

**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): August 11, 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 August 11, 2022, Finch Therapeutics Group, Inc. (the "Company") issued a press release announcing its recent business highlights and financial results for the quarterly period ended June 30, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated August 11, 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: August 11, 2022

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

Finch Therapeutics Provides Corporate Updates and Reports Second Quarter 2022 Financial Results

- On track to proceed with enrollment in PRISM4 Phase 3 trial of CP101 in recurrent CDI in H2 2022
- On track to submit IND for FIN-211 in children with autism and significant GI symptoms in Q4 2022
- Additional results from PRISM-EXT Phase 2 trial of CP101 in recurrent CDI accepted for presentation at ACG 2022

SOMERVILLE, Mass., August 11, 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 corporate updates and reported financial results for the second quarter ended June 30, 2022.

"We are excited by the advances we made this quarter related to our lead program in recurrent *C. difficile* infection, including significant progress on a number of activities that we expect will position us to proceed with enrollment in our PRISM4 Phase 3 trial of CP101 later this year. We are also pleased to be presenting microbiome data from our PRISM-EXT Phase 2 open-label trial of CP101 in recurrent *C. difficile* at ACG 2022," said Mark Smith, PhD, Chief Executive Officer of Finch Therapeutics.

Dr. Smith continued, "Additionally, we are preparing to submit the IND for FIN-211 in children with autism and significant GI symptoms, with the submission anticipated later this year. We look forward to continuing to advance our mission to harness the microbiome to transform outcomes for people impacted by conditions linked to microbiome disruption."

Recent Program Highlights

CP101 for Prevention of Recurrent *C. difficile* Infection (CDI):

- **Continued Progress with Enrollment-Enabling Activities for the PRISM4 Phase 3 Trial of CP101:** Finch has made significant progress preparing to proceed with enrollment in PRISM4, including progress on several manufacturing activities and working with our clinical sites in preparation for PRISM4. Additionally, Finch recently submitted for the FDA's review and agreement the validation package for one of its release tests and a PRISM4 protocol amendment that reflects previously announced changes to the PRISM4 protocol. Pending feedback from the FDA on this recent submission and the completion of certain remaining quality and manufacturing activities, Finch expects to proceed with enrollment in PRISM4.
 - **Clinical Data from PRISM-EXT and PRISM3 Phase 2 Trials Presented at Digestive Disease Week (DDW) 2022:** In an oral presentation, Finch presented topline efficacy and safety data from the PRISM-EXT Phase 2 open-label trial of CP101 in recurrent CDI. As previously announced, 80.3% and 78.8% of participants who received CP101 following standard-of-care (SOC) antibiotics in PRISM-EXT were without CDI recurrence through 8 weeks and 24 weeks post-treatment, respectively (n=132). In a poster presentation, Finch presented a combined, post-hoc analysis of data from the PRISM3 Phase 2 placebo-controlled trial and the PRISM-EXT trial. Across PRISM3 and PRISM-EXT, 85.0% of participants who received CP101 following SOC antibiotics were without CDI recurrence through 8 weeks (n=214). No drug-related serious adverse events were reported in any participants that received CP101 in PRISM3 or PRISM-EXT. Drug-related treatment emergent adverse events were mild (Grade 1) or moderate (Grade 2), and primarily gastrointestinal in nature. The topline data presented at DDW 2022 are available under the 'Publications' section of the Finch website.
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- **Translational Results from the PRISM-EXT Phase 2 Trial Accepted for Presentation at ACG 2022:** Today, Finch announced that microbiome diversity and engraftment data from the PRISM-EXT trial were accepted for presentation at the American College of Gastroenterology (ACG) 2022 Annual Scientific Meeting taking place October 21-26, 2022.
- **Anticipated Upcoming Milestones:** Finch expects to proceed with enrollment in PRISM4 in H2 2022 and anticipates that topline data from PRISM4 will be available in H1 2024.

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

- **Continued Progress Preparing for the FIN-211 IND Submission and AUSPIRE Phase 1b Trial:** Finch is preparing for the submission of the FIN-211 investigational new drug (IND) application and the AUSPIRE Phase 1b trial of FIN-211 in children with ASD and constipation. The AUSPIRE trial is designed to enroll approximately 36 children who will be randomized to receive either FIN-211 or placebo daily for eight weeks. 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.
- **Anticipated Upcoming Milestones:** Finch anticipates submitting the IND for FIN-211 in Q4 2022. Finch plans to provide further guidance on the expected timing of the AUSPIRE trial in the future.

Second Quarter 2022 Financial Results

- Finch reported a net loss of \$22.7 million for the second quarter of 2022, compared to a net loss of \$15.2 million for the same period in 2021. The net loss was driven by an increase in operating expenses of \$3.1 million compared to the second quarter of 2021, in addition to a decrease in revenue of \$2.5 million, primarily due to the August 2021 amendment to the Takeda Agreement, pursuant to which Finch 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. Additionally, the prior period benefitted from other income due to the gain on extinguishment of the PPP Loan of \$1.8 million, while in the current quarter the Company incurred other expense of \$0.1 million.
 - Research and development (R&D) expenses were relatively flat, with \$13.9 million of expenses for the second quarter of 2022, compared to \$14.0 million for the same period in 2021. This is due to an increase in platform related expenses including personnel and manufacturing costs, as Finch continues to build out its manufacturing platform. This increase was offset by a decrease in costs related to Finch's inflammatory bowel disease program due to the transition of primary responsibilities for TAK-524 from Finch to Takeda in the third quarter of 2021, in addition to a decrease in costs associated with Finch's previously announced decision to suspend its chronic hepatitis B virus program.
 - General and administrative (G&A) expenses were \$8.2 million for the second quarter of 2022, compared to \$5.9 million for the same period in 2021. The increase in G&A expense quarter-over-quarter was primarily due to an increase in professional fees, in addition to an increase in facility-related costs and stock-based compensation expense. This increase was partially offset by a decrease in consulting related expenses.
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- Finch's cash and cash equivalents as of June 30, 2022 was \$104.7 million, compared to \$133.5 million as of December 31, 2021. Finch believes its cash and cash equivalents on hand as of June 30, 2022, together with income under an executed sublease for a portion of one of its office and lab facilities, will fund its operations into Q1 2024. As the Takeda-partnered TAK-524 program nears the next decision point in development, Takeda has informed Finch that they are conducting a review of the plans, timeline, and budget for the TAK-524 program as part of their portfolio review process. As a result, the associated near-term milestones have been removed from Finch's cash runway analysis until Takeda has completed its review.

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. Finch routinely posts information that may be important to its investors on its website at www.finchtherapeutics.com. Finch 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 advance its mission; Finch's ability to complete activities that it expects will position it to proceed with enrollment in PRISM4 later this year; Finch's plans to advance FIN-211 into the clinic; the timeline for topline data from PRISM4 and plans to present translational data from PRISM-EXT; the timeline for submission of the IND for FIN-211; the design and anticipated enrollment in AUSPIRE; 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, 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 supplemented by Finch's Quarterly Report on Form 10-Q filed with the SEC on May 16, 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 JUNE 30,		FOR THE SIX MONTHS ENDED JUNE 30,	
	2022	2021	2022	2021
Revenue:				
Collaboration revenue	\$ 361	\$ 2,830	\$ 715	\$ 6,383
Total revenue	<u>361</u>	<u>2,830</u>	<u>715</u>	<u>6,383</u>
Operating expenses:				
Research and development	13,923	13,964	29,453	26,939
General and administrative	8,164	5,882	17,568	10,433
Restructuring expense	903	-	903	-
Total operating expenses	<u>22,990</u>	<u>19,846</u>	<u>47,924</u>	<u>37,372</u>
Loss from operations	(22,629)	(17,016)	(47,209)	(30,989)
Other (expense) income	(71)	1,847	(58)	1,839
Net loss	<u>\$ (22,700)</u>	<u>\$ (15,169)</u>	<u>\$ (47,267)</u>	<u>\$ (29,150)</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (0.48)</u>	<u>\$ (0.32)</u>	<u>\$ (0.99)</u>	<u>\$ (0.95)</u>
Weighted-average common stock outstanding—basic and diluted	<u>47,576,349</u>	<u>47,379,887</u>	<u>47,552,780</u>	<u>30,798,698</u>

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

	JUNE 30, 2022	DECEMBER 31, 2021
Assets:		
Cash and cash equivalents	\$ 104,673	\$ 133,481
Other assets	123,628	91,888
Total assets	<u>\$ 228,301</u>	<u>\$ 225,369</u>
Liabilities, redeemable convertible preferred stock and stockholders' equity		
Liabilities	69,209	23,145
Stockholders' equity	159,092	202,224
Total liabilities, redeemable convertible preferred stock and stockholders' equity	<u>\$ 228,301</u>	<u>\$ 225,369</u>

