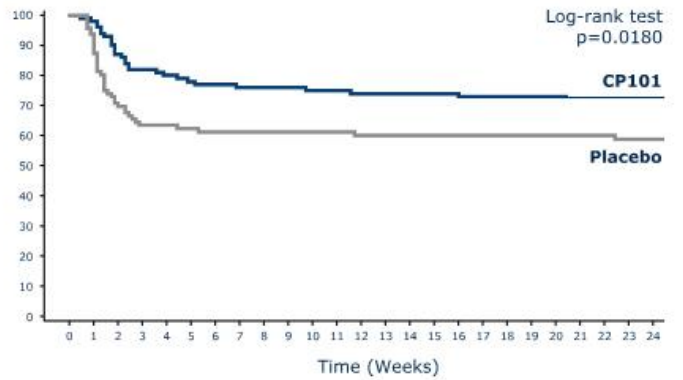
CP101 achieved 33.8% relative risk reduction for CDI recurrence through Week 8

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



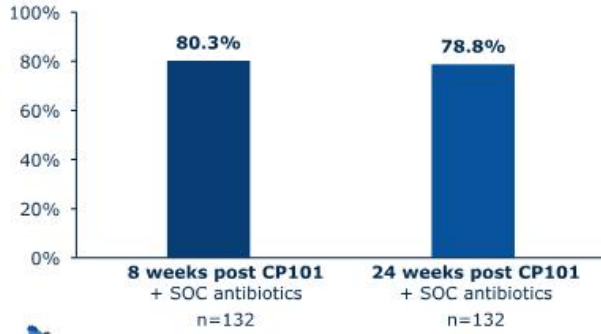
CP101 met its primary efficacy endpoint, with no treatment-related SAEs in the CP101 arm

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



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*



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)

PRISM4 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 Features

1. Extension of antibiotic washout period to enhance engraftment
2. Sample size increased to enhance power
3. 2:1 randomization to CP101 or placebo
4. Global study to support marketing authorizations outside the US

**Enrollment
expected to
proceed in
H2 2022***

*Finch expects to proceed with enrollment in PRISM4 after it completes certain manufacturing activities and quality system updates related to the recently resolved clinical hold regarding Finch's SARS-CoV-2 screening procedures, and submits for the FDA's review and agreement the validation package for one of its release tests and a PRISM4 protocol amendment. The PRISM4 protocol amendment will implement changes to the algorithm used to diagnose suspected CDI recurrences and revisions to the planned statistical analysis.

**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



4.6M

Children and adults in the U.S. 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 U.S.

FIN-211 is designed to address both behavioral and gastrointestinal (GI) symptoms of ASD

FIN-211 is an orally-administered Enriched Consortia product candidate



- FIN-211 is designed to deliver a diverse microbial community that is enriched with select bacteria grown in pure culture to ensure key mechanisms are consistently engaged
- FIN-211 is designed to target:
 - Reduced neuroinflammation
 - Enhanced gut barrier function
 - Oxytocin production

Finch's platform provides the opportunity to leverage third-party clinical data to inform the FIN-211 clinical development plan

Early FIN-211 clinical development objectives:



1. Evaluate safety and tolerability



2. Identify the optimal treatment regimen, including dosing and pre-treatment regimen

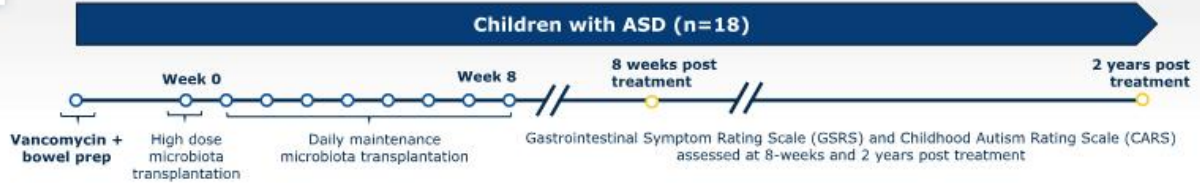


3. Generate early proof-of-concept data to support the design and power calculations for later stages of development

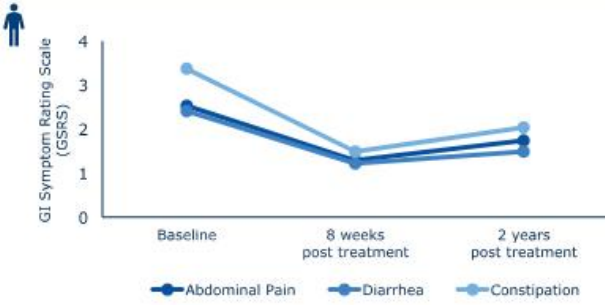
Enhanced design of the Phase 1b trial of FIN-211 reflects insights from recent third-party clinical data

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

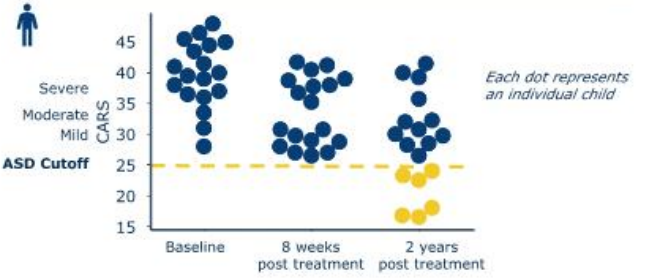
Study 1



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



Sources: Kang Microbiome 2017; Kang Sci Rep 2019

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

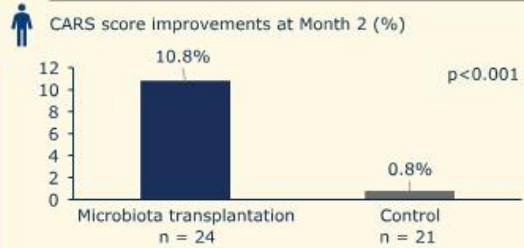
Study 2



Results at 2 months post microbiota transplantation

- 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 microbiota transplantation



New open-label clinical data continue to emerge showing GI and behavioral improvements following microbiota transplantation (n=40)

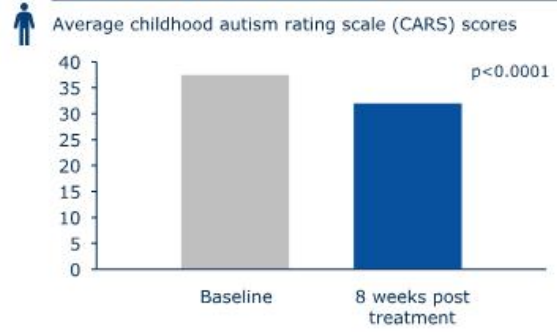
Study 3



Gastrointestinal symptoms improved following microbiota transplantation



Behavioral scores improved following microbiota transplantation



Third-party microbiota transplantation studies provide insight into optimal treatment regimen in children with ASD and GI symptoms

Study	Number of participants	Vanco pre-treatment	Bowel prep	GI improvement	Behavioral improvement
Ward (2016)	9	Y	N	N/A	✓
Kang (2017/2019)	18	Y	Y	✓	✓
Zhao (2019)	24	N	N	✓	✓
Li (2019)	85	N	N	✓	✓
Huanlong (unpublished)	31	N	-	✓	✓
Li (2021)	40	N	Y	✓	✓
Total	207				

Enhancements to AUSPIRE Phase 1b trial design leverage insights from latest third-party clinical data

Enhanced AUSPIRE Phase 1b trial is designed to provide early proof of concept and inform later stage development

Anticipated changes to the AUSPIRE trial design are expected to provide insights into the potential impact of FIN-211 on behavioral and GI symptoms, in addition to establishing safety and tolerability



Ph1b Endpoints

Primary endpoint	Safety and tolerability
Secondary endpoints	Childhood Autism Rating Scale (CARS) and consistency of bowel movements using the Bristol Stool Scale
Exploratory endpoints	Additional behavioral endpoints and GI endpoints, as well as PK/PD

IND filing expected in Q4 2022

Finch is advancing a portfolio of product candidates to address significant unmet needs



	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					
	FIN-525	Crohn's Disease	Targeted					
Neuro	FIN-211	Autism Spectrum Disorder	Enriched					

Expected runway into Q2 2024*, through key clinical milestones, including topline data from PRISM4 and initial safety data from AUSPIRE

*Expected runway includes cash and cash equivalents on hand as of March 31, 2022, together with recent debt facility, expected near term milestones from the Takeda partnership, and the expected subletting of one of Finch's office and lab facilities.



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

