Finch Therapeutics Provides Corporate Update and Reports First Quarter 2022 Financial Results

May 16, 2022

- *FDA lifted clinical hold on IND for CP101*
- *Enrollment in PRISM4 Phase 3 trial of CP101 in recurrent CDI expected to proceed in H2 2022*
- *$15 million drawn from new $55 million term debt facility*
- *Anticipated cash runway into Q2 2024*
- *Corporate update call today at 8am ET*

SOMERVILLE, Mass., May 16, 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 a corporate update and reported financial results for the first quarter ended March 31, 2022.

“Finch made several important strides this quarter, including the resolution of the FDA clinical hold previously placed on our IND for CP101. We are pleased to have addressed the FDA’s questions related to our SARS-CoV-2 screening procedures and look forward to completing the additional activities that we believe will enable us to proceed with enrollment in PRISM4, our Phase 3 trial of CP101 in recurrent *C. difficile* infection,” said Mark Smith, PhD, Chief Executive Officer of Finch Therapeutics. “We are also preparing to advance FIN-211 into the clinic, which is our investigational microbiome therapeutic in development for children with autism and significant GI symptoms. We recently made several modifications to the design of AUSPIRE, our Phase 1b trial of FIN-211, such as the addition of a placebo arm which we believe will enable us to draw more meaningful insights into the potential impact of FIN-211 on behavioral and GI symptoms.”

Dr. Smith continued, “With our recent decision to prioritize our *C. difficile* and autism programs, in addition to our Takeda-partnered work in inflammatory bowel disease, and the recent debt financing with Hercules Capital, we believe that we are well positioned to execute upon our mission and strategic priorities, with expected cash runway through key clinical milestones, including topline data from PRISM4 and initial safety data from AUSPIRE.”

Recent Program Highlights

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

- **FDA Removed Clinical Hold on CP101 IND:** In April 2022, Finch announced that the U.S. Food and Drug Administration (FDA) removed the clinical hold on its investigational new drug (IND) application for CP101 following a review of information Finch provided related to its SARS-CoV-2 screening procedures and associated informed consent language.

  As previously announced, Finch expects to proceed with enrollment in PRISM4 after the Company 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 protocol amendment will implement changes to the algorithm used to diagnose suspected CDI recurrences and revisions to the planned statistical analysis.

- **Updated Timeline for PRISM4 Phase 3 Trial of CP101 in Recurrent CDI:** Finch expects to proceed with enrollment in PRISM4 in H2 2022 and plans to provide further guidance on the expected timing of a topline PRISM4 data readout in the future.

- **Clinical Data from PRISM-EXT and PRISM3 Phase 2 Trials Accepted for Presentation at Digestive Disease Week (DDW) 2022:** In March 2022, 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. The topline data presented at DDW will be available in the “Publications” section of the Finch website after the meeting.

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

- **Update on FIN-211 Development Timeline:** Finch anticipates submitting the IND for FIN-211 in Q4 2022. The IND submission is expected to reflect recent enhancements to the design of the AUSPIRE Phase 1b trial of FIN-211 and manufacturing updates related to the recently resolved clinical hold on the IND for CP101. Finch plans to provide guidance in the future on the expected timing of a topline AUSPIRE data readout.

- **Enhanced AUSPIRE Phase 1b Trial Design, Including the Addition of a Placebo Arm:** In the new AUSPIRE trial design, Finch plans to randomize approximately 36 participants to receive FIN-211 or placebo daily for 8 weeks, with the addition of a placebo arm expected to provide greater insights into the therapeutic potential of FIN-211. 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.

Recent Corporate Updates

- **Secured $55 Million Term Debt Facility from Hercules Capital, Inc. (NYSE: HTGC):** Under the terms of the debt facility with Hercules Capital, $15 million was drawn at closing, two tranches of $10 million are each available at Finch's discretion, and an additional $20 million is available upon achievement of a milestone linked to topline data from PRISM4.

- **Appointed Susan E. Graf as Chair of Board of Directors (Board):** In April 2022, Finch announced that Susan E. Graf, who joined Finch's Board in April 2021, will serve as Chair of its Board of Directors. Ms. Graf brings more than 25 years of leadership experience in the life sciences industry, including previously serving as the Chief Executive Officer of Akamara Therapeutics, Inc. and the Chief Business Officer and Principal Financial Officer at Epizyme, Inc.

- **Appointed Howard Franklin, MD, as Interim Chief Medical Officer (CMO):** Finch has appointed Howard Franklin, MD, as Interim CMO. Dr. Franklin, who served as CMO at Salix Pharmaceuticals, Inc. prior to joining Finch, has more than 20 years of experience as a general surgeon and biopharmaceutical executive, with deep expertise spanning clinical development, regulatory strategy, medical affairs, and product commercialization.

- **Restructured Workforce to Focus Resources on Key Development Programs:** In April 2022, Finch announced plans to reduce its workforce by approximately 20%. This workforce reduction is intended to allow the company to focus its financial resources on its recurrent CDI and ASD development programs, two wholly-owned programs that Finch is prioritizing, along with its Takeda-partnered work in inflammatory bowel disease (IBD).

Corporate Update Conference Call and Webcast

Finch management will host a conference call and live webcast on Monday, May 16, 2022, at 8:00 am ET to discuss updates to its development programs and other business highlights. The conference call can be accessed by dialing (833) 649-1186 (domestic) or (270) 823-1080 (international) and entering conference ID 8451806. The live webcast can be accessed by visiting the "Investors & News" section of the Finch website and selecting "Events & Presentations." The webcast will be archived on the website for approximately 30 days following the event.

First Quarter 2022 Financial Results

- Finch reported a net loss of $24.6 million for the first quarter of 2022, compared to a net loss of $14.0 million for the same period in 2021. The net loss was driven by an increase in operating expenses of $7.4 million compared to the first quarter of 2021, in addition to a decrease in revenue of $3.2 million, primarily due to the November 2021 amendment to the agreement with Takeda, pursuant to which we 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.

- Research and development expenses were $15.5 million for the first quarter of 2022, compared to $13.0 million for the same period in 2021. The increase was 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. The increase was partially offset by a decrease in IBD program expenses due to the transition of primary responsibilities for TAK-524 from Finch to Takeda in the third quarter of 2021.

- General and administrative expenses were $9.4 million for the first quarter of 2022, compared to $4.6 million for the same period in 2021. The increase was primarily due to an increase in personnel costs including stock-based compensation, an increase in directors and officers insurance expense, and an increase in legal and professional costs, including costs associated with being a public company.

- Finch's cash and cash equivalents as of March 31, 2022 was $106.9 million, compared to $133.5 million as of December 31, 2021. Finch believes its cash and cash equivalents on hand as of March 31, 2022, together with anticipated, non-dilutive sources of additional cash, will fund its operations into Q2 2024. These anticipated sources of cash include $15 million of funding that has now been drawn under the recent debt facility with Hercules Capital, a $10 million tranche of funding that is available at Finch's discretion under this debt facility, expected near term milestones from the Takeda partnership, and the expected subletting of one of Finch's office and lab facilities.

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. We routinely post information that may be important to our investors on our website at www.finchtherapeutics.com. The Company 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 execute upon its mission and strategic priorities; Finch's ability to complete additional activities that it believes will enable it to proceed with enrollment in PRISM4 and the anticipated timeline for results from the trial; the design of Finch's AUSPIRE trial, Finch's plans to advance FIN-211 into the clinic and the anticipated timeline for submitting an IND for FIN-211; the potential for the modifications to the AUSPIRE trial design to enable the company to draw more meaningful insights into the potential impact of FIN-211 on behavioral and GI symptoms; the workforce reduction and Finch's ability to focus its financial resources on its existing development programs; Finch's ability to build its platform and plan for its future development of commercial supply needs; and Finch's anticipated runway, including accessing additional sources of capital. 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 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 (Unaudited)
(in thousands, except share and per share data)

	FOR THE THREE MONTHS ENDED MARCH 31,	
	2022	**2021**
Revenue:		
Collaboration revenue	$ 354	$ 3,553
Total revenue	354	3,553
Operating expenses:		
Research and development	15,530	12,975
General and administrative	9,404	4,552
Total operating expenses	24,934	17,527
Loss from operations	(24,580)	(13,974)
Other income (expense)	13	(7)
Net loss	$ (24,567)	$ (13,981)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.52)	$ (1.00)
Weighted-average common stock outstanding—basic and diluted	47,528,948	14,033,273

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

	MARCH 31, 2022	**DECEMBER 31, 2021**
Assets:		
Cash and cash equivalents	$ 106,931	$ 133,481
Other assets	97,702	91,888

Total assets	$ 204,633	$ 225,369
Liabilities, redeemable convertible preferred stock and stockholders' equity		
Liabilities	24,842	23,145
Stockholders' equity	179,791	202,224
Total liabilities, redeemable convertible preferred stock and stockholders' equity	$ 204,633	$ 225,369