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): April 28, 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 **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 8.01 Other Events.

On April 28, 2022, Finch Therapeutics Group, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has removed the clinical hold on the Company's investigational new drug application for CP101. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated April 28, 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: April 28, 2022

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

Exhibit 99.1

Finch Therapeutics Announces Removal of FDA Clinical Hold on CP101 IND

SOMERVILLE, Mass., April 28, 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 announced that the U.S. Food and Drug Administration (FDA) has removed the clinical hold on Finch’s investigational new drug (IND) application for CP101. CP101 is the Company’s investigational orally administered microbiome therapeutic which is in late-stage clinical development for the prevention of recurrent *C. difficile* infection (CDI). The FDA lifted the clinical hold following a review of information Finch provided related to its SARS-CoV-2 screening procedures and associated informed consent language.

“We are grateful that the FDA has completed its review of the information we provided, and we are pleased that the clinical hold on our CP101 IND has been lifted,” said Mark Smith, PhD, Chief Executive Officer of Finch Therapeutics. “We look forward to completing the additional activities that we believe will enable us to proceed with enrollment in PRISM4, our Phase 3 study of CP101 in recurrent *C. difficile* infection, and we thank our PRISM4 trial partners for their continued support and dedication to serving patients who are battling recurrent *C. difficile* infection.”

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, 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. In parallel with these activities, Finch will continue to work with its PRISM4 trial sites to prepare for enrollment.

Finch plans to provide an update on the anticipated timing of both its PRISM4 trial and its planned AUSPIRE Phase 1b trial of FIN-211 in children with autism spectrum disorder and significant gastrointestinal symptoms when the Company reports its first quarter 2022 results.

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.

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 complete additional activities to enable it to proceed with enrollment in PRISM4, including completion of certain manufacturing activities and quality system updates and submission to the FDA's satisfaction of a PRISM4 protocol amendment and the validation package for one of its release tests, its ability to continue working with PRISM4 trial sites to prepare for enrollment and its plans to provide an update on the timing of the PRISM4 trial and the AUSPIRE trial. 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; uncertainties relating to regulatory applications and related filing and approval timelines; Finch's limited operating history and historical losses; the possibility that Finch may be delayed in initiating, enrolling or completing any clinical trials; 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; 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 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.

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