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

November 10, 2022

- *Patient dosing underway in PRISM4 Phase 3 trial of CP101 in recurrent CDI*
- *Topline PRISM4 data anticipated in H1 2024*
- *Anticipated cash runway into Q2 2024*

SOMERVILLE, Mass., Nov. 10, 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 third quarter ended September 30, 2022.

“We are pleased with the tremendous progress our team has made recently to advance the development of our lead program, with patient dosing now underway in our PRISM4 Phase 3 trial of CP101, a product candidate that we believe holds the potential to fulfill the need for a convenient, one-time oral therapy to prevent recurrent *C. difficile* infection,” said Mark Smith, PhD, Chief Executive Officer of Finch Therapeutics. “In an effort to accelerate our timeline to topline PRISM4 data and conserve capital, we are evaluating possible modifications to PRISM4 for future discussion with FDA, such as a reduction in the size of the randomized portion of the trial, an approach that may be informed in part by regulatory insights from the recent FDA advisory committee meeting for an enema-based microbiome product candidate. We look forward to providing additional updates as we continue to advance this important program.”

Recent Program Highlights

- **Proceeded with Patient Dosing in PRISM4 Recurrent CDI Trial, with Topline PRISM4 Data Anticipated in H1 2024:** In October 2022, Finch announced that it had proceeded with patient dosing in PRISM4, a Phase 3 trial of CP101 for the prevention of recurrent *C. difficile* infection (CDI). The PRISM4 trial has two parts: a randomized, double-blind, placebo-controlled portion and an open-label portion for eligible participants who experience a recurrence during the randomized portion of PRISM4. Topline data from the randomized portion of PRISM4 is anticipated in the first half of 2024. To expand the safety database for CP101 in support of a potential Biologics License Application (BLA), Finch plans to allow direct entry into the open-label portion of PRISM4 following the completion of enrollment in the randomized portion of PRISM4.

- **Presented CP101 PRISM-EXT Biomarker Data at ACG 2022:** In October 2022, Finch announced the presentation of biomarker data from the PRISM-EXT open-label trial of CP101 in recurrent CDI at the American College of Gastroenterology (ACG) 2022 Annual Scientific Meeting. Following open-label administration of CP101 after standard-of-care (SOC) CDI antibiotics, there was a significant increase in microbiome diversity from baseline through week 8 and week 24 in PRISM-EXT participants. Higher engraftment of CP101-associated taxa and improvement in diversity were both associated with prevention of CDI recurrence through week 8 in PRISM-EXT participants. As previously reported, 80.3% and 78.8% of participants who received CP101 following SOC antibiotics in PRISM-EXT were without CDI recurrence through week 8 and week 24, respectively (n=132).

- **Conducted Strategic Portfolio Review:** Following a recent strategic review of its portfolio, which includes wholly-owned microbiome product candidates for recurrent CDI, inflammatory bowel disease (IBD) and autism spectrum disorder (ASD), Finch is prioritizing the development of CP101 in recurrent CDI and exploring opportunities to potentially advance the development of its pre-clinical candidates for IBD through strategic partnerships. In connection with the strategic review, Finch has suspended efforts to initiate a Phase 1 trial of FIN-211 in ASD while the Company explores opportunities to leverage clinical data generated by ongoing third-party studies to inform its autism program strategy going forward, as previously announced.

Recent Corporate Highlights

- **Appointed Howard Franklin, MD, MBA, as Chief Medical Officer:** Dr. Franklin, a general surgeon and biopharmaceutical executive with more than 20 years of experience spanning clinical practice, clinical development, medical affairs, regulatory strategy, and product commercialization, previously served as Interim Chief Medical Officer for Finch. Prior to Finch, Dr. Franklin served as Chief Medical Officer at Salix Pharmaceuticals, where he provided leadership and expertise to program teams focused on the development of GI therapeutics. Prior to Salix, he held leadership roles within early-stage biotechnology companies as well as large pharmaceutical companies, including Icon Bioscience, Oceana Therapeutics, The Medicines Company, and Esprit Pharma.

Third Quarter 2022 Financial Results

- Finch reported a net loss of $40.4 million for the third quarter of 2022, compared to a net loss of $10.0 million for the same period in 2021. The net loss was driven by a charge of $18.1 million for the full impairment of the Company’s goodwill during the current quarter. Additionally, there was a decrease in revenue of $11.2 million due to changes under Finch’s collaboration agreement with Takeda, including Takeda’s election in August 2022 to terminate the agreement. Finch also reported an increase in restructuring expenses of $1.3 million quarter-over-quarter.

- Research and development (R&D) expenses were $11.9 million for the third quarter of 2022, compared to $15.5 million for the same period in 2021. The decrease in R&D expense was driven by a decrease in expenses related to the CP101 program, primarily due to a decrease in external clinical research organization costs, in addition to a decrease in IBD program expenses due to Takeda's election in August 2022 to terminate its collaboration agreement with Finch. Additionally, there was a decrease in expenses associated with both the hepatitis B (HBV) and ASD programs, due to the Company's decision to suspend its HBV program, announced on March 31, 2022, and its subsequent decision, announced on September 1, 2022, to suspend its Phase 1 clinical trial in ASD.

- General and administrative (G&A) expenses were $9.6 million for the third quarter of 2022, compared to $5.7 million for the same period in 2021. The increase in G&A expense 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 employee-related expenses due to reduced headcount.

- Finch's cash and cash equivalents as of September 30, 2022 were $85.3 million, compared to $133.5 million as of December 31, 2021. Finch believes its cash and cash equivalents on hand as of September 30, 2022, together with anticipated cash inflows from executed subleases for one of the Company's office and lab facilities, will fund its operations into Q2 2024.

About the PRISM4 Phase 3 Trial

PRISM4 is a randomized, double-blind, placebo-controlled, multi-center Phase 3 trial evaluating the efficacy and safety of a one-time oral administration of CP101 for the prevention of recurrent *C. difficile* infection (CDI). After completing standard-of-care CDI antibiotics for their most recent CDI recurrence, eligible participants will be randomized in a 2:1 ratio to receive either CP101 or placebo. Participants will be evaluated for CDI recurrence and safety through week 8, the primary endpoint, as well as through week 24. Participants who qualify may enroll in the optional open label arm and receive CP101 if they experience a CDI recurrence through week 8 of the trial. To learn more about the trial, visit clinicaltrials.gov (Identifier: NCT05153499) or the study website at https://prism4trial.com/.

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. 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 exploring strategic options to potentially advance the development of its pre-clinical candidates FIN-524 for ulcerative colitis and FIN-525 for Crohn's disease and its pre-clinical program in autism spectrum disorder. 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: the therapeutic potential of Finch's product candidates, including the potential of CP101 to fulfill the need for a convenient, one-time oral therapy for the prevention of recurrent CDI; possible modifications to PRISM4 and Finch's ability to leverage regulatory insights from a recent FDA advisory committee meeting; Finch's ability to accelerate its timeline to topline PRISM4 data and conserve capital; the anticipated timing for topline data from PRISM4; Finch's plans to allow direct entry in the open-label portion of PRISM4 to expand the safety database for CP101; potential strategic partnerships to advance Finch's product candidates; opportunities to leverage clinical data generated by third-party studies to inform Finch's ASD program strategy; Finch's cash runway; and Finch's ability to develop a novel class of orally administered biological drugs. 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, those related to: 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, including PRISM4; 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; 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 could 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; 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 Reports on Form 10-Q filed with the SEC on May 16, 2022 and August 11, 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 SEPTEMBER 30,		FOR THE NINE MONTHS ENDED SEPTEMBER 30,	
	2022	**2021**	**2022**	**2021**
Revenue:				
Collaboration revenue	$ 138	$ 11,343	$ 853	$ 17,726
Total revenue	138	11,343	853	17,726
Operating expenses:				
Research and development	11,859	15,537	41,312	42,476
General and administrative	9,584	5,739	27,152	16,173
Impairment of goodwill	18,057	—	18,057	—
Restructuring expense	1,270	—	2,173	—
Total operating expenses	40,770	21,276	88,694	58,649
Loss from operations	(40,632)	(9,933)	(87,841)	(40,923)
Other income (expense)	261	(22)	203	1,818
Net loss	$ (40,371)	$ (9,955)	$ (87,638)	$ (39,105)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.85)	$ (0.21)	$ (1.84)	$ (1.07)
Weighted-average common stock outstanding—basic and diluted	47,728,130	47,445,195	47,611,872	36,408,506

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

	SEPTEMBER 30, 2022	DECEMBER 31, 2021
Assets:		
Cash and cash equivalents	$ 85,292	$ 133,481
Other assets	102,676	91,888
Total assets	$ 187,968	$ 225,369
Liabilities, redeemable convertible preferred stock and stockholders' equity		
Liabilities	67,102	23,145
Stockholders' equity	120,866	202,224
Total liabilities and stockholders' equity	$ 187,968	$ 225,369