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): March 31, 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		**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 March 31, 2022, Finch Therapeutics Group, Inc. (the "Company") issued a press release announcing its recent business highlights and financial results for the quarter and year ended December 31, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated March 31, 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 31, 2022

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

Finch Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Updates

SOMERVILLE, Mass., March 31, 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 reported fourth quarter and full year 2021 financial results and provided business updates.

"Finch achieved many significant milestones in 2021, including new clinical data readouts that support our lead product candidate, CP101, for the prevention of recurrent *C. difficile* infection and the advancement of our TAK-524 ulcerative colitis development program to Takeda for further development. Following a strategic review of our pipeline, we have decided to focus on our *C. difficile* and autism programs, in addition to our partnership with Takeda focused on inflammatory bowel disease, and we have paused development of CP101 for the treatment of chronic hepatitis B infection, preserving capital for our prioritized programs," said Mark Smith, PhD, Chief Executive Officer of Finch Therapeutics. "With regards to PRISM4, our Phase 3 trial of CP101 in recurrent *C. difficile*, we have been in communication with the FDA and recently submitted a complete response to the clinical hold related to our IND for CP101 and our SARS-CoV-2 donor screening protocols and we look forward to working closely with the FDA to address their recent requests."

"Today, we are also announcing the upcoming retirement of Greg Perry, our Chief Financial Officer, who has been an incredible partner to Finch over the past several years and played an instrumental role in our growth from an early-stage private company to a public company with multiple development programs," added Dr. Smith. "On behalf of our entire team, I want to thank Greg for his many contributions and wish him the best as he heads into his retirement. Greg's team will be in good hands, with Marc Blaustein, our current Chief Operating Officer, expanding his responsibilities to include leadership of our finance organization."

Recent Program Highlights

Recurrent *C. difficile* Infection (CDI):

- **Update on PRISM4 Phase 3 Trial of CP101 in Recurrent CDI**: Today, Finch announced that it has submitted a complete response to the previously announced clinical hold related to the investigational new drug (IND) application for CP101 and requests from the FDA regarding Finch's SARS-CoV-2 donor screening protocols and associated informed consent language. Subsequent to the recent clinical hold letter, Finch has received additional correspondence from the FDA requesting changes to the testing algorithm used to diagnose suspected CDI recurrences in PRISM4, as well as additional information about the proposed statistical analysis plan for PRISM4 and the validation package for one of Finch's release tests. Enrollment in PRISM4 will remain paused until Finch is able to resolve the clinical hold, address the most recent FDA feedback and conduct additional manufacturing activities to satisfy requests related to SARS-CoV-2 donor screening. Finch is evaluating the extent of the expected delay to the timing for resuming enrollment in PRISM4 and, based on manufacturing timelines, expects at least a one quarter delay.
- **Clinical Data from PRISM-EXT and PRISM3 Phase 2 Trials Accepted for Presentation at Digestive Disease Week (DDW) 2022:** Today, 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.

- **Reported Positive Topline Results from PRISM-EXT Phase 2 Open-Label Trial of CP101 in Recurrent CDI:** In November 2021, Finch reported topline data from PRISM-EXT in which 80.3% and 78.8% of participants who received CP101 following standard-of-care (SOC) antibiotics were without CDI recurrence through 8 weeks and 24 weeks post-treatment, respectively (n=132). There were no treatment-related serious adverse events (SAEs) reported and CP101 exhibited an overall safety profile consistent with the profile observed in PRISM3.

- **Presented 24-Week Efficacy and Safety Data from PRISM3 Phase 2 Placebo-Controlled Trial of CP101 in Recurrent CDI at American College of Gastroenterology (ACG) Annual Meeting:** In October 2021, Finch presented data from its PRISM3 Phase 2 trial in which 73.5% of participants who received CP101 following SOC antibiotics (n=102) were without CDI recurrence through 24 weeks post-treatment, versus 59.4% who received placebo following SOC antibiotics (n=96) (p=0.0347). There were no treatment-related SAEs reported in the CP101 arm of the trial and the rates of adverse events and treatment-related adverse events were similar in the CP101 and placebo arms through 24 weeks post-treatment.

Autism Spectrum Disorder (ASD) with Significant Gastrointestinal (GI) Symptoms:

- **Update on AUSPIRE Phase 1b Trial of FIN-211 in Children with ASD and Significant GI Symptoms:** Finch has determined that the AUSPIRE Phase 1b trial of FIN-211, a product candidate that includes donor-derived components, will be delayed in connection with the clinical hold related to the IND for CP101. To address the FDA's requests related to SARS-CoV-2 donor screening protocols, Finch will need to complete additional manufacturing activities for components of FIN-211. Finch is evaluating the extent of the expected delay to the timing of AUSPIRE and, based on manufacturing timelines, expects at least a one quarter delay.

- **Strengthened Patent Portfolio with Two New U.S. Patents Granted for FIN-211:** In January 2022, Finch announced the issuance of two new U.S. patents covering its FIN-211 enriched consortia microbiome product candidate. Finch's patent portfolio now includes more than 55 issued U.S. and foreign patents with more than 140 patent applications pending.

Chronic Hepatitis B Virus (HBV) Infection:

- **Paused Development of CP101 for Chronic HBV, Focusing Resources on Wholly-Owned CDI and ASD Programs:** Today, Finch announced that it has paused development of CP101 for the treatment of chronic HBV following a strategic review of the Company's pipeline. The Company believes this decision will allow it to maximize its working capital available for investment in its wholly-owned recurrent CDI and ASD programs.

Inflammatory Bowel Disease (IBD):

- **Transitioned TAK-524 Ulcerative Colitis Development Program to Takeda for Clinical Development:** In August 2021, Finch announced that Takeda elected to accelerate the transition of development responsibility for the TAK-524 ulcerative colitis development program, previously known as FIN-524, with Takeda to lead further development of the program. TAK-524, which contains select spore-forming and non-spore-forming bacterial strains, is the first targeted consortia product candidate developed with Finch's machine learning-based platform.

- **Finch and Takeda Continue FIN-525 Discovery Work Targeting Crohn's Disease:** In collaboration with Takeda, Finch continues to advance FIN-525 discovery work. FIN-525 is a discovery-stage program aimed at the development of a targeted consortia product candidate for the treatment of Crohn's disease.

Recent Corporate Highlights:

- **Retirement of Chief Financial Officer:** Today, Finch announced that Greg Perry will retire from his position as Chief Financial Officer, effective April 30, 2022. Following his retirement, Mr. Perry plans to continue to provide strategic advice to the Company through the end of 2022 as a consultant. Marc Blaustein, who joined Finch in September 2021 as Chief Operating Officer (COO), will serve as the Company's Principal Financial Officer and Principal Accounting Officer in addition to his role as COO, upon Mr. Perry's retirement. Mr. Blaustein has more than 20 years of leadership experience in the biotechnology industry, including significant experience leading corporate finance initiatives.
- **Strengthened Senior Leadership Team:** In February 2022, Finch announced the appointment of Bryan Gillis, MBA, as its Chief Technology Officer, Alka Batycky, PhD, as its Chief Development Officer, and Howard Franklin, MD, MBA, as its Senior Vice President, Late-Stage Development and GI Therapeutic Area Lead. Additionally, in December 2021, Finch announced the promotion of Joseph Vittiglio, JD, to Chief Business and Legal Officer.
- **Completed Construction of New Manufacturing Facility:** In November 2021, Finch announced the completion of construction of its new manufacturing facility designed to support the manufacture of its microbiome product candidates for clinical trials and to support potential commercialization needs. Commissioning and qualification activities are underway for the newly constructed facility.

Financial Results:

Finch reported a net loss of $19.1 million for the fourth quarter of 2021, compared to a net loss of $13.1 million for the same period in 2020. Finch reported a net loss of $58.2 million for the full year of 2021, compared to a net loss of $39.3 million for the prior year.

Research and development (R&D) expenses were $14.8 million for the fourth quarter of 2021, compared to $8.6 million for the same period in 2020. R&D expenses were $57.3 million for fiscal year 2021, compared to $33.1 million for the prior year. The increases were 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.

General and administrative (G&A) expenses were $5.1 million for the fourth quarter of 2021, compared to $6.4 million for the same period in 2020. The decrease in G&A expense quarter-over-quarter was primarily due to a decrease in stock-based compensation expense resulting from the sale of common stock in the fourth quarter of 2020 by certain executives. No similar expense was recorded in 2021. This decrease was offset by an increase in salaries and related personnel costs in the fourth quarter of 2021 to support Finch's operational growth. G&A expenses were $21.2 million for fiscal year 2021, compared to $14.0 million for the prior year. The year-over-year increase is primarily related to an increase in headcount to support Finch's operational growth, directors and officers insurance expense and costs associated with Finch's transition to a public company in March 2021.

Finch's cash and cash equivalents as of December 31, 2021 was $133.5 million, compared to $99.7 million as of December 31, 2020. Finch expects that the cash and cash equivalents it had on hand as of

December 31, 2021 will be sufficient to fund its 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. 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.

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

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 timing and the resolution of the FDA clinical hold related to Finch's SARS-CoV-2 donor screening protocols and informed consent process and the impact of the clinical hold on Finch's clinical and pre-clinical programs; the structure, timing and planned milestones of Finch's clinical trials, including specifically PRISM4, Finch's Phase 3 clinical trial in CDI, and AUSPIRE, Finch's Phase 1 trial in ASD; Finch's ability to advance the development of a novel class of therapeutics; increased efficiencies as a result of Finch's strategic refocus; and Finch's anticipated 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 risk that Finch may not be able to address the FDA's concerns regarding SARS-CoV-2 testing protocols and informed consent 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, 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 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

Finch Therapeutics Group, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	FOR THE THREE MONTHS ENDED DECEMBER 31,		FOR THE YEAR ENDED DECEMBER 31,	
	2021	2020	2021	2020
Revenue:				
Collaboration revenue	$ 806	$ 1,794	$ 18,532	$ 7,376
Royalty revenue from related party	-	13	-	343
Total revenue	806	1,807	18,532	7,719
Operating expenses:				
Research and development	14,803	8,567	57,279	33,144
General and administrative	5,065	6,372	21,238	14,011
Total operating expenses	19,868	14,939	78,517	47,155
Loss from operations	(19,062)	(13,132)	(59,985)	(39,436)
Other income	7	41	1,825	95
Net loss	$ (19,055)	$ (13,091)	$ (58,160)	$ (39,341)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.40)	$ (1.56)	$ (1.48)	$ (4.83)
Weighted-average common stock outstanding—basic and diluted	47,491,731	8,380,808	39,202,086	8,144,855

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

	DECEMBER 31, 2021	DECEMBER 31, 2020
Assets:		
Cash and cash equivalents	$ 133,481	$ 99,710
Other assets	91,888	65,628
Total assets	$ 225,369	$ 165,338
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Liabilities	23,145	28,002
Redeemable convertible preferred stock	—	233,054
Stockholders' equity (deficit)	202,224	(95,718)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 225,369	$ 165,338