



Finch Therapeutics Reports Third Quarter 2021 Financial Results and Provides Business Updates

November 10, 2021

- *New positive topline data from 132-participant PRISM-EXT Phase 2 open-label trial of CP101 in recurrent *C. difficile* infection (CDI) show 80.3% sustained clinical cure rate through 8 weeks, with a similar rate maintained through 24 weeks*
- *New data presented at ACG annual meeting from PRISM3 Phase 2 trial of CP101 in recurrent CDI show a statistically significant improvement in sustained clinical cure and a safety profile similar to placebo through 24 weeks*
- *Initiated enrollment in PRISM4 Phase 3 trial of CP101 in recurrent CDI*
- *Continued progress advancing platform and development programs, with construction completed on new manufacturing facility and two programs positioned to enter the clinic in 2022*

SOMERVILLE, Mass., Nov. 10, 2021 (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 financial results for the third quarter ended September 30, 2021 and provided business updates.

"We are pleased to have recently shared additional positive clinical data supporting our lead candidate CP101 for the prevention of recurrent *C. difficile* infection, including new topline data from our PRISM-EXT Phase 2 open label trial, as well as additional data from our PRISM3 Phase 2 trial that were presented at this year's ACG meeting. These data highlight the growing evidence and momentum supporting our lead candidate, and more broadly, provide a firm foundation for the development of the next wave of candidates in our growing pipeline," said Mark Smith, PhD, Chief Executive Officer of Finch Therapeutics. "As we look ahead, Finch is poised to enter a transformational period, with a Phase 3 trial underway for CP101 and our development programs targeting autism and chronic hepatitis B infection scheduled to enter the clinic in 2022. We believe that readouts from these next programs will further demonstrate the potential for microbiome therapeutics to become the next new modality that transforms patient care across multiple therapeutic areas."

Recent Highlights

- **Reported Positive Topline Results from PRISM-EXT Phase 2 Trial of CP101 in Recurrent CDI:** In November 2021, Finch reported positive topline results from PRISM-EXT, a Phase 2 open-label trial evaluating CP101 for the prevention of recurrent CDI. Of the 132 participants who received CP101 following standard-of-care antibiotics, 80.3% and 78.8% of participants achieved sustained clinical cure through 8 weeks and 24 weeks post-treatment, respectively. There were no treatment-related serious adverse events reported and CP101 exhibited an overall safety profile consistent with the profile observed in PRISM3. The PRISM-EXT results are consistent with and build on the previously reported PRISM3 Phase 2 trial results, which showed that CP101 met its primary efficacy endpoint with a statistically significant improvement in the prevention of recurrent CDI compared to placebo through 8 weeks post-treatment. Across PRISM-EXT and PRISM3, 234 doses of CP101 have been administered to 214 participants, which we believe is the largest clinical dataset reported to date for an orally administered investigational microbiome therapeutic.
- **Initiated Enrollment in PRISM4 Phase 3 Trial of CP101 in Recurrent CDI:** In November 2021, Finch announced the start of enrollment in PRISM4, a Phase 3 randomized, placebo-controlled trial that is expected to enroll approximately 300 participants with recurrent CDI. PRISM4 is designed to serve as the second pivotal trial of CP101 for the prevention of recurrent CDI.
- **Presented Additional Positive Data from PRISM3 Phase 2 Placebo-Controlled Trial of CP101 in Recurrent CDI at American College of Gastroenterology (ACG) Annual Meeting:** Data presented at ACG in October 2021 from the PRISM3 Phase 2 trial showed that CP101 demonstrated statistically significant improvement in the prevention of recurrent CDI compared to placebo and a safety profile similar to placebo through 24 weeks post-treatment.
- **Completed Construction of New Manufacturing Facility:** Finch recently completed the construction of its new manufacturing facility designed to support the manufacture of its microbiome product candidates for clinical trials and potential commercialization. Commissioning and qualification activities are underway for the newly constructed facility.
- **AUSPIRE Phase 1b Trial of FIN-211 in Children with Autism Spectrum Disorder (ASD) and Gastrointestinal Symptoms Expanded to Include a Second Cohort:** The AUSPIRE Phase 1b trial of FIN-211 in children with ASD and gastrointestinal (GI) symptoms will include a dose escalation portion (Part A) and a recently added expansion cohort (Part B). In Part A, two weeks of a low and high dose of FIN-211 will be evaluated in trial participants. In Part B, eight weeks of the highest tolerated FIN-211 dose from Part A will be evaluated in two groups, one that will receive vancomycin pre-treatment and one without vancomycin pre-treatment.
- **Takeda Accelerated Leadership Role in TAK-524 (formerly FIN-524) Ulcerative Colitis (UC) Development Program:** In August 2021, Finch announced that Takeda elected to accelerate the transition of development responsibility for TAK-524, a targeted consortia microbiome product candidate developed by Finch and Takeda for the treatment of UC. The transition will enable Takeda to leverage its expertise in inflammatory bowel disease throughout the clinical development of TAK-524.

Leadership Updates:

- **Transition of Chief Medical Officer (CMO):** In November 2021, Finch announced that Zain Kassam, MD, MPH elected to step down as CMO in order to return to Canada to attend to a family health matter. Dr. Kassam will continue to support Finch as a special advisor. Debra Silberg, MD, PhD, an accomplished gastroenterologist and pharmaceutical executive with 18 years of experience in clinical development, will serve as Finch's interim CMO and support the company through the transition and search for a new CMO.
- **Expanded Board of Directors:** In October 2021, Finch appointed Samuel Allen (AI) Hamood to its Board of Directors. Mr. Hamood is an accomplished executive with over 30 years of experience in finance, business development, corporate strategy, and M&A across several global industry sectors.
- **Strengthened Executive Leadership Team:** In September 2021, Finch appointed Marc Blaustein as Chief Operating Officer. Mr. Blaustein is a seasoned biopharmaceutical executive with more than 20 years of experience building and leading companies and critical business functions including operations, business development, program management, and manufacturing.

Key Anticipated Milestones

- Initiation of AUSPIRE Phase 1b trial of FIN-211 in children with ASD and GI symptoms anticipated in the first half of 2022, with an interim readout expected from the dose escalation portion of the trial in the second half of 2022 and topline data from the expansion cohort expected in 2023.
- Initiation of RECLAIM Phase 1b trial of CP101 in chronic HBV infection anticipated in early 2022, with topline data from an initial cohort expected in the second half of 2022.
- Topline data readout from PRISM4 Phase 3 trial of CP101 in recurrent CDI expected in the first half of 2023.

Third Quarter 2021 Financial Results

- Finch reported a net loss of \$10.0 million for the third quarter of 2021 as compared to a net loss of \$10.1 million for the same period in 2020. The net loss was driven by an increase in research and development expenses, as well as increased costs related to the infrastructure needed to support Finch's growth, which was offset by collaboration revenue earned through our agreement with Takeda.
- Research and development expenses for the third quarter of 2021 were \$15.5 million compared with \$9.0 million for the same period in 2020. The increase was primarily due to an increase in personnel costs, manufacturing related expenses and early asset discovery work. Increases were also due to expansion and development of Finch's chronic HBV and ASD programs.
- General and administrative expenses for the third quarter of 2021 were \$5.7 million, as compared with \$2.8 million for the same period in 2020. The increase was primarily due to increased headcount to support Finch's operational growth, an increase in business insurance costs and an increase in professional fees to support Finch's transition to a public company.
- Finch's cash and cash equivalents as of September 30, 2021 was \$149.2 million compared to \$99.7 million as of December 31, 2020. Finch expects that the cash and cash equivalents it had on hand at September 30, 2021 will be sufficient to fund 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. In June 2020, Finch announced that CP101 met its primary efficacy endpoint in PRISM3, the first of two pivotal trials to support the development of CP101 for the prevention of recurrent CDI. PRISM4, a Phase 3 trial, is designed to serve as the second pivotal trial of CP101 for recurrent CDI. Finch is also developing CP101 for the treatment of chronic hepatitis B virus infection, and FIN-211 for the treatment of the gastrointestinal and behavioral symptoms of autism spectrum disorder. 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 structure and timing of Finch's clinical trials and the period during which the results of trials will be available, including specifically the total enrollment of PRISM4, Finch's Phase 3 clinical trial in CDI and the initiation of Phase 1 trials in ASD and chronic HBV, and the release of topline data from each of those trials; Finch's ability to advance the development of a novel class of therapeutics, including through the manufacture of its product candidates at its newly completed manufacturing facility; and the therapeutic value, development, and commercial potential of microbiome therapeutics. 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: 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 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); 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; anticipated regulatory approvals may be delayed or refused; 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 August 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:

Laurence Watts
 Gilmartin Group
 (619) 916-7620
 laurence@gilmartinir.com

or

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)

	<u>FOR THE THREE MONTHS ENDED SEPTEMBER 30,</u>		<u>FOR THE NINE MONTHS ENDED SEPTEMBER 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Revenue:				
Collaboration revenue	\$ 11,343	\$ 1,733	\$ 17,726	\$ 5,582
Royalty revenue from related party	—	38	—	330
Total revenue	<u>11,343</u>	<u>1,771</u>	<u>17,726</u>	<u>5,912</u>
Operating expenses:				
Research and development	15,537	9,045	42,476	24,577
General and administrative	5,739	2,807	16,173	7,639
Total operating expenses	<u>21,276</u>	<u>11,852</u>	<u>58,649</u>	<u>32,216</u>
Loss from operations	(9,933)	(10,081)	(40,923)	(26,304)
Other (expense) income	(22)	(9)	1,818	54
Net loss	<u>\$ (9,955)</u>	<u>\$ (10,090)</u>	<u>\$ (39,105)</u>	<u>\$ (26,250)</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (0.21)</u>	<u>\$ (1.22)</u>	<u>\$ (1.07)</u>	<u>\$ (3.25)</u>
Weighted-average common stock outstanding—basic and diluted	<u>47,445,195</u>	<u>8,258,537</u>	<u>36,408,506</u>	<u>8,065,730</u>

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

	<u>SEPTEMBER 30, 2021</u>	<u>DECEMBER 31, 2020</u>
	Assets:	
Cash and cash equivalents	\$ 149,200	\$ 99,710
Other assets	83,779	65,628
Total assets	<u>\$ 232,979</u>	<u>\$ 165,338</u>

Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)

Liabilities	13,178	28,002
Redeemable convertible preferred stock	—	233,054
Stockholders' equity (deficit)	<u>219,801</u>	<u>(95,718)</u>
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 232,979</u>	<u>\$ 165,338</u>