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): February 24, 2022

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, Suite 400 **Somerville, Massachusetts 02143** **(Address of Principal Executive Offices)**	**02143** **(Zip Code)**

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

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

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

Emerging growth company ☒

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

Item 8.01 Other Events.

Finch Therapeutics Group, Inc. (the "***Company***") today announced that it has paused enrollment in PRISM4, its Phase 3 clinical trial of CP101 in patients with recurrent *C. difficile* infection ("***CDI***") following receipt of a clinical hold letter from the U.S. Food and Drug Administration (the "***FDA***") on February 24, 2022, requesting additional information about the Company's SARS-CoV-2 donor screening protocols.

At the outset of the coronavirus disease 2019 ("***COVID-19***") pandemic in March 2020, the FDA issued a public safety alert regarding the potential risk of transmission of SARS-CoV-2 virus through the use of donor-derived investigational microbiome therapies and the need for additional safety precautions. At such time, the FDA placed the Company's investigational new drug application ("***IND***") for CP101 and the IND of its then-contract manufacturer, OpenBiome, on partial clinical hold, requiring the implementation of new screening measures to mitigate the risk of transmission of SARS-CoV-2 from donor to recipient for any microbiota material donated on or after December 1, 2019. Notwithstanding the partial clinical hold notices, the Company was able to continue dosing patients in its then-ongoing PRISM-EXT Phase 2 open-label trial of CP101 in recurrent CDI as all of the CP101 lots used for PRISM-EXT were manufactured from material donated prior to December 1, 2019.

In January 2021, the Company's then-contract manufacturer, OpenBiome, was released from clinical hold after implementing a direct testing method for SARS-CoV-2. The test, developed with a third-party vendor, was part of a donor screening program to mitigate the risk of transmission of infectious agents, including SARS-CoV-2. In March 2021, the Company acquired certain manufacturing assets from OpenBiome, and in November 2021, the Company began dosing participants in PRISM4 with CP101 lots that had been screened for SARS-CoV-2 using the same testing method and vendor used by OpenBiome.

Following communications with the FDA in January 2022, on February 24, 2022, the FDA sent a letter to the Company stating that it required additional information about the Company's SARS-CoV-2 screening protocols and that a clinical hold remains in effect until the FDA's requests have been satisfactorily addressed. Finch has informed the FDA that participants were dosed in PRISM4 while the clinical hold was in effect and Finch is conducting a review of the matter.

In their letter, the FDA requested, among other things, additional detail on how samples are shipped to the vendor performing the SARS-CoV-2 testing and how inconclusive test results will be handled. The letter did not reference any adverse clinical outcome experienced in any of Finch's clinical trials. The Company expects to expeditiously provide the requested information to the FDA and intends to work closely with the FDA to resolve the clinical hold as soon as possible. The Company is evaluating what impact, if any, the clinical hold may have on the timing of the expected readout of topline data from its PRISM4 trial.

On March 1, 2022, the Company issued a press release announcing the clinical hold. A copy of this press release is filed herewith as Exhibit 99.1 to this Current Report.

Cautionary Note Regarding Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. All statements in this Current Report on Form 8-K other than statements of historical fact could be deemed forward looking including, but not limited to, statements regarding the Company's ability to resolve the clinical hold including the likelihood that the clinical hold will be lifted and timing of any such resolution; the Company's communication plans with the FDA related to the clinical hold and the timing for receiving written correspondence from the FDA; and the Company's plans and expectations for discussions with the FDA and the outcomes from the discussions. Words such as "plans," "expects," "will," "shall," "anticipates," "continue," "expand," "advance," "believes," "guidance," "target," "may," "remain," "project," "outlook," "intend," "estimate," "could," "should," and other words and terms of similar meaning and expression are intended to identify forward-looking statements, although not all forward-looking statements contain such terms. The forward-looking statements in this Current Report on Form 8-K speak only as of the date of this Current Report on Form 8-K, and the Company undertakes no obligation to update these forward-looking statements. Forward-looking statements are based on management's current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the risk that the written questions that the Company received from the FDA may require the Company to collect additional data or information beyond what it currently expects; the risk that the Company may not be able to address the FDA's concerns regarding SARS-CoV-2 testing protocols quickly or at all; uncertainties relating to regulatory applications and related filing and approval timelines, including the risk that FDA may not remove the clinical hold; early research or clinical trials do not demonstrate safety and/or efficacy in later preclinical studies or clinical trials; the risk that the Company may not obtain approval to market its product candidates; uncertainties associated with performing clinical trials, regulatory filings, applications and other interactions with regulatory bodies; risks associated with reliance on third parties to successfully conduct clinical trials; the ability of the Company to comply with regulatory requirements or experience unanticipated problems with any of its product candidates; ongoing regulatory obligations and continued regulatory review may result in significant additional expense to the Company and the Company may be subject to penalties for failure to comply; and other risks associated with the process of discovering, developing and commercializing drugs. Given these risks and uncertainties, you are cautioned not to place undue reliance on such forward-looking statements. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the section titled "Risk Factors" in the Company's Quarterly Report on Form 10-Q filed with the SEC on

November 10, 2021, as updated by the Company's subsequent filings with the Securities and Exchange Commission. All information in this Current Report on Form 8-K is as of the date of the release, and the Company undertakes no duty to update this information or to publicly announce the results of any revisions to any of such statements to reflect future events or developments, except as required by law.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated March 1, 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: March 1, 2022

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

Finch Therapeutics Provides an Update on its Phase 3 Trial of CP101 in Recurrent *C. difficile* Infection

SOMERVILLE, Mass., March 1, 2022 (GLOBE NEWSWIRE) — Finch Therapeutics Group, Inc. (“Finch” or “Finch Therapeutics” or “Company”) (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 announced that it has paused enrollment in PRISM4, its Phase 3 clinical trial of CP101 in recurrent *C. difficile* infection (CDI) following receipt of a clinical hold letter from the U.S. Food and Drug Administration (FDA) on February 24, 2022, requesting additional information about Finch’s SARS-CoV-2 donor screening protocols.

At the outset of the COVID-19 pandemic in March 2020, the FDA issued a public safety alert regarding the potential risk of transmission of SARS-CoV-2 virus through the use of donor-derived investigational microbiome therapies and the need for additional safety precautions. At that time, the FDA placed Finch’s investigational new drug application (IND) for CP101 and the IND of its then-contract manufacturer, OpenBiome, on partial clinical hold, requiring the implementation of SARS-CoV-2 testing protocols for any microbiota material donated on or after December 1, 2019. Notwithstanding the partial clinical hold notices, Finch was able to continue dosing patients in its then-ongoing PRISM-EXT Phase 2 open-label trial of CP101 in recurrent CDI as all of the CP101 lots used for PRISM-EXT were manufactured from material donated prior to December 1, 2019.

In January 2021, Finch’s then-contract manufacturer, OpenBiome, was released from clinical hold after implementing a direct testing method for SARS-CoV-2 provided by a third-party vendor. In March 2021, Finch acquired certain manufacturing assets from OpenBiome, and in November 2021, began dosing participants in PRISM4 with CP101 lots that had been screened for SARS-CoV-2 using the same test method and vendor used by OpenBiome.

Following communications with FDA in January 2022, on February 24, 2022, the FDA sent a letter stating that it needs additional information about Finch’s SARS-CoV-2 screening protocols and that a clinical hold remains in effect until the FDA’s requests have been satisfactorily addressed. Finch has informed the FDA that participants were dosed in PRISM4 while the clinical hold was in effect and Finch is conducting a review of the matter.

In their letter the FDA requested, among other things, additional detail on how samples are shipped to the vendor performing the SARS-CoV-2 testing and how inconclusive test results will be handled. The letter did not reference any adverse clinical outcome experienced in any of Finch’s clinical trials. Finch expects to expeditiously provide the requested information and intends to work closely with the FDA to resolve the clinical hold as soon as possible. Finch is evaluating what impact, if any, the clinical hold may have on the timing of the expected readout of topline data from the PRISM4 trial.

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.

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

Cautionary Note Regarding 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 Finch’s ability to resolve the clinical hold including the likelihood that the clinical hold will be lifted and timing of any such resolution; Finch’s communication plans with the FDA related to the clinical hold and the timing for receiving written correspondence from the FDA; and Finch’s plans and expectations for discussions with the FDA and the outcomes from the discussions. 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 the written questions that Finch received from the FDA may require Finch to collect additional data or information beyond what it currently expects; the risk that Finch may not be able to address the FDA’s concerns regarding SARS-CoV-2 testing protocols quickly or at all; uncertainties relating to regulatory applications and related filing and approval timelines, including the risk that FDA may not remove the clinical hold; 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 may not generate the benefits to patients that are anticipated; unexpected regulatory actions or delays, including requests for additional safety and/or efficacy data or analysis of data, or government regulation generally; the ability of Finch to comply with regulatory requirements or experience unanticipated problems with any of its product candidates; 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 to support 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 November 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.

Investor Contact:

Stephen Jasper
Gilmartin Group
(858) 525-2047
stephen@gilmartinir.com

Media Contact:

Jenna Urban
Berry & Company Public Relations
(212) 253-8881
jurban@berrypr.com