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 10, 2021

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, Suite 400 Somerville, Massachusetts 02143		**02143**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (617) 229-6499

Not Applicable
(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 1.01. Entry into a Material Definitive Agreement.

On August 9, 2021, Finch Therapeutics, Inc. ("FTI"), a direct, wholly owned subsidiary of Finch Therapeutics Group, Inc. (the "Company") and Takeda Development Center Americas, Inc. ("Takeda"), entered into an amendment (the "Amendment") to the Amended and Restated Agreement, dated October 21, 2019, by and between FTI and Millennium Pharmaceuticals, Inc. ("Millennium"), a wholly owned subsidiary of Takeda Pharmaceuticals USA, Inc. (the "Takeda Agreement").

Under the terms of the Takeda Agreement, among other things, FTI and Millennium agreed to jointly develop the microbiome therapeutic candidate FIN-524, with FTI primarily responsible for early-stage development and manufacturing activities. Pursuant to the Amendment, FTI and Takeda will transition primary responsibility for such development and manufacturing activities from FTI to Takeda in accordance with a transition plan, and Takeda will assume sole responsibility for regulatory matters with respect to FIN-524. FTI will have the right to provide input with respect to the design of the first Phase 1 and Phase 2 clinical trials of FIN-524 in ulcerative colitis in the United States. Further, FTI will remain responsible for certain development activities designated in the FIN-524 development plan, for which FTI will continue to receive reimbursement from Takeda.

The foregoing description of the Amendment is qualified in its entirety by reference to the complete text of the Amendment, a copy of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending September 30, 2021.

Item 8.01. Other Events.

On August 10, 2021, the Company issued a press release announcing the Amendment. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated August 10, 2021.
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 10, 2021

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

Finch Therapeutics Announces Takeda to Accelerate Leadership Role in FIN-524 Ulcerative Colitis Development Program

- *Finch to transfer FIN-524 program to Takeda for clinical development*
- *Finch and Takeda to continue discovery efforts targeting Crohn's disease*

SOMERVILLE, Mass., August 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 announced that Takeda Pharmaceutical Company Limited ("Takeda") has elected to accelerate the transition of development responsibility for the FIN-524 ulcerative colitis development program. Takeda will assume primary development responsibility for the program, now known as TAK-524, ahead of the planned initiation of clinical-stage development. The transition will enable Takeda to leverage its expertise in inflammatory bowel disease (IBD) throughout the clinical development of FIN-524/TAK-524.

"Microbiome research is an important pillar of our drug discovery strategy as we continue to invest in novel approaches to treat chronic GI disorders," said Gareth Hicks, PhD, Vice President & Head of Gastroenterology Drug Discovery Unit at Takeda. "Through our successful collaboration with our expert partners Finch, TAK-524 is now poised to become Takeda's third clinical-stage program leveraging state-of-the-art approaches to intervene in the gut microbiome for the treatment of GI disease."

"We are thrilled that Takeda, a global leader in the treatment of IBD, has opted to accelerate its role in advancing TAK-524 for ulcerative colitis. We believe that Takeda's leadership and experience in IBD will be a critical asset for the program as Takeda prepares to advance TAK-524 into clinical development," said Mark Smith, PhD, Chief Executive Officer of Finch Therapeutics. "We look forward to continuing our collaboration with Takeda to support the TAK-524 program along with our joint discovery work in Crohn's disease, while we continue to advance other exciting programs in our pipeline."

FIN-524/TAK-524 is an investigational, orally administered targeted consortia product candidate composed of both spore-forming and non-spore-forming bacterial strains selected for the treatment of ulcerative colitis. FIN-524/TAK-524 is designed to treat ulcerative colitis by harnessing the gut microbiome's ability to modulate the host immune system.

About the Collaboration and License Agreement

In 2017, Finch entered into a worldwide collaboration agreement with Takeda to jointly develop FIN-524/TAK-524 for the treatment of inflammatory bowel disease. Under the terms of the agreement, Finch received an upfront payment of $10 million from Takeda for the exclusive worldwide rights to develop and commercialize FIN-524/TAK-524. Finch has received $4 million in milestone payments to date for FIN-524/TAK-524 and is eligible to receive up to an additional $176 million in payments upon achievement of certain development, regulatory, and commercial milestones, as well as tiered royalties ranging from mid to high-single digits on worldwide net sales of FIN-524/TAK-524. Under the terms of the original agreement, Finch was primarily responsible for early-stage development activities through

Phase 2 clinical trials. Under the terms of an amended agreement executed in August 2021, Takeda will assume primary development responsibility for FIN-524/TAK-524 prior to the start of clinical-stage development. After the transition, Finch plans to provide Takeda with ongoing technical support through the anticipated Phase 1 trial of FIN-524/TAK-524 in ulcerative colitis.

About FIN-524/TAK-524 for Ulcerative Colitis

FIN-524/TAK-524 is an investigational, orally administered targeted consortia product candidate composed of both spore-forming and non-spore-forming bacterial strains selected for the treatment of ulcerative colitis. The consortia is designed to include strains that target multiple defined mechanisms of action combined with donor strains linked to remission following fecal microbiota transplantation (FMT) in patients with ulcerative colitis. The design of FIN-524/TAK-524 leverages Finch's machine-learning based platform and data from FMT studies in ulcerative colitis. Machine learning was used to identify microbes and microbial functions deficient in patients with ulcerative colitis. Human FMT data was leveraged to identify organisms consistently enriched in ulcerative colitis patients that successfully responded to FMT. Target organisms were isolated directly from the specific donors whose samples induced response or remission in clinical studies of FMT for ulcerative colitis. The manufacture of FIN-524/TAK-524 is donor independent, with the strains grown from master cell banks.

About Ulcerative Colitis

Ulcerative colitis is one of the most common types of inflammatory bowel disease (IBD), an autoimmune condition that causes inflammation of the gastrointestinal (GI) tract. Approximately 10 million people are affected by IBD worldwide, including about three million people in the US. Symptoms of IBD include severe, chronic abdominal pain, diarrhea, GI bleeding, weight loss, and fatigue. Current treatment options are ineffective for many people with IBD.

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, 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.

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: Finch’s ability to advance the development of a novel class of therapeutics, including with respect to FIN-524/TAK-524; the therapeutic value and development of FIN-524/TAK-524 for the treatment of ulcerative colitis, including Takeda’s ability and timing to initiate clinical trials; the results of the Collaboration and License Agreement; Finch’s pipeline and ability to develop additional product candidates; and the initiation and timing of Finch’s clinical trials. 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 or Takeda 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 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 FIN-524/TAK-524, 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 and Takeda’s ability to maintain patent and other intellectual property protection and the possibility that Finch or Takeda’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 May 13, 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.

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

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