UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2021

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-40227

FINCH THERAPEUTICS GROUP, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**82-3433558**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
200 Inner Belt Road, Suite 400 Somerville, Massachusetts	**02143**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 229-6499

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

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of common stock held by non-affiliates of the registrant computed by reference to the price of the registrant's common stock as of June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $354.9 million (based on the last reported sale price on the Nasdaq Global Select Market as of such date). For this computation, the registrant has excluded the market value of all shares of common stock reported as beneficially owned by its executive officers, directors and stockholders that the registrant has concluded are affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 24, 2022, there were 47,532,573 outstanding shares of the registrant's common stock, par value of $0.001 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement for the 2022 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year ended December 31, 2021, are incorporated by reference in Part III of this Form 10-K.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report on Form 10-K are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will” or “would,” or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the initiation, timing, progress and results of our current and future preclinical studies and clinical trials and related preparatory work and the period during which the results of the trials will become available, as well as our research and development programs, including our ability to resolve the clinical hold on our investigational new drug application for CP101;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to obtain regulatory approval of CP101, FIN-211 and any other current or future product candidates that we develop;
- our ability to identify and develop additional product candidates;
- our ability to advance product candidates into, and successfully complete, preclinical studies and clinical trials;
- business disruptions affecting the initiation, patient enrollment, development and operation of our clinical trials, including a public health emergency, such as the ongoing COVID-19 pandemic and any variants;
- our expectations regarding the potential market size and the rate and degree of market acceptance for any product candidates that we develop;
- the effects of competition with respect to CP101, FIN-211 or any of our other current or future product candidates, as well as innovations by current and future competitors in our industry;
- our ability to fund our working capital requirements;
- our intellectual property position, including the scope of protection we are able to establish, maintain and enforce for intellectual property rights covering our product candidates;
- our financial performance and our ability to effectively manage our anticipated growth;
- our ability to obtain additional funding for our operations; and
- other risks and uncertainties, including those listed under the section titled “Risk Factors.”

These forward-looking statements are based on our management’s current expectations, estimates, forecasts and projections about our business and the industry in which we operate, and management’s beliefs and assumptions and are not guarantees of future performance or development. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under “Risk Factors” and elsewhere in this report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

SPECIAL NOTE REGARDING COMPANY REFERENCES

Unless the context otherwise requires, references in this Annual Report on Form 10-K to "FTG," the "Company," "we," "us" and "our" refer to Finch Therapeutics Group, Inc. and its subsidiaries.

SPECIAL NOTE REGARDING TRADEMARKS

All trademarks, trade names and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners.

RISK FACTORS SUMMARY

The following is a summary of the principal risks that could adversely affect our business, financial condition, operating results, cash flows or stock price. Discussion of the risks listed below, and other risks that we face, are discussed in the section titled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K.

- We face substantial competition, which may result in others developing or commercializing drugs before or more successfully than us.
- Our business and operations may be adversely affected by the evolving and ongoing COVID-19 global pandemic.
- We are currently subject to a clinical hold on our IND for CP101. We need to resolve the FDA clinical hold issues in order to proceed with enrollment in our PRISM4 clinical trial and initiate our Phase 1b clinical trial in Autism Spectrum Disorder (ASD). Our business may be adversely affected if the clinical hold is not resolved in a timely manner or if regulatory concerns lead to additional delays and/or FDA enforcement actions.
- We have a limited operating history, have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.
- We will require substantial additional funding to finance our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our product development programs or other operations.
- We are heavily dependent on the success of our product candidates, which are in clinical and preclinical development. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.
- Our product candidates are based on microbiome therapeutics, which is an unproven approach to therapeutic intervention.
- Our product candidates may be associated with serious adverse, undesirable or unacceptable side effects or other properties or safety risks, which may delay or halt their clinical development, or prevent marketing approval.
- The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- The manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-up of our manufacturing capabilities.
- We rely on third-party donors of biological material to manufacture certain product candidates such as CP101 and FIN-211, and if we do not obtain an adequate supply of acceptable material from those qualified donors, the clinical and commercial supply of these product candidates may be adversely impacted.
- We operate our own manufacturing facility for certain product candidates, which requires significant resources and we may fail to successfully operate our facility, which could adversely affect our clinical trials and the commercial viability of our product candidates.
- We have never commercialized a product candidate and may experience delays or unexpected difficulties in obtaining regulatory approval for our current or future product candidates for our initial or potential additional indications.
- We rely on third parties to supply and manufacture our product candidates, and we expect to continue to rely on third parties to manufacture our products, if approved.
- If we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market.

PART I

Item 1. Business.

Overview

We are a clinical-stage microbiome therapeutics company leveraging our Human-First Discovery platform to develop a novel class of orally administered biological drugs. The microbiome consists of trillions of microbes that live symbiotically in and on every human and are essential to our health. When key microbes are lost, the resulting dysbiosis can increase susceptibility to immune disorders, infections, neurological conditions, cancer and other serious diseases. We are developing novel therapeutics designed to deliver missing microbes and their clinically relevant biochemical functions to correct dysbiosis and the diseases that emerge from it. Our Human-First Discovery platform uses reverse translation to identify diseases of dysbiosis and to design microbiome therapeutics that address them. We believe that our differentiated platform, rich pipeline and the broad therapeutic potential of this new field of medicine position us to transform care for a wide range of unmet medical needs.

Our lead product candidate, CP101, is an orally administered complete microbiome therapeutic in development for the prevention of recurrent *Clostridioides difficile* infection, or CDI. In June 2020, we reported positive topline data from our Phase 2 placebo-controlled clinical trial of CP101 for the prevention of recurrent CDI, which we refer to as the PRISM3 trial, and in November 2021, we reported positive topline data from our open-label, Phase 2 clinical trial of CP101 for the prevention of recurrent CDI, which we refer to as the PRISM-EXT trial. We have designed a Phase 3 clinical trial, which we refer to as the PRISM4 trial, to serve as our second pivotal trial of CP101 for the prevention of recurrent CDI. On March 1, 2022, we announced that enrollment in PRISM4 was paused following receipt of a clinical hold letter on February 24, 2022 from the U.S. Food and Drug Administration, or the FDA, in connection with our investigational new drug application, or IND, for CP101, requesting additional information regarding our SARS-CoV-2 donor screening protocols, including, among other things, that we address the risk of SARS-CoV-2 transmission in the informed consent process, additional detail on how samples are shipped to the vendor performing the SARS-CoV-2 testing of the donor material and how inconclusive test results will be handled. We are also preparing to initiate a Phase 1b clinical trial of FIN-211 in autism spectrum disorder, or ASD; however, because FIN-211 includes donor-derived components, the clinical hold related to our IND for CP101 will also delay initiation of our clinical trial in ASD. We plan to manufacture additional lots of CP101 and FIN-211 to satisfy the FDA's requests related to SARS-CoV-2 screening and testing. We are currently evaluating the extent of the delay the clinical hold and related manufacturing activities will have on the timing for our clinical trials in CDI and ASD, which we expect to be at least one quarter based on manufacturing timelines; we describe the clinical hold and related matters further in the section entitled “Our Clinical Programs”.

CP101: Our Lead Product Candidate for the Prevention of Recurrent CDI

Our lead candidate, CP101, consists of a microbial community harvested from rigorously screened healthy donors that is lyophilized and formulated in orally administered capsules designed to release at the appropriate location in the gastrointestinal tract. CP101 is designed to deliver a complete microbiome, addressing the community-level dysbiosis that characterizes CDI. Patients with CDI suffer from severe diarrhea, which can progress to toxic megacolon and death, with more than 44,000 CDI-attributable deaths annually in the United States. In addition to the human cost, the economic impact of CDI is significant, with 2.4 million in-patient days and more than $5 billion in direct treatment costs each year in the United States alone. CDI often returns after cessation of antibiotic treatment because antibiotics do not address the dysbiosis that underlies this disease. We estimate there are approximately 200,000 cases of recurrent CDI annually in the United States.
In June 2020, we announced that PRISM3, the first pivotal trial of CP101, which was a randomized, blinded, placebo-controlled multi-center Phase 2 clinical trial, met its primary efficacy endpoint. Overall, 74.5% of participants who received a single administration of CP101 achieved a sustained clinical cure, defined as the absence of CDI through week 8, achieving statistical significance for the primary efficacy endpoint, with a clinically meaningful 33.8% relative risk reduction for CDI recurrence compared to placebo. In October 2021, we shared additional data from PRISM3 showing that the proportion of participants with sustained clinical cure (defined as absence of CDI recurrence) through week 24 remained significantly higher in the CP101 arm compared to the placebo arm. In PRISM3, the prevalence of adverse events was similar across CP101 and placebo arms, with no treatment-related serious adverse events in the CP101 arm.

In November 2021, we announced positive topline results from the 132-participant PRISM-EXT trial. The primary efficacy endpoint of the PRISM-EXT trial was sustained clinical cure (defined as absence of CDI recurrence) through 8 weeks post-treatment. Overall, 80.3% of participants who received a single oral administration of CP101 following standard-of-care, or SOC, antibiotics in PRISM-EXT achieved sustained clinical cure through week 8. At week 24, 78.8% of participants had

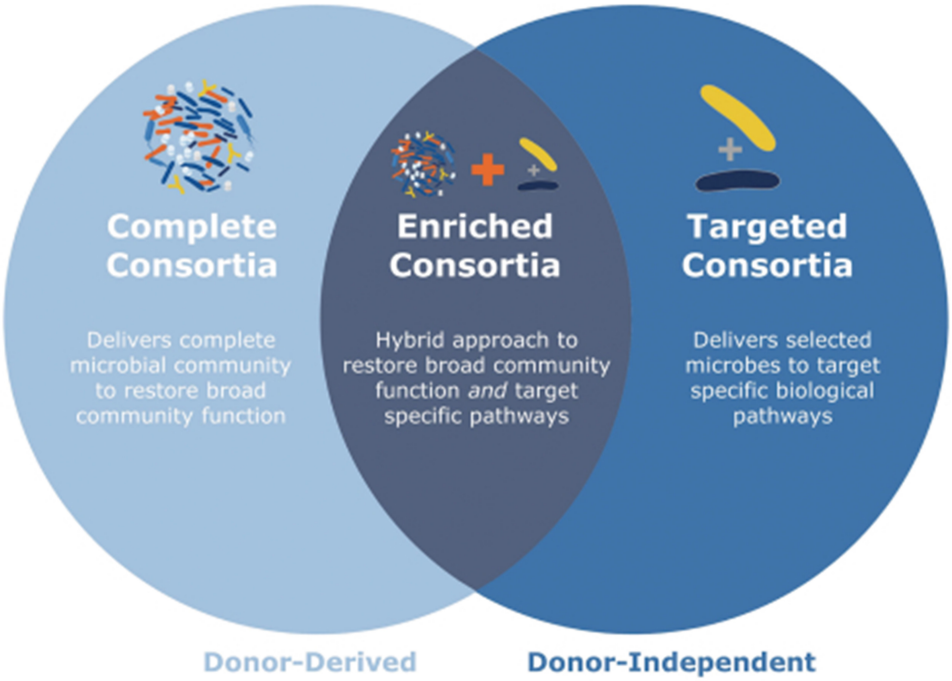
sustained clinical cure. In the PRISM-EXT trial, there were no treatment-related serious adverse events reported and CP101 exhibited an overall safety profile consistent with the profile observed in PRISM3. The PRISM-EXT results are consistent with and build on our previously reported PRISM3 results.

CP101 Program for the Treatment of Chronic HBV

Following a strategic review of our pipeline and business, we announced in March 2022 the decision to pause the development of CP101 for the treatment of chronic hepatitis B virus, or HBV. We believe this decision will allow us to maximize our working capital available for investment in our wholly-owned recurrent CDI and ASD programs. We may continue our research efforts in HBV in the future as our portfolio continues to mature.

Developing Capabilities for Targeted and Enriched Consortia Product Candidates

In addition to developing CP101, a Complete Consortia product candidate designed to address community-level dysbiosis, or disruption across many functional pathways and species, we are also developing Targeted Consortia product candidates that consist of individual bacteria grown from master cell banks to engage narrower pathway-level dysbiosis. The ability to pursue both of these product strategies enables us to tailor our product candidates to the pathophysiology of each indication. This combination of capabilities also enables us to pursue a third product strategy, Enriched Consortia, which addresses dysbiosis at both the community and pathway level. These product strategies are summarized in the schema below:



Our Human-First Discovery platform informs each of these product strategies using clinical interventional data, through a process of reverse translation. Core to this strategy is our ability to deploy our proprietary machine learning algorithms to mine clinical data generated internally and by third parties, including experience with fecal microbiota transplantation, or FMT, a procedure that has been used to restore the gut microbiome and address community-level dysbiosis. FMT is a procedure, not a product. It is not approved by the FDA, and there are no standards for testing, processing and delivery of FMT, though it typically requires a colonoscopy. Despite these limitations, FMT has been used to treat more than 60,000 patients, with hundreds of clinical studies ongoing across a range of disease areas. We believe that this data can be used to (1) identify diseases where addressing dysbiosis provides therapeutic benefit, (2) reveal the mechanisms that underlie these results and (3) uncover key microbes and functional pathways that drive these clinical outcomes. We believe this reverse translation strategy is the optimal approach to developing microbiome therapeutics, providing causal insights that cannot be gleaned from preclinical *in vitro* or *in vivo* experiments alone. We further believe that we are uniquely positioned to execute

on this strategy because of our proprietary FMT database and biorepository, our broad network of collaborators that supports the rapid growth of our data assets and our proprietary machine learning algorithms that enable the efficient translation of clinical data into therapeutic insights.

FIN-211: Our Product Candidate to Address Gastrointestinal and Behavioral Symptoms of ASD

We have used our Human-First Discovery platform to develop FIN-211, an Enriched Consortia product candidate that we are advancing to address the gastrointestinal and behavioral symptoms of ASD. Scientific research in human and animal models have highlighted the "gut-brain axis" linking dysbiosis to neurological and neurobehavioral conditions, as the microbiome impacts the enteric nervous system and the production of neurotransmitters. This basic research is supported by a growing body of third-party clinical research. An open-label, proof-of-concept FMT trial observed that, two years after treatment, 33% of the study participants who had previously been diagnosed with ASD were below the ASD diagnostic cutoff score for the Childhood Autism Rating Scale (CARS), a commonly used ASD diagnostic tool. In another open-label randomized, controlled trial, children with ASD receiving FMT and behavioral therapy showed a statistically significant improvement in their behavioral symptoms compared to those receiving behavioral therapy alone. Both studies also observed marked improvements in the gastrointestinal symptoms that many autistic children suffer from. There are no FDA-approved therapies for the core symptoms of ASD and the total financial burden of care for this condition is estimated to exceed $100 billion in the United States annually. We have received feedback from the FDA that demonstrating a benefit for either gastrointestinal or behavioral symptoms of ASD could support a biologics license application. Building on our discussions with the FDA, we aim to continue to validate behavioral instruments as part of our clinical development plans. We have designed FIN-211 to address both behavioral and gastrointestinal aspects of ASD, which we plan to assess, along with safety and tolerability, in a Phase 1b clinical trial of FIN-211 in ASD. We believe FIN-211 has the potential to transform care for patients with ASD.

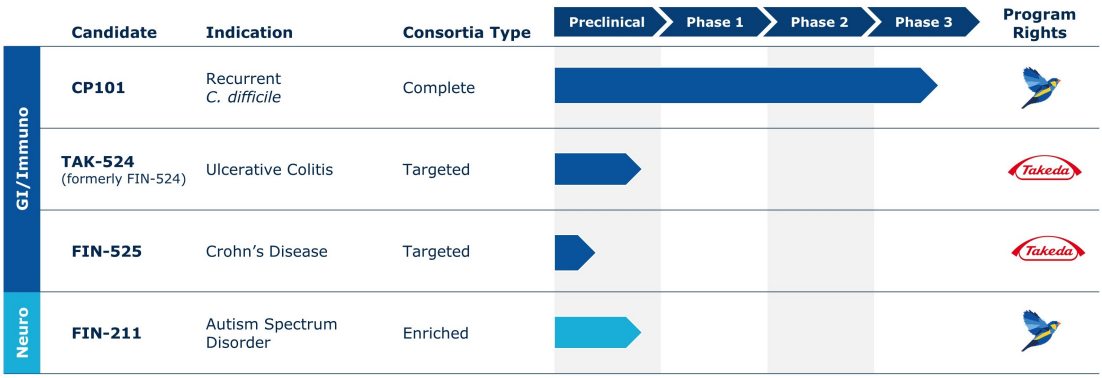
TAK-524 (formerly FIN-524) Ulcerative Colitis Development Program in Collaboration with Takeda

In collaboration with Takeda Pharmaceutical Company Limited, or Takeda, we are also developing Targeted Consortia product candidates for inflammatory bowel disease. In August 2021, we announced that Takeda elected to accelerate its leadership role in the FIN-524 ulcerative colitis development program, now known as TAK-524. Accordingly, we transferred the program to Takeda for further development. The design of product candidate TAK-524 leverages computational and molecular analysis of data from 146 patients treated with FMT and 19 observational studies of an additional 2,210 patients. We believe that the development program for TAK-524, which is a Targeted Consortia product candidate composed of strains grown from master cell banks, is not affected by the clinical hold related to our IND for CP101.

FIN-525 for the Treatment of Crohn's Disease in Collaboration with Takeda

We continue to partner with Takeda on discovery efforts targeting the development of FIN-525 for the treatment of Crohn's disease. We believe that the development program for FIN-525, which is a Targeted Consortia product candidate composed of strains grown from master cell banks, is not affected by the clinical hold related to our IND for CP101.

Our Pipeline



The Human Microbiome and its Impact on Disease

The human microbiome describes the community of more than 30 trillion microbes that reside on and inside the human body. By evolving together over millions of years, microbes and humans have developed an intricate and mutually beneficial relationship that has only recently been uncovered. Enabled by the genomic revolution, researchers have discovered that humans carry over 1,000-fold more microbial genes than host genes and that microbiome signaling is fundamentally intertwined with many aspects of human physiology ranging from immune and metabolic functions to neurological function and reproductive health. The deep inter-relationship between microbes and their human hosts is a co-evolution that has resulted in a learned dependency, leaving humans now reliant on inputs from this previously unrecognized organ system.

Disruption of the gut microbiome is associated with a large number of diseases that have dramatically increased in prevalence among populations in developed countries over the past century. We believe these epidemiological trends are linked to changes in the microbiome, which if reversed could potentially address an underlying cause of these diseases and change the epidemiology as a result. The rise of these chronic illnesses coincides with our adoption of a number of practices that disrupt the microbiome: more than 42 billion doses of antibiotics are administered annually, many killing 40-60% of microbial species in the gut; a third of babies in the United States today are born by caesarean sections, and are consequently unable to inherit this organ from their mother; and a highly sanitized and artificial environment, absent the environmental inputs expected by our microbiome, applies further pressure on this ecosystem within us. The effects of these environmental inputs coalesce around the gut microbiome resulting in dysbiosis and these changes are linked to a wide variety of chronic diseases. For example, antibiotic exposure doubles the risk of developing IBD, as well as significantly increases the risk of developing over 10 types of cancer. Early microbiome disruption is also associated with ASD, autoimmune indications such as celiac diseases, and allergies and asthma, and microbiome disruption later in life has been linked to neurodegenerative diseases, including Alzheimer’s disease and Parkinson’s disease. Importantly, in multiple animal models, these diseases can be induced by microbiome disruption and corrected by restoration, providing evidence of causality. For several of these therapeutic areas, this has been further bolstered by clinical data with FMT.

The effects of gut microbiome dysbiosis reverberates throughout the body, both because immune cells are heavily concentrated in the gut, where more than 70% of the body’s immune cells are located, and because microbial metabolites enter systemic circulation, acting on organs throughout the body. For example, researchers at the California Institute of Technology showed that the transfer of the microbiome from human donors with ASD into microbiome-free mice promoted hallmark autistic behaviors. In addition, a large body of research has documented the connection between over a dozen different microbiome species and molecular pathways connecting the gut’s enteric nervous system to the brain. We believe the gut-brain axis is but one example of how the microbiome can provide therapeutic benefits to diseases beyond the gut.

Restoring the microbiome, or its inputs, is an opportunity to directly address the underlying causes of many diseases driven by dysbiosis. Many existing drugs target only the downstream symptoms of disease, for example, anti-tumor necrosis factor, or anti-TNF, biologics are prescribed to IBD patients to suppress systemic immunity, without addressing the underlying drivers of gut inflammation and immune dysregulation. This can lead to unintended side effects as well as an incomplete resolution of disease. Treating the root cause of disease is more likely to deliver a therapeutic breakthrough and for many diseases of dysbiosis, we believe that only through the restoration of the critical physiological role of the microbiome organ can this be achieved. Currently there are no microbiome therapeutics approved by the FDA. We believe that our ability to target both community- and pathway-level dysbiosis through our Human-First Discovery platform uniquely positions us to deliver on this transformational opportunity to improve human health through microbiome therapeutics.

The human microbiome, a new organ system

>30 trillion cells	as many as human cells
>20 million genes	99.9% of the unique genes in humans are microbial
10,000 species	co-exist on and within us

The microbiome drives key elements of human physiology

Immune modulation	Metabolic function
Pathogen resistance	Neurological function

Our Approach

We develop microbiome therapeutics following a three-stage process that combines aspects of traditional drug development with the unique opportunities enabled by our platform. In the first stage, Human-First Discovery, we use human data to identify promising clinical indications, microbial mechanisms and a consortia that engages these mechanisms. The second stage consists of IND-enabling activities, including bioprocess and formulation development, quality control and current Good Manufacturing Practices, or cGMP, production. The third stage is clinical development, in which we leverage customized pharmacokinetic and pharmacodynamic assays to understand optimal dosing and delivery. Importantly, data from clinical development can feed directly back into Human-First Discovery, enabling iterative development of differentiated follow-on product candidates.

1.Our Human-First Discovery platform is designed to significantly reduce drug development time and translational risk. We have developed our Human-First Discovery platform to choose clinical indications, reveal mechanisms and create microbial compositions that engage our target mechanisms.

- **Clinical Indication Selection**: We aim to de-risk development by targeting indications with known underlying dysbiosis, an understanding of relevant mechanistic pathways and, critically, data from FMT that provide proof-of-concept that a microbial intervention has the potential to positively impact clinically meaningful outcomes. We have exclusive access to certain data and samples from groups that we believe are the largest providers of FMT in the world, including OpenBiome, which has delivered more than 60,000 FMTs to over 1,000 clinical sites. With more than 300 third-party clinical studies evaluating FMT around the world, we are uniquely well positioned to leverage this trove of clinical data to identify promising new drug development opportunities. We believe that by requiring a foundation of clinical data prior to indication selection and program initiation, our programs are already significantly de-risked before we begin development.
- **Target Identification and Validation**: We use translational assays and high-throughput sequencing to generate curated datasets from FMT studies, observational clinical studies, and sometimes preclinical models, for each target indication. We then use our expertise in microbial ecology enhanced by our proprietary machine learning tools to identify microbiome compositions and functions that are deficient in our target population and whose restoration is causally linked to improved outcomes. We believe that observational clinical studies and preclinical models are valuable for generating mechanistic hypotheses which can then be validated using interventional data from FMT. Taken together, these efforts provide molecular and microbial targets, specific metabolites or bacteria, that are linked to clinical outcomes.
- **Candidate Selection and Consortia Design**: To engage these targets, we deliver designed microbial consortia. The capability to deliver both a complete microbiome and targeted microbes gives us the flexibility to engage a diversity of mechanisms and therefore develop treatments for a wide range of indications. In diseases characterized by community-level dysbiosis like CDI, we are able to deploy Complete Consortia product candidates like CP101. In diseases where we are able to target pathway-level dysbiosis like IBD, we are able to deploy Targeted Consortia product candidates like TAK-524. Importantly, we have obtained exclusive access to

a library of more than 10,000 samples from certain donors that have each been administered to patients through FMT. We are able to cryo-revive and manufacture strains from these samples, enabling precise matching of the exact strain that was associated with clinical outcomes with FMT. We believe that this direct chain of custody from a clinical sample into a Targeted Consortia significantly reduces translational risk and is uniquely enabled by our proprietary partnerships. We are also able to engage both the Targeted and Complete Consortia product strategies in a single Enriched Consortia product candidate like FIN-211 for conditions like ASD that have both community- and pathway-level dysbiosis. We believe we are uniquely positioned to align product strategy with mechanism because of our capabilities to address community- or pathway-level dysbiosis.

2.Our IND-enabling workflow drives accelerated advancement into the clinic. We have developed a standardized workflow of key IND-enabling activities, transforming consortia designed to engage key microbial mechanisms into IND-ready product candidates.

- **Bioprocess and Formulation Development**: We have developed proprietary methods for growing, harvesting, purifying, preserving and delivering microbiome consortia. Of particular note, our advanced lyophilization technology enables the preservation of a complete microbiome in a stable formulation with at least two years of stability at 2°–8°C and up to six months of stability at room temperature to accommodate excursions during delivery and administration. Furthermore, we have developed orally administered, targeted release technologies, enabling intestinal release that facilitates robust pharmacokinetics. We believe that our deep expertise in bioprocess and formulation development have, and will continue to, enable rapid development of differentiated products.
- **Quality Control and Product Safety**: Unlike other product candidates in development, we have developed manufacturing processes that do not rely on non-specific biocides like ethanol to exclude potential pathogens. Instead, each of our product candidates leverages molecular screening technology to exclude potential pathogens and harmful antibiotic resistance or virulence elements. This technology enables us to exclude unwanted agents without compromising potentially beneficial microbes. In addition to these purity assays, we have also developed both culture-based and culture-independent measures of viability to provide consistent potency across lots.
- **cGMP Production**: We have developed cGMP production capabilities as a strategic asset, internalizing key activities that we believe we are uniquely positioned to execute, while externalizing activities that can be completed by third parties, in order to maximize our capital efficiency. As an example of this strategy in action, we are developing cGMP production capabilities for CP101, an orally administered Complete Consortia product candidate. With nearly a decade of operational experience and know-how enabling our Complete Consortia manufacturing platform, we believe we are uniquely positioned to enable this manufacturing process. By contrast, we have worked closely with third parties for the production of certain Enriched Consortia and Targeted Consortia product candidates. For these product candidates, there are rapidly maturing providers able to leverage analogous experience with large scale fermentation, including the required capital equipment and infrastructure to enable cGMP manufacture of these product candidates.

3.Our clinical development strategy is designed to enable rapid progression, expansion and iteration.

- **Progression**: We have developed a suite of customized pharmacokinetic and pharmacodynamic assays to maximize learning from our clinical programs to guide progression through clinical development. Our pharmacokinetic assays quantitatively assess the engraftment, or colonization in the intestine, of our consortia. Our pharmacodynamic assays measure the production of microbial metabolites and their downstream effects on the host.

- **Expansion**: When we initiate clinical development of a new program, we aim not only to inform the progression of the specific program under evaluation, but also to inform expansion into other indications. As an example, having determined that we are able to engraft a diverse microbial community and effectively restore missing metabolic pathways with CP101 for recurrent CDI, we are now able to use similar compositions in other indications that are tied to community-level dysbiosis. Because this community-level dysbiosis is common to many microbiome-associated diseases, we believe this particular product strategy may have broad applications, such that clinical validation in one indication de-risks the development of other indications with similar characteristics.

- **Iteration**: In addition to positioning our clinical development and translational medicine strategy to generate data that may inform expansion opportunities into new indications, we also believe that clinical data generated from

the development of product candidates like FIN-211 will provide a rich pool of data that we can mine with our Human-First Discovery platform to inform follow-on product candidates in the same indication with even more favorable product attributes. In this way, our clinical development is designed to feed back into discovery, enabling iterative improvement and life cycle management as we establish franchises in new indications.

Our Clinical Programs

CP101 for the Treatment of Recurrent CDI

Overview

Our lead product candidate, CP101, is an orally administered, complete microbiome therapeutic capsule designed to deliver an intact, functional microbiome to durably repair community-level dysbiosis. CP101 contains microbial communities harvested from rigorously screened, healthy human stool samples that have been purified, tested, stabilized, characterized and formulated in acid-resistant capsules to facilitate intestinal release after passage through the stomach.

Pathogen exclusion in CP101 is based on proprietary testing and characterization technology developed through discussions with the FDA; unlike other orally administered microbiome therapeutic candidates in development, it does not rely on non-specific biocides such as ethanol, which inactivate both beneficial and potentially pathogenic bacteria. Instead, our technology enables us to identify suitable microbial communities prior to manufacture, without requiring destructive interference in the healthy community needed to repair community-level dysbiosis. This enables CP101 to deliver a complete consortium of microbial communities rather than narrow and variable subsets of the microbiome. Our product qualification strategy is supported by the proprietary chemistry and processing techniques that optimize community viability during lyophilization, processing and administration. This fully integrated manufacturing process is designed to consistently deliver a complete microbiome.

Our production process for CP101 is designed to be scalable. We typically collect many samples from each donor and we are able to produce many treatments from each sample collected. As a result, a small pool of donors can support a large production base. For example, we believe a pool of 200 active donors could support production of approximately 100,000 treatments of CP101 annually. Furthermore, our process is designed to yield a favorable stability profile, with at least 24 months of stability at 2°–8°C and up to six months of stability at 25°C to allow for temperature excursions during delivery and administration. We believe this favorable stability profile will simplify supply chain logistics and enable more convenient care. CP101 has received Fast Track designation and Breakthrough Therapy designation from the FDA for the prevention of recurrent *Clostridioides difficile* infection, or recurrent CDI. Breakthrough Therapy designation provides expedited review and access to collaborate with the FDA on rapid development of CP101.

Clinical Hold

Following receipt of a clinical hold letter from the FDA related to our IND for CP101 on February 24, 2022, or the February 2022 Clinical Hold Letter, we paused enrollment in PRISM4, our Phase 3 clinical trial of CP101 in recurrent CDI. In the February 2022 Clinical Hold Letter, the FDA requested additional information about our SARS-CoV-2 donor screening protocols, including, for example, additional detail on how samples are shipped to the vendor performing the SARS-CoV-2 testing of the donor material and how inconclusive test results will be handled, as well as updating the informed consent process to address the risk of SARS-CoV-2 transmission, including, for example, the limitations of laboratory screening.

In March 2020, at the outset of the COVID-19 pandemic, the FDA issued a public safety alert regarding the potential risk of transmission of SARS-CoV-2 virus through the use of donor-derived investigational microbiome therapies and the need for additional safety precautions. At that time, the FDA placed our IND for CP101 on partial clinical hold, requiring us to implement new SARS-CoV-2 screening measures for any microbiota material donated on or after December 1, 2019 and to address the risk of SARS-CoV-2 transmission in the informed consent process. At that time, the FDA also placed the IND of OpenBiome, a manufacturer that we had contracted with to produce clinical raw material, on a partial clinical hold for the same reasons. Notwithstanding the partial clinical hold notices, we were able to continue dosing patients in our then-ongoing PRISM-EXT trial of CP101 in recurrent CDI as all of the CP101 lots used for PRISM-EXT were manufactured from material donated prior to December 1, 2019.

In January 2021, OpenBiome was released from partial clinical hold after implementing, among other things, a direct testing method for SARS-CoV-2. In March 2021, we acquired certain manufacturing assets from OpenBiome, and in November

2021, we began dosing participants in PRISM4 with CP101 lots that had been screened for SARS-CoV-2 using the same testing method and vendor used by OpenBiome.

Following communications with the FDA in January 2022, on February 24, 2022, the FDA sent the February 2022 Clinical Hold Letter to us stating that the FDA required additional information about our SARS-CoV-2 screening protocols and related informed consent language, and that a clinical hold remains in effect until the FDA's requests have been satisfactorily addressed. The February 2022 Clinical Hold Letter did not reference any adverse clinical outcome experienced in any of our clinical trials. We have informed the FDA that participants were dosed in PRISM4 while the clinical hold was in effect and we are conducting a quality investigation of the matter. We are communicating with the FDA regarding the quality investigation, and we have committed to addressing any relevant findings prior to proceeding with enrollment in PRISM4. We have submitted a Complete Response to the February 2022 Clinical Hold Letter and we are communicating with the FDA to resolve the clinical hold as soon as possible.

On March 17, 2022, we received an additional letter from the FDA, or the March 2022 Letter, 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 our release tests. We are unable to proceed with enrollment in PRISM4 until the FDA removes the clinical hold, we address findings from our related quality investigation, we complete related manufacturing activities to satisfy the FDA's requests related to SARS-CoV-2 screening and testing (which includes manufacturing additional lots of CP101), and we satisfactorily address the matters raised in the March 2022 Letter. We are currently evaluating the extent of the delay these activities will have on the anticipated timing for resuming enrollment in PRISM4 and, based on manufacturing timelines, we expect at least a one-quarter delay.

Indication Overview

Clostridioides difficile, or *C. difficile*, is a toxin-producing, spore-forming bacterium that causes severe and persistent diarrhea in infected individuals. *C. difficile* expresses toxins that lead to inflammation of the colon, severe diarrhea and abdominal pain, as well as potentially more serious clinical outcomes including toxic megacolon, perforation of the colon, and death. The Centers for Disease Control and Prevention considers CDI to be one of the top five most urgent antibiotic resistant threats and the most common healthcare-associated infection in the United States. We estimate that there are over 450,000 cases of primary CDI and approximately 200,000 cases of recurrent CDI annually in the United States, collectively resulting in more than 44,000 CDI-attributable death per year. In addition to this human toll, the economic impact is substantial, with 2.4 million inpatient days and greater than $5 billion in direct treatment costs each year in the United States. Between 2001 and 2012, there was an increase in the annual CDI incidence of 43%; however, cases of multiply recurrent CDI increased 188% over that same period.

Rationale for Microbiome Therapeutics in Recurrent CDI

Dysbiosis: Observational clinical data suggests that patients with recurrent CDI have significant community-level dysbiosis compared to healthy controls, with reduced microbiome diversity, in part, due to the many courses of antibiotics that are typically used to treat these patients. Initial episodes of CDI are predominantly linked to treatment with antibiotics, creating a direct link between dysbiosis and disease onset.

Mechanism of Action: The microbiome plays an important role in the pathophysiology of recurrent CDI, and third-party preclinical models and human studies support our understanding of this mechanism. Among healthy individuals, an intact microbiome outcompetes *C. difficile* for its main energy source, primary bile acids produced by the host. This competitive exclusion enabled by an intact microbiome is described as colonization resistance. However, when there is community-level dysbiosis and competitors are eliminated, *C. difficile*, typically a poor competitor for bile acid metabolism, is able to overcome colonization resistance, resulting in infection. In addition to competing for resources, a healthy microbiome generates microbiome-derived secondary bile acids that inhibit residual *C. difficile* spores from germinating into their vegetative, toxin-producing form. Organisms that are able to convert primary bile acids into *C. difficile*-inhibiting secondary bile acids remove a food resource (primary bile acids) and create a potent inhibitor of toxin production (secondary bile acids). Antibiotics are able to suppress vegetative, toxin-producing *C. difficile*, but residual *C. difficile* spores are not susceptible to antibiotics and are able to persist. Accordingly, when an antibiotic course is complete, the residual *C. difficile* spores can germinate into vegetative, toxin-producing *C. difficile*, driving CDI recurrence, a key element of morbidity, mortality and cost in CDI care. Until the underlying microbiome dysbiosis is addressed, patients remain susceptible to CDI recurrence.

Third-Party Clinical Data: Numerous cohort studies, observations from clinical practice and small randomized clinical trials have demonstrated that FMT is able to prevent recurrent CDI. CP101 builds on these human data that suggest repairing community-level dysbiosis may restore colonization resistance and break the cycle of CDI recurrence.

Existing Therapeutics and Their Limitations

Antibiotics

Although antibiotics are considered standard of care to treat CDI, they also impair the diversity of the resident microbiome, affording a potential microbial niche for resident *C. difficile* spores to germinate into toxin-producing cells. Recurrence rates following antibiotic therapy are high as these agents exacerbate community-level dysbiosis. A commonly used CDI antibiotic, vancomycin, is non-specific and causes significant disruption to the microbiome. New generation medications, such as fidaxomicin, were designed as an alternative, narrow-spectrum antibiotic, with reduced activity against other microbes compared to vancomycin. Increasingly sophisticated and precision-targeted antibiotics can mitigate further harm to the microbiome but they do not address what we believe to be the root cause of recurrent CDI—the dysbiosis caused by antimicrobials.

Antibodies

Bezlotoxumab is an approved intravenous monoclonal antibody product that targets the toxins produced by *C. difficile*. However, like antibiotic therapy, it fails to repair dysbiosis, the underlying cause of recurrent CDI.

Probiotics

Probiotics are dietary supplements or foods that contain microbes and are typically derived from fermented foods such as yogurt. However, probiotics are not designed to durably colonize the human intestine and no clinical trials have demonstrated durable repair of dysbiosis with probiotics to date. Recent ACG guidelines have recommended against the use of probiotics for the prevention of CDI.

Fecal Microbiota Transplantation

FMT is the process of transplanting stool and accompanying microbes from healthy donors into patients suffering from diseases of dysbiosis. FMT has generated remarkable outcomes in CDI, supporting the rationale for targeting dysbiosis. However, FMT is a procedure, not a product, and often requires a colonoscopy for administration. There are no defined regulatory standards for screening, processing and delivery of FMT, and this treatment has not been approved by the FDA. There is no FDA-approved agent that addresses the community-level dysbiosis that underlies recurrent CDI.

Our Product Candidate: CP101

We have designed CP101 to break the cycle of CDI recurrence by restoring a complete microbiome. We believe that CP101 has the following advantages when compared to existing therapeutic approaches and other microbiome therapeutic candidates in development for the treatment of recurrent CDI:

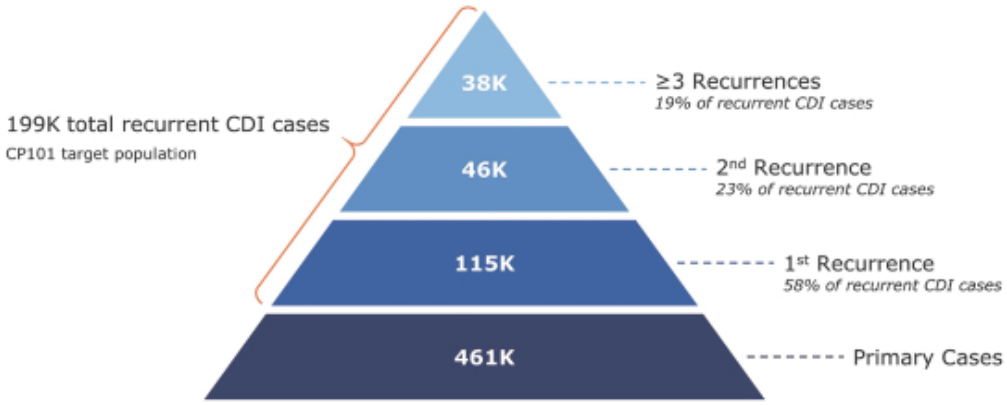
- **Differentiated manufacturing enables the delivery of a complete microbiome**. Our manufacturing technology enables us to exclude pathogens through donor and stool screening, without destruction of the majority of the microbiome through non-specific biocides like ethanol. Besides enabling CP101 to address community-level dysbiosis, rather than a limited subset of the microbiome, we believe that creating a manufacturing process that moves beyond reliance on biocides enables higher yields and more efficient, less costly manufacturing. We believe these advantages will be particularly important as we evaluate CP101 in new indications where ethanol-sensitive organisms, which comprise the majority of the microbiome, are likely to play a critical role and scalable manufacturing will enable us to serve large markets.
- **Novel class of therapy that addresses the underlying cause of disease by restoring the microbiome.** While antibiotics are the current standard of care for the treatment of recurrent CDI, they fail to address the underlying community-level dysbiosis that causes recurrence of the disease. CP101 is designed to durably repair community-level dysbiosis, restoring colonization resistance and production of protective microbiome-derived secondary bile acids. Through its novel mechanism, CP101 also avoids contributing to antibiotic resistance.
- **Achieved primary endpoint in a broad patient population.** CP101 is the only orally administered, microbiome therapeutic candidate drug in development that achieved its primary endpoint in a pivotal trial that included

patients across all stages of recurrent CDI, including first recurrence, which represents more than half of all recurrent CDI episodes. PRISM3 included participants 65 years of age or older who were experiencing their first recurrence of CDI and PRISM-EXT included adults of all ages who were experiencing their first recurrence of CDI. Other drugs in development have focused on patients with multiple recurrences, rather than the more challenging hurdle of delivering meaningful clinical outcomes in front-line care for recurrent CDI. CP101 achieved its primary endpoint in a population that included patients diagnosed by either polymerase chain reaction, or PCR, testing or toxin enzyme immunoassay, or EIA, testing. Other drugs in development failed to demonstrate efficacy among patients diagnosed by PCR and have subsequently focused development exclusively on those diagnosed by toxin EIA. This is commercially important because PCR is the method used to diagnose more than 80% of all CDI cases each year in the United States. By incorporating patients with first recurrence and diagnosed by PCR testing into our study design, we expanded the addressable patient population more than 10-fold relative to products in development that were evaluated only in patients with multiple recurrences and diagnosed by toxin EIA testing. We believe based on the results of our PRISM3 trial, CP101 will have broad applicability across all stages of recurrent CDI and all methods of CDI diagnosis. Data from our PRISM-EXT trial also supports the use of CP101 as rescue therapy for patients who do not respond to a first dose of treatment.

- **Favorable tolerability profile with no treatment-related SAEs observed.** In our PRISM3 trial, CP101 was observed to be well-tolerated, with a similar prevalence of adverse events across the CP101 and placebo arms and no treatment-related SAEs within the CP101 group. We believe this promising tolerability profile is enabled by our robust product and process design.

Market Opportunity

Recurrent CDI represents a robust market opportunity and we estimate there are approximately 200,000 cases each year in the United States. As shown in the figure below, the first recurrence of CDI represents more than half of these cases. Unlike pivotal trials for other microbiome programs, the PRISM3 trial design included first recurrence CDI for patients 65 years of age or older, demonstrating benefit in a broad patient population.



We expect that prescriptions of CP101 will be predominantly fulfilled in the outpatient setting, through the specialty pharmacy channel. While initial presentation of recurrent CDI may occur either in the hospital setting or in the outpatient setting, the majority of hospitalized patients are discharged while being treated with standard-of-care antibiotics, prior to when CP101 would be administered. We believe that this outpatient setting, which provides favorable pricing and reimbursement dynamics relative to the hospital setting, will allow us to better realize value in the recurrent CDI market opportunity.

Clinical Trials of CP101 for the Treatment of Recurrent CDI

Overview

The development of CP101 for the prevention of recurrent CDI is supported by positive topline results from a Phase 1 open-label clinical trial (n=49), a Phase 2 placebo-controlled clinical trial referred to as the PRISM3 trial (n=198), and a Phase 2 open-label clinical trial referred to as the PRISM-EXT trial (n=132), as further summarized elsewhere in this Annual Report. CP101 is currently in late-stage clinical development and being evaluated in a Phase 3 clinical trial, referred to as the

PRISM4 trial, anticipated to enroll approximately 300 participants. We plan to have further discussions with the FDA regarding the size and make-up of the safety database for CP101, which could result in the need for additional studies. PRISM4 is currently on clinical hold, pending product availability and resolution of matters related to the February 2022 Clinical Hold Letter and the March 2022 Letter.

PRISM4 Trial

We have designed a Phase 3 clinical trial, which we refer to as the PRISM4 trial, to serve as our second pivotal trial of CP101 for the prevention of recurrent CDI. The PRISM4 trial is a multi-center trial expected to enroll approximately 300 adult participants with recurrent CDI. PRISM4 has two parts: a randomized, double-blind, placebo-controlled part (Part A) and an optional, open-label treatment part (Part B). In Part A, eligible participants will be randomized in a 2:1 ratio to receive either a one-time oral administration of CP101 or placebo after completing standard-of-care, or SOC, CDI antibiotics for their most recent CDI recurrence. The primary efficacy endpoint of the trial will be CDI recurrence through 8 weeks post-treatment. The primary safety endpoint is the incidence of treatment emergent adverse events through week 8. Secondary endpoints include safety and CDI recurrence through 24 weeks post-treatment. The design of Part A is shown below.

PRISM4 Part A Trial Design

Like our previously completed PRISM3 Phase 2 clinical trial, the PRISM4 trial will enroll participants with recurrent CDI, including participants experiencing their first CDI recurrence that are 65 years of age or older. At study entry, all guideline recommended test methods for *C. difficile*, including PCR- or toxin EIA-based test methods, will be accepted for the diagnosis of the qualifying episode of CDI.

Participants in Part A of the PRISM4 trial that experience a CDI recurrence within 8 weeks of randomization will have the option to enroll in the open-label, Part B component of the trial, in which they will receive CP101 following completion of SOC antibiotics.

On March 1, 2022, we announced that enrollment in PRISM4 was paused following receipt of the February 2022 Clinical Hold Letter. We have submitted a Complete Response to the February 2022 Clinical Hold Letter and we are communicating with the FDA to resolve the clinical hold and related matters, as described above in the section entitled "Clinical Hold".

PRISM3 Trial

We evaluated CP101 for the treatment of recurrent CDI in our pivotal PRISM3 trial, which represents the first positive pivotal trial with an orally administered complete microbiome product candidate. PRISM3 was a Phase 2, 1:1 randomized, placebo-controlled, multi-national trial designed to demonstrate the superiority of CP101 following standard-of-care CDI antibiotics compared to antibiotics alone in preventing recurrence among patients with recurrent CDI. A total of 206 participants were enrolled across 51 sites, of which 198 were evaluable. Patients were recruited from across all stages of recurrent CDI, including patients experiencing their first recurrence that were 65 years of age or older. Qualifying episodes of recurrent CDI were diagnosed using all standard-of-care laboratory tests, including PCR- or toxin EIA-based test methods. All participants were treated with standard-of-care CDI antibiotic therapy prior to randomization. Following antibiotic treatment, participants were randomized to receive either a one-time oral administration of CP101 or a placebo, without the need for bowel preparation. The trial design is shown below.

PRISM3 Trial Design

Baseline characteristics were balanced between the two study arms, with no meaningful clinical differences. Participants with a first CDI recurrence at study entry represented approximately 30% of the study population.

Treatment Groups Had No Meaningful Clinical Differences at Baseline

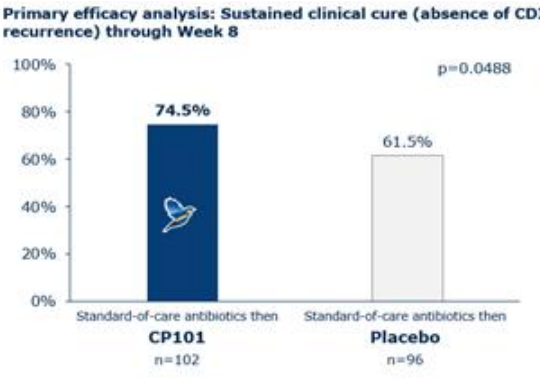
	Standard-of-care antibiotics then **CP101 (n=102)**	Standard-of-care antibiotics then **Placebo (n=96)**
Age (years) Mean ± standard deviation	65.9 ± 17.3	66.5 ± 14.3
Sex n female (% female)	69 (67.6%)	65 (67.7%)
Number of CDI recurrences at study entry		
First recurrence[1] n (%)	28 (27.5%)	29 (30.2%)
Second or further recurrence n (%)	73 (71.6%)	67 (69.8%)
Antibiotics for study entry-qualifying CDI episode[2]		
Vancomycin n (%)	87 (85.3%)	84 (87.5%)
Fidaxomicin n (%)	21 (20.6%)	19 (19.8%)
Metronidazole n (%)	2 (2.0%)	4 (4.2%)

Notes: 1. Participants entering with first recurrence were ≥65 years of age; CDI recurrence status at study entry not reported for 1 participant in CP101 arm 2. Antibiotics were alone or in combination, and some participants were on multiple antibiotics

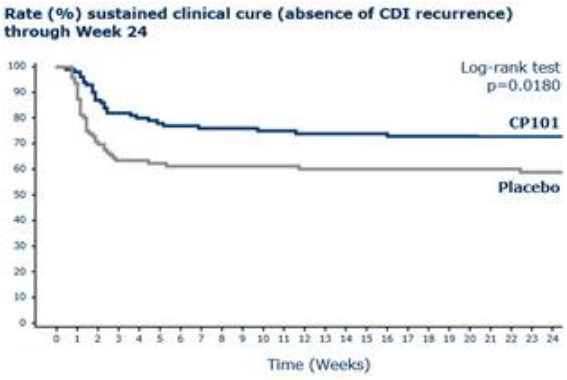
A result is considered to be statistically significant when the probability of the result occurring by random chance, rather than from the efficacy of the treatment, is sufficiently low. The conventional method for determining the statistical significance of a result is known as the "p-value," which represents the probability that random chance caused the result (e.g., a p-value = 0.01 means that there is a 1% probability that the difference between the control group and the treatment group is purely due to random chance). Generally, a p-value less than 0.05 is considered statistically significant.

PRISM3 achieved its primary efficacy endpoint, which was sustained clinical cure defined as the absence of CDI recurrence through eight weeks following administration of study drug. Sustained clinical cure was determined by a blinded adjudication board of independent experts evaluating the totality of clinical and laboratory data including central laboratory data with PCR, toxin EIA and toxigenic culture testing. Following standard-of-care CDI antibiotics, 74.5% of participants treated with CP101 achieved sustained clinical cure, a statistically significant improvement over those receiving placebo (61.5%; p=0.0488), meeting the primary efficacy endpoint and representing a clinically meaningful 33.8% relative risk reduction for CDI recurrence, as shown below on the left. On long-term assessment, CP101 demonstrated clinically meaningful durability and the proportion of participants with sustained clinical cure, defined as the absence of CDI recurrence, through Week 24 remained significantly higher in the CP101 arm compared to placebo (73.5% [75/102] vs 59.4% [57/96], p=0.0347). Time-to-event analysis through Week 24 showed a statistically significant and durable benefit, favoring CP101 compared to placebo (p=0.018), as shown below on the right.

CP101 Achieved 33.8% Relative Risk Reduction for CDI Recurrence in PRISM3



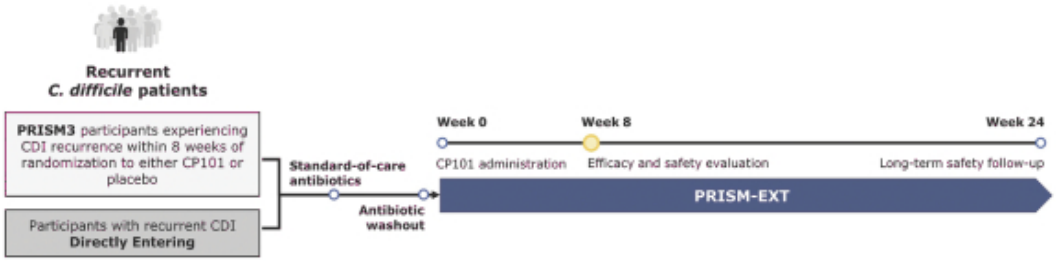
Sustained Clinical Cure at Week 8 Was Maintained Through Week 24 in PRISM3



PRISM3 Extension Trial

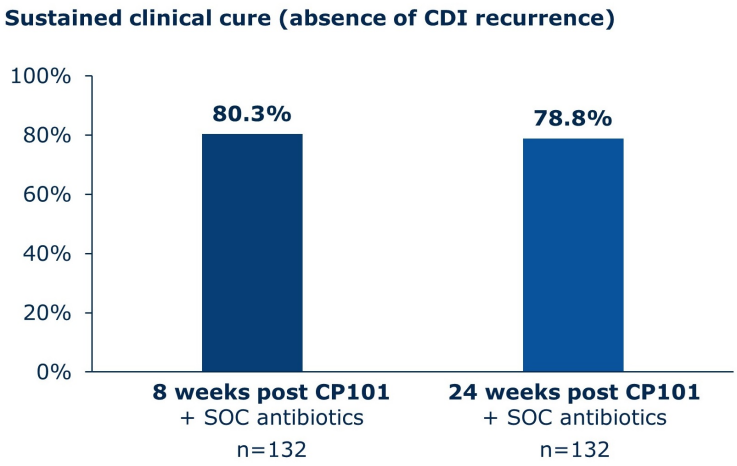
PRISM-EXT was an open-label Phase 2 clinical trial evaluating the safety and efficacy of CP101 for the prevention of recurrent CDI. Initially, the study only enrolled participants who had previously enrolled in the randomized, placebo-controlled PRISM3 trial and experienced a CDI recurrence. After PRISM3 enrollment was complete, a protocol amendment expanded the inclusion criteria to allow participants with recurrent CDI to enroll directly in PRISM-EXT without having previously enrolled in PRISM3. The trial design is shown below.

PRISM3 Extension Trial Design



In November 2021, we reported positive topline results from the PRISM-EXT trial. A total of 132 participants were analyzed, including one cohort that directly enrolled in the trial following a recent CDI recurrence without having previously participated in PRISM3 (n=82) and one cohort that enrolled after experiencing a CDI recurrence following administration of placebo or a single dose of CP101 in PRISM3 (n=50). The primary efficacy endpoint was sustained clinical cure (defined as absence of CDI recurrence) through 8 weeks post-treatment. Overall, 80.3% of participants who received a single oral administration of CP101 following standard-of-care antibiotics in PRISM-EXT achieved sustained clinical cure (defined as absence of CDI recurrence) through week 8 and 78.8% had sustained clinical cure through week 24, as shown below. The PRISM-EXT results are consistent with and build on the previously reported PRISM3 results.

CP101 Demonstrated Robust Sustained Clinical Cure in PRISM-EXT



Among the 102 participants who were treated with CP101 in PRISM3, 20 were enrolled in PRISM-EXT and treated with a second dose of CP101. Of the participants who received either a single dose of CP101 in PRISM3 (n=82) or a second dose by enrolling in PRISM-EXT (n=20), a post-hoc analysis shows that a total of 90 participants achieved sustained clinical cure through 8 weeks after their final dose, resulting in a cumulative efficacy of 88.2% (n=102).

Phase 1 Clinical Trials

The first clinical trial to evaluate CP101 for the treatment of recurrent CDI was a 49 patient, single-center, open-label Phase 1 clinical trial conducted at the University of Minnesota. The trial enrolled patients who had experienced two or more recurrences of CDI. The primary endpoint was the safety and tolerability of CP101. Clinical success was defined as absence of CDI recurrence within two months post-treatment. No related SAEs occurred and 43 of the 49 patients treated achieved clinical success, resulting in an efficacy rate of 87.8% after treatment with CP101. Because the study was designed with a single arm and did not have concurrent control participants, the statistical significance of the observed efficacy rate was not assessed in this study. Approximately a third of patients reported mild, transient gastrointestinal symptoms following the treatment. Multiple doses were evaluated in this first cohort, including a high dose range ($1.25\text{-}2.5 \times 10^{12}$) and a low dose range ($2.1\text{-}2.5 \times 10^{11}$), with no meaningful dose response at the dosing levels tested. An intermediate dose of 6×10^{11} was selected for further process development and tested in an additional 10-patient cohort at the University of Minnesota. In this second cohort, seven of ten patients achieved clinical success through eight weeks following CP101. These promising clinical results from Phase 1 were used to secure Fast Track designation and Breakthrough Therapy designation from the FDA.

Safety and Tolerability

CP101 has been well-tolerated throughout all stages of development to date, and there have been no treatment-related SAEs reported. In the PRISM3 safety population, treatment-emergent AEs and treatment-related AEs were similar between treatment groups, with 16.3% (17/104) of participants in the CP101 arm versus 19.2% (19/99) of participants in the placebo arm experiencing treatment-related adverse events, or AEs, through 24 weeks. In the CP101 arm, treatment-related AEs were mild (Grade 1: 16/17) and moderate (Grade 2: 1/17), and primarily gastrointestinal in nature.

The most common treatment-emergent AEs reported in the CP101 arm through week 8 were predominantly gastrointestinal symptoms, as shown in the table below. Among the five most common adverse events in the CP101 arm, four adverse events were observed more frequently in participants treated with placebo relative to participants treated with CP101. For instance, we observed significantly fewer participants with abdominal pain among those treated with CP101 (30.8%) relative to those treated with placebo (59.6%; $p<0.0001$).

Most Frequent Adverse Events in the PRISM3 CP101 Arm Through Week 8

	CP101 n (%)	Placebo n (%)
Diarrhea	55 (52.9)	48 (48.5)
Abdominal pain	32 (30.8)	59 (59.6)
Defecation urgency	34 (32.7)	38 (38.4)
Nausea	27 (26.0)	27 (27.3)
Abdominal distension	26 (25.0)	30 (30.3)

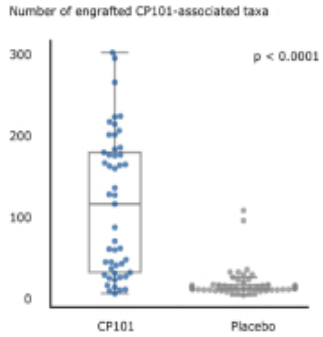
Source: PRISM3 safety population

Additionally, in the 132-participant PRISM-EXT trial, there were no treatment-related SAEs reported and CP101 exhibited an overall safety profile consistent with the profile observed in PRISM3.

Pharmacokinetics

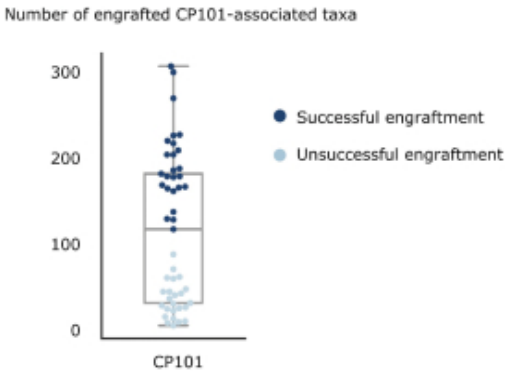
We used data from these clinical trials to confirm potential mechanisms underlying the clinical outcomes observed with CP101 for recurrent CDI. We used high-throughput sequencing to characterize the engraftment of CP101 Taxa, or groups of genetically similar bacteria, among participants treated in the PRISM3 study. As expected, participants treated with CP101 had dramatically higher engraftment of CP101 Taxa than patients treated with placebo, as shown in the graphic below, highlighting our ability to effectively deliver a viable consortia to the appropriate location in the gastrointestinal tract with our targeted oral capsule.

CP101 Shows Significant Engraftment Overall

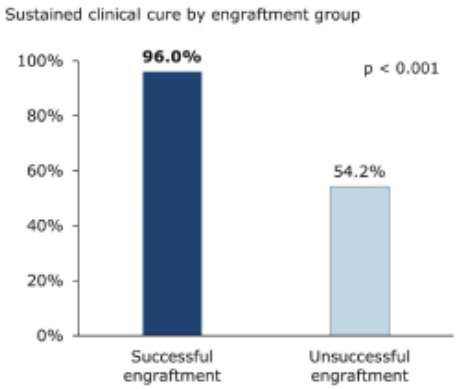


We also observed a strong relationship between engraftment of the microbes delivered in CP101 and clinical outcomes in PRISM3. Among patients with successful engraftment at week 1 following CP101 administration, 96.0% achieved a sustained clinical cure, while 54.2% of those without successful engraftment at week 1 achieved a sustained clinical cure ($p < 0.001$).

CP101 Engraftment Shows a Bimodal Distribution



CP101 Engraftment Correlates with Sustained Clinical Cure



We believe one factor that may have reduced engraftment among some PRISM3 participants who received CP101 is the persistence of residual vancomycin, a broad spectrum antibiotic with activity against a number of CP101 microbes, prior to treatment with CP101. As part of the study protocol, all patients enrolled in PRISM3 completed a course of standard of care antibiotics, which could have included either vancomycin or fidaxomicin, prior to randomization and administration of study drug.

To limit the impact of residual standard of care antibiotics on CP101, participants in PRISM3 completed a minimum two-day antibiotic washout period prior to administration of study drug to provide time for antibiotic clearance from the colon. Recent scientific literature shows, however, that the stool concentration of vancomycin two days after cessation of administration remains at approximately 65% of peak concentrations and declines to approximately 15% of peak concentrations after a three-day washout. These data suggest that a two-day washout period may have been insufficient to clear residual vancomycin.

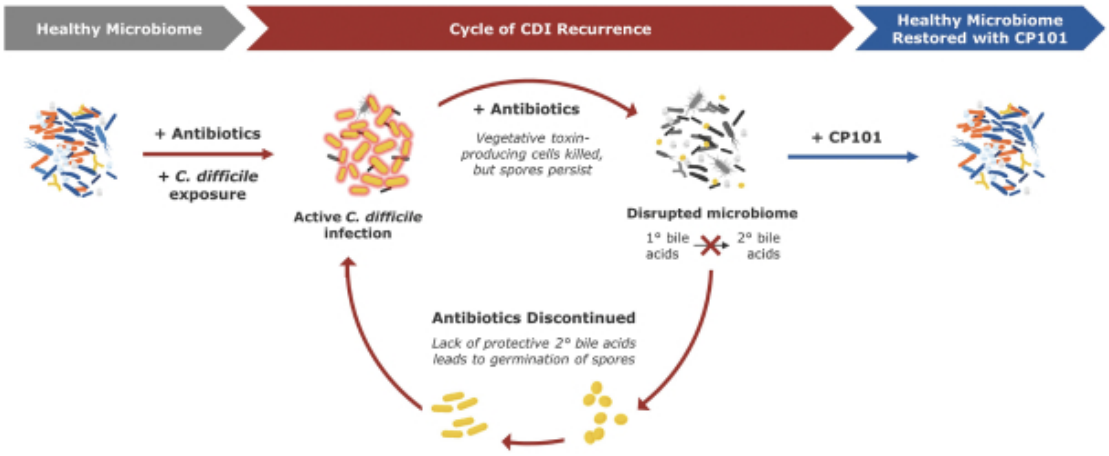
To address this limitation, we have extended the minimum antibiotic washout period prior to administration of CP101 in our PRISM4 trial from two days to four days.

Pharmacodynamics

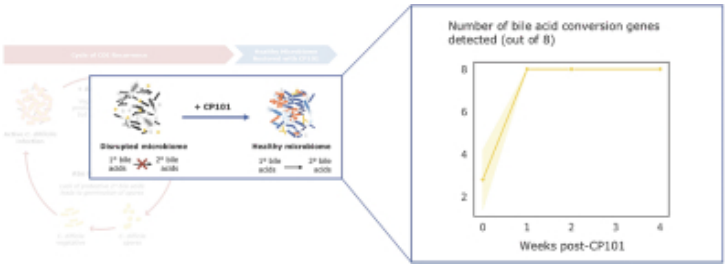
We believe bile acid metabolism plays a key role in the pathogenesis of recurrent CDI. A healthy microbiome generates microbiome-derived secondary bile acids that inhibit residual *C. difficile* spores from germinating into their vegetative toxin-producing form. Patients with recurrent CDI have depleted secondary bile acids and a higher concentration of primary bile acids, a key energy source for *C. difficile*. There are eight microbial genes that are critical for the conversion of primary bile acids into secondary bile acids. We used high-throughput metagenomic sequencing to measure the presence of these genes before and after treatment with CP101. At baseline, we found participants with recurrent CDI had between zero and four of these genes, missing key components of the pathway. Among participants evaluated for pharmacodynamics in Phase 1 (n=5), we found that all participants had all eight genes at all timepoints measured after treatment with CP101, highlighting the ability of CP101 to restore an important pathway in the pathogenesis of recurrent CDI.

These data show that in keeping with similar host-targeted gene therapies, we are able to deliver a lasting transformation in the genetic capacity of the treated patient in a manner that improves clinical outcomes. With our treatment, however, we do not need to modify the host genome, instead we can deliver these genetic capabilities through microbes that are able to engraft and reproduce in the host. Importantly, because more than 99% of all genes found in humans are found in the microbiome, this opens a much broader suite of targets than those which are accessible through host-targeted gene therapies.

CP101 is Designed to Break the Cycle of CDI Recurrence by Restoring Bile Acid Metabolism



CP101 Restores Bile Acid Metabolism – A Key Biomarker for Treatment in Recurrent CDI



Chronic HBV

Following a strategic review of our pipeline and business, we announced in March 2022 the decision to pause the development of CP101 for the treatment of chronic HBV. We believe this decision will allow us to maximize our working capital available for investment in our wholly-owned recurrent CDI and ASD programs. We continue to believe that CP101, or other product candidates that we may develop in the future, may have the potential to treat chronic HBV, a chronic infection linked to microbiome dysbiosis. We may continue our research efforts in HBV in the future as our portfolio continues to mature.

FIN-211 to Address Symptoms of Autism Spectrum Disorder

Overview

FIN-211 is an orally administered, Enriched Consortia product candidate designed to deliver both a complete microbiome and targeted microbes not found in most healthy donors. We believe FIN-211 has the ability to address both the gastrointestinal and behavioral symptoms of autism spectrum disorder, or ASD.

Indication Overview

ASD is a behaviorally defined condition characterized by reduced social interaction, impaired communication skills and the presence of repetitive or restrictive behaviors. Beyond the core symptoms by which it is defined, ASD is recognized as a heterogeneous medical condition by the FDA, and patients can exhibit highly varied symptoms and behaviors such as irritability, heightened sensitivities and movement disorders. A subset of patients with ASD, comprising at least 30% of the

population, experience significant gastrointestinal symptoms, with the most common gastrointestinal symptom being constipation (ASD-C). There is a correlation between the severity of these gastrointestinal symptoms and the severity of behavioral symptoms. Standard treatments for constipation are often ineffective, which may be because the underlying biology of gastrointestinal symptoms is distinct in children with ASD compared to neurotypical children. We believe by addressing this underlying biology with a microbiome therapeutic, we will be able to improve ASD gastrointestinal symptom and neurobehavioral development.

The diagnosed prevalence of ASD is currently 1 in 44 for children in the United States, a prevalence that has increased substantially over the past few decades. Worldwide prevalence estimates vary but are thought to be similar in other developed countries. It is believed there are more than 4.6 million children and adults in the United States with ASD. By some estimates, the total financial burden of care for patients with ASD exceeds $100 billion in the United States annually.

Existing Therapeutics and Their Limitations

There is no FDA-approved pharmaceutical treatment for the core symptoms of ASD. The only widely accepted intervention with substantial supportive evidence is a form of long-term behavioral therapy, called Applied Behavioral Analysis, or ABA. Children with ASD usually begin ABA as soon as they are diagnosed, typically between ages 2-6 years, and are recommended to receive 30-40 hours of therapy every week. ABA may continue into adulthood and parents are often faced with making difficult choices between school or continuing ABA therapy. The only FDA-approved pharmaceutical treatment for ASD are anti-psychotics, which are only prescribed to treat the irritability that often accompanies ASD, but is not a core symptom of the disorder. While ASD-C may be treated with laxatives or enemas, these can be poorly tolerated and are often ineffective. As a result, a high unmet medical need remains across both gastrointestinal and behavioral symptoms.

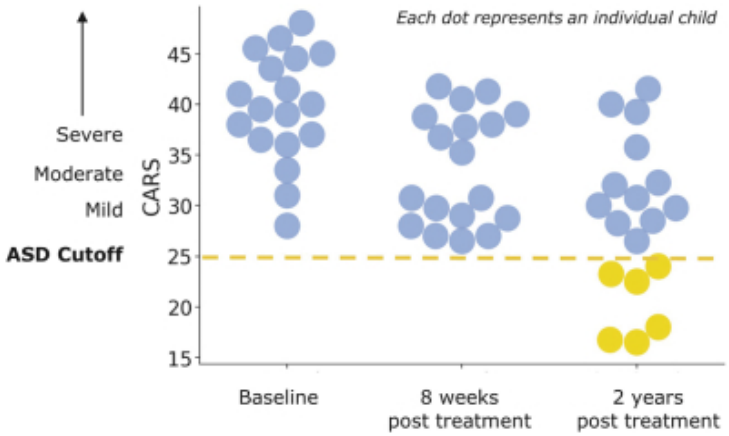
Rationale for Microbiome Therapeutics in ASD

Dysbiosis: Microbiome signals, epidemiological risk factors and gut symptoms all suggest a link between ASD and the microbiome. ASD is frequently accompanied by severe gastrointestinal manifestations, revealing symptoms more proximal to the activities of the gut microbiome. Moreover, the risk of developing ASD is significantly increased among children born by caesarean section or those exposed to multiple courses of antibiotics early in life. Mouse studies have demonstrated the ability to transfer ASD-like symptoms by transferring stool from humans with ASD. Conversely, certain ASD-mouse models have shown that ASD-like symptoms can be reduced by microbiome transfer from a neurotypical donor.

Mechanism of Action: Once considered a strictly neurological condition, the modern view of ASD has evolved to encompass multiple systems, including interactions between the central nervous system, the enteric nervous system and the gut microbiome, also called the gut-brain axis. Many well-known neuro-active signaling molecules such as gamma-aminobutyric acid, or GABA, serotonin and oxytocin are either produced or modulated by the microbiome, which has led to efforts to better understand the role of the microbiome across a range of behavioral and neurological conditions, including ASD. Current research highlights several pathways in the gut-brain axis that may be key to ASD. Neuro-active metabolites that are exclusively produced by the microbiome, such as 4-ethylphenylsulfate, or 4EPS, are significantly elevated among children with ASD relative to neurotypical controls, and are capable of inducing ASD-like symptoms in mice. Oxytocin, a neuropeptide responsible for regulating social bonding and behavior, has long been a target for drug development in ASD, but exogenous agonism of oxytocin has been challenging due to a short half-life of oxytocin. Certain microbes can induce endogenous production of oxytocin, providing an alternative means to engage this important pathway. Preclinical work has demonstrated that introduction of oxytocin-inducing bacteria can restore neurotypical behavior in three independent ASD murine models. This rescue is dependent on the vagus nerve which connects the enteric nervous system in the gut with the central nervous system and was eliminated when the gene for the oxytocin receptor was knocked out. This pathway-level dysbiosis and previously described community-level dysbiosis suggest the potential role for an Enriched Consortia product strategy.

Third-Party Clinical Data: At least five investigator-sponsored clinical studies have found that the restoration of a healthy microbiome by FMT is associated with marked improvements in behavioral and gastrointestinal symptoms among children with ASD. An open-label proof-of-concept trial administering FMT for 8 weeks reported that, two years after treatment, most participants reported gastrointestinal symptoms remaining improved compared to baseline and 44% of study participants who had previously been diagnosed with ASD fell below the Childhood Autism Rating Scale (CARS) score cut-off used to classify autism. Even using a more stringent CARS score cut-off of 25, we find that 33% of participants no longer meet the diagnostic criteria for ASD, as shown in the below graph. Additionally, in a randomized, controlled trial, children with ASD receiving FMT and behavioral therapy showed a statistically significant improvement in their behavioral symptoms compared to the control group receiving behavioral therapy alone.

Behavioral Scores Improved Dramatically Over Two Years in an Open-Label, Proof-of-Concept FMT Trial



Our Product Candidate: FIN-211

FIN-211 is an orally administered, Enriched Consortia product candidate designed to deliver both a complete microbiome and targeted microbes not found in most healthy donors. Based on our understanding of the biology of ASD, we have identified species capable of inducing oxytocin production and improving gastrointestinal barrier function. We believe these organisms may have important therapeutic benefits for individuals with ASD. These organisms are not ubiquitous in healthy donors, so our Complete Consortia product strategy would not generally include these microbes. Accordingly, we have decided to pursue an Enriched Consortia product strategy that includes both strains targeting oxytocin-production and a complete microbiome to address community-level dysbiosis, which we believe best positions FIN-211 to potentially address both the gastrointestinal and behavioral symptoms of ASD.

Clinical Development of FIN-211 to Address Symptoms of ASD

We are preparing to initiate a Phase 1b clinical trial, which we refer to as AUSPIRE, of FIN-211 in children with ASD (ages 5–17 years) with constipation. Although FIN-211 is not directly addressed in the February 2022 Clinical Hold Letter, it is an Enriched Consortia product candidate that includes donor-derived components. Because the February 2022 Clinical Hold Letter is concerned with SARS-CoV-2 screening measures for donor-derived microbiota material, the clinical hold will delay initiation of AUSPIRE and will require us to conduct additional manufacturing activities (including manufacturing additional components of FIN-211) in order to satisfy the FDA's requests related to SARS-CoV-2 screening and testing. We have submitted a Complete Response to the February 2022 Clinical Hold Letter and we are communicating with the FDA to resolve the clinical hold as soon as possible. We are evaluating the extent of the delay the clinical hold and the related manufacturing activities will have on the expected timing of AUSPIRE; based on manufacturing timelines, we expect at least a one-quarter delay.

Based on clinical FMT data and preclinical data with oxytocin-inducing strains, we believe FIN-211 is positioned to address both the gastrointestinal and behavioral symptoms of ASD. The FDA has indicated that either gastrointestinal or behavioral endpoints could support a biologics license application and we are evaluating both gastrointestinal and behavioral endpoints. Given the absence of FDA-approved therapies and building on our discussions with the FDA, we aim to continue to validate behavioral instruments as part of our clinical development plans. We believe FIN-211 can potentially address adults with ASD as well as both adults and children without gastrointestinal symptoms, expanding beyond our initial population of pediatrics with gastrointestinal symptoms where we expect to observe an enriched signal.

We believe this development strategy represents an attractive entry into the gut-brain axis, providing two opportunities to provide therapeutic benefit to patients with ASD, both for behavioral symptoms and lower-risk gastrointestinal endpoints. Furthermore, we believe that ASD could validate our microbiome-based approach to addressing additional gut-brain axis indications. We plan to leverage existing and emerging clinical data from our academic collaborators to inform the development strategy of future product candidates to address additional neurological disorders that are associated with the gut-brain axis.

TAK-524 (Ulcerative Colitis) & FIN-525 (Crohn's Disease) for the Treatment of Inflammatory Bowel Disease

Overview

TAK-524 (formerly known as FIN-524) and FIN-525 are each orally administered Targeted Consortia product candidates designed for the treatment of ulcerative colitis (TAK-524) and Crohn's disease (FIN-525). We initially partnered with Takeda, a global leader in inflammatory bowel disease, or IBD, to develop TAK-524. TAK-524 comprises targeted strains identified by our Human-First Discovery platform, which do not require donors. Following the achievement of certain preclinical milestones in the development of TAK-524 for ulcerative colitis, we expanded our development partnership with Takeda to include FIN-525, a program to develop a live biotherapeutic product optimized for Crohn's disease that also comprises targeted strains identified by our Human-First Discovery platform. In August 2021, Takeda accelerated its leadership role in TAK-524, taking responsibility for clinical development, while we continue to conduct discovery efforts on FIN-525. We believe that the development programs for TAK-524 and FIN-525, which are Targeted Consortia product candidates composed of strains grown from master cell banks, are not affected by the February 2022 Clinical Hold Letter.

Indication Overview

Ulcerative colitis and Crohn's disease are the two principal sub-types of IBD. IBD comprises a set of heterogeneous autoimmune conditions that cause inflammation of the gastrointestinal tract. Symptoms of IBD include severe, chronic abdominal pain, diarrhea, gastrointestinal bleeding and weight loss. Patients have substantially higher risk of colon cancer, gastrointestinal perforations and infections, and many eventually require surgical resection of portions of their gastrointestinal tract or colectomy. Patients undergo periods of active disease (flares) accompanied by intermittent periods of little or no disease activity (remission). Over 3 million Americans and 10 million people globally are thought to suffer from IBD, and the incidence has increased rapidly over the past few decades. By some estimates, the total financial burden of care for patients with IBD exceeds $31 billion in the United States annually.

Existing Therapeutics and Their Limitations

The current treatment options vary by disease types and severity, and are designed to reduce inflammation, but do not address the underlying cause of disease. Active mild-to-moderate ulcerative colitis is often treated with 5-ASA agents. However, over 70% of patients fail to enter remission. Active mild-moderate Crohn's disease have limited therapeutic options. Corticosteroids are commonly used in active disease; however, the long-term side effect profile is poor and includes increased risk of infections, type 2 diabetes, weight gain, mood disturbances and hypertension. Biologic agents that suppress inflammatory cytokines or cell trafficking are not typically orally administered agents, and have poor rates of inducing remission. There is a single, recently approved oral biologic for moderate to severe Crohn's disease; however, similar to other biologics, it is associated with increased risk for severe infections, blood clots and the development of malignancy. Commonly used anti-TNF biologic agents may lead to serious infections due to immunosuppression, and there have been reports of hepatosplenic T-cell lymphoma, a rare form of lymphoma that is fatal in some patients.

Overall, current treatments for IBD fail to address the underlying causes of inflammation, and there is a significant need for well-tolerated, easily administered, disease-modifying agents in IBD.

Rationale for Microbiome Therapeutics in IBD

Dysbiosis*:* Over the last decade, a number of lines of evidence have pointed to the promise of microbiome therapeutics in treating ulcerative colitis and Crohn's disease. Inflammatory bowel disease is one of the suite of chronic inflammatory diseases that has risen dramatically in prevalence in developed nations marked by gastrointestinal dysbiosis.

Mechanism of Action: Extensive preclinical work has demonstrated the criticality of the microbiome, including specific microbial metabolites, in regulating gastrointestinal tract inflammation, predicting response to therapy and determining the risk of disease recurrence after surgery. The improvement of gut barrier integrity, reduction of local immune activation and modulation of gut inflammation are all modulated by the microbiome.

Third-Party Clinical Data: FMT studies in IBD were key in our decision to develop Targeted Consortia product candidates for ulcerative colitis and Crohn's disease. Data from over 40 FMT studies, including five randomized, placebo-controlled trials in ulcerative colitis and one randomized, placebo-controlled trial in Crohn's disease, have shown promising clinical outcomes. Some of these interventional studies also served as our main discovery datasets to select which strains and functions to include in our Targeted Consortia approach for IBD. Clinical studies with only spore-forming compositions have

yielded mixed results, highlighting the value of our approach, which leverages both spore-forming and non-spore forming compositions.

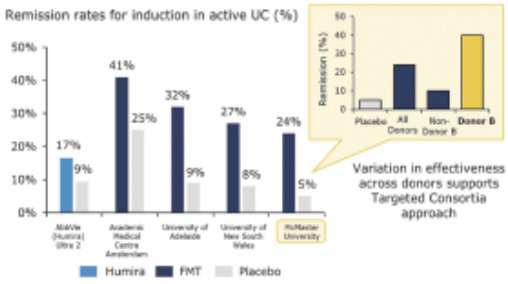
TAK-524 and FIN-525

TAK-524 is a Targeted Consortia product candidate of nine bacterial strains selected for the treatment of ulcerative colitis, and is orally administered in a lyophilized formulation. We designed this consortium to target three specific modes of action: two classes of immunoregulatory metabolites, each targeting a different set of host pathways, and donor strains linked to remission following FMT in patients with ulcerative colitis. Takeda now leads development of TAK-524.

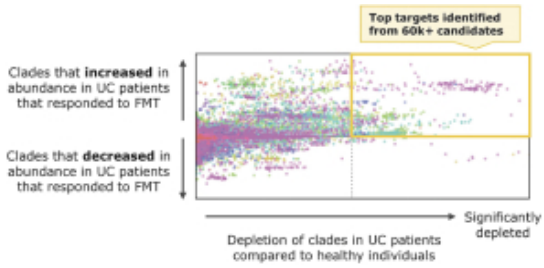
FIN-525 is a discovery-stage program designing a Targeted Consortia product candidate for the treatment of Crohn's disease. The strategy for this consortium, which is differentiated from ulcerative colitis, includes donor strains depleted in Crohn's patients and linked to remission following FMT in these patients, as well as several classes of metabolites, each targeting a different set of host pathways.

TAK-524 and FIN-525 leverage data collected from over two dozen cohorts comprising over 2,300 patients, including six FMT studies in ulcerative colitis and five in Crohn's disease. Our machine learning platform identified microbes and microbial functions deficient in patients with ulcerative colitis and Crohn's disease compared to non-IBD controls. We tested these hypotheses with FMT data to identify the subset most likely to be causal, focusing on organisms consistently shown to be enriched among successful FMTs and subjects without IBD. To reduce the translational risk of these empirical signals, we isolated target organisms directly from specific donor samples that induced remission in clinical studies of FMT in IBD. *In vitro* and *in vivo* measurements on the isolated strains and consortia then confirmed the signals of biological activity hypothesized by our machine learning platform. We are currently conducting discovery efforts on FIN-525.

Remission Rates in Active Ulcerative Colitis among Four Placebo-Controlled FMT Trials and a TNF Biologic Trial



Platform Used to Identify "Super Donor" Strains as Potential Therapeutic Candidates



Selecting a strain associated with positive FMT outcomes starts with machine learning models of clinical data. For TAK-524, an analysis of data from over 1000 patients was used to quantify the relationship between each clade of bacteria (each represented as a dot) and ulcerative colitis. On the x-axis, the degree to which each clade is depleted from a patient's microbiome relative to healthy controls is shown. On the y-axis, the impact of each clade in driving remission when added to a patient's microbiome by FMT is shown. Colors indicate the higher-level phylogenetic group each dot is assigned to. The bacterial clades with the greatest effect (top right quadrant) are the targets we isolated for in-vitro validation.

Our Collaborations and License Agreements

Takeda Collaboration

In January 2017, we entered into an agreement, or the Takeda Agreement, with Takeda, pursuant to which we granted Takeda a worldwide, exclusive license, with the right to grant sublicenses, under our rights in certain patents, patent applications and know-how to develop, have developed, manufacture, have manufactured, make, have made, use, have used, offer for sale, sell, have sold, commercialize, have commercialized and import our microbiome therapeutic candidate TAK-524 for the prevention, diagnosis, theragnosis or treatment of diseases in humans. We subsequently amended and restated the Takeda Agreement in October 2019 to provide a worldwide, exclusive license to a second microbiome therapeutic candidate, FIN-525. We further amended the Takeda Agreement in August 2021 to transition primary responsibility for further development and manufacturing activities of TAK-524 to Takeda in accordance with a transition plan, and Takeda assumed sole responsibility for regulatory matters with respect to TAK-524. In November 2021, we further amended the Takeda Agreement to enable us to carry out certain FIN-525 preliminary evaluation activities.

Under the terms of the Takeda Agreement, we agreed to design TAK-524 (a product candidate optimized for ulcerative colitis) for Takeda based on selection criteria within a product-specific development plan. We also agreed to conduct feasibility studies on FIN-525 (a program to develop a live biotherapeutic product optimized for Crohn's disease) for Takeda, and Takeda can determine whether to initiate a full product-specific development plan for FIN-525 following its review of the data from our feasibility studies. The FIN-525 feasibility study was completed in March 2021. Takeda is to select one optimal microbial cocktail for each of TAK-524 and FIN-525 after completion of certain initial product development activities. Thereafter, prior to initiation of the first Phase 3 clinical trial for TAK-524 or FIN-525, as applicable, Takeda has the right to substitute the initially selected microbial cocktail for another microbial cocktail selected by Takeda from certain alternative cocktails that were designated by Takeda at the time of selecting the initial microbial cocktail.

Pursuant to the Takeda Agreement, we are primarily responsible for early-stage development activities for FIN-525 pursuant to an agreed upon development plan and budget, including potentially through Phase 2 clinical trials, subject to Takeda's right to either co-develop a product with us at Phase 2 or assume responsibility for such development. After the successful completion of the first Phase 2 clinical trial for FIN-525, Takeda will assume primary responsibility for the Phase 3 clinical program. Initially, we are responsible for clinical supply of FIN-525; however, Takeda is required to assume responsibility for such manufacture and supply no later than six months after completion of the first Phase 2 clinical trial for the first FIN-525 product candidate. All such development and manufacturing activities will be overseen by certain joint committees. Pursuant to the August 2021 amendment to the Takeda Agreement, Takeda assumed primary responsibility for early-stage development and manufacturing activities with respect to TAK-524. Takeda also assumed sole responsibility for regulatory matters with respect to TAK-524. We remain responsible for certain development activities designated in the TAK-524 development plan, for which we will continue to receive reimbursement from Takeda.

Takeda is responsible for up to 110% of our budgeted full-time equivalent costs in connection with our development activities for TAK-524 (and FIN-525, if Takeda elects to initiate a full development plan for FIN-525) as well as all costs related to chemistry, manufacturing and control development or other development costs incurred after the initial selection of an optimal microbial cocktail. Takeda is solely responsible for all commercial activities related to the TAK-524 and FIN-525 product candidates, at its cost.

We have agreed that prior to completion of the first Phase 2 clinical trial for the first TAK-524 product candidate being developed with the intention of seeking U.S. regulatory approval, other than as part of any development activities under the Takeda Agreement, we shall not engage in any research and development directed toward any product candidate for the treatment of IBD, or access or use certain fecal microbiota source material or any data generated from that material in IBD for any purpose. Additionally, we have agreed that prior to completion of the first Phase 2 clinical trial for the first FIN-525 product candidate being developed with the intention of seeking U.S. regulatory approval, other than as part of any development activities under the Takeda Agreement, we shall not engage in any research and development directed toward any product for the treatment of Crohn's disease, or access or use certain fecal microbiota source material or any data generated from that material in Crohn's disease for any purpose. We have also agreed for the remainder of the term of the Takeda Agreement to certain restrictions on our access or use of certain bacterial strains having at least a threshold genetic relatedness to the strains incorporated into TAK-524 or FIN-525, our access or use of certain fecal microbiota source material, and our ability to conduct certain research and development directed toward products for the treatment of IBD and Crohn's disease that contain bacterial strains having less than a threshold genetic divergence from the bacterial strains in TAK-524 and FIN-525, respectively.

Pursuant to the Takeda Agreement, we granted Takeda a right of first offer in the event that we seek to commence a program for the treatment of IBD, as well as an exclusive option to negotiate that the parties undertake an additional development program for a microbial composition.

In connection with entry into the Takeda Agreement, we received a one-time, upfront payment from Takeda in the amount of $10.0 million. Additionally, we received $4.0 million in the aggregate for the achievement of certain development milestones for TAK-524 therapeutic products and are entitled to receive up to $176.0 million in the aggregate, for the achievement of specified development, regulatory and commercial sale milestones for TAK-524 therapeutic products. We are entitled to receive up to $177.7 million in the aggregate, for the achievement of specified development, regulatory and commercial sale milestones for FIN-525 therapeutic products, subject, to certain specified reductions based upon the nature of the FIN-525 product and certain additional milestones to be negotiated by the parties. We are also entitled to receive up to $10.0 million for the first diagnostic product for each of TAK-524 and FIN-525, subject to certain reductions in the event that Takeda uses a third party to develop such diagnostic products. Pursuant to this agreement, Takeda is obligated to pay us a royalty on net sales of TAK-524 and FIN-525 products ranging from mid to high-single digits, subject to certain reductions. Such royalties are payable on a product-by-product and country-by-country basis, during the period beginning on the date of first commercial sale of such product in such country and ending on the later to occur of the expiration of the last-to-expire valid

claim of any patents or patent applications controlled by us and licensed in such country that covers the composition of matter of such product, the date that regulatory exclusivity of such product expires in such country, or eight years from the date of the first commercial sale of such product in such country.

The Takeda Agreement expires on the date of expiration of the last royalty payment obligation. Either party may terminate the Takeda Agreement in the event of an uncured material breach by the other party. Takeda has the right to terminate the Takeda Agreement, in whole or in party, on a program-by-program basis upon specified notice to us or immediately following the withdrawal of a product from any market as a result of bona fide concerns based on specific and verifiable information that such product is unsafe for administration to humans. Additionally, the parties may mutually agree to terminate the Takeda Agreement on a program-by-program basis.

Exclusive License Agreement with Arizona State University

In July 2017, we entered into a license agreement, or the Arizona State Agreement, with Skysong Innovations LLC (formerly Arizona Science and Technology Enterprises LLC), or Skysong, pursuant to which we obtained a worldwide, royalty-bearing, exclusive license, with the right to grant sublicenses, under certain patents and patent applications of Arizona State University to make, have made, use, have used, sell, have sold, offer to sell, have offered for sale, import, have imported, export or have exported products and services that are covered by such licensed patents. In July 2018, we subsequently amended the Arizona State Agreement to include certain additional patents and patent applications of Arizona State University. The patents and patent applications that we have exclusively licensed from Arizona State University under the Arizona State Agreement relate generally to compositions and methods to treat autism spectrum disorder and related symptoms and comorbidities. If issued, the patents within the licensed intellectual property would be expected to expire beginning in 2033.

Pursuant to the terms of the Arizona State Agreement, we are obligated to use commercially reasonable efforts in connection with the development and commercialization of products and services, the manufacture, use, sale, offering for sale, importation or exportation of which, but for the license granted under the Arizona State Agreement, would infringe one or more licensed patents, or licensed products. Such efforts are limited to the United States and include a specific performance milestone.

Under the terms of the Arizona State Agreement, we paid Skysong an upfront fee of $10,000 and reimbursed Skysong for prior patent prosecution expenses. Additionally, we have agreed to make a low-six digits milestone payment upon the first commercial sale of a product in each of the United States, England, France, Germany, Italy, Spain and Japan, and a one-time commercial milestone payment in the low-seven digits upon the achievement of cumulative, worldwide net sales of all licensed products by us, our sublicensees or respective affiliates in the low-nine digits. We are also obligated to pay Skysong a low-single digit royalty on net sales of licensed products, including a minimum annual royalty payment in the mid-four digits to low-five digits that is creditable against the royalties due in such year. The royalty obligations continue on a country-by-country basis as to each licensed product until expiry of the last to expire claim within the licensed patents that covers such licensed product in such country. Moreover, we are obligated to pay a percentage of any non-royalty consideration received by us from a sublicensee in the high-second decile.

The Arizona State Agreement expires on the date of expiration of all royalty obligations. Upon expiration of our royalty obligations with respect to a licensed product in a country we will have a royalty-free, irrevocable, perpetual license to such licensed product in such country. We may terminate the Arizona State Agreement earlier for any reason or upon an uncured material breach of the agreement by Skysong. Skysong may terminate the Arizona State Agreement earlier upon our uncured material breach of the agreement, our insolvency, our initiation of any proceeding or claim challenging the validity or enforceability of any licensed patent, or our failure to meet a specific performance milestone.

Exclusive Patent License Agreement with University of Minnesota

In March 2012, CIPAC Limited, an entity under the laws of Malta, or CIPAC, entered into a license agreement, or the UMN Agreement, with Regents of the University of Minnesota, or UMN, pursuant to which CIPAC obtained a worldwide, royalty-bearing, exclusive license, with the right to grant sublicenses, under certain patents and inventions of the University of Minnesota to make, have made, use, offer to sell or sell, offer to lease or lease, import, or otherwise offer to dispose or dispose of any product or service that is covered by such licensed patents. The UMN Agreement was subsequently amended in June 2014 and October 2014. In May 2015, CIPAC transferred its interest in the UMN Agreement to us. Subsequent to such transfer, the UMN Agreement was subsequently amended in December 2016 and September 2017. We amended and

restated the UMN Agreement in January 2022, to consolidate earlier amendments and extend the deadline for satisfying performance milestones by one year.

Pursuant to the terms of the UMN Agreement, we are obligated to use commercially reasonable efforts to commercialize the licensed inventions and to manufacture and sell licensed products, including by meeting certain specific performance milestones.

Under the terms of the UMN Agreement, we paid UMN an aggregate upfront fee of $155,000, and are obligated to pay annual maintenance fees in the mid-four digits. We are also obligated to pay UMN a royalty on net sales of licensed products ranging in the low-single digits depending on which licensed patents cover such licensed product, subject to a minimum annual royalty payment escalating over time in the low-five digits to low-six digits payable at the end of each applicable year. Such minimum annual royalty payments begin in 2021. The royalty obligations continue on a country-by-country basis as to each licensed product until expiry of the last to expire claim within the licensed patents that covers such licensed product in such country. Moreover, we are obligated to pay a percentage of any non-royalty consideration received by us from a sublicensee in the high-second decile.

The UMN Agreement expires on the date of expiration of all claims under the licensed patents. We may terminate the UMN Agreement earlier upon an uncured material breach of the agreement by UMN. UMN may terminate the UMN Agreement earlier upon our uncured material breach of the agreement, our insolvency, or upon the commencement by us of any proceeding asserting or alleging the invalidity or unenforceability of the licensed patents.

Competition

The biotechnology and pharmaceutical industries, including the field of microbiome therapeutics, are characterized by rapidly changing technologies, significant competition and a strong emphasis on intellectual property. While we believe that our scientific knowledge, technology and development experience provide us with competitive advantages, we face substantial competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide.

Any product candidates that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future. We are aware of a number of companies focused on developing microbiome therapeutics in various indications. For CP101, we are aware that Seres Therapeutics, Inc. and Rebiotix Inc. each have a product candidate that has completed Phase 3 trials for recurrent CDI and are pursuing FDA approval to enable subsequent commercialization. In November 2021, Rebiotix filed a BLA for RBX-2660, their lead product in recurrent CDI, and Seres has indicated that they plan to file a BLA in 2022. In addition to these late-stage competitors, we are also aware of competitive microbiome therapies in earlier stages of clinical development, including VE303 (Vedanta Biosciences), NCTD-M3 (Destiny Pharma plc), MET-2 (NuBiyota), and RBX7455 (Rebiotix). Any advances in microbiome therapies made by a competitor may be used to develop therapies that could compete against any of our product candidates.

We are aware of a number of large pharmaceutical and biotechnology companies, as well as smaller, early-stage companies, that are pursuing the development of products and disease indications we are targeting. These companies include AbbVie Inc., Arena Pharmaceuticals Inc., Bristol-Myers Squibb Company, Gilead Sciences, Inc., GlaxoSmithKline plc, Johnson & Johnson, Merck & Co., Inc., UCB S.A. and Vir Biotechnology, Inc. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others may be based on entirely different approaches.

Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and other resources than we do, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than us, which might result in competitors establishing a strong market position before we are able to enter the market.

Many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than us. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our current and future product candidates, novel discoveries, product development technologies and know-how; to operate without infringing on the proprietary rights of others; and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and patent applications related to our proprietary technology that are important to the development and implementation of our business. We seek to obtain domestic and international patent protection, and endeavor to promptly file patent applications for new commercially valuable inventions. We file new patent applications as we conduct research and development, initiate new programs, and monitor the activities of others within the microbiome field. We also rely on trademarks, trade secrets, know-how, and continuing technological innovation to develop and maintain our proprietary position.

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent may be challenged in courts after issuance. Moreover, many jurisdictions permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or at all, whether the claims of any patent applications, should they issue, will cover our product candidates, or whether the claims of any issued patents will provide sufficient protection from competitors or otherwise provide any competitive advantage.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially even longer, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries and patent application filings, we cannot be certain of the priority of inventions covered by pending patent applications. Accordingly, we may not have been the first to invent the subject matter disclosed in some of our patent applications or the first to file patent applications covering such subject matter.

Our patent portfolio leverages both offensive and defensive strategies to protect our business. We have a large and diverse patent portfolio consisting of more than 55 issued U.S. and foreign patents and more than 140 pending patent applications that we own or exclusively license from others. Our patent portfolio has broad applicability across the microbiome field, and provides protection for our lead product candidates CP101, FIN-211, TAK-524, FIN-525, as well as additional Complete, Enriched and Targeted Consortia product candidates that we may develop. For CP101 specifically, our patent portfolio includes more than ten U.S. patents that cover CP101 and methods of use and manufacture. These patents have expiration dates between 2031 and 2037.

Foundational Protection for Multiple Product Candidates

Many of our broadest patents and patent applications originate from patent families that embody pioneering work in the microbiome by Dr. Thomas Borody, a prolific inventor and founder of the Centre for Digestive Diseases in Australia, and Drs. Alexander Khoruts and Michael Sadowsky at the University of Minnesota. These patent families have priority dates that precede the entry into the microbiome field by many of our competitors. As a result, we have been successful in obtaining broad patent coverage from these patent families over the composition formulation, method of manufacture and method of using our product candidates. These patent families include:

- We own a patent family that includes over fifteen issued U.S. patents, three pending U.S. patent applications, granted foreign patents in Australia, Brazil, Canada, China, Israel, Mexico, Republic of Korea, New Zealand and Japan, and three pending foreign patent applications. Representative issued U.S. patents in this family include U.S. 10,022,406, U.S. 9,962,413, U.S. 10,328,107, U.S. 10,278,997, and U.S. 10,617,724, that have claims

directed to pharmaceutical compositions comprising stool bacterial material and a cryoprotectant, methods of processing stool received from healthy human donors, methods of manufacturing, and formulations. Patent applications, if issued, and patents in this family are expected to expire in 2031, assuming all required maintenance fees are paid and absent any applicable patent term extension or patent term adjustment.

- We exclusively in-license a patent family from the Regents of the University of Minnesota that includes over five issued U.S. patents, one pending U.S. patent application, granted foreign patents in Australia, Europe, Canada and China, and three pending foreign patent applications. Representative issued U.S. patents within this family include U.S. 10,028,980, U.S. 10,286,011, U.S. 10,286,012, and U.S. 10,251,914, that have claims directed to formulations comprising fecal bacteria, methods of increasing fecal microbiota diversity, and methods of decreasing relative abundance of a bacteria. Patent applications, if issued, and patents in this family are expected to expire in 2032, assuming all required maintenance fees are paid and absent any applicable patent term extension or patent term adjustment.
- We own a patent family that includes three issued U.S. patents U.S. 9,901,603, U.S. 10,821,138 and U.S. 11,123,377, one pending U.S. patent application, granted patents in Australia, Japan and China, and nine pending foreign patent applications. These issued U.S. patents have claims directed to room temperature stable products containing human-derived bacteria. Patent applications, if issued, and patents in this family are expected to expire in 2036, assuming all required maintenance fees are paid and absent any applicable patent term extension or patent term adjustment.

Complete Consortia Product Candidates, including CP101

Our patent portfolio provides comprehensive patent protection for our Complete Consortia product candidates, including CP101. Representative patents and patent applications from our foundational patent families that have claims that cover CP101 and our Complete Consortia product candidates include:

- One owned issued U.S. patent (U.S. 10,617,724) covering capsules containing lyophilized fecal microbiota from healthy donors, expected to expire in 2031.
- Three owned issued U.S. patents (U.S. 9,962,413, U.S. 10,328,107, and 10,849,937) covering the collection and processing of stool from healthy donors, expected to expire in 2031.
- One owned issued U.S. patent (U.S. 10,022,406) covering compositions comprising fecal microbiota derived from healthy donors, expected to expire in 2031.
- Four in-licensed issued U.S. patents (U.S. 10,028,980, U.S. 10,286,011, U.S. 10,286,012, and U.S. 10,251,914) covering formulations of fecal microbiota derived from healthy donors and their use, expected to expire in 2032.
- Two owned issued U.S. patents (U.S. 9,901,603 and U.S. 10,821,138) covering room-temperature stable products containing human-derived bacteria.
- One in-licensed issued U.S. patent (U.S. 10,849,936) covering a method of treating *C. difficile* infection using lyophilized fecal microbiota, expected to expire in 2037.

Targeted Consortia Product Candidates

For our Targeted Consortia product candidates and their manufacture, our portfolio consists of several issued U.S. patents from our foundational patent families that provide patent coverage. We are also pursuing product-specific patent protection for each of our Targeted Consortia product candidates including TAK-524. Representative patents that we own and provide protection for our Targeted Consortia product candidates include issued U.S. patents (U.S. 10,610,551 and U.S. 10,278,997) covering compositions having lyophilized bacteria from the genus *Bacteroides* or the phylum *Firmicutes* derived from healthy donors and their manufacture, which are expected to expire in 2031.

Enriched Consortia Product Candidates

Our Enriched Consortia product candidates, such as FIN-211, are protected by many of the same patents and patent applications that cover our Complete Consortia product candidates. We also have patent protection for these Enriched Consortia product candidates specifically as well as various pending applications directed to these product candidates. Representative patents and patent applications that have claims that cover our Enriched Consortia product candidates include:

- One owned issued U.S. patent (U.S. 11,207,356) covering encapsulated compositions containing donor-derived microbiota enriched with one or more cultured bacterial strains, expected to expire in 2031.
- One in-licensed issued U.S. patent (U.S. 11,202,808) covering methods of treating ASD or an associated gastrointestinal symptom by orally administering a donor-derived microbial community and a bacterial isolate from a genus with potential therapeutic applications in ASD, expected to expire in 2037.
- One owned issued U.S. patent (U.S. 10,022,406) covering compositions comprising fecal microbiota derived from healthy donors, expected to expire in 2031.
- Three owned issued U.S. patents (U.S. 9,962,413, U.S. 10,328,107, and 10,849,937) covering the collection and processing of stool from healthy donors, expected to expire in 2031.
- Two owned issued U.S. patents (U.S. 9,901,603 and U.S. 10,821,138) covering room temperature stable formulations containing human-derived bacteria, expected to expire in 2036.
- One in-licensed issued U.S. patent (U.S. 10,286,012) covering the use of formulations of fecal microbiota derived from healthy donors, expected to expire in 2032.

Patent Term

Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. In some cases, the term of a U.S. patent may be shortened by terminal disclaimer, which reduces its term to that of an earlier-expiring patent.

Patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 is available for one U.S. patent that includes at least one claim covering the composition of matter of a first approved FDA drug product, or its methods of use or manufacture. The extended patent term cannot exceed the shorter of five years beyond the non-extended expiration of the patent or fourteen years from the date of the FDA approval of the drug product, and a patent cannot be extended more than once or for more than a single product. During the period of extension, if granted, the scope of exclusivity is limited to the approved product for approved uses. Some foreign jurisdictions, including Europe and Japan, have analogous patent term extension provisions, which allow for extension of the term of a patent that covers a drug approved by the applicable foreign regulatory agency. If and when our product candidates receive FDA approval, we expect to apply, if appropriate, for patent term extension on patents covering those product candidates, their methods of use and/or methods of manufacture.

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. We typically rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We protect trade secrets and know-how by establishing confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and collaborators. These agreements provide that all confidential information developed or made known during the course of an individual or entities' relationship with us must be kept confidential during and after the relationship. These agreements also provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties.

Agreements with OpenBiome

Asset Purchase Agreement

In November 2020, we entered into an asset purchase agreement, or the OpenBiome Agreement, with Microbiome Health Research Institute, Inc., or OpenBiome, pursuant to which we acquired certain biological samples, including aliquots of human stool that have been used in clinical trials and under enforcement discretion for the treatment of CDI not responding to standard therapy, and obtained a perpetual license to certain OpenBiome technology, and, upon closing of the transaction, we acquired certain additional assets of OpenBiome, including capital equipment (comprising lab equipment) and contracts relating to the operating maintenance of a lab facility. In connection with entering into the OpenBiome Agreement, we terminated our existing agreements with OpenBiome, as such agreements were superseded by the OpenBiome Agreement and certain other agreements entered into concurrently with the OpenBiome Agreement.

In connection with the signing of the OpenBiome Agreement, OpenBiome granted us a worldwide, irrevocable and perpetual license, with the right to grant sublicenses (through multiple tiers) under certain of OpenBiome's technology that is necessary or useful in the manufacture of products manufactured directly from stool from a stool donor source without the use of culturing or replication, which we refer to as Natural Products, including technology pertaining to the selection of human stool donors, the collection and processing of stool from human donors and the preparation of stool-based products, and under any improvements to our intellectual property previously developed by OpenBiome or developed by OpenBiome during a specified period of time after the closing of the transaction, in each case to exploit products and services. In addition to the foregoing license, except under certain limited circumstances, OpenBiome agreed to not license or transfer to our competitors any rights to those aspects of its manufacturing technology that are not publicly available as of the date of the OpenBiome Agreement.

Pursuant to the OpenBiome Agreement, for the period prior to the closing of the transaction we granted OpenBiome a worldwide, non-exclusive license under certain of our intellectual property rights to make, use, sell, offer for sale, import and export certain Natural Products solely for the treatment of recurrent CDI in the United States under an FDA policy of enforcement discretion and to conduct clinical research in all fields other than the diagnosis, treatment, palliation or prevention in humans of CDI not subject to an FDA policy of enforcement discretion, IBD, ASD or HBV. Additionally, for the period beginning on the closing of the transaction, we granted OpenBiome a worldwide, non-exclusive license under certain of our intellectual property rights to sell certain Natural Products manufactured prior to the closing of the transaction solely for the treatment of recurrent CDI in the United States under enforcement discretion, and to make, use, sell, offer for sale, import and export certain Natural Products for purposes of conducting clinical research in all fields other than the diagnosis, treatment, palliation or prevention in humans of CDI not subject to an FDA policy of enforcement discretion, IBD, ASD or HBV. Notwithstanding the foregoing license, OpenBiome has agreed to certain restrictions related to the use, sale and supply of such products in connection with clinical research of our competitors. Additionally, the license grant excludes any license to exploit a Natural Product wherein processed stool is lyophilized (such as in the case of CP101).

In connection with the signing of the OpenBiome Agreement, we paid OpenBiome $1.0 million in the form of an upfront payment and $150,000 as reimbursement for OpenBiome's attorneys' fees and expenses in connection the negotiation of the OpenBiome Agreement. On the closing of the transaction, we paid OpenBiome $2.25 million, plus an additional $1.6 million if no regulatory restrictions were in place preventing the sale and distribution of OpenBiome's products under enforcement discretion as of the date of closing. In addition to the foregoing payments, we are obligated to pay to OpenBiome a low single digit royalty on net sales of Natural Products by us and our affiliates and a high single digit royalty of certain sublicensing revenue (including royalties) received in connection with Natural Products, as well as a low single digit royalty on net sales of TAK-524, FIN-525 and any product that is not a Natural Product or a product that comprises both material manufactured directly from stool from a stool donor source without the use of culturing or replication and drug substance or drug product comprising one or more active pharmaceutical ingredients, and, in either case contains one or more isolates derived from certain stool donors that are exclusive to us, or Cultured Products, by us and our affiliates and a high single digit percentage of certain sublicensing revenue (including royalties) received in connection with Cultured Products. On a country-by-country basis, our payment obligations with respect to Natural Products expires twenty-five years after first commercial sale of such Natural Product in such country, and, with respect to Cultured Products expires fifteen years after first commercial sale of such Cultured Product in such country. We are also obligated to pay OpenBiome up to $6.0 million in the aggregate upon achievement of certain development and regulatory milestones with Natural Products and $20.0 million in the aggregate upon achievement of certain commercial milestones with Natural Products.

LMIC License Agreement

In November 2020, concurrently with entering into the OpenBiome Agreement, we entered into a license agreement, or the LMIC Agreement, with OpenBiome, pursuant to which we granted OpenBiome a non-exclusive license, with the right to grant sublicenses, under certain of our patents, patent applications and know-how that are reasonably necessary or useful for the exploitation of products manufactured directly from stool from a stool donor source without the use of culturing or replication, or Natural Products, to make, use, sell, have sold, offer for sale and import Natural Products and formulated liquid suspensions derived from the stool of a stool donor source that may be incorporated into a Natural Product, in either case for the treatment in humans of malnutrition and neglected tropical diseases in certain low- and middle-income countries, or the LMIC Territory. The license grant excludes any license to exploit a Natural Product wherein processed stool is lyophilized (such as in the case of CP101) or to otherwise use the licensed intellectual property to lyophilize a product.

Pursuant to the LMIC Agreement, we own all improvements, enhancements or modifications to the licensed intellectual property (whether or not patentable) invented by either party during the term of the LMIC Agreement. OpenBiome has agreed to assign to us its interest in and to any such improvements, enhancements or modifications.

Pursuant to the LMIC Agreement, we are entitled to receive tiered royalties on net sales of Natural Products and products that incorporate formulated liquid suspensions derived from the stool of a stool donor source that may be incorporated into a Natural Product in the LMIC Territory ranging from mid-single digit to low-second decile. Royalties are payable on a product-by-product and country-by-country basis during the period beginning on the first commercial sale of such product in such country and ending on the later of the expiration of the last to expire valid claim from a licensed patent that covers such product or ten years from the date of the LMIC Agreement.

The LMIC Agreement expires on product-by-product and country-by-country basis upon expiry of the applicable royalty obligation for such product in such country. OpenBiome has the right to terminate the LMIC Agreement upon specified prior written notice to us. Either party may terminate the LMIC Agreement in the event of an uncured material breach by the other party of either the LMIC Agreement (or uncured breach by OpenBiome of the OpenBiome Agreement), provided that if such uncured material breach is limited to a breach of the LMIC Agreement in a particular country, our right to terminate the LMIC Agreement is limited to just such country. Either party may terminate the LMIC Agreement in the event of the insolvency of the other party. We may terminate the LMIC Agreement in the event that OpenBiome brings, or assists in bringing, a challenge to the validity, patentability, scope, construction, inventorship, ownership, enforceability or non-infringement of any licensed patent or patent application.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries and jurisdictions including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biological products, such as our product candidates and any future product candidates. We, along with third-party contractors, will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable regulatory requirements at any time during the product development process or post-approval may subject an applicant to delays in development or approval or licensure, as well as administrative or judicial sanctions.

Regulatory Approval of Biological Products in the United States

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and their implementing regulations. Biological products are also subject to other federal, state, local and foreign statutes and regulations. The process required by the FDA before biological product candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory and animal studies in accordance with applicable regulations, including studies conducted in accordance with the FDA's Good Laboratory Practice, or GLP, requirements;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin and must be updated annually and when certain changes are made;

- approval by an institutional review board, or IRB, or independent ethics committee at each clinical trial site before each clinical trial may be commenced;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, Good Clinical Practice, or GCP, requirements and other clinical trial-related regulations to establish the safety, purity and potency of the product candidate for each proposed indication;
- preparation and submission to the FDA of a biologics license application, or BLA, after completion of all clinical trials;
- payment of any user fees for FDA review of the BLA;
- a determination by the FDA within 60 days of its receipt of a BLA to accept the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the biological product, or components thereof, will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- satisfactory completion of any potential FDA audits of the clinical trial sites that generated the data in support of the BLA to assure compliance with GCPs and integrity of the clinical data; and
- FDA review and approval of the BLA, to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical Studies

Before testing any biological product candidates in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of product biological characteristics, chemistry, toxicity, formulation and stability, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. Some long-term preclinical testing may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may or may not result in the FDA allowing clinical trials to commence.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with GCPs, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing, among other things, the objectives of the trial, dosing procedures, subject selection and eligibility criteria, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated in the trial. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about certain clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website. Information related to the investigational product, patient population, phase of investigation, clinical trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Disclosure of the results of these clinical trials can be delayed in certain circumstances.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if, among other things, the clinical trial was conducted with qualified investigators in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

For purposes of BLA submission and approval, clinical trials are generally conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, which may overlap or be combined:

- Phase 1 clinical trials generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the biological product candidate. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. The primary purpose of these clinical trials is to assess the safety, dosage tolerance, absorption, metabolism and distribution of the biological product candidate in humans, the side effects associated with increasing doses, and, if possible, early evidence of effectiveness.
- Phase 2 clinical trials generally involve studies conducted in a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide statistically significant evidence of clinical efficacy of the biological product candidate for its intended use, further evaluate its safety and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval and labeling. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the biological product candidate.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

The FDA may, at any time while clinical trials are ongoing under the IND, impose a partial or complete clinical hold based on concerns for patient safety and/or noncompliance with regulatory requirements. This order issued by the FDA would delay a proposed clinical study or cause suspension of an ongoing study until all outstanding concerns have been adequately addressed, and the FDA has notified the company that investigations may proceed. Additionally, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including non-compliance with regulatory requirements or a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product candidate has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within fifteen calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the biological product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, companies must

develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over their shelf life.

FDA Review Processes of Biological Products

Assuming successful completion of all required testing and clinical trials of a biological product candidate in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product candidate's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product candidate, or from a number of alternative sources, including studies initiated by independent investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the identity, quality, safety, purity and potency of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

The cost of preparing and submitting a BLA is substantial. Under the Prescription Drug User Fee Act, or PDUFA, each BLA must be accompanied by a substantial user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. The applicant under an approved BLA is also subject to an annual program fee.

The FDA reviews a submitted BLA to determine if it is substantially complete before the FDA accepts it for filing and may request additional information from the sponsor. The FDA must make a decision on accepting a BLA for filing within 60 days of receipt, and may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission. In this event, the BLA must be resubmitted with any additional information requested. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. The FDA reviews a BLA to determine, among other things, whether the biological product candidate is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. Under the goals agreed to by the FDA under PDUFA, the FDA has ten months, from the filing date, in which to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process can be extended by FDA requests for additional information or clarification. This review typically takes twelve months from the date the BLA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision. The review process and the PDUFA goal date for both standard and priority review BLAs may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission within the last three months before the PDUFA goal date.

Before approving a BLA, the FDA will typically conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether such facilities comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

The FDA also may inspect one or more clinical sites and audit data from clinical trials to ensure compliance with GCP requirements and the integrity of the data supporting safety, purity, and potency of the product candidate. Additionally, the FDA may refer applications for novel product candidates or product candidates that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it generally considers such recommendations carefully when making decisions on approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product is produced, it will issue either an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the biological product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the BLA and may require additional clinical data, additional pivotal clinical trial(s)

and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing in order for the FDA to reconsider the application for approval. If a CRL is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing. The FDA has committed to reviewing such resubmissions in two or six months from receipt, depending on the type of information included. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations to specific diseases and dosages or the indications for use for which such product may be marketed. For example, the FDA may require a Risk Evaluation and Mitigation Strategy, or REMS, to help ensure that the benefits of the biological product outweigh the potential risks to patients. A REMS is a safety strategy implemented to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use. A REMS can include medication guides, communication plans for healthcare professionals and elements to assure a product's safe use, or ETASU. An ETASU can include, but is not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring and the use of patient-specific registries. The requirement for a REMS can materially affect the potential market and profitability of the product. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require, or companies may voluntarily pursue, one or more post-market clinical trials, sometimes referred to as Phase 4 clinical trials, and testing and surveillance programs to further assess and monitor the product's safety and effectiveness after approval, and may limit further marketing of the product based on the results of these post-marketing studies.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product candidate intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making the product for this type of disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation on its own does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Among the benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee. In addition, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication. In the latter case, because healthcare professionals are free to prescribe products for off-label uses, the competitor's product could be used off-label for the orphan indication despite another product's orphan exclusivity.

A designated orphan drug many not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if a second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. For example, Fast Track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and where preclinical or clinical data demonstrate the potential to address unmet medical needs for the disease condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a biological product candidate can request the FDA to designate the candidate for a specific indication for Fast Track status concurrent with, or after, the submission of the IND for the candidate. The FDA must determine if the biological product candidate qualifies for Fast Track designation within 60 days of receipt of the sponsor's request. The sponsor of a Fast Track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the product candidate may be eligible for priority review. A Fast Track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. Any product submitted to the FDA for approval, including under the Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval.

Breakthrough Therapy designation may be granted for product candidates that are intended, alone or in combination with one or more other products, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over available therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Under the Breakthrough Therapy program, the sponsor of a new biological product candidate may request that the FDA designate the candidate for a specific indication as a Breakthrough Therapy concurrent with, or after, the submission of the IND for the biological product candidate. The FDA must determine if the biological product qualifies for Breakthrough Therapy designation within 60 days of receipt of the sponsor's request. The FDA may take certain actions with respect to product candidates designated as breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team and taking other steps to design the clinical studies in an efficient manner. The designation also includes all of the Fast Track program features, including eligibility for rolling review of BLA submissions if the relevant criteria are met.

Priority review may be granted for product candidates that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in the safety and effectiveness of the treatment, diagnosis or prevention of serious conditions when compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application for a new biological product designated for priority review in an effort to facilitate the review. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Accelerated approval may be granted for products that are intended to treat a serious or life-threatening condition and that generally provide a meaningful therapeutic advantage to patients over existing treatments and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on an intermediate clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that is reasonably likely to predict the clinical benefit of the product candidate and substitutes for a direct measurement of how a patient feels, functions or survives. The accelerated approval pathway is contingent on a sponsor's agreement to conduct additional post-approval confirmatory studies to verify and describe the product's clinical benefit. These confirmatory trials must be completed with due diligence and, in some cases, the FDA may require that the trial be designed, initiated and/or fully enrolled prior to approval. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA prior to the intended date or dissemination or publication.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, Breakthrough Therapy designation, priority review and accelerated approval do not change the standards for approval, but may expedite the development or approval process.

Pediatric Information and Exclusivity

Under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA for a novel product (e.g. new active ingredient, new indication, etc.) must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA generally does not apply to any biological product for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides a six-month extension of any exclusivity—patent or non-patent—for a biological product if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Post-Approval Requirements for Biological Products

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, reporting updated safety and efficacy information, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. Once a BLA is approved, a product will be subject to certain additional post-approval requirements, such as quality control, biological product manufacture, packaging and labeling procedures that must continue to conform to cGMPs after approval. Biologic manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Manufacturers of biological products are required to comply with applicable requirements in the cGMP regulations, including quality control, quality assurance and maintenance of records and documentation. Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA, including those focused on manufacturing facilities to assess compliance with cGMPs. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market or product recalls;
- fines, warning or other enforcement-related letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biological products, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biological products. As with drugs, after approval of a biological product candidate, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

U.S. Patent Term Restoration, Biosimilars and Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our biological product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. In addition, a patent can only be extended once and only for a single product. The United State Patent and Trademark Office, or USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our patents, if and as applicable, to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, signed into law in 2010, includes a subtitle called The Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. This amendment to the PHS Act attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes

by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA an application for a biosimilar or interchangeable product may not be accepted by the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product.

International Regulation

In addition to regulations in the United States and Europe, a variety of foreign regulations govern clinical trials, commercial sales and distribution of product candidates. The approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA or European Commission approval.

Coverage and Reimbursement

In the United States, market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations, pharmacy benefit management organizations, and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is a covered benefit under its health plan; safe, effective and medically necessary; appropriate for the specific patient; cost-effective; and neither experimental nor investigational.

While no uniform policy for coverage and reimbursement exists in the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Therefore, one payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage, and adequate reimbursement, for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Further, third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Accordingly, third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost-effectiveness of a product, to qualify for reimbursement, which could be costly and divert resources.

Outside of the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental

authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Further, the commercial success of any approved products will also depend in large part on the availability of insurance coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, and managed care organizations, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Moreover, coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. If government and other healthcare payors were not to provide adequate insurance coverage and reimbursement levels for one any of our products once approved, market acceptance and commercial success would be limited.

Other Healthcare Laws and Regulations and Legislative Reform

Healthcare Laws and Regulations

Healthcare providers, including physicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our operations, including any arrangements with professionals, principal investigators, consultants, third-party payors and customers subject us to various federal and state fraud and abuse and other healthcare laws that may affect the business or financial arrangements and relationships through which we would market, sell and distribute our products. Our current and future operations are subject to regulation by various federal, state, and local authorities in addition to the FDA, including but not limited to the Centers for Medicare & Medicaid Services, or CMS, the U.S. Department of Health and Human Services (including the Office of Inspector General, Office for Civil Rights and the Health Resources and Services Administration), or HHS, the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. The healthcare laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for, or to induce or reward either the referral of an individual for, or the purchase, lease, order or arrangement for, or recommendation of the purchase, lease, order, or arrangement for, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term “remuneration” has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Additionally, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the ACA, signed into law in 2010, provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- federal civil and criminal false claims laws, such as the False Claims Act, which can be enforced by private citizens through civil qui tam actions, and civil monetary penalty laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of or approval from the federal government, including Medicare, Medicaid and other government payors, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. Drug manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. For example, pharmaceutical companies have been prosecuted under the False Claims Act in connection with their alleged off-label promotion of drugs,

purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, among other things, imposes civil and criminal liability for knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense. HIPAA also creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which impose privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates and their covered subcontractors that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal transparency requirements under the Physician Payments Sunshine Act, created under the ACA, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to (i) payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare providers (such as physicians assistants and nurse practitioners), and teaching hospitals and (ii) physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- state and foreign laws that are analogous to each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by non-governmental third-party payors, including private insurers, and state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and
- state and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other healthcare providers; state laws that require the reporting of marketing expenditures or drug pricing, including information pertaining to and justifying price increases; state and local laws that require the registration of pharmaceutical sales representatives; state laws that prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals; state laws that require the posting of information relating to clinical trials and their outcomes; and other federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

If our operations are found to be in violation of any of these laws or any other current or future healthcare laws that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Legislative Reform

We operate in a highly regulated industry, and new laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, related to healthcare availability, the method of delivery and payment for healthcare products and services could negatively affect our business, financial condition and prospects. There is significant interest in promoting healthcare reforms, and it is likely that federal and state legislatures within the United States and the governments of other countries will continue to consider changes to existing healthcare legislation.

For example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In 2010, the U.S. Congress enacted the ACA, which included changes to the coverage and reimbursement of drug products under government healthcare programs such as:

- increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program;
- established a branded prescription drug fee that pharmaceutical manufacturers of certain branded prescription drugs must pay to the federal government;
- expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program;
- established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;
- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- established a Center for Medicare and Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- created a licensure framework for follow-on biologic products.

There have been judicial, executive branch and congressional challenges to certain aspects of the ACA. For example, in 2017, the U.S. Congress enacted the Tax Cuts and Jobs Act of 2017, or Tax Act, which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or congressional challenges in the future. It is unclear how any such challenges and the health reform measures of the Biden administration will impact the ACA and our business.

In addition, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. In 2011, the U.S. Congress enacted the Budget Control Act, which included provisions intended to reduce the federal deficit. The Budget Control Act resulted in the imposition of 2% reductions in Medicare payments to providers beginning in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031, absent additional congressional action. The Coronavirus Aid, Relief and Economic Security Act, and subsequent legislation, suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In addition, in 2012, the U.S. Congress enacted the American Taxpayer Relief Act, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If government spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA, to continue to function at current levels, which may impact the ability of relevant agencies to timely review and approve research and development, manufacturing and marketing activities, which may delay our ability to develop, market and sell any product candidates we may develop. Moreover, any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented, or any significant taxes or fees that may be imposed on us, as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, could have an adverse impact on our anticipated product revenues.

Furthermore, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several congressional inquiries and proposed legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. At the federal level, the former Trump administration used several means to propose implementing drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, President Trump signed several executive orders aimed at lowering drug prices. As a result, the FDA released a final rule and guidance in September 2020 providing pathways for states to build and submit importation plans for drugs from Canada. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform initiatives.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. We expect that additional state and federal healthcare reform measures will be adopted in the future.

Employees and Human Capital Resources

As of December 31, 2021, we had 189 employees. Of these 189 employees, 156 are engaged in research and development activities and 33 are engaged in business development, finance, legal, information systems, facilities, human resources or administrative support. None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purpose of our 2021 Equity Incentive Plan is to attract, retain and motivate selected employees, consultants and directors through the granting of equity-based compensation awards.

We believe that our long-term success requires a diverse and inclusive workforce. We value diversity at all levels of the organization and continue to focus on extending our diversity, equity and inclusion initiatives across our entire workforce, including through our Diversity, Equity and Inclusion Committee, which is a cross-functional group designed to create programs focused on understanding employees' intersecting identities, honoring differences and rooting out systemic inequity. In addition, we pride ourselves on an open culture that respects co-workers, values employees' health and well-being and fosters professional development. We conduct regular employee engagement surveys, and our board of directors provides input on important decisions relating to these matters, including with respect to employee compensation and benefits and talent acquisition and retention.

Corporate Information

We were originally incorporated in Delaware in November 2014 and until September 21, 2017, or the Merger Date, we conducted our business through Finch Therapeutics, Inc., a Delaware corporation. On the Merger Date, pursuant to the terms of the agreement and plan of merger, or the Merger Agreement, Finch Therapeutics, Inc. and Crestovo Holdings LLC, a Delaware limited liability company, completed a merger of equals. Pursuant to the terms of the Merger Agreement, each of Finch Therapeutics, Inc. and Crestovo Holdings LLC became a wholly-owned subsidiary of Finch Therapeutics Group, Inc. Crestovo Holdings LLC was renamed Finch Therapeutics Holdings LLC in November 2020.

Our principal executive office is located at 200 Inner Belt Road, Suite 400, Somerville, Massachusetts 02143. Our telephone number is (617) 229-6499. Our website address is www.finchtherapeutics.com. Information contained in, or accessible through, our website does not constitute a part of, and is not incorporated into, this Annual Report on Form 10-K.

Available Information

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and, accordingly, file reports, proxy statements and other information with the Securities and Exchange Commission, or SEC. The SEC maintains a website (http://www.sec.gov) that contains material regarding issuers that file electronically, such as ourselves, with the SEC.

We make available free of charge on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Item 1A. Risk Factors

Our business is subject to numerous risks. You should consider carefully the risks and uncertainties described below, in addition to other information contained in this Annual Report on Form 10-K as well as our other public filings with the Securities and Exchange Commission, or the SEC. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and growth prospects and cause the trading price of our common stock to decline.

Risks Related to Our Financial Position and Capital Needs

We have a limited operating history, have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.

We are a clinical-stage microbiome therapeutics company with a limited operating history. Since our inception, we have focused primarily on developing and progressing our product candidates through clinical development, organizing and staffing our company, research and development activities, establishing and protecting our intellectual property portfolio, including for our Human-First Discovery platform, and raising capital. Consequently, we have no meaningful operations upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drug products. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have not yet demonstrated the ability to progress any product candidate through clinical trials, we have no products approved for commercial sale and we have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. For the years ended December 31, 2021 and 2020, we reported net losses of $58.2 million and $39.3 million, respectively. As of December 31, 2021, we had an accumulated deficit of $161.0 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for our therapeutic product candidates CP101, for the prevention of recurrent *Clostridioides difficile* infection, or CDI, FIN-211, to address symptoms of autism spectrum disorder, or ASD, and any other current or future product candidates we may develop.

We anticipate that our expenses will increase substantially if, and as, we:

- continue our ongoing and planned development of CP101 for the prevention of recurrent CDI, including our Phase 3 clinical trial of CP101, and seek to resolve the clinical hold on our investigational new drug application, or IND, for CP101, which is expected to extend timelines and increase costs;
- initiate preclinical studies and clinical trials for our other product candidates and any additional product candidates that we may pursue in the future, including our earlier-stage programs such as our planned Phase 1b clinical trial of FIN-211 to address symptoms of autism spectrum disorder, or ASD;
- develop, optimize and scale our manufacturing processes and capabilities, including commissioning and qualifying newly constructed facilities to support the commercial scale production of CP101 and, in the future, similar scale-up for our other drug candidates, which may include the development of new technology;
- establish and expand a donor program to support our clinical supply for trial and initial commercial needs;
- increase the amount of research and development activities to identify and develop product candidates using our proprietary discovery approach;
- make milestone, royalty or other payments under in-license or collaboration agreements;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing, quality systems and commercialization efforts and our operations as a public company;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties;

- invest in or in-license other technologies; and
- experience any delays or encounter any issues with any of the above, including, but not limited to, failed studies, complex results, manufacturing challenges, quality issues, safety issues or other regulatory challenges, or as a result of the ongoing COVID-19 pandemic.

To become and remain profitable, we, our collaborators and any potential future collaborators must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities as to which we can make no assurances that we will be successful, including resolving the clinical hold on our IND for CP101, addressing findings from the related quality investigation, completing related manufacturing activities with respect to both CP101 and FIN-211, and providing additional information to the FDA regarding our PRISM4 protocol and the validation package for one of our release tests, which is utilized for both CP101 and FIN-211. We will also need to be successful in completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require substantial additional funding to finance our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our product development programs or other operations.

To date, we have primarily funded our operations through the IPO, private placements of equity securities and upfront and milestone payments received pursuant to our collaboration agreement with Takeda Pharmaceutical Company Limited, or Takeda. We expect to spend substantial amounts to advance our product candidates into clinical development and to complete the clinical development of, seek regulatory approvals for and, if approved, commercialize, our product candidates. We will require additional capital, which we may raise through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources to enable us to complete the development and potential commercialization of our product candidates. Adequate additional financing may not be available to us on acceptable terms, or at all. Our ability to raise capital is dependent on a number of factors, including the market demand for our common stock, which is uncertain. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate certain of our research and development programs.

As of December 31, 2021, our cash and cash equivalents were $133.5 million. We believe that our existing cash on hand will enable us to fund our operating expenses and capital expenditure requirements into mid-2023. However, we will need to obtain substantial additional funding in connection with our continuing operations and planned activities. Our future capital requirements will depend on many factors, including:

- the timing, costs, progress and results of our ongoing and planned clinical trials of CP101, FIN-211 and other product candidates, including our ability to resolve the clinical hold on our IND for CP101, address findings from our related quality investigation, complete related manufacturing activities with respect to both CP101 and FIN-211, and provide additional information to the FDA regarding our PRISM4 protocol and the validation package for one of our release tests, which is utilized for both CP101 and FIN-211;
- the progress of preclinical development and possible clinical trials of our current earlier-stage programs;
- the scope, progress, results and costs of our research programs and preclinical development of other product candidates that we may pursue;

- the development requirements of other product candidates that we may pursue;
- any possible delays or interruptions with our clinical trials, our receipt of services from our third-party service providers on whom we rely, our supply chain or other regulatory challenges, including those due to the COVID-19 pandemic or to other unforeseen global events;
- our headcount growth and associated costs as we conduct our research and development and establish a commercial infrastructure;
- the timing and amount of milestone and royalty payments that we are required to make or eligible to receive under our current or future licensing and collaboration agreements;
- the cost of establishing a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration, or the FDA, and any comparable foreign regulatory authority;
- the costs and timing of future commercialization activities, including product manufacturing and related quality systems implementation, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs associated with operating our commercial scale manufacturing facility;
- the cost of expanding, maintaining and enforcing our intellectual property portfolio, including filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of potential stockholder litigation or regulatory investigations, which may involve past or future significant announcements, transactions or disclosures since our IPO; for example, several class action plaintiff law firms have issued press releases announcing that the firms are investigating securities law claims on behalf of our stockholders following our March 1, 2022 announcement that enrollment in PRISM4 was paused following receipt of the clinical hold letter on February 24, 2022;
- the cost of potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our product candidates, such as the complaint filed by Rebiotix Inc. and Ferring Pharmaceuticals Inc., seeking a declaratory judgment of non-infringement and invalidity with respect to seven U.S. patents owned by us;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale manufacturing capabilities for future product candidates;
- the extent to which we partner our programs, acquire or in-license other product candidates and technologies or enter into additional strategic collaborations;
- the revenue, if any, received from commercial sales of CP101, FIN-211, and any future product candidates for which we receive marketing approval;
- the cost of equipment and physical infrastructure to support our research and development; and
- the costs of operating as a public company, including costs associated with compliance, disclosure and insurance.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, CP101, FIN-211 and any future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether terminate our research and development programs or future commercialization efforts.

Raising additional capital will cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our product candidates.

Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights.

If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish certain valuable rights to our intellectual property, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our clinical development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

Risks Related to the Development of Our Product Candidates

We are currently subject to a clinical hold on our IND for CP101. We need to resolve the FDA clinical hold issues in order to proceed with enrollment in our PRISM4 clinical trial and initiate our Phase 1b clinical trial in ASD. Our business may be adversely affected if the clinical hold is not resolved in a timely manner or if regulatory concerns lead to additional delays and/or FDA enforcement actions.

CP101 is our lead product candidate, and as announced on March 1, 2022, we paused enrollment in our Phase 3 clinical trial of CP101 in recurrent CDI, which we refer to as the PRISM4 trial, in response to receipt of a clinical hold letter from the FDA on February 24, 2022.

In March 2020, at the outset of the COVID-19 pandemic, the FDA issued a public safety alert regarding the potential risk of transmission of SARS-CoV-2 virus through the use of donor-derived investigational microbiome therapies and the need for additional safety precautions. At that time, the FDA placed our IND for CP101 on partial clinical hold, requiring us to implement new SARS-CoV-2 screening measures for any microbiota material donated on or after December 1, 2019 and to address the risk of SARS-CoV-2 transmission in the informed consent process. Following communications with the FDA in January 2022, on February 24, 2022, the FDA sent us a clinical hold letter, stating that the FDA required additional information about our SARS-CoV-2 screening protocols and related informed consent language, and that a clinical hold remains in effect until the FDA's requests have been satisfactorily addressed. We also received an additional letter from the FDA, dated March 17, 2022, requesting changes to the testing algorithm used to diagnose suspected CDI recurrences in PRISM4, as well as additional information regarding the proposed statistical analysis plan for PRISM4 and the validation package for one of our release tests, which is utilized for both CP101 and FIN-211.

We are unable to proceed with enrollment in the PRISM4 trial until: the FDA removes the clinical hold; we address findings from our ongoing quality investigation in connection with the clinical hold; we conduct additional manufacturing activities with respect to CP101 to satisfy certain of the FDA's requests related to SARS-CoV-2 screening and testing; and we satisfactorily address the FDA's additional questions regarding PRISM4 and the validation package for one of our release tests. Because FIN-211, our product candidate designed to address symptoms of ASD, includes donor-derived components, the clinical hold will also delay initiation of our Phase 1b clinical trial of FIN-211 and will require us to conduct additional manufacturing activities with respect to components of FIN-211 in order to satisfy the FDA's requests. If we are delayed longer than anticipated in successfully addressing the FDA’s concerns underlying the clinical hold and the subsequent letter regarding PRISM4, our costs and timelines associated with our clinical trials in recurrent CDI and ASD would change, potentially in a significant manner.

In November 2021, we began dosing participants in our PRISM4 trial with CP101. Since we dosed participants while the clinical hold was in effect, we may be subject to an additional clinical hold or FDA administrative, advisory, or enforcement actions, which could include, among other things, a warning letter, and the participants dosed during this time may not be considered part of the per protocol population and/or efficacy analysis for PRISM4. An additional clinical hold or FDA administrative, advisory, or enforcement actions could result in a significant delay in our development of CP101, FIN-211 and other current or future product candidates, a significant increase in costs, could delay or potentially jeopardize our ability

to commence product sales and generate revenue, could result in adverse publicity, and could cause a decline in our stock price, any of which may adversely affect our business. In addition, if we are unable to resolve the clinical hold favorably or if the FDA or other regulatory agencies express any concerns regarding the use of donor material in microbiome therapeutics, it could adversely affect our ability to develop CP101, FIN-211 and other current or future product candidates.

We are heavily dependent on the success of our product candidates, which are in clinical and preclinical development. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. We are early in our product candidate development efforts, as CP101 is our only product candidate to reach clinical development to date. Because CP101 is our lead product candidate, and the IND for CP101 is currently under clinical hold by the FDA, if CP101 encounters safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be significantly harmed.

Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of CP101, FIN-211 and any other current or future product candidates we develop, which may never occur. CP101, FIN-211 and any other product candidates we develop will require additional preclinical and clinical development, management of clinical, preclinical, manufacturing and quality activities, marketing approval in the United States and other jurisdictions for specific indications for use, demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization and substantial investment and significant marketing efforts before we generate any revenues from product sales. The success of our current and future product candidates will depend on several factors, including the following:

- our ability to resolve the clinical hold on our IND for CP101, address findings from our related quality investigation, complete related manufacturing activities with respect to both CP101 and FIN-211, and provide additional information to the FDA regarding our PRISM4 protocol and the validation package for one of our release tests, which is utilized for both CP101 and FIN-211;
- successful and timely completion of clinical trials and preclinical studies for which the FDA or any comparable foreign regulatory authority agree with the design, endpoints or implementation;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receiving regulatory approvals or authorizations for conducting our planned clinical trials or future clinical trials;
- initiation and successful patient enrollment in, and completion of, additional clinical trials on a timely basis;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate is safe and effective as a treatment for our targeted indications or, in the case of an applicable product candidate that is regulated as a biological product, that the applicable product is safe, pure, and potent and controlled for our targeted indications and in either case, that our quality management systems are sufficient to ensure such results;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate’s risk-benefit ratio for its proposed indication is acceptable;
- timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishing and scaling up, either alone or with third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing that meet current Good Manufacturing Practices, or cGMP, and other legal and regulatory requirements, if any of our product candidates are approved;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates, both in the United States and internationally;
- successfully scaling a sales and marketing organization and launching commercial sales of our product candidates, if approved;

- acceptance of our product candidates' benefits and uses, if approved, by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety profile of our product candidates following approval, including long-term safety;
- effectively competing with companies developing and commercializing other therapies in the indications that our product candidates target;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors; and
- enforcing and defending against intellectual property rights and claims.

Many of these risks are beyond our control, including the risks related to clinical development, the regulatory review process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborators. If we are unable to develop, receive regulatory approval for, or successfully commercialize our current or future product candidates, or if we experience delays as a result of any of these risks or otherwise, our business could be materially harmed.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize CP101, FIN-211 or any other current or future product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for our current and future product candidates, we may not be able to continue our operations.

Our product candidates are based on microbiome therapeutics, which is an unproven approach to therapeutic intervention.

All of our product candidates are based on microbiome therapy, a therapeutic approach that is designed to treat disease by restoring the function of a dysbiotic microbiome. We have not, nor to our knowledge, has any other company, received regulatory approval for a therapeutic based on this approach. We cannot be certain that our approach will lead to the development of approvable or marketable products. In addition, the efficacy potential of our microbiome therapeutics may vary based on indication and use in different patient populations including geographical areas. Finally, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of products based on microbiome therapeutics, which could result in a longer than expected regulatory review process or evolving FDA standards and guidance, increase our expected development costs and delay or prevent commercialization of our product candidates. Regulatory requirements governing microbiome therapies are still developing and may change in the future or may be influenced by our competitors' product candidates if they receive FDA approval before we do. Regulatory authorities and advisory groups, and the new guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our current or future product candidates or lead to significant post-approval limitations or restrictions.

Microbiome therapies in general may not be successfully developed or commercialized or gain the acceptance of the public or the medical community. Our success will depend upon physicians who specialize in the treatment of diseases targeted by our product candidates that we pursue as drugs, prescribing potential treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Our success will also depend on consumer acceptance and adoption of our products that we commercialize. Adverse events in non-IND human clinical studies and clinical trials of our product candidates, or in non-IND human clinical studies and clinical trials of others developing similar products or products that are perceived to be similar to ours, such as fecal microbiota transplant, or FMT, materials, as well as any other adverse findings that arise in connection with research and development in the microbiome field, could result in negative publicity and a decrease in demand for any product that we may develop. In addition, responses by the federal, state or foreign governments to negative public perception or ethical concerns may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval, identify alternate regulatory pathways to market or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop.

Our microbiome therapeutics platform relies in part on third parties for biological materials, including human stool. Some biological materials have not always met our expectations or requirements, and any disruption in the supply of these

biological materials could materially adversely affect our business. For example, if any supplied biological materials are contaminated with pathogens or disease organisms, we would not be able to use such biological materials. Although we have control processes and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. While we screen for a broad set of pathogens as a part of our manufacturing process, the donated human stool may contain organisms of which we are not aware and that could have an adverse effect on the safety of our product candidates and on the outcomes of our preclinical studies or clinical trials. For example, our SARS-CoV-2 donor screening protocols may not be satisfactory to regulatory authorities, as the FDA has requested information about our protocols in the clinical hold letter we received in February 2022. Improper storage or shipment of these materials, by us or any third-party suppliers, may require us to destroy some of our raw materials or products which could create supply shortages, interruptions or other delays or require identification and contracting of additional third-party suppliers which we may not be able to do in a timely manner or on favorable terms.

Our relationship with OpenBiome may adversely affect our ability to develop our product candidates and subject us to increased liability.

The Microbiome Health Research Institute, Inc., or OpenBiome, is a non-profit organization that was co-founded in 2012 by our Chief Executive Officer and member of our board of directors, Mark Smith, Ph.D. OpenBiome operates a stool bank and sells and distributes fecal microbiota transplant products, or OpenBiome FMT Materials, for clinical research and for use in treating CDI not responding to standard therapy under its interpretation of the FDA's policy of enforcement discretion. In July 2013, the FDA issued guidance stating that it intended to exercise a policy of enforcement discretion regarding the IND regulatory requirements for the use of FMT used to treat CDI not responding to standard therapies, provided that the treating physician obtains appropriate informed consent from the patient or his or her legally authorized representative. We have historically had a close relationship with OpenBiome and are currently and have previously been party to several agreements with OpenBiome related to, among other things, the license of various technology and intellectual property rights. In addition, Carolyn Edelstein, the co-founder and former Executive Director of OpenBiome, is married to Dr. Smith. Although we believe our agreements with OpenBiome have been negotiated at an arms-length basis, there may be a perception that the terms of any such agreements have not been fairly negotiated, which could increase regulatory scrutiny, adversely impact our reputation or otherwise impair our ability to operate effectively.

In 2016, we entered into a Master Strategic Affiliation Agreement with OpenBiome, or the Strategic Agreement, pursuant to which, among other things, we manufactured OpenBiome FMT Materials to specifications defined by OpenBiome for distribution and sale by OpenBiome through February 2019. These OpenBiome FMT Materials have been and may continue to be distributed and sold by OpenBiome, and administered to patients. The FDA may not agree with OpenBiome's interpretation or application of the FDA's enforcement discretion policy to its product distribution. We terminated the Strategic Agreement in 2020 as part of signing an asset purchase agreement, or the OpenBiome Agreement, and license agreement with OpenBiome, pursuant to which we acquired certain biological materials, equipment, and other assets, and cross-licensed certain intellectual property. The OpenBiome Agreement also retained certain existing intellectual property and biological materials licenses from the Master Strategic Affiliation Agreement into a stand-alone agreement. Although we are indemnified for causes of action relating to the distribution and sale of the OpenBiome FMT Materials, we may nonetheless become parties to potential product liability claims that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products such as OpenBiome FMT Materials.

Moreover, the availability of OpenBiome FMT Materials under the FDA's policy of enforcement discretion, and for use in clinical research, may negatively prejudice and slow enrollment of clinical trials sponsored by us or our collaborators that are directed at the same or similar disease or condition, such as CDI. Additionally, while each of CP101 and FIN-211 is an orally administered biologic consisting of a complete microbiome and a distinct product from OpenBiome FMT Materials, with additional testing, manufacturing and control steps, it is possible that the FDA and others might perceive CP101, FIN-211 or any of our other product candidates as similar owing to their common raw material. The FDA has issued three safety alerts since 2019 related to the use of FMT treatment, including in March 2020 after OpenBiome reported occurrences of enteropathogenic E. coli and shigatoxin-producing E. coli in FMT recipients. This and similar adverse safety events associated with OpenBiome FMT Materials or other similar products manufactured or supplied by other third-party stool banks, physicians or others may cause the FDA to perceive CP101 or FIN-211 as unsafe and bring increased regulatory scrutiny to our clinical and manufacturing operations more broadly, lead to decreased confidence by patients and physicians in our product candidates, and result in reduced demand for any product that we may develop.

OpenBiome has also supplied us with biological materials derived from human stool, which we have used as raw materials, subject to additional testing, screening and processing, in the manufacture of our product candidates, such as CP101 and FIN-211, for use in our current and planned clinical trials. During the time we engaged OpenBiome to supply us with such human stool material, OpenBiome received a clinical hold from the FDA with respect to the need for new screening measures to

mitigate the risk of transmission of SARS-CoV-2 from donor to recipient of its OpenBiome FMT materials, and the need for additional information regarding OpenBiome's quality systems. This clinical hold was removed in January 2021. Although the OpenBiome clinical hold did not preclude us from receiving OpenBiome-supplied biological materials for our manufacturing activities, given that some materials were received while OpenBiome was under clinical hold, we may not be able to use these materials for such purposes if the FDA or other parties perceive such materials to be unsuitable for use in an investigational drug. For example, the FDA or other regulatory agencies may determine that the materials should not be used for reasons underlying the clinical hold, or different reasons. In addition, while we have tested these materials and reviewed manufacturing records to ensure they meet our quality standards, we are using an assay to screen for COVID-19 that the FDA may not deem acceptable; moreover, in its February 2022 clinical hold letter for our CP101 IND, the FDA requested additional information regarding this assay. In addition, we may not be able to recoup the costs associated with acquiring these biological materials from OpenBiome.

In addition, in connection with the closing of the transactions contemplated by the OpenBiome Agreement, we acquired certain capital equipment and assumed the contracts with certain service providers to which OpenBiome was a party. Although the OpenBiome Agreement is structured to exclude the assumption of any liabilities of OpenBiome, we may be subject to unknown liabilities with respect to the assets we have acquired or contracts we have assumed.

Clinical trials are difficult to design and implement, and they involve a lengthy and expensive process with uncertain outcomes. We may experience delays in completing, or ultimately be unable to complete, the development and commercialization of CP101, FIN-211 or any other current or future product candidates.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. We cannot guarantee that any of our ongoing and planned clinical trials will be conducted as planned or completed on schedule, if at all; for example, we have decided to pause development of CP101 in HBV at this time, which we believe will allow us to maximize our working capital available for investment in our wholly-owned recurrent CDI and ASD programs. Moreover, even if these trials are initiated or conducted on a timely basis, issues may arise that could result in the suspension or termination of such clinical trials.

We may experience delays in our ongoing clinical trials or preclinical studies and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or in sufficient numbers, have sufficient drug supply for our product candidates on a timely basis or be completed on schedule, if at all. For example, enrollment in PRISM4 is currently paused following receipt from the FDA of a clinical hold letter on February 24, 2022. Further, because FIN-211 includes donor-derived components, the clinical hold will also delay initiation of our Phase 1b clinical trial in ASD. A failure of one or more clinical trials can occur at any stage of testing, and our ongoing and future clinical trials may not be successful. We also may experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize CP101, FIN-211 or any other current or future product candidates, including:

- delays in or failure to obtain regulatory authorizations to commence clinical trials;
- delays in reaching a consensus with regulatory agencies as to the design or implementation of our clinical trials; for example, we plan to have further discussions with the FDA regarding the size and make-up of the safety database for CP101 and we recently received a letter from the FDA requesting changes to the testing algorithm used to diagnose suspected CDI recurrences in PRISM4, as well as additional information regarding the proposed statistical analysis plan for PRISM4 and the validation package for one of our release tests, any of which could result in the need for additional studies or delays in our development timelines;
- delays in or failure to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in or failure to obtain institutional review board, or IRB, approval at each site;
- delays in or failure to recruit a sufficient number of suitable patients to participate in a trial;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- delays in adding new clinical trial sites;

- failure to manufacture sufficient quantities of our product candidates at the required quality for use in clinical trials in a timely manner, including the failure to acquire sufficient starting material from third-party donors;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or safety or tolerability concerns that could cause us or our collaborators, as applicable, to suspend or terminate a trial if we or our collaborators find that the participants are being exposed to unacceptable health risks;
- failure to perform clinical trials in accordance with the FDA's or any other regulatory authority's good clinical practices, or GCP, requirements, or regulatory guidelines in other countries;
- changes in regulatory requirements, policies and guidelines;
- failure of our third-party research contractors to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- delays in establishing the appropriate dosage levels in clinical trials;
- the quality or stability of our product candidates falling below acceptable standards; and
- business interruptions resulting from geo-political actions, including war and terrorism, an outbreak of a contagious disease, such as the COVID-19 pandemic, or natural disasters including earthquakes, typhoons, floods and fires.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing preclinical studies and clinical trials, as applicable. We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA or comparable foreign regulatory authorities, or recommended for suspension or termination by the Data Safety Monitoring Board for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or comparable foreign regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

Our business and operations may be adversely affected by the evolving and ongoing COVID-19 global pandemic.

Our business and operations may be adversely affected by the effects of the ongoing COVID-19 global pandemic, which has resulted in various restrictions aimed at containing the virus, including public health directives and orders that, among other things and for various periods of time, directed individuals to shelter in place, directed businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings and events, and ordered cessation of non-essential travel. Future remote work policies and similar government orders or other restrictions on the conduct of business operations related to the COVID-19 pandemic, including as a result of variants of COVID-19, may negatively impact productivity and may disrupt our ongoing research and development activities and our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. Further, such orders also may impact the availability or cost of materials, which would disrupt our supply chain and manufacturing efforts and could affect our ability to conduct ongoing and planned clinical trials and preparatory activities.

In connection with the COVID-19 pandemic, we experienced a slowdown to enrollment in our PRISM-EXT and PRISM4 clinical trials, as well as interruptions to operations at our donor centers, including certain periods during which we accepted limited donations due to staffing constraints. We may experience additional COVID-19 related disruptions in the future that could severely impact our clinical trials, including:

- delays, difficulties or a suspension in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- interruptions in our ability to manufacture and deliver drug supply for trials, including related to a lack of human donors for stool due, in part, to the fact that qualified donors may be hesitant to visit a donor center, or related to the failure of third-party manufacturers and suppliers to timely provide such supply;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- changes in local regulations as part of a response to the COVID-19 pandemic that may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- interruption of key clinical trial activities, such as clinical trial site monitoring, and the ability or willingness of subjects to travel to trial sites due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the manufacture and testing of our products and the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA to accept data from clinical trials in certain affected geographies.

Known or unanticipated impacts of the COVID-19 pandemic, including as a result of variants of COVID-19, may have a material adverse effect on our business. While the ultimate economic impact brought by, and the duration of, the COVID-19 pandemic are difficult to assess or predict, the pandemic has resulted, and could further result, in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the COVID-19 pandemic could materially affect our business and the value of our common stock.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the COVID-19 pandemic impacts our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence at the time of this Annual Report on Form 10-K, such as the ultimate geographic spread of the disease, the duration of the outbreak, the impact of emerging variants, the duration and effect of business disruptions and the short- and long-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements, occupancy limits, vaccine mandates and business closures in the United States and other countries to contain and treat the disease, and the effectiveness and acceptance of vaccines. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

The demand for vaccines for COVID-19 and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials. Moreover, since the Office of Vaccines Research and Review at FDA, which is responsible for review and approval of microbiome product candidates, is responsible for the review of COVID-19 vaccines, responses from FDA may be delayed. Many Review Divisions at FDA, including the Office of Vaccines Research and Review at FDA, have experienced delays in some timelines related to the Prescription Drug User Fee Act due to demands brought about by COVID-19.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this “Risk Factors” section.

Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, including CP101, FIN-211 and any other current or future product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our investigational drug products are safe and effective for use in each targeted indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. For example, in addition to gastrointestinal endpoints, our development program for FIN-211 in ASD includes exploration of behavioral endpoints, which are not yet well-established. If we fail to validate behavioral instruments for use in our ASD clinical protocols, we would not be able to rely upon those instruments or endpoints to support FDA approval. Further, the process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications, patient population and regulatory agency. Prior to obtaining approval to commercialize CP101, FIN-211 and any other current or future product candidates in the United States or abroad, we, our collaborators or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. For example, we plan to have further discussions with the FDA regarding the size and make-up of the safety database for CP101 which could result in the need for additional studies or delays in our development timelines.

Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.

Even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do. More trials could be required before we submit our product candidates for approval, especially for indications such as ASD, for which clinical endpoints are not well-established. We cannot guarantee that the FDA or comparable foreign regulatory authorities will view our product candidates as having efficacy even if positive results are observed in clinical trials. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, approval of CP101, FIN-211 and any other current or future product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate, which may also limit its commercial potential.

The results of preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Initial success in third-party studies or our ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later-stage trials.

The results of nonclinical and preclinical studies and clinical trials may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Furthermore, we have relied on third-party clinical research in order to inform certain aspects of our own clinical trials and preclinical studies. We have not independently verified the accuracy, safety or other results of such third-party studies, and we may be unable to replicate the results from such third-party studies. For example, insights gained from the use of FMT materials, including FMT clinical data, may not be predictive of our clinical trials, particularly given that the dosage form and potency, delivery mechanisms and manufacturing process vary significantly.

Accordingly, there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for product candidates proceeding through clinical trials. Many companies in the biotechnology and pharmaceutical industries, including certain of our competitors in microbiome therapeutics, have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval. For example, we recently received a letter from the FDA requesting changes to the testing algorithm used to diagnose suspected CDI recurrences in PRISM4, which had been used in PRISM3. Additionally, products used in small early-stage studies may be from a limited number of donors, and it is possible that efficacy might be linked to the microbial community found in a specific donor or a limited set of donors, such that the results might not apply for a broader group of donors with varying microbial compositions. Any such setbacks in our clinical development could have a material adverse effect on our business, financial condition and results of operations.

Additionally, some of the clinical trials we conduct, including a portion of the PRISM4 trial, may include open-label trials conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved product or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Given that we plan to in the future conduct open-label clinical trials, the results from these clinical trials may not be predictive of future clinical trial results with these or other product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

Our product candidates may be associated with serious adverse, undesirable or unacceptable side effects or other properties or safety risks, which may delay or halt their clinical development, or prevent marketing approval. If such side effects are identified during the development of our product candidates or following approval we may suspend or abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval.

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. While we have observed no treatment-related serious adverse events, or SAEs, to date in clinical trials of our lead product candidate CP101, the results from future preclinical studies and clinical trials of our other product candidates may identify safety concerns or other undesirable properties of our product candidates. Additionally, if we expand our product development for current or future product candidates into new patient populations or disease areas, side effects or adverse events not seen by our product candidates in earlier clinical research could emerge.

The results of our clinical trials of CP101, FIN-211 and future clinical trials of our other product candidates may show that our product candidates cause undesirable or unacceptable side effects or even death. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and results of operations significantly.

Moreover, if our product candidates are associated with undesirable side effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate, if approved.

Additionally, adverse developments in clinical trials of pharmaceutical and biopharmaceutical products conducted by others or with commercial products offered by others may cause the FDA or other regulatory oversight bodies to suspend or

terminate our clinical trials or change the requirements for approval of any of our product candidates or otherwise adversely impact the clinical and commercial development of our product candidates. Such adverse developments may cause the FDA to perceive CP101 or other current or future product candidates as unsafe and bring increased regulatory scrutiny to our clinical operations more broadly, lead to decreased confidence by patients, physicians and contract research organizations, or CROs, in our product candidates, and result in reduced demand for any product that we may develop if approved. For example, in June 2019, the FDA issued a safety alert regarding the risk of serious adverse reactions due to the transmission of multi-drug resistant organisms in connection with FMT treatment provided by a local, hospital-based FMT program. Two immunocompromised adults, one of whom later died, received FMT treatment from this hospital-based FMT program and subsequently developed infections caused by extended-spectrum beta-lactamase-producing E. coli. In March 2020, the FDA issued another safety alert regarding the potential of serious or life-threatening infections with the use of FMT treatment after OpenBiome reported occurrences of enteropathogenic E. coli and shigatoxin-producing E. coli in FMT recipients. Also in March 2020, FDA issued a safety alert regarding the potential risks of transmission of COVID-19 by FMT and placed our IND for CP101 on partial clinical hold.

Additionally, if any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- site IRBs or safety monitoring committees may recommend that enrollment or dosing be placed on hold or that additional safety measures be implemented for ongoing trials;
- regulatory authorities may withdraw or limit approvals of such product and require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a risk evaluation and mitigation strategy, or REMS, plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the way the product is dosed, distributed or administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our product candidates, if approved.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent us from proceeding with, or otherwise adversely affect, clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timely completion of our clinical trials in accordance with their protocols depends, among other things, on our ability to recruit a sufficient number of eligible patients to participate and remain in the trial until its conclusion. Patients may be unwilling to participate in our clinical trials because of negative publicity from adverse events related to novel therapeutic approaches, competitive clinical trials for similar patient populations, the existence of current treatments, such as FMT, or for other reasons, including the ongoing COVID-19 pandemic and negative perceptions of our product candidates. For example, enrollment in PRISM4 commenced later than we anticipated due to, among other things, vendor delays and staffing shortages in connection with the COVID-19 pandemic. Enrollment in PRISM4 is currently paused following receipt from the FDA of a clinical hold letter on February 24, 2022, requesting additional information about our SARS-CoV-2 donor screening protocols. Further, because FIN-211 includes donor-derived components, the clinical hold will also delay initiation of our Phase 1b clinical trial in ASD. Any delays related to patient enrollment could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of the clinical trials altogether. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with the required or

desired characteristics, to complete our clinical trials in a timely manner. Patient enrollment and trial completion is affected by many factors, including the:

- size and nature of the patient population and process for identifying patients;
- proximity and availability of clinical trial sites for prospective patients;
- eligibility and exclusion criteria for the trial;
- design of the clinical trial;
- burden or perceived burden of participation in the trial;
- safety profile, to date, of the product candidate under study;
- perceived risks and benefits of the product candidate under study;
- perceived risks and benefits of our approach;
- approval and availability of competing product candidates currently under investigation for the treatment of similar diseases or conditions, or competing clinical trials, including several ongoing trials of our competitors of which we are aware, for similar product candidates or targeting patient populations meeting our patient eligibility criteria;
- severity of the disease under investigation;
- degree of progression or stage of the patient's disease at the time of enrollment;
- ability to obtain and maintain patient consent;
- risk that enrolled patients will drop out before completion of the trial;
- patient referral practices of physicians; and
- ability to adequately monitor patients during and after treatment.

Enrollment risks are heightened with respect to indications that are rare or orphan diseases, which may limit the pool of patients that may be enrolled in our planned clinical trials. For example, we are developing CP101 for the prevention of recurrent CDI, which does not have a large patient population, and, as a result, we may encounter difficulties enrolling subjects in our clinical trials evaluating CP101 for the prevention of recurrent CDI due, in part, to the small size of this patient population.

In addition, our clinical trials will compete with products that are available for use in the same therapeutic areas of our product candidates, and other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. For example, the availability of FMT materials for CDI not responding to standard therapies may affect our ability to enroll patients in our studies of CP101 in CDI. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our future clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, topline or preliminary data from our clinical trials. Preliminary and interim data from our clinical trials may change as more patient data become available. Preliminary or interim data from our clinical trials are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available and we issue our final clinical trial report. Interim, topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result,

preliminary, topline and interim data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects. In addition, certain patient and product samples from our clinical trials are or will be retained by third parties and used by them for further research and studies, and the data from such studies may be inconsistent or contrary to the results from our earlier clinical trials.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, interpretations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, if any, and our company in general. For example, regulatory agencies may disagree with our inclusion or exclusion of certain trial subjects from our clinical trial data or our interpretation of such data. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, if any, product candidate or our business. If the preliminary and interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

Before we can commence clinical trials for any product candidate, we may be required to complete extensive preclinical studies that support any future Investigational New Drug, or IND, applications in the United States, or similar applications in other jurisdictions. Conducting preclinical testing is a lengthy, time-consuming and expensive process and delays associated with product candidates for which we are directly conducting preclinical testing and studies may cause us to incur additional operating expenses. We cannot be certain of the timely completion or outcome of our preclinical testing and studies for CP101, FIN-211 or our other current or future product candidates and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and foreign clinical trials will ultimately support the further development of our other product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or comparable foreign regulatory authorities allowing clinical trials to begin.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, laws or regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, including requiring us to enroll more patients than originally expected, including with respect to the anticipated size of the safety database to be collected to support a biologics license application, or BLA, filing and possible approval;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective as a treatment for our targeted indications, or, in the case of a product candidate regulated as a biological product, that the product candidate is safe, pure and potent and controlled for its proposed indication, or, in either case, that our quality management systems are sufficient to ensure such results;

- the population studied may not be sufficiently broad or representative to assure safety or efficacy in the population for which we seek approval, including as a result of our agreement with the FDA prior to unblinding to exclude certain patients enrolled at two GCP-non-compliant trial sites from adjudication and inclusion in our efficacy analysis;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including whether our statistical analysis plan meets FDA expectations;
- regulatory requirements for microbiome therapeutics may be influenced by our competitors' interactions with the FDA or comparable foreign regulatory authorities, including the possibility that a competitor fails to receive regulatory approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the FDA or comparable foreign regulatory authorities may require additional preclinical studies or clinical trials beyond those that we currently anticipate;
- the FDA may conclude that our product candidate is the "same drug" as a competitor product that has been approved and has received orphan drug exclusivity for the same intended use;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA to the FDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes, testing regime or facilities operated by us or third-party manufacturers with which we contract for clinical and commercial supplies, including with certain technology transfer initiatives; and
- the approval policies or regulations of the FDA or any comparable foreign regulatory authorities or the laws they enforce may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, financial condition and results of operations. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or comparable foreign regulatory authorities.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, if any, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Even if we receive regulatory approval of a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with such product candidate.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, testing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application, and previous responses to inspection

observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing and testing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability including, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling.

The holder of a BLA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to

confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

The policies of the FDA and of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

We may in the future conduct clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We have previously conducted, and plan in the future to conduct, one or more clinical trials outside the United States, including in, but not limited to, Canada, Europe, Australia, New Zealand and Hong Kong. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. Results for our clinical trials may differ by jurisdiction as a result of varying standards of care or local restrictions on reimbursement from third-party payors for clinical trials, thereby affecting the willingness of the FDA or any comparable foreign regulatory authority to accept such data. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction. In addition, conduct of clinical trials on a global basis may expose us to geopolitical risks impacting the ability of institutions and patients to participate in our trials.

We may pursue the development of certain of our product candidates in combination with other therapies, and regulatory approval, safety or supply issues with these other therapies may delay or prevent the development and approval of our product candidates.

In the near future, we may explore the use of our product candidates in combination with other therapies, including those that are not yet approved. If we choose to develop a product candidate for use in combination with an approved therapy, we are subject to the risk that the FDA or comparable foreign regulatory authorities could revoke approval of, or that safety, efficacy, manufacturing or supply issues could arise with, the therapy used in combination with our product candidate. If the therapies we use in combination with our product candidates are replaced as the standard of care, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials, or we may not be able to obtain adequate reimbursement from third-party payors. The occurrence of any of these risks could result in our product candidates, if approved, being removed from the market or being less successful commercially.

Where we develop a product candidate for use in combination with a therapy that has not been approved by the FDA or comparable foreign regulatory authorities, we will not be able to market our product candidate for use in combination with such an unapproved therapy, unless and until the unapproved therapy receives regulatory approval. These unapproved therapies face the same risks described with respect to our product candidates currently in development, including serious adverse effects and delays in their clinical trials. In addition, other companies may also develop their products or product candidates in combination with the unapproved therapies with which we are developing our product candidates for use in combination. Any setbacks in these companies' clinical trials, including the emergence of serious adverse effects, may delay or prevent the development and approval of our product candidates.

If the FDA or comparable foreign regulatory authorities do not approve or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, therapies we choose to evaluate in combination with any of our product candidates, we may be unable to obtain regulatory approval of or to commercialize such product candidates in combination with these therapies.

Risks Related to the Manufacture of Our Product Candidates

The manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-up of our manufacturing capabilities.

Our product candidates are biologics that consist of bacteria and may include other microorganisms. The process of manufacturing our products is complex, highly regulated and subject to multiple risks. The manufacture of our product candidates involves complex processes, including obtaining biological material (human stool) from qualified third-party donors for CP101 and FIN-211. As a result of these complexities, the cost to manufacture our product candidates in particular is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce.

Further, as our product candidates are developed through early- to late-stage clinical trials towards approval and commercialization, we may make alterations to these products and their method of manufacture and use, including changes to our manufacturing processes, in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently than they did in the past and affect the results of planned clinical trials or other future clinical trials. In such circumstances, the FDA or foreign regulatory authorities may require that we conduct bridging comparability testing or other additional clinical studies to confirm the clinical relevance of prior data. For example, early prototype versions of CP101 were manufactured by investigators at the University of Minnesota using certain different techniques and equipment than we have used and intend to use as we continue to advance CP101.

Historically, early versions of CP101 were manufactured using unoptimized processes by third-party research collaborators that we have not used, or do not intend to use, in more advanced clinical trials or commercialization. We have, and may continue to, alter our manufacturing processes, product release criteria, dose strength or dosing regimen, and other aspects of CP101 to optimize it for late-stage clinical trials or commercialization. Although we are working to develop commercially viable processes, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials. As a result of these challenges, we may experience delays in our clinical development and/or commercialization plans. For example, in recent correspondence, the FDA has asked for additional information regarding the validation package for one of our release tests, which is utilized for both CP101 and FIN-211; that validation package will need to be reviewed by the FDA before we are able to proceed with enrollment in PRISM4, which could delay the trial. If we receive additional questions from the FDA regarding the validation package, the timelines for our trials could be further delayed.

We are still in the process of developing and scaling-up our manufacturing processes and quality systems for certain of our other product candidates. These products contain proprietary bacterial strains that have never been manufactured in a scale sufficient for use in a clinical trial or for commercialization. We can make no assurances that we will be able to manufacture these products, or components of these products, in a cost effective manner or at the level required for clinical trials or commercialization.

Further, we plan in the future to conduct one or more clinical trials outside the United States. Jurisdictions outside of the United States, including Europe, have distinct regulatory requirements that our facilities, materials, manufacturing processes, and quality systems may not satisfy. If we are unable to meet required standards, we may be unable to conduct trials or commercialize our product candidates in certain jurisdictions outside of the United States.

We rely on third-party donors of biological material to manufacture certain product candidates such as CP101 and FIN-211, and if we do not obtain an adequate supply of acceptable material from those qualified donors, the clinical and commercial supply of these product candidates may be adversely impacted.

We use human stool from extensively-screened third-party donors as starting material in the manufacture of several of our product candidates, including CP101 and FIN-211. The stool that is received from these third-party donors is tested for certain pathogens and processed without the use of replication or culturing to form an active ingredient in our products. Our ability to manufacture CP101, FIN-211 and other product candidates using donor-derived materials at clinical and commercial scale depends on obtaining a consistent and adequate supply of stool material. We are not currently aware of alternative sources of supply that would be sufficient to meet our clinical and commercial needs. Therefore, any delay of our ability to manufacture using donor-derived materials could significantly impact our clinical timelines.

In the past, we have relied on stool donor programs operated by OpenBiome and the University of Minnesota for the supply of human stool material used in the manufacture of our product candidates, including CP101. In connection with the Asset Purchase Agreement with OpenBiome, we have licensed certain technology and have acquired assets that enable our internal stool donor program in support of the clinical development and commercialization of CP101 and our other product candidates.

The stool donor program on which we rely involves the screening of potential human stool donors using defined screening criteria. Only a small fraction of potential human donors that we will evaluate will be able to meet these criteria and enroll in our donor program. There can be no assurances that we will have enough qualified third-party donors within our donor program, or enough material derived from donors in our program, to meet clinical or commercial demand. We may also have difficulty enrolling and retaining enough qualified donors in our donor program. If we are unable to enroll a sufficient number of qualified donors in our stool donor program, or if we are unable to retain donors within our program or receive enough stool from donors within our program, our ability to manufacture CP101, FIN-211 and other product candidates may be delayed or adversely impacted.

While the stool donor program on which we rely involves extensive screening of potential entrants, we can make no assurances that it will screen for, or be able to identify, all diseases and conditions that could adversely affect the health of persons who use or consume products that contain biological material from those donors. The screening processes may fail to identify certain existing diseases or conditions in the humans that we evaluate for entry into our donor program. In addition, donors enrolled in our donor program may develop new diseases or conditions, or the worsening of pre-existing or underlying diseases or conditions, that we may fail to identify. The use of stool material from a third-party donor who has a certain condition or disease may result in material adverse effects to our business, including supply chain disruptions resulting from the recall or destruction of affected starting material or product, or adverse reactions in patients who use or consume products derived from that donor. For example, in March 2020, the FDA required retrospective testing and the recall and destruction of the affected product after OpenBiome, a supplier of human stool material, reported occurrences of enteropathogenic E. coli and shigatoxin-producing E. coli in FMT recipients.

While we extensively test the biological materials that we receive from qualified third-party donors or suppliers for the presence of certain pathogens and other microorganisms, there can be no assurances that we will detect all pathogens and other microorganisms in our products, which could result in an adverse reaction in persons who use or consume our products. Our testing processes may fail to identify pathogens in the stool that we receive from donors within our donor program, or such testing processes may be unacceptable to regulatory authorities. For example, in the clinical hold letter we received on February 24, 2022 for our CP101 IND, the FDA requested more information with respect to, among other things, our SARS-CoV-2 testing methods. In addition, the emergence of new pathogens could affect the availability of stool donors, or require us to develop new testing processes to test both new and existing material and product, either of which could cause delays or shortage in the manufacture and distribution of our products. The presence of pathogens in the stool material that we receive from third-party donors may also result in adverse reactions in persons who use or consume products that are derived from that material. Additionally, regulatory or industry pathogen testing requirements may change over time, possibly making it more challenging to locate qualified donors, or requiring the development and validation of new test methods, which could adversely affect our ability to collect adequate supply and increase costs related to product manufacturing. For example, screening for enteropathogenic E. coli has resulted in exclusion of otherwise qualified donors.

We operate our own manufacturing facility for certain product candidates, which requires significant resources and we may fail to successfully operate our facility, which could adversely affect our clinical trials and the commercial viability of our product candidates.

We recently completed construction of our manufacturing facility to support the manufacture of our product candidates, including CP101 and FIN-211, for use in clinical development or for potential commercial sale. We may not be able to manufacture enough product at this facility to meet the clinical and commercial demand for our product candidates. We also cannot be sure that the manufacturing processes employed by us will result in products that will be safe and effective or that we will be able to demonstrate to the satisfaction of the FDA or other regulatory authorities that our quality management systems are sufficient to ensure such results. Moreover, we may run into delays or cost overruns in connection with the qualification and validation of our manufacturing facility, including the transfer of technology into that recently completed facility, which would increase our net losses and have an adverse effect on our stockholders' equity and working capital. For example, the FDA may find deficiencies in our technology transfer process or require one or more comparability studies of our drug product using test methods that we would need to develop. The actual cost to manufacture and process our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates, if approved. There is a lack of third-party CMOs willing or able to manufacture whole community product candidates like CP101 and FIN-211. If we are unable to successfully manufacture and process our product candidates, we

might not be able to produce some of our products at a level that would be sufficient to meet our clinical and commercial needs.

The manufacture of microbiome therapeutics is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. Manufacturers of products derived from human biological material often encounter difficulties in production, particularly in scaling out and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of raw materials or in our manufacturing facilities or manufacturing facilities operated by our third-party suppliers, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability or other issues relating to the manufacture of our product candidates will not occur in the future.

Our operations will remain subject to review and oversight by the FDA and the FDA could object to our use of our manufacturing facility. Prior to licensure to manufacture our product candidates, we must first receive approval from the FDA, which we may never obtain. Such approval may be contingent on a pre-approval inspection of our manufacturing facility. Even if approved, we would be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations. Our license to manufacture product candidates will be subject to continued regulatory review.

In addition, we may fail to manage the logistics of storing and shipping our product candidates, particularly as our product candidates are required to be stored at certain pre-defined refrigerated temperatures. Storage failures and shipment delays and problems caused by us, our vendors or other factors not in our control, such as weather, could result in loss of usable product or prevent or delay the delivery of product candidates to patients. We may also experience manufacturing difficulties due to resource constraints or as a result of labor disputes. If we were to encounter any of these difficulties, our ability to develop and commercialize our product candidates would be jeopardized.

Risks Related to the Commercialization of Our Product Candidates

We have never commercialized a product candidate and may experience delays or unexpected difficulties in obtaining regulatory approval for our current or future product candidates for our initial or potential additional indications.

We have never obtained regulatory approval for, or commercialized, a drug. It is possible that the FDA may refuse to accept any or all of our planned BLAs for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval for any product candidates. If the FDA does not approve any of our planned BLAs, it may require that we conduct additional costly clinical, nonclinical or manufacturing validation studies before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any BLA or other application that we submit may be significantly delayed, possibly for several years, or may require us to expend more resources than we have available. Any failure or delay in obtaining regulatory approvals would prevent us from commercializing our current or future product candidates, generating revenues and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any BLA or other application that we submit. If any of these outcomes occur, we may be forced to abandon the development of our product candidates, which would materially adversely affect our business and could potentially cause us to cease operations. We face similar risks for our applications in foreign jurisdictions.

We currently have no marketing and sales organization and have no experience as a company in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue arrangements with third-party sales, marketing, and distribution collaborators regarding the sales and marketing of our products, if approved. However, there can be no assurance that we will be able to establish or maintain such arrangements on favorable terms or at all, or if we are able to do so, that these third-party arrangements will provide effective sales forces or marketing

and distribution capabilities. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

We have received Fast Track designation for CP101 for the prevention of recurrent CDI, and we may seek Fast Track designation for our other product candidates. Even if received, Fast Track designation may not actually lead to a faster review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We have received Fast Track designation for CP101 for the prevention of recurrent CDI, and we may seek Fast Track designation for our other product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for Fast Track designation for a particular indication. There is no assurance that the FDA will grant this status to any of our other proposed product candidates. If granted, Fast Track designation makes a product eligible for more frequent interactions with FDA to discuss the development plan and clinical trial design, as well as rolling review of the application, which means that the company can submit completed sections of its marketing application for review prior to completion of the entire submission. Marketing applications of product candidates with Fast Track designation may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide any assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation at any time if it believes that the designation is no longer supported by data from our clinical development program.

We have received Breakthrough Therapy designation for CP101 for the prevention of recurrent CDI, and we may seek Breakthrough Therapy designation for our other product candidates. Even if received, Breakthrough Therapy designation may not actually lead to a faster review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We have received Breakthrough Therapy designation for CP101 for the prevention of recurrent CDI, and may, in the future, apply for Breakthrough Therapy designation for other product candidates in the United States. A Breakthrough Therapy product candidate is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that such product candidate may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. The FDA will seek to ensure the sponsor of a Breakthrough Therapy product candidate receives: (i) intensive guidance on an efficient drug development program; (ii) intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review; and (iii) a rolling review process whereby the FDA may consider reviewing portions of a BLA before the sponsor submits the complete application. Product candidates designated as breakthrough therapies by the FDA may be eligible for priority review if supported by clinical data.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and, in any event, does not assure ultimate approval by the FDA. In addition, even though CP101 has been designated as a Breakthrough Therapy product candidate, the FDA may later decide that it no longer meets the conditions for designation or decide that the time period for FDA review or approval will not be shortened.

Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain product candidates over other potential product candidates. These decisions may prove to have been wrong and may adversely affect our ability to develop our own programs, our attractiveness as a commercial partner and may ultimately have an impact on our commercial success.

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. For example, we have decided to pause development of CP101 in HBV, which we believe will allow us to maximize our working capital available for investment in our wholly-owned recurrent CDI and ASD programs. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the biopharmaceutical industry, in particular for our lead product candidate, our business, financial condition and results of operations could be materially adversely affected and may cause us to reprioritize our planned trials and use of funds for planned trials.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals and others in the medical community.

The use of microbiome therapies is a recent development and may not become broadly accepted by physicians, patients, hospitals and others in the medical community. Various factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over current or future alternative treatments;
- our ability to demonstrate the advantages of our product candidates over other microbiome therapies;
- the prevalence and severity of any side effects;
- the prevalence and severity of any side effects for other microbiome medicines and public perception of other microbiome medicines;
- product labeling or product insert requirements of the FDA or comparable foreign regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or comparable foreign regulatory authorities;
- the timing of market introduction of our product candidates as well as competitive products;
- the FDA's policy of enforcement discretion for FMT materials to treat CDI not responding to standard therapies;
- the cost of treatment and the availability of testing for patient selection;
- the pricing of our products, if approved, and the availability of adequate coverage and reimbursement by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are approved for commercialization but fail to achieve market acceptance among physicians, patients, hospitals or others in the medical community, we will not be able to generate significant revenue.

In addition, although our product candidates differ in certain ways from other microbiome approaches, SAEs or deaths in other clinical trials involving the microbiome, or in clinical trials involving therapeutic approaches similar to ours, even if not ultimately attributable to our product or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of our product candidates, stricter labeling requirements for those product candidates that are licensed, and a decrease in demand for any such product candidates.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

If the market opportunities for our product candidates are smaller than we believe they are, even assuming approval of a product candidate, our business may suffer.

Our projections of both the number of people who are affected by diseases within our potential target indications, as well as the subset of these people who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, healthcare utilization databases and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our business, financial condition and results of operations.

We face substantial competition, which may result in others developing or commercializing drugs before or more successfully than us.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other drugs that are able to achieve similar or better results that our product candidates. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly as they develop novel approaches to treating disease indications that our product candidates are also focused on treating. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

We face competition from segments of the pharmaceutical, biotechnology and other related markets that pursue the development of microbiome therapies. We are aware of a number of companies focused on developing microbiome therapeutics in various indications. For CP101, we are aware that Seres Therapeutics, Inc. and Rebiotix, Inc. each have a product candidate that has completed Phase 3 trials for recurrent CDI and are pursuing FDA approval to enable subsequent commercialization. In November 2021, Rebiotix filed a BLA for RBX-2660, their lead product in recurrent CDI, and Seres has indicated that they plan to file a BLA in 2022. In addition, we face competition from other therapies which are designed to treat the indications targeted by our product candidates.

We anticipate that we will continue to face intense and increasing competition as new treatments enter the market and advanced technologies become available. There can be no assurance that our competitors are not currently developing, or will not in the future develop, products that are equally or more effective or are more economically attractive than any of our current or future product candidates. Competing products may gain faster or greater market acceptance than our products, if any, and medical advances or rapid technological development by competitors may result in our product candidates becoming non-competitive or obsolete before we are able to recover our research and development and commercialization expenses. If we or our product candidates do not compete effectively, it may have a material adverse effect on our business, financial condition and results of operations.

If either we or our collaborators obtain approval to commercialize any of our product candidates outside of the United States, a variety of risks associated with international operations could adversely affect our business.

If any of our product candidates are approved for commercialization, we may seek to enter into agreements with third parties to market them in certain jurisdictions outside the United States. We expect that we would be subject to additional risks related to international pharmaceutical operations, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries, including the potential time and expense associated with establishing foreign manufacturing processes or facilities;
- reduced protection for intellectual property rights;
- foreign reimbursement, pricing and insurance regimes;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- business interruptions resulting from geopolitical actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods and fires, or from economic or political instability, or public health emergencies, such as the ongoing COVID-19 pandemic and related shelter-in-place orders, travel, social distancing and quarantine policies, boycotts, curtailment of trade and other business restrictions;
- greater difficulty with enforcing our contracts;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- increased complexity and costs if foreign regulators require that certain manufacturing facilities, such as a stool donor program facility, be operated locally; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

As an organization, we have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by individual countries in Europe with which we may need to comply. If we are unable to successfully manage the challenges of international expansion and operations, our business and operating results could be harmed.

Coverage and adequate reimbursement may not be available for CP101, FIN-211 or any other current or future product candidates, which could make it difficult for us to sell profitably or at all, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations, pharmacy benefit management organizations, and other private health insurers. Microbiome therapy is a novel therapeutic approach and neither we nor, to our knowledge, any other company has received regulatory approval for a therapeutic based on this approach. We cannot be certain that third-party payors will provide sufficient reimbursement for any product candidates that we commercialize, if approved. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor’s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

While no uniform policy for coverage and reimbursement exists in the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Therefore, one payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage, and adequate reimbursement, for the drug. Obtaining positive Medicare coverage and reimbursement will be critical to the commercial success of CP101, if approved, as a large portion of the patient population with CDI are Medicare beneficiaries. Even if favorable coverage and reimbursement status is attained for CP101 or any current or future product candidate for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Thus, if we are not able to secure coverage and Medicare reimbursement at sufficient levels, we may not be able to reach our intended target market for CP101, if approved, which would adversely affect our revenue and profits. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. We expect that the price of CP101, if approved, will be substantial, so the availability of coverage and reimbursement from third-party payors will be necessary to make CP101 assessable to patients. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize CP101 or any other current or future product candidates that we develop. Outside the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Even if we are successful in obtaining regulatory approval, commercial success of any approved products will also depend in large part on the availability of insurance coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, and managed care organizations, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost-effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. Further, coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. If government and other healthcare payors were not to provide adequate insurance coverage and reimbursement levels for one any of our products once approved, market acceptance and commercial success would be limited.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of biopharmaceutical products. While we currently have no products that have been approved for commercial sale, from 2017 to 2019, we manufactured FMT materials, produced to specifications defined by OpenBiome, that were and may still be distributed and sold by OpenBiome for use under its interpretation of the FDA's policy of enforcement discretion for CDI not responding to standard therapies and for use in clinical research. This past use, as well as the current and future use of product candidates by us and our collaborators in clinical trials, and the potential sale of any approved products in the future, may expose us to liability claims. The FDA may not agree with OpenBiome's interpretation or application of the FDA's enforcement discretion policy to its product distribution activities, including its distributions to clinical sites without an IND in place with the FDA. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies, our collaborators or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a product, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products due to negative public perception;
- injury to our reputation;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales; and
- the inability to commercialize any of our product candidates, if approved.

Although we believe we maintain adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Should any of the events described above occur, this could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Government Regulation

Our relationships with customers, healthcare providers, including physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, including physicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the

federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations promulgated under such laws. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs, and other interactions with healthcare professionals. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for, or to induce, either the referral of an individual for, or the purchase, lease, order or arrangement for or recommendation of the purchase, lease, order or arrangement for any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers, and formulary managers, on the other. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. A person does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, signed into law in 2010, provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- the federal civil and criminal false claims laws, including, without limitation, the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and the federal Civil Monetary Penalty Law that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from the federal government, including Medicare, Medicaid and other government payors, that are false or fraudulent or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the United States federal government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), or knowingly and willfully falsifying, concealing or covering up, by any trick or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which impose, among other things, requirements on health plans, healthcare clearinghouses and certain healthcare providers, known as "covered entities", and their respective HIPAA "business associates", which are independent contractors that perform certain services for or on behalf of covered entities involving the use or disclosure of individually identifiable health information and their subcontractors that use, disclose or otherwise process individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal transparency laws, including the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to: (i) payments or other "transfers of value'' made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or that otherwise restrict payments that may be made to healthcare providers; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, any of which could harm our business.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action taken against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy.

Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials that could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

If approved, our product candidates will be regulated as biologics, and thus may face competition from biosimilars approved through an abbreviated regulatory pathway.

We anticipate that our product candidates will be regulated as biological products. The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of litigation. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the United States pharmaceutical industry. The ACA, among other things: (i) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs; (ii) expanded the entities eligible for discounts under the 340B drug pricing program; (iii) increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP; (iv) expanded the eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (v) created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected; (vi) created a new Medicare Part D coverage gap discount program in which, as a condition of coverage of its products under Medicare Part D, manufacturers must now agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of 2019); (vii) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and (viii) established the Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug.

There have been executive, judicial and congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate."

Further, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or congressional challenges in the future. It is unclear how any such challenges and the healthcare reform efforts of the Biden Administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, will remain in effect through 2031, unless additional congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. These laws may result in additional reductions in Medicare, Medicaid and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the former Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, former President Trump announced several executive orders related to prescription drug pricing that sought to implement several of the former administration's proposals. As a result, the FDA released a final and guidance rule in September 2020, providing pathway for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020 CMS issued an interim final rule implementing the Most Favored Nation, or MFN, model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. As a result of litigation challenging the MFN model, on December 27, 2021, CMS published a final rule that rescinded the MFN model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in

reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. The Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these requirements will be interpreted and implemented and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for CP101, FIN-211 or any other current or future product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of CP101, FIN-211 or any other current or future product candidates, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including most recently from December 22, 2018 to January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

If we or our third-party manufacturers and suppliers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste

products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

We are subject to U.S. anti-corruption, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

We are subject to anti-corruption laws, including the U.S. domestic bribery statute contained in 18 U.S.C. 201, the U.S. Travel Act, and the U.S. Foreign Corrupt Practices Act of 1977, as amended. These anti-corruption laws generally prohibit companies and their employees, agents, and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to recipients in the public or private sector. We can be held liable for the corrupt or illegal activities of our agents and intermediaries, even if we do not explicitly authorize or have actual knowledge of such activities. We are also subject to other U.S. laws and regulations governing export controls, as well as economic sanctions and embargoes on certain countries and persons.

Violations of these laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. Likewise, any investigation of potential violations of such laws could also have an adverse impact on our reputation, our business, results of operations and financial condition.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators, contracted laboratories and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, contracted laboratories and third-party CROs, to conduct our preclinical studies and clinical trials in accordance with applicable regulatory requirements and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with good laboratory practices, or GLPs, as applicable, and GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GLPs and GCPs through periodic inspections of laboratories conducting GLP studies, trial sponsors, principal investigators and trial sites. If we, our investigators or any of our CROs or contracted laboratories fail to comply with applicable GLPs and GCPs, the clinical data generated in our clinical trials may be deemed unreliable, the statistical analysis and clinical meaning of our datasets could be compromised and the FDA or comparable foreign regulatory authorities may limit our ability to include impacted data or require us to perform additional preclinical studies or clinical trials before approving our marketing applications. For example, we identified GCP compliance issues at two clinical trial sites that participated in our PRISM3 study. In consultation with the FDA, we terminated those two sites and excluded data from the trial participants at those sites. While we monitor our clinical trial sites, we cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our preclinical studies or clinical trials comply with

all applicable GLP or GCP regulations. In addition, our clinical trials must be conducted with product, including biologic product, produced in compliance with applicable cGMP regulations. Our failure or the failure of any third parties with whom we may contract comply with these regulations may require us to repeat preclinical studies or clinical trials, which would delay the regulatory approval process.

Further, these laboratories, investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent laboratories, investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is noncompliant, fraudulent or substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. Such laboratories, investigators and CROs may make errors while conducting trials or other clinical development activities, which could render any data derived therefrom incorrect or unusable. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party laboratories, CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative laboratories, CROs or investigators or to do so in a timely manner or on commercially reasonable terms. If laboratories, CROs or clinical investigators do not successfully carry out their legal, regulatory or contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols, regulatory requirements, professional standards of integrity or for other reasons, our preclinical or clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional laboratories or CROs (or investigators) involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new laboratory or CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our contracted laboratories and CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and results of operations.

In addition, clinical investigators may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the preclinical study or clinical trial, the integrity of the data generated at the applicable preclinical study or clinical trial site may be questioned and the integrity or validity of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidate or any future product candidates.

We rely on third parties to supply and manufacture our product candidates, and we expect to continue to rely on third parties to manufacture our products, if approved. The development of such product candidates and the commercialization of any products, if approved, could be stopped, delayed or made less profitable if any such third party fails to provide us with sufficient quantities of product candidates or products or fails to do so at acceptable quality levels or prices or fails to maintain or achieve satisfactory regulatory compliance. We have not, nor to our knowledge, has any other company, received regulatory approval for a therapeutic based on this approach.

We do not currently have the infrastructure or capability internally to manufacture all our product candidates for use in the conduct of our preclinical studies and clinical trials or for commercial supply, if our products are approved. We rely on, and expect to continue to rely on, contract manufacturing organizations, or CMOs. Any replacement of our CMOs could require significant effort and expertise because there may be a limited number of qualified CMOs. This could be particularly problematic where we rely on a single-source supplier. Additionally, our current CMOs may fail to manufacture our product candidates or placebo due to technical difficulties or other issues beyond our control. For example, while our CMO has experience manufacturing similar microbial products, FIN-211 contains a specific bacterial strain that our CMO has never manufactured in a scale sufficient for commercialization and which it may be unable to supply in the quantities and at the

rates we anticipate requiring. Furthermore, we have limited stability data for this material, and if we determine that its stability profile is insufficient for our needs, our trials could be delayed and the commercial potential for FIN-211 could be reduced. We can make no assurances that we will be able to manufacture our product candidates, or components of our product candidates, in a cost-effective manner or at the level required for clinical trials or commercialization. Reliance on third-party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We are dependent on our CMOs for the production of our product candidates in accordance with relevant regulations, such as cGMP, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation. Moreover, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting product development activities that could harm our competitive position.

Our third-party manufacturers may be subject to damage or interruption from, among other things, fire, natural or man-made disaster, disease outbreaks or public health pandemics, power loss, telecommunications failure, unauthorized entry, computer viruses, denial-of-service attacks, acts of terrorism, human error, vandalism or sabotage, financial insolvency, bankruptcy and similar events. For example, the extent to which COVID-19 may impact our manufacturing and supply chain will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

If we were to experience an unexpected loss of supply of or if any supplier were unable to meet our demand for any of our product candidates, we could experience delays in our research or planned clinical trials or commercialization. We could be unable to find alternative suppliers of acceptable quality, in the appropriate volumes who could meet our timelines at an acceptable cost. Moreover, our suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. The long transition periods necessary to switch manufacturers and suppliers, if necessary, could significantly delay our preclinical studies, our clinical trials and the commercialization of our products, if approved, which could materially adversely affect our business, financial condition and results of operation.

In complying with the applicable manufacturing regulations of the FDA and comparable foreign regulatory authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. The failure to comply with these requirements could result in an enforcement action against us, including the seizure of products and shutting down of production. We and any of these third-party suppliers may also be subject to audits by the FDA and comparable foreign regulatory authorities. If any of our third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize the products could suffer significant interruptions. We face risks inherent in relying on CMOs, as any disruption, such as a fire, natural hazards, vandalism or an outbreak of contagious disease affecting the CMO or any supplier of the CMO could significantly interrupt our manufacturing capability. In case of a disruption, we will have to establish alternative manufacturing sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we would likely experience months of manufacturing delays as the CMO builds or locates replacement facilities and seeks and obtains necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all.

Our current and future collaborations will be important to our business. If we are unable to enter into new collaborations, or if these collaborations are not successful, our business could be adversely affected.

A part of our strategy is to strategically evaluate and, as deemed appropriate, enter into partnerships in the future when strategically attractive, including potentially with major biotechnology or pharmaceutical companies. We have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we may enter into collaborations with other companies to provide us with important technologies and funding for our programs and technology. If we fail to enter into or maintain collaborations on reasonable terms or at all, our ability to develop our existing or future research programs and product candidates could be delayed, the commercial potential of our product could change and our costs of development and commercialization could increase. Furthermore, we may find that our programs require the use of intellectual property rights held by third parties, and the growth of our business may depend in part on our ability to acquire or in-license these intellectual property rights.

For example, we are currently party to a collaboration agreement with Takeda, pursuant to which we have agreed to collaborate in the clinical development of our product candidates TAK-524 for the treatment of ulcerative colitis and FIN-525 for the treatment of Crohn's disease. This and any future collaborations we enter into may pose a number of risks, including, but not limited to, the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and
- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our collaborations do not result in the successful discovery, development and commercialization of product candidates or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K also apply to the activities of our therapeutic collaborators.

Additionally, if one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate collaborative partners. Our ability to reach a definitive agreement for a partnership will depend, among other things, upon an assessment of the collaborator's resources and expertise, the terms and conditions of the proposed partnership and the proposed collaborator's evaluation of a number of factors. These factors may include the design or results of preclinical studies or clinical trials, the likelihood of regulatory approval, the potential

market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of any uncertainty with respect to our ownership of technology (which can exist if there is a challenge to such ownership regardless of the merits of the challenge) and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a partnership could be more attractive than the one with us.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization, reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and product candidates.

We cannot offer any assurances about which of our patent applications will issue, the breadth of any resulting patent or whether any of the issued patents will be found to be infringed, invalid and unenforceable or will be threatened by third parties. We cannot offer any assurances that the breadth of our granted patents will be sufficient to stop a competitor from developing and commercializing a product, including a biosimilar product that would be competitive with one or more of our product candidates. Furthermore, any successful challenge to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any of our product candidates. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

The patent prosecution process is expensive and time-consuming. We may not be able to prepare, file and prosecute all necessary or desirable patent applications at a commercially reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

In addition to the protection provided by our patent estate, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not amenable to patent protection. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, or that our trade secrets and other confidential proprietary information will not be disclosed. Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products, if approved, and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these

individuals, organizations and systems, our agreements or security measures may be breached, and we may not have adequate remedies for any breach. Also, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA is considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and if we do not obtain protection under the Hatch-Waxman Amendments and similar non-United States legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent may be extended per approved drug product, and only those claims covering the approved drug product, a method for using it, or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be impacted and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business.

If we fail to comply with our obligations in our current and future intellectual property licenses with third parties, we could lose rights that are important to our business.

We are reliant upon licenses to certain patent rights and proprietary technology for the development of our product candidates, in particular our license agreements with University of Minnesota and Skysong Innovations LLC. These license agreements impose diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations, our licensors may have the right to terminate our licenses, in which event we might not be able to develop, manufacture or market any product that is covered by the intellectual property we in-license from such licensor and may face other penalties. Such an occurrence would materially adversely affect our business prospects.

Licenses to additional third-party technology and materials that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms, or at all, which could have a material adverse effect on our business and financial condition. We do not control the prosecution, maintenance and enforcement of all of our licensed and sublicensed intellectual property relating to our product candidates, and we thus require the cooperation of our licensors and any upstream licensor, including Skysong Innovations LLC and the University of Minnesota, which may not be forthcoming. Therefore, we cannot be certain that the prosecution, maintenance and enforcement of these patent rights will be in a manner consistent with the best interests of our business. If we or our licensor fail to maintain such patents, or if we or our licensor lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that we license from third parties will also apply to patent rights we may own in the future. Further, if we fail to comply with our development obligations under our license agreements, we may lose our patent rights with respect to such agreement on a territory-by-territory basis, which would affect our patent rights worldwide.

Termination of our current or any future license agreements would reduce or eliminate our rights under these agreements and may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights

under these agreements, including our rights to important intellectual property or technology. Any of the foregoing could prevent us from commercializing our other product candidates, which could have a material adverse effect on our operating results and overall financial condition.

In addition, intellectual property rights that we in-license in the future may be sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States Congress, the federal courts and the United States Patent and Trademark Office, or USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have owned or licensed or that we might obtain in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Similarly, changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States and Europe. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Competitors may infringe the patents for which we have applied. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In certain circumstances it may not be practicable or cost effective for us to enforce our intellectual property rights fully, particularly in certain developing countries or where the initiation of a claim might harm our business relationships. We may also be hindered or prevented from enforcing our rights with respect to a government entity or instrumentality because of the doctrine of sovereign immunity.

If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. In an infringement proceeding, a court may decide that the patent claims we are asserting are invalid and/or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover the technology in question. Third

parties may also initiate legal proceedings against us claiming that our patents are not infringed, invalid and/or unenforceable. For example, on December 1, 2021, Rebiotix Inc. and Ferring Pharmaceuticals Inc. (collectively, "Rebiotix"), filed a complaint against us in the U.S. District Court for the District of Delaware. The complaint seeks a declaratory judgment of non-infringement and invalidity with respect to seven United States Patents owned by us. On February 7, 2022, we filed an answer and counterclaims against Rebiotix for infringement of three of the patents. On March 7, 2022, we filed an amended answer and counterclaims, in which we, together with the Regents of the University of Minnesota ("UMN"), alleged infringement by Rebiotix of three United States Patents owned by UMN and exclusively licensed to us. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose some, and perhaps all, of the patent protection on our product candidates. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could have a material adverse impact on our business. Moreover, even if we are successful in any litigation, we may incur significant expense in connection with such proceedings, and the amount of any monetary damages may be inadequate to compensate us for damage as a result of the infringement and the proceedings.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patent applications. An unfavorable outcome could require us to cease using the related technology or force us to take a license under the patent rights of the prevailing party, if available. Furthermore, our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may be unsuccessful in licensing or acquiring intellectual property from third parties that may be required to develop and commercialize our product candidates.

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to acquire or obtain a license to such intellectual property from these third parties, and we may be unable to do so on commercially reasonable terms or at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability and the ability of future collaborators, if any, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our

product candidates and technology, including interference proceedings, post grant review and *inter partes* review before the USPTO or equivalent foreign regulatory authority. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Numerous patents and pending applications are owned by third parties in the fields in which we are developing product candidates, both in the United States and elsewhere. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products.

There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Foreign courts will have similar burdens to overcome in order to successfully challenge a third party claim of patent infringement.

We are aware of a patent estate with granted claims in the United States, Japan and China that may impact our competitive position with respect to one of our preclinical product candidates. While we believe that the granted claims may not be valid and that they may be reasonably challenged for validity, there can be no assurance that any such challenge would be successful. If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidate. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our product candidates or force us to cease some or all of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies. In addition, we use publications that are subject to copyright, as well as proprietary information and materials from third parties in our research. Some of the information and materials we use from third parties may be subject to agreements that include restrictions on use or disclosure. Although we strive to ensure proper safeguards, we cannot guarantee strict compliance with such agreements, nor can we be sure that our employees, consultants and advisors do not use proprietary information, materials, or know-how of others in their work for us. We may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

We may be subject to claims challenging the inventorship or ownership of our future patents and other intellectual property.

We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patent applications, our future patents, or other intellectual property, including as an inventor or co-inventor. We may be subject to ownership or inventorship disputes in the future arising, for example, from conflicting obligations of consultants, contractors or others who are involved in developing our product candidates. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed to others.

If we rely on third parties to manufacture or commercialize our product candidates, or if we collaborate with additional third parties for the development of such product candidates, we may need to, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our trade secrets and other proprietary technology in part by entering into confidentiality agreements with third parties prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection or where enforcement rights are not as strong as those in the United States or Europe. These products may compete with our product candidates, and our future patents or other intellectual property rights may not be effective or sufficient defend our rights adequately.

In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family

may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology. For example, certain jurisdictions do not allow for patent protection with respect to method of treatment.

While we seek to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property rights, which could make it difficult for us to stop the infringement of our future patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our future patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and/or applications and any patent rights we may obtain in the future. Furthermore, the USPTO and various non-United States government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse of a patent or patent application can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market, which could have a material adverse effect on our business.

Any trademarks we have obtained or may obtain may be infringed or otherwise violated, or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish our product candidates, if approved for marketing, from the drugs of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe or otherwise violate our trademarks and we may not have adequate resources to enforce our trademarks. Any of the foregoing events may have a material adverse effect on our business.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to or otherwise competitive with our product candidates but that are not covered by the claims of our current or future patents;
- an in-license necessary for the manufacture, use, sale, offer for sale or importation of one or more of our product candidates may be terminated by the licensor;
- we or future collaborators might not have been the first to make the inventions covered by our issued or future issued patents or our pending patent applications;
- we or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or in-license may be held invalid or unenforceable as a result of legal challenges by our competitors;
- issued patents that we own or in-license may not provide coverage for all aspects of our product candidates in all countries;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Our Business Operations, Employee Matters and Managing Growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on our management team, including Mark Smith, Ph.D., our Chief Executive Officer. Each member of our management team may currently terminate their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Over the last several years, the challenges of recruiting and retaining employees across the biotechnology industry, and in the Boston area specifically, have increased substantially due to current industry job market dynamics. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

We may experience difficulties in managing the growth of our organization, which could disrupt our operations.

As of December 31, 2021, we had 189 full-time employees, including 156 employees engaged in research and development. As our clinical development and commercialization plans and strategies develop, and as we continue operating as a public company, we may need additional managerial, operational, sales, marketing, financial, legal and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our development efforts effectively, including the clinical trials of CP101, FIN-211 and our other product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. The services include substantially all aspects of clinical trial management and manufacturing for certain of our product candidates. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our preclinical studies or clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of our product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring qualified new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a significant disruption of our product development programs and our ability to operate our business effectively.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber-attacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient. The COVID-19 pandemic has generally increased the attack surface available for exploitation, as more companies and individuals work online and work remotely, and as such, the risk of a cybersecurity incident potentially occurring, and our investment in risk mitigations against such an incident, is increasing. For example, there has been an increase in phishing and spam emails as well as social engineering attempts from “hackers” hoping to use the recent COVID-19 pandemic to their advantage.

While we have not experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials by us or our CROs could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, cause us not to comply with federal and/or state breach notification laws and foreign law equivalents and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. Security breaches and other inappropriate access can be difficult to

detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, such measures may not prevent service interruptions or security breaches that could adversely affect our business and to the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, CMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce certain of our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions, including civil or criminal penalties, private litigation, and adverse publicity and could negatively affect our operating results and business.

We and any current and future collaborators may be subject to federal, state, municipal and foreign data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, including Section 5 of the Federal Trade Commission Act, that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our current or future collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

We are subject to a variety of privacy and data security laws, and our failure to comply with them could harm our business.

We maintain a large quantity of sensitive information, including confidential business and personal information in connection with the conduct of our clinical trials and related to our employees, and we are subject to laws and regulations governing the privacy and security of such information. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. Each of these laws, the requirements of which sometimes evolve with amendments, regulations and case law, can be subject to varying interpretations. In addition, new laws regulating privacy and data security continue to be passed in jurisdictions all over the world. In May 2018, a new privacy regime, the General Data Protection Regulation, or the GDPR, took effect in the European Economic Area, or the EEA. The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of European persons. Among other things, the GDPR imposes requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing

authorities, changes the lawful bases on which personal data can be processed, expands the definition of personal data and requires changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws, and imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our consolidated annual worldwide gross revenue). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

In addition, within the United States, states regularly adopt new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California enacted the California Consumer Privacy Act, or the CCPA, on June 28, 2018. This law, which took effect on January 1, 2020, became enforceable by the California Attorney General on July 1, 2020, and has been dubbed the first "GDPR-like" law in the United States. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. In addition, some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States as other states develop similar laws and we have already seen other states propose laws that are similar to the CCPA.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

Risks Related to Our Common Stock

An active trading market for our common stock may not develop and you may not be able to resell your shares of our common stock at an attractive price, if at all.

Prior to our IPO in March 2021, there was no public market for our common stock. Although our common stock is currently listed on The Nasdaq Global Select Market, we cannot assure you that an active trading market for our shares will develop or be sustained. If an active market for our common stock does not develop or is not sustained, it may be difficult for you to sell shares you purchased at an attractive price or at all. An inactive market may also impair our ability to raise capital to continue to fund our operations by selling our common stock and may impair our ability to acquire other companies or technologies by using our common stock as consideration.

The market price of our common stock has been and is likely to continue to be volatile and fluctuate substantially, which could result in substantial losses for our common stock.

The market price of our common stock has been and is likely to continue to be volatile. The stock market in general and the market for biopharmaceutical or pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. The market price for our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including the factors listed below and other factors described in this "Risk Factors" section:

- the results of our clinical trials of CP101, FIN-211 or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for CP101, FIN-211 or any other current or future product candidate we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including, without limitation, the FDA's issuance of a "refusal to file" letter or a request for additional information, such as the clinical hold letter we received from the FDA on February 24, 2022 and additional requests from the FDA regarding PRISM4, including a letter from the FDA in March 2022;
- adverse results from, delays in or termination of clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- unanticipated serious safety concerns related to the use of CP101, FIN-211 or any other product candidate;
- unexpected regulatory actions related to the manufacture and testing of CP101, FIN-211 or any other product candidate;
- changes in financial estimates by us or by any equity research analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcement by our competitors of regulatory developments or new data;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- our relationships with our collaborators;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;

- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- changes in the structure of healthcare payment systems;
- general political and economic conditions, including the effects of the ongoing COVID-19 pandemic; and
- other events or factors, many of which are beyond our control.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. As a newly public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. If at any time we do have equity research analyst coverage, we do not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

Sales of our common stock in the public market could cause the market price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. Many of our existing equity holders have substantial unrecognized gains on the value of the equity they hold, and therefore they may take steps to sell their shares or otherwise secure the unrecognized gains on those shares. We are unable to predict the timing of or the effect that such sales may have on the prevailing market price of our common stock.

In addition, we have registered the shares of common stock subject to options or other equity awards issued or reserved for future issuance under our 2017 Equity Incentive Plan, as amended, or the 2017 Plan, our 2021 Equity Incentive Plan, or the 2021 Plan, and our 2021 Employee Stock Purchase Plan, or the ESPP. Such shares will be available for sale in the public market subject to vesting arrangements and exercise of options or warrants and the restrictions of Rule 144 in the case of our affiliates.

Additionally, the holders of a significant number of shares of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

As of December 31, 2021, our executive officers, directors and beneficial owners of 5% or more of our common stock and their respective affiliates beneficially owned greater than 50% of our outstanding common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

We are an "emerging growth company" and a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until December 31, 2026 or, if earlier, (i) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (ii) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, or (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may, under certain circumstances, still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We incur significant costs and demands upon management as a result of being a public company.

As a public company listed in the United States, we incur significant legal, accounting and other costs. These costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the Securities and Exchange Commission, or SEC, and the Nasdaq Stock Market, or Nasdaq, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting.

Commencing with our fiscal year ending December 31, 2022, we must provide a management certification of our internal control over financial reporting in our 2022 Annual Report on Form 10-K, as required by Section 404(a) of the Sarbanes-Oxley Act. This certification will state the responsibility of our management to establish and maintain an adequate internal control structure and procedures for financial reporting and will also contain an assessment of the effectiveness of our internal control over financial reporting. The requirement to provide an internal control over financial reporting certification will require that we incur additional professional fees and internal costs. Furthermore, when we lose our status as an "emerging growth company" and a "smaller reporting company," our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. Prior to our IPO in March 2021, we have never been required to test our internal control within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We may identify weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial statements in a timely manner, which may adversely affect our business, investor confidence in our company and the market value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. We are not yet required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will also need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we remain an emerging growth company, we intend to take advantage of the exemption permitting us not to comply with the independent registered public accounting firm attestation requirement.

In March 2021, in connection with our IPO and in the course of reviewing our 2019 financial statement for our IPO, management and our independent registered public accounting firm identified material weaknesses in our internal control over financial reporting as we did not design and maintain effective review and approval controls over certain transactions and accounts.

The material weaknesses in our system of internal controls as of December 31, 2019 related to (1) an ineffective control environment, including a lack of sufficient accounting personnel and personnel with financial reporting expertise; (2) ineffective controls over cutoff, recording and classification of certain accounts, and the valuation and recognition of intangible assets acquired in a business combination that occurred in 2017; (3) ineffective risk assessment controls, including those policies and practices that would identify changes in our business practices, which could significantly impact our consolidated financial statements and system of internal controls; and (4) ineffective monitoring of controls related to the financial close and reporting process. As a result, there were adjustments required in connection with closing our books and

records and preparing our 2019 financial statements. During 2021, we hired additional finance and accounting personnel with appropriate expertise to perform specific functions and build out our financial infrastructure, implemented improved processes and internal controls and further developed and documented our accounting policies and financial reporting procedures, including ongoing senior management review and audit committee oversight. Management concluded that, as a result of the implementation of these actions, the previously-identified material weaknesses have been remediated as of December 31, 2021.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by The Nasdaq Stock Market LLC, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Changes in U.S. tax law could adversely affect our financial condition and results of operations.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in U.S. tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisors regarding the implications of potential changes in U.S. tax laws on an investment in our common stock.

We might not be able to utilize a significant portion of our net operating loss carryforwards.

We expect to generate significant federal and state net operating loss, or NOL, carryforwards in the future. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs, or the Tax Act, as modified by the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, federal NOLs incurred in taxable years beginning after December 31, 2017 and in future taxable years may be carried forward indefinitely, but the deductibility of such federal NOLs incurred in the taxable year beginning after December 31, 2020 is limited. It is uncertain how various states will respond to the Tax Act and CARES Act. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. The completion of our IPO in March 2021, together with private placements and other transactions that have occurred since our inception, may trigger such an ownership change pursuant to Section 382. We have not yet completed a Section 382 analysis. We may experience ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our NOL carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors will have the authority to issue up to 10,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative claim or cause of action brought on our behalf;
- any claim or cause of action asserting a breach of fiduciary duty;
- any claim or cause of action against us arising under the Delaware General Corporation Law;
- any claim or cause of action arising under or seeking to interpret our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any claim or cause of action against us that is governed by the internal affairs doctrine.

The provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation will further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal office is located in Somerville, Massachusetts, where we lease approximately 36,285 square feet of research and development, laboratory and office space under a lease that terminates in 2026. Additionally, we entered into a ten-year lease in August 2021 for approximately 61,139 square feet of office and laboratory space in Charlestown, Massachusetts. The lease commences in 2022 upon completion of construction of the leased space (see Note 5). We believe that these facilities will be adequate for our near-term needs.

Item 3. Legal Proceedings.

On December 1, 2021, Rebiotix Inc. and Ferring Pharmaceuticals Inc. (collectively, "Rebiotix") filed a complaint against us in the U.S. District Court for the District of Delaware. The complaint seeks a declaratory judgment of non-infringement and invalidity with respect to seven United States Patents owned by us: U.S. Patent Nos. 10,675,309 (the "'309 patent"); 10,463,702 (the "'702 patent"); 10,328,107 (the "'107 patent"); 10,064,899; 10,022,406; 9,962,413; and 9,308,226. On February 7, 2022, we filed an answer and counterclaims against Rebiotix for infringement of the '107, '702, and '309 patents. On March 7, 2022, we filed an amended answer and counterclaims, in which we, together with the Regents of the University of Minnesota ("UMN"), alleged infringement by Rebiotix of three U.S. Patents owned by UMN and exclusively licensed to us: U.S. Patent Nos. 10,251,914, 10,286,011, and 10,286,012. The U.S. District Court for the District of Delaware set a trial date for a 5-day trial beginning on May 20, 2024. The pending lawsuit is subject to inherent uncertainties, and the actual legal fees and costs will depend upon many unknown factors. The outcome of the pending lawsuit cannot be predicted with certainty.

We may also be a party to litigation and subject to claims incident to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock trades under the symbol "FNCH" on the Nasdaq Global Select Market and has been publicly traded since March 19, 2021. Prior to this time, there was no public market for our common stock. On March 24, 2022, the closing price of our common stock on The Nasdaq Global Select Market was $5.19 per share.

Holders of Our Common Stock

As of March 24, 2022, there were approximately 77 stockholders of record of shares of our common stock, one of which is Cede & Co., a nominee for Depository Trust Company, or DTC. All of the shares of common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are considered to be held of record by Cede & Co. as one stockholder.

Dividends

We have never declared or paid any dividends on our capital stock. We currently intend to retain all available funds and any future earnings for the operation and expansion of our business and, therefore, we do not anticipate declaring or paying cash dividends in the foreseeable future. The payment of dividends will be at the discretion of our board of directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements, any limitations on payment of dividends present in any future debt agreements and other factors that our board of directors may deem relevant.

Recent Sales of Unregistered Securities

None.

Issuer Purchase of Equity Securities

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the section titled "Risk Factors" set forth in Part I, Item 1A of this Annual Report on Form 10-K to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking Statements." You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

Overview

We are a clinical-stage microbiome therapeutics company leveraging our Human-First Discovery platform to develop a novel class of orally administered biological drugs. The microbiome consists of trillions of microbes that live symbiotically in and on every human and are essential to our health. When key microbes are lost, the resulting dysbiosis can increase susceptibility to immune disorders, infections, neurological conditions, cancer and other serious diseases. We are developing novel therapeutics designed to deliver missing microbes and their clinically relevant biochemical functions to correct dysbiosis and the diseases that emerge from it. Our Human-First Discovery platform uses reverse translation to identify diseases of dysbiosis and to design microbiome therapeutics that address them. We believe that our differentiated platform, rich pipeline and the broad therapeutic potential of this new field of medicine position us to transform care for a wide range of unmet medical needs.

Our lead product candidate, CP101, is an orally administered complete microbiome therapeutic in development for the prevention of recurrent *Clostridioides difficile* infection, or CDI. In June 2020, we reported positive topline data from our Phase 2 placebo-controlled clinical trial of CP101 for the prevention of recurrent CDI, which we refer to as the PRISM3 trial, and in November 2021, we reported positive topline data from our open-label, Phase 2 clinical trial of CP101 for the prevention of recurrent CDI, which we refer to as the PRISM-EXT trial. We have designed a Phase 3 clinical trial, which we refer to as the PRISM4 trial, to serve as our second pivotal trial of CP101 for the prevention of recurrent CDI. On March 1, 2022, we announced that enrollment in PRISM4 was paused following receipt of a clinical hold letter on February 24, 2022 from the U.S. Food and Drug Administration, or the FDA, in connection with our investigational new drug application, or IND, for CP101, requesting additional information regarding our SARS-CoV-2 donor screening protocols, including, among other things, that we address the risk of SARS-CoV-2 transmission in the informed consent process, additional detail on how samples are shipped to the vendor performing the SARS-CoV-2 testing of the donor material and how inconclusive test results will be handled. We are also preparing to initiate a Phase 1b clinical trial of FIN-211 in autism spectrum disorder, or ASD; however, because FIN-211 includes donor-derived components, the clinical hold related to our IND for CP101 will also delay initiation of our clinical trial in ASD. We plan to manufacture additional lots of CP101 and FIN-211 to satisfy the FDA's requests related to SARS-CoV-2 screening and testing. We are currently evaluating the extent of the delay the clinical hold and related manufacturing activities will have on the timing for our clinical trials in CDI and ASD, which we expect to be at least one quarter; we describe the clinical hold and related matters further above in the section entitled "Item 1. Business--Our Clinical Programs".

Following a strategic review of our pipeline and business, we announced in March 2022 the decision to pause the development of CP101 for the treatment of chronic hepatitis B virus, or HBV. We believe this decision will allow us to maximize our working capital available for investment in our wholly-owned recurrent CDI and ASD programs. We continue to partner with Takeda on the development of targeted microbiome therapeutics for inflammatory bowel disease. We believe that development of our targeted microbiome therapeutics, which are composed of strains grown from master cell banks, is not affected by the clinical hold.

Since our inception, we have focused primarily on developing and progressing our product candidates through clinical development, organizing and staffing our company, research and development activities, establishing and protecting our intellectual property portfolio, including for our Human-First Discovery platform, and raising capital. We do not have any product candidates approved for sale and have not generated any revenue from product sales. Since our inception, we have funded our operations primarily with proceeds from the IPO, the sale of convertible preferred stock and from collaboration revenue.

On March 12, 2021, we effected a 1-for-14.444 reverse stock split of our issued and outstanding shares of common stock and redeemable convertible preferred stock, as well as effected a proportional adjustment to the existing conversion ratios for our redeemable convertible preferred stock. All historical share and per share information shown herein and in our audited financial statements and related notes have been retroactively adjusted to give effect to the reverse stock split.

On March 18, 2021, we completed an IPO in which we issued and sold 7,500,000 shares of our common stock at a public offering price of $17.00 per share, resulting in aggregate gross proceeds of $127.5 million. On April 20, 2021, we issued and sold 192,877 additional shares of common stock, pursuant to the underwriters' partial exercise of their overallotment option, at a public offering price of $17.00 per share, for aggregate gross proceeds of $3.3 million. Inclusive of the underwriters' option to purchase additional shares, we received approximately $118.8 million in net proceeds from the IPO after deducting underwriting discounts and commissions and offering costs. Upon completion of the IPO, all 31,253,609 shares of outstanding redeemable convertible preferred stock automatically converted into 31,253,609 shares of common stock.

Since our inception, we have incurred significant operating losses. Our net losses were $58.2 million and $39.3 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $161.0 million. We expect to continue to generate operating losses and negative operating cash flows for the foreseeable future if and as we:

- continue the research and development of our product candidates;
- initiate clinical trials for, or additional preclinical development of, our product candidates;
- further develop and refine the manufacturing processes for our product candidates;
- seek regulatory and marketing authorizations for any of our product candidates that successfully complete development;
- seek to identify and validate additional product candidates;
- acquire or license other product candidates, technologies or biological materials;
- make milestone, royalty or other payments under any current or future license agreements;
- obtain, maintain, protect and enforce our intellectual property portfolio;
- seek to attract and retain new and existing skilled personnel;
- incur lease and construction expenses in connection with the expansion of our corporate headquarters;
- create additional infrastructure to support our operations as a public company, and incur increased legal, accounting, investor relations and other expenses; and
- experience delays or encounter issues with any of the above.

We will not generate any revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution.

As a result, we will need substantial additional funding to support our operating activities as we advance our product candidates through clinical development, seek regulatory approval and prepare for and, if any of our product candidates are approved, proceed to commercialization. Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including collaborations, licenses or similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all.

If we are unable to obtain funding, we will be forced to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. Although we continue to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all.

We expect that our existing cash and cash equivalents of $133.5 million as of December 31, 2021 will enable us to fund our operating expenses and capital expenditure requirements into mid-2023. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and Capital Resources."

COVID-19 Business Update

In response to the ongoing global COVID-19 pandemic, we established a cross-functional task force and have implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on our employees and our business, including our clinical trials. We have taken measures to secure our research and development activities, while work in laboratories and facilities has been organized to reduce risk of COVID-19 transmission. The extent of the impact of the COVID-19 pandemic, including variants of COVID-19, on our business, operations and clinical development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak, including with respect to variants of the virus, and its impact on our clinical trial enrollment, trial sites, contract research organizations, or CROs, contract manufacturing organizations, and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. Given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, our business, financial condition and results of operations ultimately could be materially adversely affected. We continue to closely monitor the COVID-19 pandemic as we evolve our business continuity plans, clinical development plans and response strategy.

Components of Our Results of Operations

Revenue

We have no products approved for commercial sale. We have not generated any revenue from product sales and do not expect to generate any revenue from the sale of licensed products for the foreseeable future. Our revenue to date has been generated primarily through collaboration and license agreements. We recognize revenue over our expected performance period under each agreement. We expect that our revenue for the next several years will be derived primarily from our current collaboration agreement and any additional collaborations that we may enter into in the future, and any collaboration revenue we generate will fluctuate from period to period as a result of the timing and amount of milestones and other payments. To date, we have not received any royalties under our collaboration agreement with Takeda Pharmaceutical Company Limited, or Takeda. However, during the year ended December 31, 2020, we received royalties in the aggregate of $0.3 million pursuant to our 2019 Asset Purchase and License Agreement, or APL Agreement, with OpenBiome, which was terminated in November 2020. We will continue to earn royalties under the OpenBiome Agreement based on sales of FMT materials.

Collaboration and License Agreement with Takeda

In January 2017, we entered into a research collaboration and exclusive license agreement, or the Takeda Agreement, with Takeda, pursuant to which we granted Takeda a worldwide, exclusive license, with the right to grant sublicenses, under our rights in certain patents, patent applications and know-how to develop, have developed, manufacture, have manufactured, make, have made, use, have used, offer for sale, sell, have sold, commercialize, have commercialized and import our microbiome therapeutic candidate TAK-524, for the prevention, diagnosis, theragnosis or treatment of diseases in humans. We subsequently amended and restated the Takeda Agreement in October 2019 to provide a similar worldwide, exclusive license to a second microbiome therapeutic candidate, FIN-525. We amended the Takeda Agreement in August 2021 to transition primary responsibility for further development and manufacturing activities with respect to TAK-524 from us to Takeda in accordance with a transition plan, and Takeda will assume sole responsibility for regulatory matters with respect to TAK-524. In November 2021, we amended the Takeda Agreement to enable us to carry out certain FIN-525 preliminary evaluation activities.

In connection with entry into the Takeda Agreement, we received a one-time, upfront payment from Takeda in the amount of $10.0 million. Additionally, we received $4.0 million in the aggregate for the achievement of certain development milestones for TAK-524 therapeutic products and are entitled to receive up to $176.0 million in the aggregate, for the achievement of specified development, regulatory and commercial sale milestones for TAK-524 therapeutic products. We are entitled to receive up to $177.7 million in the aggregate, for the achievement of specified development, regulatory and commercial sale milestones for FIN-525 therapeutic products, subject, to certain specified reductions based upon the nature of the FIN-525 product and certain additional milestones to be negotiated by the parties. We are also entitled to receive up to $10.0 million for the first diagnostic product for each of TAK-524 and FIN-525, subject to certain reductions in the event that Takeda uses a third party to develop such diagnostic products. None of these milestones were impacted by the amendments to the Takeda Agreement noted above. Revenue under the Takeda Agreement is recognized as our research and development services are provided and is recorded as collaboration revenue on our consolidated statement of operations.

Agreements with OpenBiome

We have historically collaborated with OpenBiome under several agreements related to, among other things, the license of various technology and intellectual property rights, and the supply of certain materials, as further described below.

In February 2017, we entered into the Quality System and Supply Agreement, or QSS Agreement, with OpenBiome, which was subsequently amended in September 2017 and was partially terminated in February 2019. Under the QSS Agreement, OpenBiome granted us an exclusive license, eligible for sublicense, of certain OpenBiome technology and intellectual property. Additionally, we acquired certain assets of OpenBiome for use in manufacturing and supplying product. The QSS Agreement allowed us to use the licensed OpenBiome technology and intellectual property for our own research and development efforts in exchange for up to $27.5 million in milestone payments associated with development and commercialization efforts. We were responsible for providing support to OpenBiome related to manufacturing product, produced to OpenBiome's specifications, which has been included as service revenue in our consolidated statements of operations. Revenue under the QSS Agreement was recorded as either contract manufacturing revenue or royalty revenue in our consolidated statements of operations.

On November 19, 2020, we entered into the LMIC License Agreement, or the LMIC Agreement, with OpenBiome, pursuant to which we granted OpenBiome a non-exclusive royalty-bearing license, with the right to grant sublicenses, under certain patents, patent applications, and know-how that are reasonably necessary or useful for the exploitation of products manufactured directly from stool from a stool donor source without the use of culturing or replication, or certain natural products. The license granted to OpenBiome excludes a license under our intellectual property to exploit a lyophilized Natural Product (such as CP101) where processed stool is lyophilized. The only consideration provided to us under the LMIC Agreement is in the form of future royalties on net sales of these products, which are not currently commercially viable. We are entitled to receive tiered royalties on net sales of certain products, ranging from mid-single digit to low second decile digits on a product-by-product and country-by-country basis. We did not recognize any revenue related to the LMIC Agreement for the years ended December 31, 2021 and 2020, as there are currently no products available for sale.

Also on November 19, 2020, we entered into an asset purchase agreement with OpenBiome, or the OpenBiome Agreement, the effect of which was to terminate certain existing agreements with OpenBiome and internalize some of the functions for which we have previously relied on OpenBiome. Pursuant to the OpenBiome Agreement, we acquired certain biological samples and obtained a license to certain OpenBiome technology and, upon closing of the transaction, which occurred March 1, 2021, we acquired certain additional assets, including biological samples, capital equipment and contracts. As of December 31, 2021, we have made payments of $5.0 million to OpenBiome related to the OpenBiome Agreement, which is the full amount agreed upon. We are also required to pay certain milestones up to $26.0 million upon the occurrence of certain research and development events, regulatory approvals, and commercial sales, and low single digit royalties on net sales of products on a product-by-product and country-by-country basis, as well as a mid-single digit royalties on sublicensing revenue related to such products.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our product candidates. We expense research and development costs as incurred, which include:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- upfront, milestone and maintenance fees incurred under license, acquisition and other third-party agreements;
- costs of laboratory supplies and acquiring, developing and manufacturing study materials;
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs; and
- costs of outside consultants, including their fees and related travel expenses engaged in research and development functions.

Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as prepaid or accrued research and development expenses. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses and expensed as the related goods are delivered or the services are performed.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase for the foreseeable future as we initiate and conduct clinical trials for our product candidates and continue to discover and develop additional product candidates. If any of our product candidates enter into later stages of clinical development, they will generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. There are numerous factors associated with the successful commercialization of any product candidates we may develop in the future, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development program and plans. We do not allocate certain employee-related costs, external costs directly related to our Human First Discovery platform, and other indirect costs to specific research and development programs because these costs are deployed across multiple product programs under development and, as such, are classified as costs of our platform research.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, corporate and business development and administrative functions. General and administrative expenses also include professional fees for legal, patent, accounting, auditing, tax and consulting services, travel expenses and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our general and administrative headcount to support our continued research and development and potential commercialization of our product candidates and expand our corporate headquarters. We also expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax compliance services, director and officer insurance costs, and investor and public relations costs.

Total Other Income, Net

Gain on Extinguishment of PPP Loan

Gain on extinguishment of PPP Loan relates to the forgiveness of our PPP Loan, under the Paycheck Protection Program, or the PPP, of the CARES Act.

Interest Income

Interest income primarily consists of interest earned on our cash and cash equivalents. Our interest income has not been significant due to low interest earned on cash balances related to our sweep account.

Gain (Loss) on Disposal of Fixed Assets

Gain on disposal of fixed assets relates to the gain we realized when we sold certain lab equipment during the year ended December 31, 2021.

Other (Expense) Income, Net

Other income (expense), net primarily consists of realized gains and losses on foreign exchange.

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020 (in thousands):

	YEAR ENDED DECEMBER 31,	
	2021	2020
REVENUE:		
Collaboration revenue	$ 18,532	$ 7,376
Royalties revenue from related party	—	343
Total revenue	18,532	7,719
OPERATING EXPENSES:		
Research and development	(57,279)	(33,144)
General and administrative	(21,238)	(14,011)
Total operating expenses	(78,517)	(47,155)
Net operating loss	(59,985)	(39,436)
OTHER INCOME, NET:		
Gain on extinguishment of PPP Loan	1,827	—
Interest income	22	106
Gain (loss) on disposal of fixed assets	28	(13)
Other (expense) income, net	(52)	2
Total other income, net	1,825	95
Net loss	$ (58,160)	$ (39,341)

Revenue

Revenue of $18.5 million and $7.7 million for the years ended December 31, 2021 and 2020, respectively, primarily consisted of collaboration revenue earned under the Takeda Agreement. Our collaboration revenue increased by $11.2 million in 2021 primarily due to our completion of the performance obligation under the Takeda Agreement.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2021 and 2020 (in thousands):

	YEAR ENDED DECEMBER 31,		
	2021	2020	Increase (Decrease)
CDI (CP101)	$ 16,779	$ 19,841	$ (3,062)
Inflammatory Bowel Diseases (TAK-524 and FIN-525)	6,328	7,610	(1,282)
Autism Spectrum Disorder (ASD) (FIN-211)	6,842	3,164	3,678
Hepatitis B (HBV) (CP101)	3,172	737	2,435
Platform	21,593	1,063	20,530
Unallocated	2,565	729	1,836
	$ 57,279	$ 33,144	$ 24,135

Research and development expenses for the year ended December 31, 2021, were $57.3 million, as compared to $33.1 million for the year ended December 31, 2020. The increase of $24.1 million in research and development expense for fiscal year 2021 included a $20.5 million increase in our platform related costs, which is primarily driven by a $10.4 million increase in personnel costs, a $4.4 million increase in manufacturing related expenses, a $1.9 million increase in external costs, and a $1.4 million increase in donor related costs. With the execution of the OpenBiome Agreement in the first quarter of 2021, we enhanced our internal manufacturing and platform research capabilities, which drove an overall increase in platform related costs, as we continue to build our platform and prepare for the future development of commercial supply needs. Additionally, there was a $3.7 million increase in expenses related to the expansion and development of our ASD program driven by a $2.1 million increase in external costs and a $1.0 million increase in personnel costs. The change also

included a $2.4 million increase in expenses related to the expansion and development of our HBV program driven by a $1.1 million increase in personnel costs and $0.8 million in contract manufacturing costs.

This increase was offset by a $3.1 million decrease in costs related to our CDI program, driven by a $1.2 million decrease in external costs, as we brought more of our development activities in-house upon execution of the OpenBiome Agreement, as well as a $1.0 million decrease in personnel related costs. Additionally, we had a $1.3 million decrease in IBD program expenses driven primarily by personnel costs.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2021 and 2020 (in thousands):

	YEAR ENDED DECEMBER 31,		
	2021	2020	Increase (Decrease)
Personnel expenses (including stock-based compensation)	$ 11,729	$ 9,041	$ 2,688
Facilities and supplies	327	581	(254)
Professional fees	5,459	3,479	1,980
Other expenses	3,723	910	2,813
	$ 21,238	$ 14,011	$ 7,227

General and administrative expenses were $21.2 million for the year ended December 31, 2021, as compared to $14.0 million for the year ended December 31, 2020. The increase of $7.2 million for fiscal year 2021 was primarily due to a $2.8 million increase in other expenses, a $2.7 million increase in personnel expenses, and a $2.0 million increase in legal and professional fees. The increase in other expenses is primarily related to directors and officers insurance costs, while the increase in personnel expenses is related to an increase in headcount to support our operational growth. The increase in professional fees is related to our transition to a public company in March 2021.

Other Income, Net

Total other income, net was $1.8 million for the year ended December 31, 2021, compared to $0.1 million for the year ended December 31, 2020. The increase of $1.7 million was primarily due to the forgiveness of the PPP Loan in full in the amount of $1.8 million.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not recognized any product revenue and have incurred operating losses and negative cash flows from our operations. We have not yet commercialized any product and we do not expect to generate revenue from sales of any products for several years, if at all. We have funded our operations primarily through equity financings and from collaboration revenue. We have raised an aggregate of approximately $177.0 million from the sale of convertible preferred stock and $14.0 million in collaboration revenue from the upfront payment and milestone payments received under our collaboration agreement. In March 2021, we completed our IPO whereby we sold an aggregate of 7,500,000 shares of our common stock. In April 2021, we sold an additional 192,877 shares of our common stock, pursuant to the underwriters' partial exercise of their overallotment option, at a public offering price of $17.00 per share, for aggregate gross proceeds of $3.3 million. In aggregate, we received approximately $118.8 million in net proceeds related to our IPO after deducting $9.2 million of underwriting discounts and commissions and $2.9 million of offering expenses.

In April 2020, we received proceeds of $1.8 million from the PPP Loan. We used the PPP Loan to retain current employees, maintain payroll and make lease and utility payments. On May 8, 2021, we received notice from the SBA that the entirety of the PPP Loan we received was forgiven. Accordingly, we are no longer required to repay the $1.8 million in principal and approximately $19,000 in accrued interest borrowed under the PPP Loan. Gain on extinguishment of the PPP Loan is recorded in other income on the consolidated statements of operations for the year ended December 31, 2021.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2021 and 2020 (in thousands):

	YEAR ENDED DECEMBER 31,	
	2021	2020
Net cash used in operating activities	$ (67,133)	$ (31,329)
Net cash used in investing activities	(15,921)	(2,633)
Net cash provided by financing activities	119,110	91,475
Net increase in cash and cash equivalents, and restricted cash	$ 36,056	$ 57,513

Operating Activities

During the year ended December 31, 2021, cash used in operating activities was $67.1 million. This cash outflow was primarily related to our net loss of $58.2 million. The cash outflow included $4.2 million in stock-based compensation expense, $2.3 million in non-cash depreciation and amortization, and $1.8 million gain on extinguishment of PPP Loan. The outflow was also impacted by a net decrease in our operating assets and liabilities of $14.5 million. The change in operating assets and liabilities includes a $13.6 million decrease in deferred revenue, a $4.7 million decrease in other non-current assets, and a $3.2 million decrease in prepaid expenses and other current assets. This was offset by a $5.4 million increase in accrued expenses and other current liabilities, a $2.3 million increase in accounts payable, and a $0.5 million increase in accounts receivable.

During the year ended December 31, 2020, cash used in operating activities was $31.3 million. This cash outflow was primarily related to our net loss of $39.3 million and was offset by non-cash charges, including $0.8 million in depreciation and amortization expense on our fixed assets and $3.1 million in stock-based compensation expense. Of the $3.1 million in stock-based compensation expense, $2.8 million was related to the sale of our common stock by certain executives and founders to SIG Global US Fund I, LLLP. The net loss was also offset by changes in our operating assets and liabilities, including a $3.7 million increase in prepaid expenses and other current assets. The changes in operating assets and liabilities also include a $3.5 million decrease in due from related party for the amounts received in 2020 related to the signing of the APL Agreement in 2019, and a $3.0 million increase in deferred revenue related to our adjustment to the amount we expect to receive for reimbursable costs under the Takeda Agreement.

Investing Activities

During the years ended years ended December 31, 2021 and 2020, we used $15.9 million and $2.6 million, respectively, of cash in investing activities. The $15.9 million used during the year ended December 31, 2021 and $1.5 million of the cash used during the year ended December 31, 2020 was related to the purchases of property and equipment. The remaining $1.2 million of cash used in investing activities during the year ended December 31, 2020 was related to payments we made to OpenBiome in conjunction with the signing of the OpenBiome Agreement in November 2020.

Financing Activities

During the year ended December 31, 2021, net cash provided by financing activities was $119.1 million, primarily related to $118.6 million of proceeds received from the IPO, net of underwriting discounts and commissions and $3.0 million of proceeds from the underwriters' exercise of their overallotment option, net of underwriting discounts and commissions. The proceeds are partially offset by $2.7 million of payments of issuance costs related to the IPO.

During the year ended December 31, 2020, net cash provided by financing activities was $91.5 million, primarily related to $90.0 million of gross proceeds received from the issuance of Series D redeemable convertible preferred stock during the year, as well as proceeds of $1.8 million from our PPP Loan. The cash provided by financing activities was offset by the payment of $0.2 million of deferred offering costs and $0.1 million in issuance costs related to the series D redeemable convertible preferred stock issuance.

Funding Requirements

As of December 31, 2021, our cash and cash equivalents were $133.5 million. We believe that our existing cash on hand will enable us to fund our operating expenses and capital expenditure requirements into mid-2023. We have based this estimate on assumptions that may prove to be wrong, and we could expend our capital resources sooner than we expect.

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. We expect that our expenses will increase substantially if and as we:

- continue the research and development of our product candidates;
- initiate and conduct clinical trials for, or additional preclinical development of, our product candidates;
- further develop and refine the manufacturing process for our product candidates;
- change or add manufacturers or suppliers of product candidate materials;
- seek regulatory and marketing authorizations for any of our product candidates that successfully complete development;
- seek to identify and validate additional product candidates;
- acquire or license other product candidates, technologies or biological materials;
- make milestone, royalty or other payments under any current or future license agreements;
- obtain, maintain, protect and enforce our intellectual property portfolio;
- seek to attract and retain new and existing skilled personnel;
- create additional infrastructure to support our operations and incur increased legal, accounting, investor relations and other expenses; and
- experience delays or encounter issues with any of the above.

Material Cash Requirements

The following table summarizes our contractual obligations as of December 31, 2021, and the effects of such obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years
Lease commitments	$ 58,629	$ 6,046	$ 18,791	$ 11,402	$ 22,390
License agreements	400	20	110	110	160
Total	$ 59,029	$ 6,066	$ 18,901	$ 11,512	$ 22,550

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions, and the approximate timing of the actions under the contracts.

Lease Commitments

We have entered into operating leases for rental space in Somerville, Cambridge, and Charlestown Massachusetts (see Note 5 to our annual consolidated financial statements appearing elsewhere in this Annual Report). The table above includes future minimum lease payments under the non-cancelable lease arrangements. The table above also includes payments due under our capital lease obligation, as related to leased equipment.

License Agreements

We have also entered into license agreements under which we are obligated to make milestone and royalty payments and incur annual maintenance fees. We owe an annual maintenance fee of $5,000 under our agreement with University of Minnesota, as well as escalating minimum royalty amounts. We also are required to pay minimum royalties under the agreement with Arizona State University of $5,000 annually until 2023, which increases to $20,000 in 2024. Future minimum payments through 2028 have been included in the table above, but our minimum payments continue in perpetuity for University of Minnesota until the agreement is terminated. We are also obligated to make regulatory milestone payments to OpenBiome aggregating up to $6.0 million upon the achievement of regulatory approvals, and sales-based milestone payments of up to $20.0 million upon the achievement of certain net sales criteria. We were also obligated to pay OpenBiome $1.25 million upon the closing of the OpenBiome Agreement, included as a portion of the closing fees of $3.9 million, as related to milestones previously achieved. We are obligated to pay to OpenBiome a low single digit royalty on net sales of licensed natural products by us and our affiliates and a high single digit percentage of certain sublicensing revenue (including royalties) received in connection with licensed natural products. These royalties are calculated on a product-by-product and country-by-country basis. See the sections titled "Business—Our Collaborations and License Agreements" and "Business—Agreements with OpenBiome" elsewhere in this Annual Report as well as Note 7 to our annual consolidated financial statements appearing elsewhere in this Annual Report for a description of our license agreements.

Purchase and Other Obligations

We enter into contracts in the normal course of business with CROs and other third parties for preclinical studies, clinical trials and testing and manufacturing services. These contracts generally do not contain minimum purchase commitments and are cancelable by us upon prior written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including non-cancelable obligations of our service providers up to one year after the date of cancellation. These payments are not included in the table above as the amount and timing and such payments are not known.

Critical Accounting Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in greater detail in Note 2 to our consolidated financial statements appearing in this Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

To date, our revenues have consisted of payments received related to our licensing agreement with Takeda. We apply the revenue recognition guidance in accordance with Financial Accounting Standards Board, Accounting Standards Codification, or ASC, Subtopic 606, *Revenue from Contracts with Customers*, which was adopted January 1, 2017 using the full retrospective method. Under ASC 606, we recognize revenue when our customers obtain control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services.

To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect consideration we are entitled to in exchange for the goods or services we transfer to our customer. All variable consideration, including milestones and royalties, are constrained until the cumulative revenue related to the consideration is no longer probable of reversal.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations which consist of licenses and other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. We currently measure progress according to the expenditure of research and development efforts, based on costs incurred, as this is the best indicator of performance.

We receive payments from our customers based on billing schedules established in each contract. Upfront payments and fees are recorded as deferred revenue upon receipt or when due until we satisfy our obligations under these arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional.

Goodwill and Acquired In-Process Research and Development

Goodwill is the amount by which the purchase price of acquired net assets in a business combination exceeded the fair values of net identifiable assets on the date of acquisition. Acquired In-Process Research and Development, or IPR&D, represents the fair value assigned to research and development assets that we acquire that have not been completed at the date of acquisition or are pending regulatory approval in certain jurisdictions. The value assigned to the acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the net cash flows to present value. Our IPR&D is considered an intangible asset with an indefinite life.

Goodwill and IPR&D are evaluated for impairment annually, or more frequently if events or changes in circumstances indicate that the asset might be impaired. Factors we consider important, on an overall company basis, that could trigger an impairment review include significant underperformance relative to historical or projected future operating results, significant changes in our use of the acquired assets or the strategy for our overall business, significant negative industry or economic trends, a significant decline in our stock price for a sustained period, or a reduction of our market capitalization relative to net book value. We have historically performed our annual goodwill and IPR&D impairment assessments as of the last day in each fiscal year. During the fourth quarter of 2020, we changed our annual impairment assessment date to the first day of the fourth quarter, or October 1.

To conduct impairment tests of goodwill, the fair value of the reporting unit is compared to its carrying value. If the reporting unit’s carrying value exceeds its fair value, we record an impairment loss to the extent that the carrying value of goodwill exceeds its implied fair value. Our annual assessments for impairment of goodwill as of October 1, 2021 and 2020 indicated that the fair value of our reporting unit exceeded the carrying value of the reporting unit.

To conduct impairment tests of IPR&D, the fair value of the IPR&D asset is compared to its carrying value. If the carrying value exceeds its fair value, we record an impairment loss to the extent that the carrying value of the IPR&D asset exceeds its fair value. We estimate the fair value for our IPR&D asset using discounted cash flow valuation models, which require the use of significant estimates and assumptions, including, but not limited to, estimating the timing of and expected costs to complete the in-process projects, projecting regulatory approvals, estimating future cash flows from product sales resulting from completed projects and in-process projects, and developing appropriate discount rates. Our annual assessments for impairment of IPR&D indicated that the fair value of our other IPR&D asset as of October 1, 2021 and 2020 exceeded their respective carrying values.

Through December 31, 2021, there have not been any events or changes in circumstances that indicate that the carrying value of goodwill or acquired intangible assets may not be recoverable. The FDA clinical hold issues could negatively impact the fair value of IPR&D and goodwill. We continue to monitor and evaluate the financial performance of our business, including the impact of general economic conditions, to assess the potential for the fair value of the reporting unit to decline below its book value. There can be no assurance that, at the time future impairment tests are completed, a material impairment charge will not be recorded.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service

fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Recently Issued Accounting Pronouncements

See Note 2 to our annual consolidated financial statements within this Report for a description of recent accounting pronouncements applicable to our financial statements.

Emerging Growth Company Status and Smaller Reporting Company Status

We are an "emerging growth company," or EGC, under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Section 107 of the JOBS Act provides that an EGC can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of delayed adoption of new or revised accounting standards and, therefore, we will be subject to the same requirements to adopt new or revised accounting standards as private entities.

As an EGC, we may take advantage of certain exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an EGC:

- we may present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations;
- we may avail ourselves of the exemption from providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;
- we may avail ourselves of the exemption from complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis;
- we may provide reduced disclosure about our executive compensation arrangements; and
- we may not require nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments.

We will remain an emerging growth company until December 31, 2026 or, if earlier, (i) the last day of our first fiscal year in which we have total annual gross revenues of at least $1.07 billion, (ii) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th or (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We are also a ‘‘smaller reporting company,’’ meaning that the market value of our stock held by non-affiliates is less than $700.0 million and our annual revenue was less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our common stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million.

If we are a smaller reporting company at the time we cease to be an EGC, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to EGCs, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to certain market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily the result of fluctuations in foreign currency exchange rates.

Interest Rate Risk

As of December 31, 2021, we had cash and cash equivalents of $133.5 million. Our exposure to interest rate sensitivity is impacted by changes in the underlying U.S. bank interest rates. Our surplus cash has been invested in money market fund accounts as well as interest-bearing savings accounts from time to time. We have not entered into investments for trading or speculative purposes. Due to the conservative nature of our investment portfolio, which is predicated on capital preservation of investments with short-term maturities, we do not believe an immediate one percentage point change in interest rates would have a material effect on the fair market value of our portfolio, and therefore, we do not expect our operating results or cash flows to be significantly affected by changes in market interest rates. As of December 31, 2021, we had no debt outstanding, therefore, we are not subject to interest rate risk related to debt.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and Board of Directors of Finch Therapeutics Group, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Finch Therapeutics Group, Inc. and its subsidiaries (the "Company") as of December 31, 2021 and 2020, the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, effective January 1, 2021, the Company adopted FASB Accounting Standards Codification Topic 842, *Leases*, using the modified retrospective approach.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 31, 2022

We have served as the Company's auditor since 2020.

FINCH THERAPEUTICS GROUP, INC.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	DECEMBER 31, 2021	DECEMBER 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 133,481	$ 99,710
Accounts receivable	494	1,034
Due from related party	—	61
Prepaid expenses and other current assets	8,576	5,359
Total current assets	142,551	106,164
Property and equipment, net	19,635	7,004
Operating right-of-use assets	5,053	—
In-process research and development	32,900	32,900
Goodwill	18,057	18,057
Deferred initial public offering costs	—	1,013
Restricted cash, non-current	2,268	—
Other assets	4,905	200
TOTAL ASSETS	$ 225,369	$ 165,338
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 3,737	$ 2,621
Accrued expenses and other current liabilities	9,925	5,228
Operating lease liabilities, current	1,128	—
Due to related party	—	266
Deferred revenue, current portion	—	3,371
Total current liabilities	14,790	11,486
Deferred tax liability	3,461	3,461
Deferred revenue, net of current portion	—	10,260
Loan payable	—	1,808
Deferred rent	—	766
Operating lease liabilities, non-current	4,887	—
Other liabilities	7	221
Total liabilities	23,145	28,002
COMMITMENTS AND CONTINGENCIES (Note 9)		
Series A redeemable convertible preferred stock, $0.001 par value; no shares authorized, issued or outstanding as of December 31, 2021; 167,496,750 shares authorized and 11,596,280 shares issued and outstanding as of December 31, 2020;	—	53,593
Series B redeemable convertible preferred stock, $0.001 par value; no shares authorized, issued or outstanding as of December 31, 2021; 74,620,739 shares authorized and 5,166,203 shares issued and outstanding as of December 31, 2020	—	36,336
Series C redeemable convertible preferred stock, $0.001 par value; no shares authorized, issued or outstanding as of December 31, 2021; 109,604,994 shares authorized and 7,588,254 shares issued and outstanding as of December 31, 2020	—	53,221
Series D redeemable convertible preferred stock, $0.001 par value; no shares authorized, issued or outstanding as of December 31, 2021; 99,705,359 shares authorized and 6,902,872 shares issued and outstanding as of December 31, 2020	—	89,904
STOCKHOLDERS' EQUITY (DEFICIT):		
Common stock, $0.001 par value; 200,000,000 and 598,232,153 shares authorized as of December 31, 2021 and December 31, 2020, respectively; 47,512,182 and 8,391,793 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	47	8
Additional paid-in capital	363,172	7,109
Accumulated deficit	(160,995)	(102,835)
Total stockholders' equity (deficit)	202,224	(95,718)
TOTAL LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 225,369	$ 165,338

See notes to consolidated financial statements.

FINCH THERAPEUTICS GROUP, INC.

Consolidated Statements of Operations

(In thousands, except share and per share data)

	YEAR ENDED DECEMBER 31,	
	2021	**2020**
REVENUE:		
Collaboration revenue	$ 18,532	$ 7,376
Royalty revenue from related party	—	343
Total revenue	18,532	7,719
OPERATING EXPENSES:		
Research and development	(57,279)	(33,144)
General and administrative	(21,238)	(14,011)
Total operating expenses	(78,517)	(47,155)
Net loss from operations	(59,985)	(39,436)
OTHER INCOME, NET:		
Gain on extinguishment of PPP Loan	1,827	—
Interest income	22	106
Gain (loss) on disposal of fixed assets	28	(13)
Other (expense) income, net	(52)	2
Total other income, net	1,825	95
Loss before income taxes	(58,160)	(39,341)
Income tax provision	—	—
Net loss	$ (58,160)	$ (39,341)
Net loss attributable to common stockholders—basic and diluted (Note 15)	$ (58,160)	$ (39,341)
Net loss per share attributable to common stockholders—basic and diluted	$ (1.48)	$ (4.83)
Weighted-average common stock outstanding—basic and diluted	39,202,086	8,144,855

See notes to consolidated financial statements.

FINCH THERAPEUTICS GROUP, INC.

Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

(In thousands, except share and per share data)

	REDEEMABLE CONVERTIBLE PREFERRED STOCK												
	$0.001 PAR VALUE SERIES A		$0.001 PAR VALUE SERIES B		$0.001 PAR VALUE SERIES C		$0.001 PAR VALUE SERIES D		COMMON STOCK $0.001 PAR VALUE		ADDITIONAL PAID-IN	ACCUMULATED	TOTAL STOCKHOLDERS'
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	CAPITAL	DEFICIT	EQUITY (DEFICIT)
BALANCE, January 1, 2020	11,596,280	$ 53,593	5,166,203	$ 36,336	7,588,254	$ 53,221	—	$ —	7,778,552	$ 8	$ 3,951	$ (63,494)	$ (59,535)
Issuance of series D redeemable convertible preferred stock, net of issuance costs of $96	—	—	—	—	—	—	6,902,872	89,904	—	—	—	—	—
Exercise of common stock options	—	—	—	—	—	—	—	—	65,881	—	59	—	59
Vesting of restricted stock	—	—	—	—	—	—	—	—	547,360	—	8	—	8
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	3,091	—	3,091
Net loss	—	—	—	—	—	—	—	—	—	—	—	(39,341)	(39,341)
BALANCE, December 31, 2020	11,596,280	$ 53,593	5,166,203	$ 36,336	7,588,254	$ 53,221	6,902,872	$ 89,904	8,391,793	$ 8	$ 7,109	$ (102,835)	$ (95,718)
Conversion of redeemable convertible preferred stock into common stock upon initial public offering	(11,596,280)	(53,593)	(5,166,203)	(36,336)	(7,588,254)	(53,221)	(6,902,872)	(89,904)	31,253,609	31	233,022	—	233,053
Initial public offering, net of underwriting discounts, commissions and net of offering costs of $11,786	—	—	—	—	—	—	—	—	7,500,000	8	115,706	—	115,714
Underwriters' exercise of overallotment option, net of underwriting discounts, commissions and initial public offering costs of $276	—	—	—	—	—	—	—	—	192,877	—	3,003	—	3,003
Shares repurchased for cashless exercise	—	—	—	—	—	—	—	—	(1,221)	—	(10)	—	(10)
Exercise of common stock options	—	—	—	—	—	—	—	—	155,821	—	181	—	181
Exercise of common stock warrants	—	—	—	—	—	—	—	—	19,303	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	4,161	—	4,161
Net loss	—	—	—	—	—	—	—	—	—	—	—	(58,160)	(58,160)
BALANCE, December 31, 2021	—	$ —	—	$ —	—	$ —	—	$ —	47,512,182	$ 47	$ 363,172	$ (160,995)	$ 202,224

See notes to consolidated financial statements.

FINCH THERAPEUTICS GROUP, INC.
Consolidated Statements of Cash Flows
(In thousands)

	YEAR ENDED DECEMBER 31,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (58,160)	$ (39,341)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	2,301	790
Stock-based compensation expense	4,161	3,099
Gain on extinguishment of PPP Loan	(1,808)	—
(Gain) loss on sale of property and equipment	(28)	13
Other non-cash operating lease cost	913	—
Changes in operating assets and liabilities:		
Accounts receivable	540	143
Due from related party	61	3,507
Prepaid expenses and other current assets	(3,217)	(3,665)
Other non-current assets	(4,689)	—
Accounts payable	2,261	440
Accrued expenses and other current liabilities	5,435	481
Due to related party	(266)	(68)
Deferred revenue	(13,631)	2,963
Deferred rent	—	309
Operating lease liabilities	(1,006)	—
Net cash used in operating activities	(67,133)	(31,329)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(15,983)	(2,633)
Proceeds from sale of property and equipment	62	—
Net cash used in investing activities	(15,921)	(2,633)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from initial public offering, net of underwriting discounts, commissions and offering costs	118,576	—
Proceeds from issuance of Series D convertible preferred stock	—	90,000
Payment of Series D redeemable convertible preferred stock issuance costs	—	(96)
Proceeds from underwriters' exercise of overallotment option, net of underwriting discounts and commissions and initial public offering costs	3,049	—
Principal payments on finance lease obligation	(27)	(47)
Proceeds from exercise of stock options, net	171	59
Proceeds from PPP Loan	—	1,808
Payment of deferred offering costs	(2,659)	(249)
Net cash provided by financing activities	119,110	91,475
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	36,056	57,513
Cash, cash equivalents and restricted cash at beginning of period	99,909	42,396
Cash, cash equivalents and restricted cash at end of period	$ 135,965	$ 99,909
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for interest	$ 9	$ 11
Cash paid in connection with operating lease liabilities	$ 1,434	$ —
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Property and equipment in accounts payable and accrued liabilities	$ 381	$ 1,398
Conversion of redeemable convertible preferred stock into common stock	$ 233,053	$ —
Operating right-of-use assets obtained in exchange for new operating leases upon adoption of ASC 842	$ 5,965	$ —
Deferred initial public offering costs in AP and accruals	$ —	$ 764

The following table provides a reconciliation of the cash, cash equivalents and restricted cash as of each of the periods shown above:

	YEAR ENDED DECEMBER 31,	
	2021	2020
Cash and cash equivalents	$ 133,481	$ 99,710
Restricted cash	2,484	199
Total cash, cash equivalents and restricted cash	$ 135,965	$ 99,909

See notes to consolidated financial statements.

1. NATURE OF OPERATIONS

Business

Finch Therapeutics Group, Inc. (the "Company" or "FTG") was incorporated in 2017 as a Delaware corporation. The Company was formed as a result of a merger and recapitalization of Finch Therapeutics, Inc. ("Finch") and Crestovo Holdings LLC ("Crestovo") in September 2017 (the "Merger"), in which the former owners of Finch and Crestovo were issued equivalent stakes in the newly formed company, FTG. Crestovo was renamed Finch Therapeutics Holdings LLC in November 2020 ("Finch Holdings"). Finch and Finch Holdings are both wholly-owned subsidiaries of FTG.

The Company is a clinical-stage microbiome therapeutics company leveraging its Human-First Discovery platform to develop a novel class of orally administered biological drugs. It is developing novel therapeutics designed to deliver missing microbes and their clinically relevant biochemical functions to correct dysbiosis and the diseases that emerge from it. The Company's Human-First Discovery platform uses reverse translation to identify diseases of dysbiosis and to design microbiome therapeutics that address them. Its lead product candidate, CP101, is an orally administered complete microbiome therapeutic in development for the prevention of recurrent *Clostridioides difficile* infection, or CDI.

Initial Public Offering

On March 18, 2021, the Company completed its initial public offering ("IPO") in which the Company issued and sold 7,500,000 shares of its common stock at a public offering price of $17.00 per share, for aggregate gross proceeds of $127.5 million and proceeds of $115.7 million after deducting underwriting discounts and commissions of $8.9 million and offering costs of $2.9 million. On April 20, 2021, the Company issued 192,877 additional shares of common stock, pursuant to the underwriters' partial exercise of their overallotment option, at a public offering price of $17.00 per share for aggregate gross proceeds of $3.3 million and net proceeds of $3.0 million after deducting underwriting discounts, commissions and offering costs.

In connection with the IPO, the Company's board of directors (the "Board") and stockholders approved an amended and restated certificate of incorporation to, among other things, effect a one-for-14.444 reverse stock split of the Company's issued and outstanding shares of common stock and redeemable convertible preferred stock, as well as to effect a proportional adjustment to the existing conversion ratios for the Company's redeemable convertible preferred stock. The reverse stock split was effected on March 12, 2021. Accordingly, all share and per share amounts of common stock for all periods presented in the accompanying audited consolidated financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect this reverse stock split and adjustment of preferred stock conversion ratios. Upon the closing of the IPO, all of the then-outstanding shares of redeemable convertible preferred stock automatically converted into 31,253,609 shares of common stock at the applicable conversion ratio then in effect. Subsequent to the closing of the IPO, there were no shares of convertible preferred stock outstanding.

Risks and Uncertainties

The Company is subject to a number of risks similar to other companies in its industry, including rapid technological change, the risk that its products will fail to demonstrate efficacy in clinical trials, uncertainty of market acceptance of its products, competition from larger pharmaceutical and biotechnology companies and dependence on key personnel.

The extent of the impact of the COVID-19 pandemic on the Company's business, operations and clinical development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak, including with respect to variants of the virus, and its impact on clinical trial enrollment, trial sites, contract research organizations, contract manufacturing organizations, and other third parties with whom the Company does business, as well as its impact on regulatory authorities and its key scientific and management personnel. While the Company is experiencing limited financial impacts at this time, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, the Company's business, financial condition and results of operations ultimately could be materially adversely affected. The Company continues to closely

monitor the COVID-19 pandemic as it evolves its business continuity plans, clinical development plans and response strategy.

At this time, it is unknown how long the adverse conditions associated with the COVID-19 pandemic will last and what the complete financial effect will be to the Company.

Liquidity

The Company has incurred recurring losses since its inception, including net losses of $58.2 million and $39.3 million for the years ended December 31, 2021 and 2020, respectively. In addition, as of December 31, 2021, the Company had an accumulated deficit of $161.0 million. The Company expects to continue to generate operating losses for the foreseeable future as it continues to develop its product candidates. The Company expects that its cash and cash equivalents of $133.5 million as of December 31, 2021, will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months beyond the date of issuance the annual consolidated financial statements.

The Company will not generate any future revenue from product sales unless and until it successfully completes clinical development and obtains regulatory approval for one or more of its product candidates. If the Company obtains regulatory approval for any of its product candidates, it expects to incur significant expenses related to developing its internal commercialization capability to support manufacturing, product sales, marketing and distribution. As a result, the Company will need substantial additional funding to support its operating activities as it advances its product candidates through clinical development, seeks regulatory approval, and if any of its product candidates are approved, proceeds to commercialization.

Until such time as the Company can generate significant revenue from product sales, if ever, the Company expects to finance its operating activities through a combination of equity offerings, debt financings, and license and development agreements in connection with any future collaborations. Adequate funding may not be available to the Company on acceptable terms, or at all. If the Company is unable to obtain funding, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

2. SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and include the operations of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses, and the disclosure of contingent assets and liabilities as of and during the reporting period. The Company bases its estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements if these results differ from historical experience, or other assumptions do not turn out to be substantially accurate, even if such assumptions are reasonable when made. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the pattern and method of recognizing revenue, the accrual of research and development costs, and the annual assessment of impairment of goodwill and in-process research and development assets. The Company assesses estimates on an ongoing basis; however, actual results could materially differ from those estimates.

Fair Value Measurements

Certain assets and liabilities are reported on a recurring basis at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. The Company has no assets or liabilities classified as Level 3 on its consolidated balance sheets as of December 31, 2021 and 2020.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents. The Company maintains its cash in bank deposit accounts which, at times, may exceed the federal insurance limit.

The Company's cash equivalents, which are funds held in a money market account, are measured at fair value on a recurring basis. The carrying amount of cash and cash equivalents was $133.5 million and $99.7 million as of December 31, 2021 and 2020, respectively, which approximates fair value and was determined based upon Level 1 inputs. The money market account is valued using quoted market prices with no valuation adjustments applied and is categorized as Level 1.

Restricted Cash

The Company had restricted cash of $2.5 million and $0.2 million as of December 31, 2021 and 2020, respectively, primarily related to a security deposit on its operating leases for its offices in Somerville and Charlestown, Massachusetts for the year ended December 31, 2021, and for its operating lease for its offices in Somerville, Massachusetts for the year ended December 31, 2020. This is included in restricted cash, non-current and other assets on the Company's consolidated balance sheets.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. The Company may maintain deposits in financial institutions in excess of government insured limits. The Company believes that it is not exposed to significant credit risk as its deposits are held at financial institutions that management believes to be of high credit quality and the Company has not experienced any losses on these deposits. As of December 31, 2021 and 2020, the Company's cash and cash equivalents were held with one financial institution. The Company believes that the market risk arising from its holdings of these financial instruments is mitigated based on the fact that many of these securities are either government-backed or of high credit rating.

Accounts Receivable

Accounts receivable are carried at the invoiced amount less an allowance for doubtful accounts. Doubtful accounts are provided for on the basis of anticipated collection losses. The estimated losses are determined from historical collection experience and a review of outstanding accounts receivable. A receivable is considered past due if the Company has not received payment within the stated payment terms. After all attempts to collect a receivable have failed, the receivable is

written off against the allowance. Based on historical receipts and collections history, management has determined that an allowance for doubtful accounts is not necessary as of December 31, 2021 and 2020.

Property and Equipment

Property and equipment are recorded at cost. Expenditures for repairs and maintenance are expensed as incurred, while any additions or improvements are capitalized. When assets are retired or disposed of, the assets and related accumulated depreciation are derecognized from the accounts, and any resulting gain or loss is included in the determination of net loss. Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets as follows:

	ESTIMATED USEFUL LIFE
Computer equipment and software	3 years
Laboratory equipment	5 years
Office furniture	5 years
Leasehold improvements	Shorter of useful life or lease term

Goodwill and In-Process Research and Development

Goodwill is the amount by which the cost of the acquired net assets in a business combination exceeds the fair value of the identifiable net assets on the date of purchase or valuation. The Company accounts for goodwill in accordance with ASC Topic 350, *Intangibles—Goodwill and Other*.

Acquired In-Process Research and Development ("IPR&D") represents the fair value assigned to research and development assets that the Company acquired that had not been completed at the date of acquisition and is accounted for as an indefinite lived intangible asset in accordance with ASC Topic 350, *Intangibles—Goodwill and Other*. The value assigned to the acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the net cash flows to present value. The Company's IPR&D is comprised of Crestovo's research and development asset related to CP101, which was acquired in the Merger.

Goodwill and IPR&D are evaluated for impairment annually on October 1, or more frequently if events or changes in circumstances indicate that the asset might be impaired. Factors the Company considers important, on an overall company basis, that could trigger an impairment review include significant underperformance relative to historical or projected future operating results, significant changes in the Company's use of the acquired asset or the strategy for its overall business, significant negative industry or economic trends, a significant decline in the Company's stock price for a sustained period, or a reduction of its market capitalization relative to net book value.

To conduct impairment tests of goodwill, the fair value of the Company's single reporting unit is compared to its carrying value. If the reporting unit's carrying value exceeds its fair value, the Company records an impairment loss to the extent that the carrying value of goodwill exceeds its fair value. The Company's annual assessments for impairment of goodwill as of October 1, 2021 and October 1, 2020 indicated that the fair value of its reporting unit exceeded the carrying value of the reporting unit.

To conduct impairment tests of IPR&D, the fair value of the IPR&D asset is compared to its carrying value. If the carrying value exceeds its fair value, the Company records an impairment loss to the extent that the carrying value of the IPR&D project exceeds its fair value. The Company estimates the fair value of IPR&D using discounted cash flow valuation models, which require the use of significant estimates and assumptions, including but not limited to, estimating the timing of and expected costs to complete the in-process projects, projecting regulatory approvals, estimating future cash flows from product sales resulting from completed projects and in-process projects, and developing appropriate discount rates. The Company's annual assessment for impairment of IPR&D indicated that the fair value of its IPR&D asset as of October 1, 2021 and October 1, 2020 exceeded the respective carrying value.

Any impairments are recognized as a loss in the year the goodwill and/or IPR&D are determined to be impaired. Impairment of IPR&D is recorded as research and development expense and impairment of goodwill is recorded separately as a loss in other income (expense) on the Company's consolidated statements of operations. To date, no impairment loss has been recognized. Additionally, there has been no change to the carrying value of goodwill and IPR&D for the years ended December 31, 2021 and 2020.

Deferred Initial Public Offering Costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity issuances as deferred initial public offering costs until such equity issuances are consummated. After consummation of the equity issuance, these costs are recorded as a reduction in the capitalized amount associated with the equity issuance. Should the equity issuance be abandoned, the deferred initial public offering costs will be expensed immediately as a charge to operating expenses in the consolidated statement of operations and comprehensive loss. On March 18, 2021, the Company completed the IPO; accordingly, the Company recognized the deferred initial public offering costs of approximately $2.9 million as a reduction from gross proceeds associated with the IPO through additional paid-in capital in the accompanying consolidated balance sheet.

On April 20, 2021, the Company issued 192,877 additional shares of common stock, pursuant to the underwriters' partial exercise of their overallotment option, and the Company recognized offering costs of less than $0.1 million as a reduction from gross proceeds associated with the overallotment through additional paid-in capital in the accompanying consolidated balance sheet. Accordingly, there were no deferred offering costs as of December 31, 2021. Deferred offering costs on the accompanying consolidated balance sheet as of December 31, 2020 were $1.0 million.

Leases

In February 2016, the FASB issued ASU 2016-02, *Leases (*ASC 842*)*, as subsequently amended, which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors), and replaces the existing guidance in ASC 840, *Leases.* The FASB subsequently issued amendments to ASC 842, which have the same effective date of January 1, 2019: (i) ASU 2018-10, *Codification Improvements to Topic 842, Leases*, which amends certain narrow aspects of the guidance issued in ASU 2016-02; and (ii) ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which allows for a transition approach to initially apply ASU 2016-02 at the adoption date and not restate prior periods presented. ASC 842 requires lessees to classify leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine the recognition pattern of lease expense over the term of the lease. The Company adopted ASC 842 during the quarter ended December 31, 2021, with an effective date of January 1, 2021, using the modified retrospective approach and utilizing the effective date as its date of initial application. As a result, prior period financial statements continue to be presented in accordance with ASC 840.

The adoption of this standard resulted in the recognition of operating lease right-of-use assets of $5.8 million and current and noncurrent operating lease liabilities of $0.9 million and $5.9 million, respectively, and the derecognition of deferred rent liabilities and unamortized lease incentives of $0.8 million and $0.2 million, respectively, on the Company's Balance Sheets as of January 1, 2021 relating to its office leases in Somerville, MA. The adoption of this standard did not have a significant impact on the Company's consolidated Statements of Operations or Statements of Cash Flows.

Prior to January 1, 2021, the Company accounted for leases under Accounting Standards Codification 840, *Leases* (''ASC 840''). At lease inception, the Company determined if an arrangement was an operating or capital lease. For operating leases, the Company recognized rent expense, inclusive of rent escalations, holidays and lease incentives, on a straight-line basis over the lease term. The difference between rent expense recorded and the amount paid was recorded as deferred rent. The Company presented lease incentives as deferred rent and amortized the incentives as a reduction to rent expense on a straight-line basis over the lease term. The Company classified deferred rent as current and noncurrent liabilities based on the portion of the deferred rent that was scheduled to mature within the next twelve months.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement including the use of an identified asset(s) and the Company's control over the use of that identified asset. The Company classifies leases with a term greater than one year as either operating or finance leases at the lease commencement date and records a right-of-use ("ROU") asset and current and non-current lease liabilities, as applicable on the balance sheet. The Company elected, as allowed under ASC 842, to not recognize leases with a lease term of one year or less on its balance sheet. When an option to extend the lease exists, a determination is made whether that option is reasonably certain of exercise based on economic factors present at the measurement date and as circumstances may change.

The Company measures and records its lease liabilities based on the present value of lease payments over the expected remaining lease term. The present value of future lease payments are discounted using the interest rate implicit in the lease contracts if that rate is readily available. As the implicit rate has not historically been readily determinable, the Company utilizes its incremental borrowing rate ("IBR"), which reflects the fixed rate at which the Company could borrow on a

collateralized basis over a similar term to fund the amount of lease payments to be made in a similar economic environment. Management determines the appropriate IBR to use based on the Company's credit standing and market environment at lease commencement. The Company measures its ROU assets as the lease liability plus initial direct costs and prepaid lease payments, less lease incentives granted by the lessor.

In accordance with ASC 842, components of a lease should be split into three categories: lease components (e.g. land, building, etc.) , non-lease components (e.g. common area maintenance, consumables, etc.), and non-components (e.g. property taxes, insurance, etc.). The fixed and in-substance fixed contract consideration (including any consideration related to non-components) must be allocated, based on the respective relative fair values, to the lease components and non-lease components. However, the Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets and allocate all of the contract consideration to the lease component only.

After lease commencement and the establishment of a ROU asset and operating lease liability, lease expense is recorded on a straight-line basis over the lease term. Variable costs associated with a lease, such as maintenance and utilities, are not included in the measurement of the lease liabilities and right-of-use assets but rather are expensed when the events determining the amount of variable consideration to be paid have occurred.

When a lease is modified and the modification is not accounted for as a separate contract, the Company remeasures its ROU assets and lease liabilities. A modification is accounted for as a separate contract if the modification grants the Company an additional right of use not included in the original lease arrangement and the increase in lease payments is commensurate with the additional right of use. The Company assesses its right-of-use assets for impairment in a manner consistent with its assessment for long-lived assets held and used in operations.

Impairment of Long-lived Assets

The Company evaluates its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. To date, no impairments have been recognized for these assets.

Research and Development Expenses

Research and development costs are charged to expense as incurred. Research and development costs consist of expenses incurred in performing research and development activities, including salaries and benefits, materials and supplies, preclinical expenses, stock-based compensation expense, depreciation of equipment, contract services, facilities, and other outside expenses. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to the Company by its vendors. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid expense or accrued research and development expense.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses and expensed as the related goods are delivered or the services are performed.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is made available for evaluation by the chief operating decision maker ("CODM") in making decisions regarding resource allocation and assessing performance. The CODM is the Company's Chief Executive Officer. The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions.

Redeemable Convertible Preferred Stock

In connection with the IPO, the Board and stockholders approved an amended and restated certificate of incorporation to, among other things, effect a one-for-14.444 reverse stock split of the Company's issued and outstanding shares of common stock and redeemable convertible preferred stock, as well as to effect a proportional adjustment to the existing conversion ratios for the Company's redeemable convertible preferred stock. The reverse stock split was effected on March 12, 2021. Accordingly, all share and per share amounts of common stock for all periods presented in the accompanying audited consolidated financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect this reverse stock split and adjustment of preferred stock conversion ratios. Upon the closing of the IPO, all of the then-outstanding shares of redeemable convertible preferred stock automatically converted into 31,253,609 shares of common stock at the applicable conversion ratio then in effect. Subsequent to the closing of the IPO, there were no shares of convertible preferred stock outstanding.

Stock-based Compensation

The Company accounts for all stock-based payment awards granted to employees and non-employees as stock-based compensation expense at fair value. The Company's stock-based payments are comprised of stock options. The measurement date for employee awards is the date of grant, and stock-based compensation costs are recognized as expense over the employees' requisite service period, which is the vesting period, on a straight-line basis. Stock-based compensation costs for non-employees are recognized as expense over the vesting period on a straight-line basis. Stock-based compensation expense is classified in the accompanying consolidated statements of operations based on the function to which the related services are provided. The Company recognizes stock-based compensation expense for the portion of awards that have vested. Forfeitures are recorded as they occur.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company has historically been a private company until its IPO in March 2021 and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Income Taxes

The Company is primarily subject to U.S. federal and Massachusetts state income tax. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the Company's consolidated financial statements and tax returns. Deferred tax assets and liabilities are determined based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards, using enacted tax rates expected to be in effect in the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that these assets may not be realized.

The Company determines whether it is more likely than not that a tax position will be sustained upon examination. If it is not more likely than not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the contingency. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes.

As of December 31, 2021 and 2020, the Company maintains a reserve against certain federal and state research and development credits that are recorded net in deferred taxes. The Company has no accruals for interest or penalties related to income tax matters. Tax years since inception remain open to examination by federal and state tax authorities.

Revenue Recognition

The Company has historically generated revenue from the following sources: (1) collaboration revenue from the collaboration agreement with Takeda Pharmaceutical Company Limited (see Note 7) and (2) royalty revenue from OpenBiome's sales of a licensed product under the Asset Purchase and License Agreement with OpenBiome (see Note 7).

The Company recognizes revenue in accordance with Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to be entitled to in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect consideration it expects to be entitled to in exchange for the goods or services it transfers to the customer.

The promised goods or services in the Company's arrangements typically consist of (1) a license, or option to license, rights to the Company's intellectual property or research and development services; (2) an obligation to transfer FMT materials; or (3) an obligation to provide pre-clinical and clinical research and support services. Under the collaboration agreement, the Company provides options to additional items, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer.

Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer and are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on its own or whether the required expertise is readily available, and whether the goods or services are integral or dependent to other goods or services in the contract. For performance obligations which consist of FMT materials, shipping and distribution activities occur prior to the transfer of control of FMT materials and are considered activities to fulfill the Company's promise to deliver goods to the customers.

The Company estimates the transaction price based on the amount expected to be entitled to for transferring the promised goods or services in the contract. The consideration may include fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of potential payment and the likelihood that the underlying constraint will be released. The Company utilizes either the most likely amount method or expected value method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. Variable consideration may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

The Company's contracts often include development and regulatory milestone payments that are assessed under the most likely amount method and are included in the transaction price only to the extent it is probable that a significant revenue reversal would not occur. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of such development and regulatory milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are added to the transaction price with a corresponding adjustment being made to the measure of progress, and, as necessary, recorded on a cumulative catch-up basis, which would affect collaboration revenue in the period of adjustment.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

For contracts which have more than one performance obligation, the total contract consideration is allocated based on observable standalone selling prices or, if standalone selling prices are not readily observable, based on management's estimate of each performance obligation's standalone selling price. The Company must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs. Variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated are consistent with the amounts the Company would expect to be entitled to for the satisfaction of each performance obligation.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. For performance obligations, revenue is recognized when control of the product is transferred to the customer and the related performance obligation is satisfied, which typically occurs upon delivery of the product to the customer, for an amount that reflects the consideration the Company expects to be entitled to receive in exchange for delivering the product. For performance obligations which consist of clinical trial participation and related support services, revenue is recognized over time as the customer simultaneously receives and consumes the benefits of the services provided.

Disaggregation of Revenue

The following table provides revenue disaggregated by timing of revenue recognition (in thousands):

	YEAR ENDED DECEMBER 31,	
	2021	2020
Transferred at a point in time	$ —	$ 343
Transferred over time	18,532	7,376
Total	$ 18,532	$ 7,719

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted-average number of common shares outstanding during the period and, if dilutive, the weighted-average number of potential shares of common stock. Net loss per share attributable to common stockholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Company's common shares and participating securities. The Company's preferred stock contains participation rights in any dividend paid by the Company and is deemed to be a participating security. Net loss attributable to common stockholders and participating preferred shares are allocated to each share on an as-converted basis as if all of the earnings for the period had been distributed. The participating securities do not include a contractual obligation to share in losses of the Company and are not included in the calculation of net loss per share in the periods in which a net loss is recorded.

Diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method. The Company allocates earnings first to preferred stockholders based on dividend rights and then to common and preferred stockholders based on ownership interests. The weighted-average number of common shares included in the computation of diluted net loss gives effect to all potentially dilutive common equivalent shares, including outstanding stock options and preferred stock.

Common stock equivalent shares are excluded from the computation of diluted net loss per share if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is generally the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2021 and 2020.

Recently Issued and Adopted Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board FASB or other accounting standard setting bodies that we adopt as of the specified effective date. Unless otherwise discussed below, we do not believe that the adoption of recently issued standards have or may have a material impact on our consolidated statements or disclosures.

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other- Internal-Use Software* (Subtopic 350- 40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract. ASU 2018-15 aligns the accounting for implementation costs incurred in a hosting arrangement that is a service contract with the guidance for capitalizing costs associated with developing or obtaining internal-use software (and hosting arrangements that include an internal-use software license). The Company adopted the standards on a prospective basis on January 1, 2021.The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes-Simplifying the Accounting for Income Taxes* ("ASU 2019-12"). ASU 2019-12 eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes, enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The standard is effective for annual periods beginning after December 15, 2020 and interim periods within those fiscal years, with early adoption permitted. Adoption of the standard requires certain changes to be made prospectively and certain others to be made retrospectively. The Company adopted this standard on January 1, 2021, and this standard did not have a material impact on its consolidated financial statements and related disclosures for the year ended December 31, 2021.

3. FAIR VALUE MEASUREMENTS

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values (in thousands):

DESCRIPTION	DECEMBER 31, 2021	QUOTED PRICES IN ACTIVE MARKETS FOR IDENTICAL ASSETS (LEVEL 1)	SIGNIFICANT OBSERVABLE INPUTS (LEVEL 2)	SIGNIFICANT OBSERVABLE INPUTS (LEVEL 3)
Asset				
Money market funds	$ 132,275	$ 132,275	$ —	$ —
Total financial assets	$ 132,275	$ 132,275	$ —	$ —

DESCRIPTION	DECEMBER 31, 2020	QUOTED PRICES IN ACTIVE MARKETS FOR IDENTICAL ASSETS (LEVEL 1)	SIGNIFICANT OBSERVABLE INPUTS (LEVEL 2)	SIGNIFICANT OBSERVABLE INPUTS (LEVEL 3)
Asset				
Money market funds	$ 98,677	$ 98,677	$ —	$ —
Total financial assets	$ 98,677	$ 98,677	$ —	$ —

There have been no transfers between fair value levels during the years ended December 31, 2021 and 2020. The carrying values of other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

4. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following as of December 31, 2021 and 2020 (in thousands):

	DECEMBER 31, 2021	DECEMBER 31, 2020
Lab equipment	$ 3,850	$ 2,363
Office furniture and fixtures	537	537
Leasehold improvements	13,894	2,143
Construction work-in-progress	329	2,635
Software	4,883	1,150
Computer equipment	368	205
Total	$ 23,861	$ 9,033
Less: Accumulated depreciation	(4,226)	(2,029)
Property and equipment, net	$ 19,635	$ 7,004

Depreciation and amortization expense was $2.3 million and $0.8 million for the years ended December 31, 2021 and 2020, respectively. During the years ended December 31, 2021 and 2020, the Company purchased $3.9 million and $1.2 million, respectively, of software, property, and equipment from a related party, under the OpenBiome Agreement.

5. LEASES

200 Inner Belt Road Lease

In December 2015, the Company entered into a 10-year lease agreement (the "Inner Belt Road Lease") for approximately 25,785 square feet of space for its primary office and laboratory space in Somerville, Massachusetts. The monthly rental payments under the Inner Belt Road Lease, which include base rent charges of $0.1 million, are subject to periodic rent increases through September 2026.

In July 2016, the Company entered into a 10-year sublease agreement (the "200 Inner Belt Road Sublease") to share its leased space under the Inner Belt Road Lease with OpenBiome, a related party, as sub-tenant. The sublease with OpenBiome is coterminous with the Inner Belt Road Lease and provides for an allocation, based on OpenBiome’s proportionate share, of base rent and other expenses under the Inner Belt Road Lease, which is subject to change each year based on current headcount and space used. OpenBiome’s proportionate share is reassessed on a quarterly basis over the term of the sublease.

In January 2017, the Company amended the Inner Belt Road Lease to lease an additional 10,500 square feet of space for its primary office and laboratory space in Somerville, Massachusetts. The term of the Inner Belt Road Lease and the sublease with OpenBiome were not affected as a result of the amendment, although OpenBiome does occupy some of this additional space. The rental payments for the additional space under the amended Inner Belt Road Lease, which include base rent charges of approximately $33,000 per month, are subject to periodic rent increases through September 2026. In November 2020, pursuant to the OpenBiome Agreement, the Company and OpenBiome amended the terms of the sublease to provide for a reduction in the size of the subleased premises upon the closing of the OpenBiome Agreement (see Note 13), which occurred on March 1, 2021. The sublease was further amended on January 15, 2021 and June 22, 2021 and terminated on December 31, 2021.

The Company's lease expense under the Inner Belt Road Lease was $1.3 million for each of the years ended December 31, 2021 and 2020. The Company recognizes sublease income under the sublease to OpenBiome as rent is received over the sublease term. Gross lease income under the sublease to OpenBiome for each of the years ended December 31, 2021 and 2020 was $0.1 million and $0.4 million, respectively, and is presented as an offset to lease expense on the consolidated statements of operations.

Cherry Street Lease

On March 1, 2021, the Company assumed a lease agreement (the “Cherry Street Lease”) in conjunction with the closing of the OpenBiome Agreement. The lease term is from March 2021 through February 2023. The Company’s lease expense under the Cherry Street Lease for the years ended December 31, 2021 and 2020 was $0.1 million and $0, respectively.

Concord Avenue Lease

On May 25, 2021, the Company entered into a lease agreement (the "Concord Avenue Lease") from May 2021 through February 2022. The Company's lease expense under the Concord Avenue Lease for the years ended December 31, 2021 and 2020 was $0.2 million and $0, respectively. On August 17, 2021 Finch extended the term of the lease for an additional two-month period through April 2022 and on February 4, 2022 Finch further extended the lease for an additional month through May 2022. The Concord Avenue Lease qualifies as a short-term lease and will be excluded from the balance sheet.

100 Hood Park Drive

On August 3, 2021 (the "Execution Date"), the Company entered into a 10-year lease agreement (the "Hood Lease") with Hood Park LLC (the "Landlord"), pursuant to which the Company will lease approximately 61,139 square feet of office and laboratory space (the "Premises"). The term of the Hood Lease commenced on the Execution Date, and Finch will become responsible for paying rent under the Hood Lease on the earlier of (i) January 1, 2022 and (ii) the date Finch's improvement on the Premises is substantially completed and Finch has commenced business operations in the Premises (the "Rent Commencement Date"). As of December 31, 2021, the Rent Commencement Date had not occurred and no lease expense, right-of-use asset, or lease liability was recognized under the Hood Lease.

The Hood Lease provides Finch with an option to extend the lease for one additional five-year term. Finch's annual base rent for the Premises will start at approximately $4.5 million, and the lease contains annual rent escalations. The Hood Lease provides for a tenant improvement allowance of approximately $14.8 million for the cost of Finch's work on the Premises. As of December 31, 2021, $5.3 million of lessor owned tenant improvements were completed by the Company and are recorded in other current assets on the consolidated balance sheet.

The Company posted a customary letter of credit in the amount of approximately $2.3 million, subject to decrease on a set schedule, as a security deposit pursuant to the Hood Lease. This is included in restricted cash, non-current on the consolidated balance sheet as of December 31, 2021.

The following table presents the classification of right-of-use assets and lease liabilities as of December 31, 2021:

	BALANCE SHEET CLASSIFICATION	DECEMBER 31, 2021
ASSETS		
Operating lease assets	Operating right-of-use assets	$ 5,053
Finance lease assets	Property and equipment, net	22
Total lease assets		5,075
Liabilities		
Current		
Operating lease liabilities	Operating lease liabilities, current	$ 1,128
Finance lease liabilities	Other current liabilities	19
Noncurrent		
Operating lease liabilities	Operating lease liabilities, non-current	4,887
Finance	Other liabilities	7
Total lease liabilities		$ 6,041

The following table represents the components of lease cost, which are included in general and administrative and research and development expense on the statement of operations, for the year ended December 31, 2021:

LEASE COST	DECEMBER 31, 2021
Finance lease cost:	
Amortization of right-of-use assets	$ 27
Interest on lease liabilities	10
Operating lease cost	1,336
Short-term lease cost	254
Variable lease cost	525
Sublease income	(88)
Total lease cost	$ 2,064

The weighted-average remaining lease term and discount rate were as follows:

LEASE TERM AND DISCOUNT RATE	DECEMBER 31, 2021
Weighted-average remining lease term (years)	
Operating leases	4.6
Finance Leases	1.2
Weighted-average discount rate	
Operating leases	6.7%
Finance Leases	30.6%

Supplemental disclosure of cash flow information related to leases was as follows:

SUPPLEMENTAL CASH FLOW INFORMATION	DECEMBER 31, 2021
Cash paid for amounts included in measurement of lease liabilities	
Operating cash flows from operating leases	$ 1,006
Financing cash flows from finance leases	$ 27

The following table represents a summary of the Company's future lease payments required as of December 31, 2021:

	OPERATING LEASE OBLIGATIONS	HOOD PARK LEASE OBLIGATIONS	FINANCE LEASE OBLIGATIONS	TOTAL LEASE OBLIGATIONS
2022	$ 1,487	$ 4,535	$ 24	$ 6,046
2023	1,440	4,663	6	6,109
2024	1,460	4,795	—	6,255
2025	1,496	4,931	—	6,427
2026	1,116	5,071	—	6,187
Thereafter	—	27,605	—	27,605
Total future minimum lease payments	$ 6,999	$ 51,600	$ 30	$ 58,629
Less: amount representing interest	(984)	—	(5)	(989)
Present value of future minimum lease payments	$ 6,015	$ 51,600	$ 25	$ 57,640

The following represents a summary of the Company's future minimum lease payments under non-cancelable lease agreements, presented in accordance with ASC 840, as of December 31, 2020:

	OPERATING LEASE OBLIGATIONS	FINANCE LEASE OBLIGATIONS	TOTAL LEASE OBLIGATIONS
2021	$ 1,351	$ 36	$ 1,387
2022	1,387	24	1,411
2023	1,424	6	1,430
2024	1,460	—	1,460
2025	1,496	—	1,496
Thereafter	1,115	—	1,115
Total minimum lease payments	$ 8,233	$ 66	$ 8,299
Less: amount representing interest	—	(14)	(14)
Present value of minimum lease payments	$ 8,233	$ 52	$ 8,285

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following as of December 31, 2021 and 2020 (in thousands):

	DECEMBER 31, 2021	DECEMBER 31, 2020
Accrued research and development	$ 1,345	$ 81
Accrued legal and professional fees	1,117	711
Accrued compensation and benefits	4,401	3,532
Accrued other	3,062	904
Total accrued expenses and other current liabilities	$ 9,925	$ 5,228

7. REVENUE

Takeda Pharmaceutical Company Limited

In January 2017, the Company entered into an agreement (the "Takeda Agreement") with Takeda Pharmaceutical Company Limited ("Takeda"), pursuant to which the Company granted Takeda a worldwide, exclusive license, with the right to grant sublicenses, under certain of its patents, patent applications and know-how to develop the Company's microbiome therapeutic candidate FIN-524, now known as TAK-524, for the prevention, diagnosis, theragnosis or treatment of diseases in humans. The Company subsequently amended and restated the Takeda Agreement in October 2019 to provide for the Company to allocate certain resources towards determining the feasibility of developing a second microbiome therapeutic candidate, FIN-525. The Company further amended the Takeda Agreement in August 2021 to transition primary responsibility for further development and manufacturing activities with respect to TAK-524 from the Company to Takeda in accordance with a transition plan, and Takeda assumed sole responsibility for regulatory matters with respect to TAK-524. In November 2021, Takeda Agreement was amended again to enable the Company to carry out certain FIN-525 preliminary evaluation activities.

Under the terms of the Takeda Agreement, the Company agreed to design TAK-524, a product candidate optimized for ulcerative colitis, for Takeda based on selection criteria within a product-specific development plan. The Company also agreed to conduct a feasibility study to potentially further develop FIN-525, a program to develop a live biotherapeutic product optimized for the treatment of Crohn's disease. The Company assessed this arrangement in accordance with ASC 606, and concluded that the contract counterparty, Takeda, is a customer. The Company identified the following material promises at the outset of the Takeda Agreement: (1) an exclusive license to use the Company's rights in intellectual property to conduct research activities; (2) R&D services for activities under the development plan; (3) two options to pursue different indications of research for the Company's right in product candidates; (4) manufacturing and supply for the Company's clinical trials; and (5) participation on a joint steering and joint development committee ("JSC" and "JDC"). The options were considered distinct from the other promises in the arrangement and analyzed for material rights; the Company concluded these were not material rights and the consideration related to them should be excluded as a performance obligation until the option is exercised. The Company determined that the remaining promises were not capable of being distinct from one another and were not distinct in the context of the contract. In accordance with the Company's ASC 606 assessment, the Takeda Agreement was determined to contain a single combined performance obligation made up of the promises above, excluding the options. The FIN-525 feasibility study was determined to be part of the single combined performance obligation due to its connection to the original license and research and development activities. The FIN-525 feasibility study was completed in March 2021.

The Company received an upfront payment from Takeda of $10.0 million in the year ended December 31, 2017 in exchange for the exclusive license of the Company's intellectual property. The Company has included the upfront payment and the estimable reimbursable R&D costs in the transaction price and is recognizing revenue associated with it over the period it expects to perform R&D services. Under the original agreement the estimated term for the R&D and manufacturing services for which the Company had primary responsibility, was through Phase 1 clinical trials.

On August 9, 2021, the Company and Takeda entered into an amendment to the amended and restated Takeda Agreement (the “Amendment”). Pursuant to the Amendment, Finch and Takeda transitioned primary responsibility for such development and manufacturing activities from Finch to Takeda in accordance with an agreed upon transition plan, and Takeda also assumed sole responsibility for regulatory matters with respect to TAK-524. The Company accounted for the Amendment as a modification to the existing contract under ASC 606, as the Amendment significantly reduced the remaining performance obligations, which were then completed by September 30, 2021. As a result, the remaining revenue that had been deferred under the Takeda Agreement was recognized in the third quarter of 2021.

In November 2021, Takeda and Finch entered into an amendment to the amended and restated Takeda Agreement ("Amendment #2"). Pursuant to Amendment #2, Finch is performing certain additional research activities related to the feasibility of the FIN-525 program prior to Takeda making the decision to initiate the full development program. Under the amendment, Takeda shall pay Finch for pass-through costs incurred and research services performed at the agreed-upon full-time equivalent (“FTE”) rate. The additional feasibility work is expected to be completed in the first quarter of 2022 at which point Takeda can determine whether to initiate a full product specific development plan for FIN-525 following its review of the data.

The Company recognized revenue related to the Takeda Agreement of $18.5 million and $7.4 million in the years ended December 31, 2021 and 2020, respectively, which is included under collaboration revenue in the consolidated statements of operations.

Takeda reimburses the Company for certain R&D costs on a quarterly basis. The Company recorded accounts receivable of $0.5 million and $1.0 million on its consolidated balance sheets as of December 31, 2021, and December 31, 2020, respectively. As of December 31, 2021, there is no remaining deferred revenue due to the Company's satisfaction of the performance obligation. As of December 31, 2020, the Company recorded deferred revenue of $13.6 million related to the Takeda Agreement.

The Takeda Agreement contains various milestone payments associated with development and commercialization efforts that provide for a maximum available amount of $180.0 million should all of the milestones be achieved. These milestones are constrained until the Company determines it is probable that the cumulative revenue related to the milestones will not be reversed. As of December 31, 2021, the Company has earned and received $4.0 million in milestone payments.

The Company is still eligible to receive royalties under the Amendment and Takeda is obligated to pay the Company mid-to-high single digit royalties based on annual aggregate net sales of the licensed products, on a product-by-product basis, subject to certain restrictions. The Company did not receive any payments or record any revenues related to sales-based royalties under the Takeda Agreement in the years ended December 31, 2021 and 2020.

OpenBiome

The Company and OpenBiome entered into an Asset Purchase and License Agreement (the “APL Agreement”) in February 2019 that was effective through November 2020. Under the APL Agreement, the Company licensed certain intellectual property and sold certain fecal microbiota transplantation, or FMT, materials and equipment to OpenBiome (see Note 13).

The Company earned $0 and $0.3 million in royalty revenue related to the APL Agreement in the years ended December 31, 2021 and 2020, respectively, which is recorded as royalty revenue from related party on the Company’s consolidated statements of operations.

On November 19, 2020, the Company entered into the LMIC License Agreement (“LMIC Agreement”) with OpenBiome, pursuant to which the Company granted OpenBiome a non-exclusive license, with the right to grant sublicenses, under certain patents, patent applications, and know-how that are reasonably necessary or useful for the exploitation of products manufactured directly from donor-sourced stool without the use of culturing or replication, or certain natural products (“OpenBiome Royalty Products”). The license granted to OpenBiome excludes a license under the Company’s intellectual property to exploit a lyophilized natural product (such as CP101) where processed stool is lyophilized. The Company owns all improvements and modifications made to the licensed intellectual property throughout the term of the LMIC Agreement, while OpenBiome is responsible for all manufacturing efforts and all expenses associated with these efforts.

The LMIC Agreement was entered into separately from the asset purchase agreement with OpenBiome (the "OpenBiome Agreement") (see Note 13) and the license granted under the LMIC Agreement is unrelated to the assets acquired under the OpenBiome Agreement. The only consideration provided to the Company under the LMIC Agreement is in the form of future royalties on net sales of OpenBiome Royalty Products. The Company is entitled to receive tiered royalties on net sales of certain products, ranging from mid-single digit to low second decile digits on a product-by-product and country-by-country basis. In the event that OpenBiome is required to pay a royalty to a third party to obtain rights under patents owned or controlled by such third party that are necessary for the exercise of its rights under the Company's intellectual property pursuant to the LMIC Agreement, then OpenBiome shall have the right to deduct a portion of the amount of the royalty due to the third party against the royalties that are due from OpenBiome to the Company. The Company has not earned any of these royalty payments as of December 31, 2021.

The LMIC Agreement will continue in perpetuity until the last royalty is earned under the LMIC Agreement unless otherwise terminated by either party. OpenBiome has the right to terminate the LMIC Agreement for convenience upon 90 days' specified prior written notice to the Company. Either party may terminate the LMIC Agreement in the event of an uncured material breach by the other party.

The Company did not recognize any revenue related to the LMIC Agreement for the years ended December 31, 2021 and 2020, as there are currently no marketable OpenBiome Royalty Products.

8. INCOME TAXES

For the years ended December 31, 2021 and 2020, the Company did not record a current or deferred income tax expense or benefit due to current and historical losses incurred by the Company.

The effective income tax rate differed from the statutory federal income tax rate due to the following:

	YEAR ENDED DECEMBER 31,	
	2021	2020
Federal income taxes at 21%	21.00%	21.00%
State income taxes, net of federal benefit and tax credits	6.90	6.04
Permanent differences	(0.19)	(1.60)
Research and development credit	2.12	2.03
Change in valuation allowance	(29.30)	(26.96)
Other adjustments	(0.53)	(0.51)
	0.00%	0.00%

Significant components of the Company's net deferred tax assets and liabilities as of December 31, 2021 and 2020 are as follows (in thousands):

	YEAR ENDED DECEMBER 31,	
	2021	2020
Deferred Tax Assets:		
Net operating losses	$ 48,419	$ 30,192
Tax credits	4,376	2,921
Deferred revenue	—	3,057
Accrued expenses	859	225
Right of Use Liabilities	1,633	0
Other	548	289
Total deferred tax assets	55,835	36,684
Valuation allowance	(49,079)	(31,963)
Total net deferred tax assets	6,756	4,721
Deferred Tax Liabilities:		
Intangibles assets	7,952	7,891
Fixed assets	563	253
Right of Use Assets	1,372	0
Other	330	38
Total deferred tax liabilities	10,217	8,182
Total net deferred tax liabilities	(3,461)	$ (3,461)

The Company regularly assesses the need for a valuation allowance against its deferred tax assets. In making that assessment, the Company considers both positive and negative evidence related to the likelihood of realization of the deferred tax assets to determine, based on the weight of available evidence, whether it is more-likely-than-not that some or all of the deferred tax assets will not be realized. In assessing the realizability of deferred tax assets, the Company considers taxable income in prior carryback years, as permitted under the tax law, forecasted taxable earnings, tax planning strategies, and the expected timing of the reversal of temporary differences. This determination requires significant judgment, including assumptions about future taxable income that are based on historical and projected information and is performed on a jurisdiction-by-jurisdiction basis.

The Company continues to maintain a partial valuation allowance against its deferred tax assets. During the years ended December 31, 2021 and 2020, management assessed the positive and negative evidence in its U.S. operations, and concluded that it is more likely than not that a portion of its deferred tax assets as of December 31, 2021 and 2020 will not be realized given the Company's history of operating losses. In determining the amount of the valuation allowance to record, the Company considered the reversal of existing taxable temporary differences as a source of taxable income against which a portion of its deferred tax assets is benefitted. The Company recorded a full valuation allowance against the remaining U.S. deferred tax assets in excess of this source of taxable income. The valuation allowance against deferred tax assets increased by approximately $17.1 million during 2021 related to a full valuation allowance recorded against additional net operating losses and tax credits generated in the year.

As of December 31, 2021, the Company had federal net operating losses of $181.9 million, which may be available to offset future federal income tax liabilities.

As of December 31, 2020, the Company had federal net operating losses of $114.4 million, which may be available to offset future federal income tax liabilities. The Company's federal net operating losses incurred prior to 2018, $37.2 million, expire through 2037, while its federal net operating losses incurred in 2018 and onwards, $144.7 million, can be carried forward indefinitely.

As of December 31, 2021, the Company had post-apportioned state net operating losses of $10.2 million that can generally be carried forward 20 years. As of December 31, 2020, the Company had post-apportioned state net operating losses of $6.1 million that can generally be carried forward 20 years.

As of December 31, 2021, the Company had $3.8 million and $0.4 million of federal and state research and development credits, respectively, which will expire at various dates through 2041. As of December 31, 2020, the Company had $2.6 million and $0.3 million of federal and state research and development credits, respectively, which will expire at various dates through 2040.

Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The Company has not, yet, conducted a study to determine if any such changes have occurred that could limit its ability to use the net operating loss and tax credit carryforward.

The calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax regulations in a multitude of jurisdictions. A tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits. As of December 31, 2021 and 2020, the total amount of uncertain tax liabilities relates to federal and state tax credit carryforwards and are all recorded net in deferred taxes.

A reconciliation of the beginning and ending balances of the total amounts of gross unrecognized tax benefits is as follows (in thousands):

	YEAR ENDED DECEMBER 31,	
	2021	2020
Balance, beginning of year	$ 1,318	$ 1,004
Additions for tax positions of current year	507	—
Additions for tax positions of prior years	(3)	314
Balance, end of year	$ 1,822	$ 1,318

The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations. As of December 31, 2021 and 2020, no accrued interest or penalties are included on the related tax liability line in the consolidated balance sheet.

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. There are currently no pending income tax examinations. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service and state tax authorities to the extent utilized in a future period.

9. COMMITMENTS AND CONTINGENCIES

Legal contingencies

On December 1, 2021, Rebiotix Inc. and Ferring Pharmaceuticals Inc. (collectively, “Rebiotix”) filed a complaint against the Company in the U.S. District Court for the District of Delaware. The complaint seeks a declaratory judgment of non-infringement and invalidity with respect to seven United States Patents owned by the Company: U.S. Patent Nos. 10,675,309 (the “‘309 patent”); 10,463,702 (the “‘702 patent”); 10,328,107 (the “‘107 patent”); 10,064,899; 10,022,406; 9,962,413; and 9,308,226. On February 7, 2022, the Company filed an answer and counterclaims against Rebiotix for infringement of the ’107, ’702, and ’309 patents. On March 7, 2022, the Company filed an amended answer and counterclaims, in which the Company, together with the Regents of the University of Minnesota (“UMN”), alleged infringement by Rebiotix of three U.S. Patents owned by UMN and exclusively licensed to the Company: U.S. Patent Nos. 10,251,914, 10,286,011, and 10,286,012. The U.S District Court for the District of Delaware set a trial date for a five-day trial beginning on May 20, 2024. The pending lawsuit is subject to inherent uncertainties, and the actual legal fees and costs will depend upon many unknown factors. The outcome of the pending lawsuit cannot be predicted with certainty. The Company has determined under ASC 450, *Contingencies*, that there is no probable or estimable loss contingency that is required to be recorded as of December 31, 2021.

License payments

The Company enters into contracts in the normal course of business with contract research organizations and other third parties for preclinical studies, clinical studies, and testing and manufacturing services. Most contracts do not contain minimum purchase commitments and are cancelable by the Company upon prior written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including non-cancelable obligations of our service providers up to one year after the date of cancellation. Under these agreements, in exchange for access to intellectual property the Company may be obligated to provide future minimum royalty payments and milestone payments related to regulatory approvals and sales-based events. The Company entered into the OpenBiome Agreement in November 2020 (see Note 13) and the closing of the OpenBiome Agreement occurred on March 1, 2021. Under the terms of the OpenBiome Agreement, the Company is required to make certain milestone and royalty payments to OpenBiome in conjunction with the license and purchase of certain intellectual property related to the underlying CMC process used to manufacture materials for its clinical trials. The OpenBiome Agreement also effectively terminated the APL Agreement and the obligations under the Material Access License Agreement (the “MAL Agreement”), which the Company entered into with OpenBiome in December 2016.

Under the APL Agreement, which was entered into in 2019 and effective through November 2020, the Company was obligated to make certain contingent payments for milestones and royalties to OpenBiome, subject to the occurrence of specific underlying criteria that were dependent on regulatory approvals and sales-based events. The Company was obligated to make regulatory milestone payments to OpenBiome aggregating up to $2.5 million upon the achievement of regulatory approvals, and sales-based milestone payments of up to $23.3 million in sales-based milestone payments upon the

achievement of certain net sales criteria. The Company paid $0.1 million to OpenBiome associated with milestones in 2020. The APL Agreement was terminated in November 2020 upon the execution of the OpenBiome Agreement (see Note 13).

Under the MAL Agreement, the Company was also obligated to pay to OpenBiome, a low single digit royalty on net sales of certain cultured products and a high single digit percentage of certain sublicensing revenue (including royalties) of licensed cultured products. These royalties were calculated on a product-by-product and country-by-country basis. The Company paid $0.2 million to OpenBiome under the MAL Agreement in 2020 related to royalty payments. During the year ended December 31, 2020, the Company recorded an additional $0.3 million owed to OpenBiome under the MAL Agreement, of which $0.1 million remained due as of December 31, 2020. The MAL Agreement was terminated in November 2020 upon the execution of the OpenBiome Agreement (see Note 13).

PPP Loan

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted to, amongst other provisions, provide emergency assistance for individuals, families and businesses affected by the COVID-19 pandemic. The CARES Act includes a Paycheck Protection Program ("PPP") administered through the Small Business Association ("SBA"). Under the PPP, beginning April 3, 2020, small businesses and other entities and individuals could apply for loans from existing SBA lenders and other approved regulated lenders that enroll in the program, subject to numerous limitations and eligibility criteria.

In April 2020, the Company issued a promissory note to Silicon Valley Bank, pursuant to which it received loan proceeds of $1.8 million (the "PPP Loan") provided under the PPP and guaranteed by the SBA. On May 8, 2021, the Company received notice from the SBA that the entirely of the PPP Loan was forgiven. Accordingly, the Company is no longer required to repay the $1.8 million in principal and approximately $19,000 in accrued interest borrowed under the PPP Loan. Gain on extinguishment of the PPP Loan is recorded in the consolidated statements of operations for the year ended December 31, 2021.

Leases

The Company's commitments under its lease agreements are described in Note 5.

10. REDEEMABLE CONVERTIBLE PREFERRED STOCK

In September 2020, the Company sold an aggregate of 6,902,872 shares of its series D redeemable convertible preferred stock ("Series D") at a purchase price of $13.0381 per share, for gross proceeds of $90.0 million. The Company incurred issuance costs of $0.1 million associated with the Series D issuance.

Upon the completion of the IPO, all 31,253,609 shares of outstanding preferred stock automatically converted into 31,253,609 shares of common stock. As of December 31, 2021, there were no shares of preferred stock authorized, issued, or outstanding.

As of December 31, 2020, preferred stock consisted of the following (in thousands, except share amounts):

	DECEMBER 31, 2020				
	PREFERRED STOCK AUTHORIZED	PREFERRED STOCK ISSUED AND OUTSTANDING	CARRYING VALUE	LIQUIDATION VALUE	COMMON STOCK ISSUABLE UPON CONVERSION
Series A	167,496,750	11,596,280	$ 53,593	$ 40,115	11,596,280
Series B	74,620,739	5,166,203	36,336	36,400	5,166,203
Series C	109,604,994	7,588,254	53,221	53,465	7,588,254
Series D	99,705,359	6,902,872	89,904	90,000	6,902,872
	451,427,842	31,253,609	$ 233,054	$ 219,980	31,253,609

11. STOCKHOLDERS' EQUITY

On February 24, 2021, the Board and the Company's stockholders approved the Company's amended and restated certificate of incorporation, which became effective immediately prior to the closing of the IPO on March 18, 2021. The certificate authorizes the issuance of up to 200,000,000 shares of $0.001 par value common stock and up to 10,000,000 shares of $0.001 par value undesignated preferred stock. The Board may designate the rights, preferences, privileges, and restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preference, and number of shares constituting any series or the designation of any series. The issuance of preferred stock could have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying or preventing a change in control. As of December 31, 2021, no shares of preferred stock were outstanding.

In conjunction with the IPO, the Company issued and sold 7,500,000 shares of common stock at a public offering price of $17.00 per share, for aggregate net proceeds of $115.7 million after deducting underwriting discounts and commissions and initial public offering costs. In connection with the IPO, all then outstanding shares of preferred stock were converted into 31,253,609 shares of common stock.

On April 20, 2021, the Company issued 192,877 additional shares of common stock, pursuant to the underwriters' partial exercise of their overallotment option, at a public offering price of $17.00 per share for aggregate gross proceeds of $3.3 million and net proceeds of $3.0 million after deducting underwriters' discounts, commissions and offering costs.

Each share of common stock entitles the holder to one vote, together with the holders of preferred stock, on all matters submitted to the stockholders for a vote. Common stockholders are also entitled to receive dividends. As of December 31, 2021, no cash dividends have been declared or paid.

The Company has issued restricted stock to founders, employees and consultants. All restricted stock was fully vested and all expense related to these shares was recognized prior to 2020.

As of December 31, 2021 and December 31, 2020, the Company has reserved the following shares of common stock for potential conversion of outstanding preferred stock, the vesting of restricted stock and exercise of stock options, common stock warrants, and shares under the employee stock purchase plan:

	DECEMBER 31, 2021	DECEMBER 31, 2020
Redeemable convertible preferred stock	—	31,253,609
Options to purchase common stock	3,264,770	1,053,874
Common stock warrants[1]	—	19,346
Shares issuable under employee stock purchase plan	45,195	—
	3,309,965	32,326,829

[1] During the fourth quarter of 2021, 19,346 common stock warrants were net exercised, resulting in 19,303 net shares.

Secondary Sale

In October 2020, certain of the Company's stockholders sold shares of the Company's common stock at a price of $13.0381 per share to an investor. The investor purchased 412,323 shares of the Company's common stock from these stockholders for an aggregate purchase price of $5.4 million, of which 258,924 shares of the Company's common stock, or an aggregate purchase price of $3.4 million, were sold by affiliates of the Company, who are considered to be related parties. The shares were sold above fair value and the excess of the price paid over the fair value was recognized as $2.8 million of stock-based compensation expense. The Company recognized the $2.8 million as general and administrative expense in the consolidated statement of operations for the year ended December 31, 2020 (see Note 12).

12. STOCK-BASED COMPENSATION

2017 Equity Incentive Plan

The Company adopted the 2017 Equity Incentive Plan (the "2017 Plan") in February 2017 for the issuance of stock options and other stock-based awards to employees, consultants, officers and directors. As of December 31, 2021, there were no shares available for future issuance since all shares in the 2017 Plan ceased to be available upon the effective date of the 2021 Equity Incentive Plan, which occurred in March 2021. There were 698,601 shares of common stock available for future grants under the 2017 Plan as of December 31, 2020.

2021 Equity Incentive Plan

In March 2021, the Board adopted, and the stockholders approved, the 2021 Equity Incentive Plan (the "2021 Plan"). The 2021 Plan became effective on the date of the underwriting agreement related to the IPO and no further grants will be made under the 2017 Plan.

The 2021 Plan provides for the grant of incentive stock options to employees, including employees of any parent or subsidiary of the Company, and for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, directors and consultants, including employees and consultants of the Company's affiliates.

Initially, the maximum number of shares of the Company's common stock that may be issued under the 2021 Plan will not exceed 5,291,446 shares of common stock, which is the sum of (1) 4,700,000 new shares, plus (2) an additional number of shares equal to the number of shares of common stock subject to outstanding stock options or other stock awards granted under the 2017 Plan that, on or after the 2021 Plan became effective, terminate or expire prior to exercise or settlement; are not issued because the award is settled in cash; are forfeited because of the failure to vest; or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price, if any, as such shares become available from time to time. In addition, the number of shares of common stock reserved for issuance under our 2021 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2022 through January 1, 2031, in an amount equal to (i) 5.0% of the total number of shares of common stock outstanding on December 31 of the year before the date of each automatic increase, or (ii) a lesser number of shares determined by the Board prior to the applicable January 1. The maximum number of shares of common stock that may be issued on the exercise of incentive stock options under the 2021 Plan will be 14,100,000 shares. Shares subject to stock awards granted under the 2021 Plan that expire or terminate without being exercised in full or that are paid out in cash rather than in shares will not reduce the number of shares available for issuance under the 2021 Plan.

As of December 31, 2021, there were 3,264,770 shares of common stock issuable upon the exercise of outstanding options and there were 2,569,454 shares available for future issuance under the 2021 Plan.

2021 Employee Stock Purchase Plan

In March 2021, the Board adopted the 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which became effective on the date of the underwriting agreement related to the IPO. The 2021 ESPP is administered by the Board or by a committee appointed by the Board. The 2021 ESPP initially provides participating employees with the opportunity to purchase up to an aggregate of 500,000 shares of common stock. The first offering period of the plan commenced on December 1, 2021 under the 2021 ESPP.

Each offering to employees to purchase shares will begin on each June 1 and December 1 and will end on the following November 30 and May 31, respectively. On each purchase date, which will fall on the last date of each offering period, ESPP participants will purchase ordinary shares at a price per share equal to 85% of the lesser of (1) the fair market value of the shares on the offering date or (2) the fair market value of the shares on the purchase date. The occurrence and duration of offering periods under the ESPP are subject to the determinations of the Company's compensation committee. As of December 31, 2021, no shares were issued under the 2021 ESPP in 2021 and 500,000 shares were available for future issuance.

Stock Option Valuation

The assumptions that the Company used in Black-Scholes option-pricing model to determine the grant-date fair value of stock options granted for the years ended December 31, 2021 and 2020 were as follows:

	2021	2020
Risk-free interest rate	0.88%	0.46%
Expected term (in years)	5.1 - 6.3	5.5 - 6.1
Expected volatility	77.7% - 93.0%	74.6% - 76.6%
Expected dividend yield	0.0%	0.0%

The following table summarizes the activity of the Company's stock options under the 2021 Plan for the year ended December 31, 2021:

	SHARES	WEIGHTED-AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL TERM (in years)	AGGREGATE INTRINSIC VALUE (in thousands)
Outstanding as of December 31, 2020	1,053,874	$ 1.51	7.5	$ 4,964
Granted	2,602,643	14.49		
Exercised	(155,821)	1.21		
Cancelled or forfeited	(211,987)	13.24		
Expired	(23,939)	12.18		
Outstanding as of December 31, 2021	3,264,770	$ 11.04	8.4	$ 7,228
Options exercisable as of December 31, 2021	846,024	$ 4.03	6.7	$ 5,589
Options vested or expected to vest as of December 31, 2021	3,264,770	$ 11.04	8.4	$ 7,228

The options granted during the years ended December 31, 2021 and 2020 were granted to employees and consultants of the Company. As of December 31, 2021, there was approximately $19.9 million of unrecognized compensation expense related to the stock-based compensation arrangements granted under the 2021 Plan remaining to be recognized. The Company expects to recognize this cost over a weighted average period of 3.24 years.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The intrinsic value of options exercised in 2021 and 2020 was $1.7 million and $0.4 million, respectively. The weighted-average grant date fair value of stock options granted in the years ended December 31, 2021 and 2020 under the Black-Scholes option pricing model was $9.87 per option and $0.87 per option, respectively.

Restricted Stock

The restricted stock was granted to the founders of the Company, as well as employees and consultants of the Company. There was approximately $8,000 of stock-based compensation expense recognized for the 547,360 shares of restricted stock vested during the year ended December 31, 2020. All restricted stock was vested as of December 31, 2020 and there is no remaining stock-compensation expense related to restricted stock to be recognized for the year ended December 31, 2021.

Stock-Based Compensation Expense

Total stock-based compensation expense recorded as research and development and general and administrative expenses, respectively, for employees, directors and non-employees during the years ended December 31, 2021 and 2020 is as follows (in thousands):

	YEAR ENDED DECEMBER 31,	
	2021	2020
Research and development	$ 1,605	$ 179
General and administrative	2,556	2,920
Total	$ 4,161	$ 3,099

The stock-based compensation expense for the year ended December 31, 2020 includes the $2.8 million recorded in relation to the secondary sale of common stock (see Note 11).

13. RELATED PARTY TRANSACTIONS

OpenBiome Historical Agreements

Under Master Strategic Affiliation Agreement with OpenBiome (the "Strategic Agreement"), OpenBiome and the Company reimbursed one another for certain administrative expenses. The Company's Chief Executive Officer and a member of the Board is the spouse of the co-founder and former Executive Director of OpenBiome, and certain of the OpenBiome directors are stockholders of the Company.

For the years ended December 31, 2021 and 2020, the Company reimbursed OpenBiome $0.1 million and $0.3 million, respectively, under the Strategic Agreement. Also under the Strategic Agreement, OpenBiome reimbursed the Company $0.1 million and $0.3 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021 and 2020, respectively the Company had no payable balance due to OpenBiome, and recorded a balance of zero and less than $0.1 million due from OpenBiome as of December 31, 2021 and 2020, respectively.

Until December 31, 2021, OpenBiome subleased office and lab space from the Company. The Company's rent income under the sublease was $0.1 million and $0.4 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021 the Company no longer had an outstanding receivable due from OpenBiome. As of December 31, 2020, the Company had less than $0.1 million receivable from OpenBiome related to the sublease recorded as due from related party in the consolidated balance sheets. This lease was amended as of March 1, 2021 (see Note 5).

The Company also earned a low single digit royalty on net sales of OpenBiome's FMT materials under the Quality System and Supply Agreement with OpenBiome (the "QSS Agreement"), which was partially terminated on February 1, 2019 and, ultimately, was fully terminated in November 2020 in connection with the Company's execution of the OpenBiome Agreement (see OpenBiome 2020 Agreements below), which closed on March 1, 2021.

OpenBiome 2020 Agreements

Clinical Supply and Services Agreement

On February 10, 2020, the Company entered into a Clinical Supply and Services Agreement (the "CSA") with OpenBiome, which terminated upon closing of the OpenBiome Agreement in March 2021. In accordance with the CSA, OpenBiome agreed to supply the Company with certain manufactured material and to provide additional support services to the Company. In consideration for these materials and services, the Company agreed to pay a monthly platform fee of $0.2 million, all direct employee overhead costs, and variable costs for consumables. Under a related payment agreement executed concurrently with the CSA, the Company paid a $0.5 million security deposit in the event of cost overruns under the CSA arrangement and approximately $1.6 million in prepaid fees. The $0.5 million security deposit was returned to the Company during the same period. The Company paid $1.1 million in total to OpenBiome under the CSA for the year ended December 31, 2021, and $3.8 million for the year ended December 31, 2020, including the security deposit that was returned. The Company had no outstanding payable balance due to OpenBiome under the CSA as of December 31, 2021, and recorded $0.2 million due to OpenBiome as of December 31, 2020, respectively, which is classified as due to related party in the Company's consolidated balance sheets.

OpenBiome Purchase Agreement

On November 19, 2020, the Company entered into the OpenBiome Agreement in order to obtain OpenBiome's CMC manufacturing process to enhance its current manufacturing capabilities for its lead program, CP101; the OpenBiome Agreement was fully executed and closed on March 1, 2021. Simultaneously with entering into the OpenBiome Agreement, the Company terminated the Strategic Agreement, the MAL Agreement, the QSS Agreement and the APL Agreement, as well as certain subject matter agreements. Upon closing of the OpenBiome Agreement on March 1, 2021, the CSA was also terminated, and the Company will not incur any additional expense to be paid to OpenBiome. The Company also amended the Strategic Agreement as part of the OpenBiome Agreement (the "A&R Strategic Agreement").

Pursuant to the OpenBiome Agreement, the Company acquired certain biological samples, software, and a non-exclusive license to OpenBiome's CMC technology upon signing in November 2020, and acquired certain biological samples, a commercial lease, contract services intellectual property and capital equipment upon the closing of the transaction in March 2021. The Company previously licensed the biological samples and OpenBiome's CMC technology under various historical agreements with OpenBiome which terminated upon signing of the OpenBiome Agreement. As such, the acquisition of the

CMC technology license was a continuation of previously granted rights. The OpenBiome Agreement also releases, for a one-year period from signing, a hiring restriction under the A&R Strategic Agreement (i.e. non-solicitation) such that the Company may hire, at its discretion, certain OpenBiome employees. The Company did not acquire any such employees as part of the transaction.

In connection with the OpenBiome Agreement, the Company paid $1.2 million for the acquisition of certain assets in November 2020, which was capitalized as property and equipment as software on the Company's consolidated balance sheet as of December 31, 2020 and paid $3.8 million upon the closing of the OpenBiome Agreement on March 1, 2021, for the remaining assets. The Company accounted for the OpenBiome Agreement as an asset acquisition and capitalized $5.0 million of property and equipment on the consolidated balance sheet as of March 31, 2021 for the acquired software and property and equipment. The Company did not assign any value to biological samples, contract services intellectual property, or the CMC technology license, as the Company did not acquire any additional rights that were not previously granted under the legacy agreements.

The Company is also required to pay certain milestones up to $26.0 million upon the occurrence of certain R&D events, regulatory approvals, and commercial sales, and low single digit royalties on net sales of products on a product-by-product and country-by-country basis, as well as a mid-single digit royalties on sublicensing revenue related to such products.

The Company previously granted OpenBiome a royalty-bearing, non-exclusive license to its intellectual property under the APL Agreement, which terminated upon the signing of the OpenBiome Agreement. The Company will continue to earn royalties under the OpenBiome Agreement based on sales of FMT materials.

14. RETIREMENT PLAN

The Company has adopted a defined contribution plan intended to qualify under Section 401(k) of the Internal Revenue Code covering all eligible employees of the Company. All employees are eligible to become participants of the plan at the beginning of the next full quarter subsequent to their hire date. Each active employee may elect, voluntarily, to contribute a percentage of their compensation to the plan each year, subject to certain limitations. The Company reserves the right to make additional contributions to this plan. The Company made contributions to the plan of $0.8 million and $0.4 million in the years ended December 31, 2021 and 2020, respectively.

15. LOSS PER SHARE

Basic and diluted loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average common shares outstanding (in thousands, except share and per share data):

	FOR THE YEAR ENDED DECEMBER 31,	
	2021	**2020**
Numerator:		
Net loss	$ (58,160)	$ (39,341)
Net loss attributable to common stockholders—basic and diluted	(58,160)	(39,341)
Denominator:		
Weighted-average common stock outstanding—basic and diluted	39,202,086	8,144,855
Net loss per share attributable to common stockholders—basic and diluted	$ (1.48)	$ (4.83)

The Company's potentially dilutive securities, which include preferred stock, restricted stock, stock options, and warrants, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following from the computation of diluted net loss per share attributable to common stockholders at December 31, 2021 and 2020 because including them would have had an anti-dilutive effect:

	YEAR ENDED DECEMBER 31,	
	2021	2020
Preferred stock	—	31,253,609
Options to purchase common stock	3,264,770	1,053,874
Common stock warrants	—	19,346
Shares issuable under employee stock purchase plan	45,195	-
	3,309,965	32,326,829

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Pursuant to Rules 13(a)-13(e) and 15(d)-15(e) under the Exchange Act, management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2021. Based on the evaluation of our disclosure controls and procedures as of December 31, 2021, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm as permitted in this transition period under the rules of the SEC for newly public companies.

Remediation of Previously-Identified Material Weaknesses in Internal Control over Financial Reporting

In connection with our IPO, we previously disclosed material weaknesses identified in our internal control over financial reporting relating to the following: (1) an ineffective control environment, including a lack of sufficient accounting personnel and personnel with financial reporting expertise; (2) ineffective controls over cutoff, recording and classification of certain accounts, and the valuation and recognition of intangible assets acquired in a business combination that occurred in 2017; (3) ineffective risk assessment controls, including those policies and practices that would identify changes in our business practices, which could significantly impact our consolidated financial statements and system of internal controls; and (4) ineffective monitoring of controls related to the financial close and reporting process.

Our management, with oversight from our audit committee, has implemented the following remediation steps to address the material weaknesses and to improve our internal control over financial reporting:

- We added finance personnel to the organization to strengthen our internal accounting team including a controller, assistant controller, associate director of SEC reporting and technical accounting, senior manager of SOX compliance and technical accounting, senior manager of accounting, and senior accountant. We reallocated responsibilities across the accounting organization to ensure that the appropriate level of knowledge and experience is applied based on risk and complexity of transactions under review.
- We engaged external accounting advisory consultants to provide additional depth and breadth in our technical accounting and financial reporting capabilities.
- With the support of internal control consultants, we completed risk assessment activities and the evaluation of the design of internal controls to address relevant risks, including developing remediation plans for any design deficiencies in our system of internal controls. We executed the remediation plans for the identified control design deficiencies and tested the effectiveness of the remediated controls.
- We implemented a financial close policy and monitoring program, including the formation of a Disclosure Committee comprised of members of our senior management team and representatives from our accounting and legal departments to review and approve SEC filings and investor communications, the results of which are discussed with the audit committee of our board of directors quarterly.

Management concluded that, as a result of the implementation of these actions, the previously-identified material weaknesses in our internal control over financial reporting have been remediated as of December 31, 2021.

Changes in Internal Control Over Financial Reporting

Except for the remediation efforts of the previously identified material weakness as described above, there have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the three months ended December 31, 2021, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, believe that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information.

Resignation of Chief Financial Officer; Appointment of Principal Financial Officer/Principal Accounting Officer

On March 30, 2022, Gregory D. Perry informed us of his intent to retire as our Chief Financial Officer effective as of April 30, 2022 (the “Retirement Date”). Mr. Perry is retiring for personal reasons and there are no disagreements between Mr. Perry and us on any matters relating to our operations, policies, or practices, including accounting principles and practices.

Effective as of the Retirement Date, the Board has appointed Marc Blaustein, our current Chief Operating Officer, to serve in the roles of principal financial officer and principal accounting officer. He will receive a salary increase of $15,000 for these additional appointments, resulting in an annual base salary of $415,000.

Mr. Blaustein, age 59, has served as our Chief Operating Officer since September 2021. Prior to joining the Company, from 2019 to 2021, he consulted as Head of Business Development for Guide Therapeutics, which was acquired by Beam Therapeutics in 2021. Prior to that time, Mr. Blaustein served as the Chief Executive Officer of NED Biosystems from 2017 to 2019 and co-founder and Chief Executive Officer of Akashi Therapeutics from 2011 to 2017. Before founding Akashi, he served in various leadership positions across several biotechnology companies, including serving as Senior Vice President of Manufacturing, Process and Commercial Operations at Dyax Corp. (now Takeda). Prior to Dyax, Mr. Blaustein held business development and management roles at Alkermes plc and worked in business development at Genetics Institute (now Pfizer). Mr. Blaustein began his career in management consulting, first at Mercer Management Consulting, and then as a founding partner of Northbridge Consulting. Mr. Blaustein has a B.A. in biology from the University of Pennsylvania and an M.P.P. from Harvard University. He is also a Chartered Financial Analyst (CFA) charterholder.

There are no arrangements or understandings between Mr. Blaustein and any other persons pursuant to which he was appointed to serve in the roles of principal financial officer and principal accounting officer. There are no family relationships between Mr. Blaustein and any of our directors or executive officers, and he does not have any direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

In connection with Mr. Perry's resignation, we and Mr. Perry intend to enter into a consulting agreement pursuant to which, among other things, following the Retirement Date, Mr. Perry will provide advisory services to the Company through the end of 2022. As consideration for his advisory services, Mr. Perry will be paid a monthly retainer.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required under this item is incorporated herein by reference to the information set forth in the sections titled “Information Regarding Director Nominees and Current Directors”, “Information Regarding the Board of Directors and Corporate Governance” and “Executive Officers” in our definitive proxy statement relating to our 2022 annual meeting of stockholders, or the 2022 Proxy Statement, to be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2021.

Item 11. Executive Compensation.

The information required under this item is incorporated herein by reference to the information set forth in the sections titled “Executive Compensation” and “Non-Employee Director Compensation” in the 2022 Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required under this item is incorporated herein by reference to the information set forth in the sections titled “Executive Compensation – Equity Compensation Plan Information” and “Security Ownership of Certain Beneficial Owners and Management” in the 2022 Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required under this item is incorporated herein by reference to the information set forth in the sections titled “Information Regarding the Board of Directors and Corporate Governance – Independence of the Board of Directors” and “Transactions with Related Persons” in the 2022 Proxy Statement.

Item 14. Principal Accounting Fees and Services.

The information required under this item is incorporated herein by reference to the information set forth in the sections titled “Principal Accounting Fees and Services” and “Pre-Approval Policies and Procedures” in the 2022 Proxy Statement.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

(1) For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(3) Exhibits:

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Finch Therapeutics Group, Inc. (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed March 23, 2021).
3.2	Amended and Restated Bylaws of Finch Therapeutics Group, Inc. (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed March 23, 2021).
4.1	Third Amended and Restated Stockholders Agreement, by and among Finch Therapeutics Group, Inc. and certain of its stockholders, dated September 2, 2020 (incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1, as amended, filed March 18, 2021).
4.2	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-1, as amended, filed March 18, 2021).
4.3*	Description of Registrant's Securities.
10.1†	2017 Equity Incentive Plan, as amended, and the forms of agreements thereunder (incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1, as amended, filed March 18, 2021).
10.2	Form of Indemnity Agreement between Finch Therapeutics Group, Inc. and its officers and directors (incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1, as amended, filed March 18, 2021).
10.3*#	Amended and Restated Exclusive License Agreement between Regents of the University of Minnesota and Finch Therapeutics Holdings LLC, dated January 28, 2022.
10.4#	Exclusive License Agreement by and between Crestovo, LLC and Arizona Science and Technology Enterprises LLC, dated as of July 3, 2017, as amended August 27, 2018 (incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1, as amended, filed March 18, 2021).
10.5#	Amended and Restated Agreement by and between Finch Therapeutics, Inc. and Millennium Pharmaceuticals, Inc., dated as of October 21, 2019 (incorporated by reference to Exhibit 10.5 of the Registrant's Registration Statement on Form S-1, as amended, filed March 18, 2021).
10.6#	Amendment, dated August 9, 2021, to the Amended and Restated Agreement by and between Finch Therapeutics, Inc. and Millennium Pharmaceuticals, Inc., dated as of October 21, 2019 (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed November 10, 2021).
10.7*#	Amendment No. 2, dated November 12, 2021, to the Amended and Restated Agreement by and between Finch Therapeutics, Inc. and Millennium Pharmaceuticals, Inc. dated as of October 21, 2019.
10.8#	Asset Purchase Agreement by and between Finch Therapeutics, Inc. and Microbiome Health Research Institute, Inc., dated as of November 19, 2020 (incorporated by reference to Exhibit 10.6 of the Registrant's Registration Statement on Form S-1, as amended, filed March 18, 2021).
10.9#	LMIC License Agreement by and between Finch Therapeutics, Inc. and Microbiome Health Research Institute, Inc., dated as of November 19, 2020 (incorporated by reference to Exhibit 10.7 of the Registrant's Registration Statement on Form S-1, as amended, filed March 18, 2021).
10.10+	Lease by and between NextBiome, Inc. and North River II LLC, dated as of December 21, 2015 (incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1, as amended, filed March 18, 2021).
10.11+	First Amendment to Lease by and between Finch Therapeutics, Inc. and North River II LLC, dated as of January 20, 2017 (incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1, as amended, filed March 18, 2021).
10.12+	Lease, dated August 3, 2021, by and between Hood Park LLC and Finch Therapeutics, Inc. (incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q, filed November 10, 2021).

10.13†	2021 Equity Incentive Plan and the forms of agreements thereunder (incorporated by reference to Exhibit 4.5 of the Registrant's Registration Statement on Form S-8, filed March 26, 2021).
10.14†	2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 4.6 of the Registrant's Registration Statement on Form S-8, filed March 26, 2021).
10.15†	Amended and Restated Executive Employment Agreement, by and between Finch Therapeutics Group, Inc. and Mark Smith, dated as of March 12, 2021 (incorporated by reference to Exhibit 10.12 of the Registrant's Registration Statement on Form S-1, as amended, filed March 18, 2021).
10.16†	Amended and Restated Executive Employment Agreement by and between Finch Therapeutics Group, Inc. and Zain Kassam, dated as of March 12, 2021 (incorporated by reference to Exhibit 10.13 of the Registrant's Registration Statement on Form S-1, as amended, filed March 18, 2021).
10.17*†	Release Agreement, dated November 4, 2021, by and between Finch Therapeutics Group, Inc. and Zain Kassam.
10.18†	Amended and Restated Executive Employment Agreement by and between Finch Therapeutics Group, Inc. and Gregory D. Perry, dated as of March 12, 2021 (incorporated by reference to Exhibit 10.14 of the Registrant's Registration Statement on Form S-1, as amended, filed March 18, 2021).
10.19*†	Executive Employment Agreement by and between Finch Therapeutics Group, Inc. and Marc Blaustein, dated as of September 8, 2021.
10.20*†	Amended and Restated Executive Employment Agreement by and between Finch Therapeutics Group, Inc. and Joseph Vittiglio, dated as of March 12, 2021
10.21*†	Amendment No. 1 to the Amended and Restated Executive Employment Agreement by and between Finch Therapeutics Group, Inc. and Joseph Vittiglio, dated as of March 18, 2021
21.1*	Subsidiaries of Finch Therapeutics Group, Inc.
23.1*	Consent of Deloitte & Touche LLP.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (the cover page interactive date is embedded within the Inline XBRL document)

* Filed herewith.
**Furnished herewith.
Certain portions of this exhibit (indicated by asterisks) have been omitted because they are not material and would likely cause competitive harm to Finch Therapeutics Group, Inc. if publicly disclosed.
+ Certain schedules and exhibits to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.
† Indicates management contract or compensatory plan.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, 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

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Mark Smith Mark Smith, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	March 31, 2022
/s/ Gregory D. Perry Gregory D. Perry	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer*)	March 31, 2022
/s/ Chris Shumway Chris Shumway	Chairman of the Board of Directors	March 31, 2022
/s/ Domenic Ferrante Domenic Ferrante	Director	March 31, 2022
/s/ Susan Graf Susan Graf	Director	March 31, 2022
/s/ Nicholas Haft Nicholas Haft	Director	March 31, 2022
/s/ Samuel A. Hamood Samuel A. Hamood	Director	March 31, 2022
/s/ Christian Lange Christian Lange	Director	March 31, 2022
/s/ Jeffrey Smisek Jeffrey Smisek	Director	March 31, 2022
/s/ Jo Viney Jo Viney, Ph.D.	Director	March 31, 2022

Exhibit 4.3

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description of our capital stock is a summary and does not purport to be complete. It is subject to, and qualified in its entirety by reference to, the applicable provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our stockholders agreement entered into in September 2020, which are filed as exhibits to our Annual Report on Form 10-K, of which this Exhibit 4.3 is a part, and are incorporated by reference herein. We encourage you to read our amended and restated certificate of incorporation, our amended and restated bylaws, our stockholders agreement and the applicable provisions of the Delaware General Corporation Law for more information. References herein to the terms "we," "our" and "us" refer to Finch Therapeutics Group, Inc. and its subsidiaries.

General

Our amended and restated certificate of incorporation authorizes us to issue up to 200,000,000 shares of common stock, $0.001 par value per share, and 10,000,000 shares of preferred stock, $0.001 par value per share, all of which shares of preferred stock will be undesignated. Our board of directors may establish the rights and preferences of the preferred stock from time to time.

Common Stock

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Under our amended and restated certificate of incorporation and amended and restated bylaws, our stockholders do not have cumulative voting rights. The affirmative vote of holders of at least $66^{2}/_{3}$% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, is required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, the classified board, the size of our board, removal of directors, director liability, vacancies on our board, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Rights and Preferences

Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Registration Rights

We are party to a stockholders agreement that provides certain holders of our common stock with rights, subject to certain conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. These shares are collectively referred to herein as registrable securities.

The stockholders agreement provides the holders of registrable securities with demand, piggyback and S-3 registration rights as described more fully below. Under the terms of the stockholders agreement, holders of registrable securities will have equivalent registration rights with respect to any additional shares of our common stock acquired by these holders.

Demand Registration Rights

At any time beginning 180 days following the effective date of the registration statement for our initial public offering, the holders of at least 20% of the registrable securities then outstanding have the right to make up to two demands that we file a registration statement under the Securities Act of 1933, as amended (the "Securities Act"), subject to specified conditions and exceptions. Such request for registration must cover shares with an anticipated aggregate offering price to the public of at least $25 million.

Piggyback Registration Rights

If we register any securities for public sale, the holders of our registrable securities then outstanding will each be entitled to notice of the registration and will have the right to include their shares in the registration statement, subject to specified exceptions. The underwriters of any underwritten offering will have the right to limit the number of shares having registration rights to be included in such registration statement, but not below 25% of the total amount of securities included in such registration.

Registration on Form S-3

If we are eligible to file a registration statement on Form S-3, the holders of at least 20% of the registrable securities then outstanding have the right to demand that we file registration statements on Form S-3, provided that the aggregate amount of securities to be sold under the registration statement is at least $5.0 million, net of underwriting discounts and commissions and specified expenses. We are not obligated to effect a demand for registration on Form S-3 by holders of our registrable securities more than two times during any 12-month period. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Expenses of Registration

We will pay all expenses relating to any demand, piggyback or Form S-3 registration, other than underwriting discounts and commissions, subject to specified conditions and limitations.

Termination of Registration Rights

The demand, piggyback and Form S-3 registration rights described above will terminate on the earliest to occur of (1) the closing of a "Deemed Liquidation Event" as defined in our amended and restated certificate of incorporation in effect immediately prior to the completion of our initial public offering, (2) with respect to each stockholder, at such time as Rule 144 under the Securities Act or another similar exemption is available for the sale of all of such holder's shares without limitation during a three-month period without registration, and (3) March 23, 2026.

Anti-Takeover Provisions

Certificate of Incorporation and Bylaws

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting

power of our shares of common stock will be able to elect all of our directors. Our amended and restated certificate of incorporation and amended and restated bylaws provide for stockholder actions at a duly called meeting of stockholders. A special meeting of stockholders may be called by a majority of our board of directors, the chair of our board of directors, or our chief executive officer or president if the chair of our board of directors is unavailable. Our amended and restated bylaws provide an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors. In addition, our amended and restated certificate of incorporation and amended and restated bylaws do not allow for the right of stockholders to act by written consent without a meeting.

In accordance with our amended and restated certificate of incorporation, our board of directors is divided into three classes with staggered three-year terms.

The foregoing provisions make it more difficult for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to preserve our existing control structure, facilitate our continued product innovation and the risk-taking that it requires, permit us to continue to prioritize our long-term goals rather than short-term results, enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of us. These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a publicly held Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (1) by persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least $66^{2}/_{3}$% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a “business combination” to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Choice of Forum

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for the following claims or causes of action under Delaware statutory or common law: (1) any derivative claim or cause of action brought on our behalf; (2) any claim or cause of action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders; (3) any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; (4) any claim or cause of action arising under or seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (including any right, obligation, or remedy thereunder); and (5) any claim or cause of action against us or any of our current or former directors, officers, or other employees that is governed by the internal-affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court having personal jurisdiction over the indispensable parties named as defendants. This choice of forum provision would not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts have exclusive jurisdiction, or the Securities Act. Our amended and restated certificate of incorporation further provides that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. Additionally, our amended and restated certificate of incorporation provides that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Transfer Agent and Registrar

Our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent's address is 6201 15th Avenue, Brooklyn, New York 11219.

Listing

Our common stock is listed on the Nasdaq Global Select Market under the trading symbol "FNCH."

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE FINCH THERAPEUTICS GROUP, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO FINCH THERAPEUTICS GROUP, INC. IF PUBLICLY DISCLOSED.

Exhibit 10.3

EXCLUSIVE LICENSE AGREEMENT

Regents of the University of Minnesota

and

Finch Therapeutics Holdings LLC

TECHNOLOGY COMMERCIALIZATION
200 Oak Street, SE | Suite 280 | Minneapolis, MN 55455

OTC Agreement Number: **A20120373**| OTC Case Number**: 20100243, 20130223, 20140139, 20140293, 20170005**

AMENDED AND RESTATED EXCLUSIVE LICENSE AGREEMENT

THIS AMENDED AND RESTATED EXCLUSIVE LICENSE AGREEMENT (this "Agreement") is made as of the Effective Date by and between Regents of the University of Minnesota, a constitutional corporation under the laws of the state of Minnesota, having a place of business at 200 Oak Street, SE, Suite 280, Minneapolis, Minnesota 55455 (the "University"), and the Licensee identified below.

WHEREAS, the University and Crestovo LLC (now Finch Research and Development LLC) ("Crestovo") are parties to that certain Exclusive Patent License Agreement dated March 26, 2012 ("Original Effective Date"), as amended by the First Amendment effective July 10, 2014, the Second Amendment effective October 23, 2014, the Third Amendment effective December 1, 2016, and the Fourth Amendment effective September 15, 2017 (collectively the "Original Agreement");

WHEREAS, on September 21, 2017, the parent of Crestovo, Crestovo Holdings LLC (now Finch Therapeutics Holdings LLC), merged with Finch Therapeutics, Inc. to create Finch Therapeutics Group, Inc. ("Finch"); and

WHEREAS, Finch desires to consolidate its intellectual property in Finch Therapeutics Holdings LLC, including the transfer of the License Agreement to Finch Holdings LLC (hereinafter, the "Licensee");

WHEREAS, in addition to this transfer, the University and Licensee desire to amend and restate the Original Agreement, in its entirety, as set forth herein;

NOW, THEREFORE, in consideration of the foregoing and the representations, warranties, covenants and agreements contained herein, the parties hereby agree as follows:

The Agreement consists of the **Business Terms**, **General Terms** and any attached and referenced exhibits or schedules.

BUSINESS TERMS

1	**LICENSEE**	Finch Therapeutics Holdings LLC (pursuant to S. 14.6 of the General Terms)
2	**TERRITORY**	Worldwide
3	**FIELD OF USE**	All fields
4	**TERM**	The Term commences on the Effective Date and, unless terminated earlier in accordance with Section 10 of the General Terms, expires on the date on which there are no Valid Claims anywhere in the Territory.
5	**LICENSED INTELLECTUAL PROPERTY**	
5.1	**LICENSED PATENTS**	[***]
5.2	**LICENSED PATENT APPLICATIONS**	[***]

5.3	**TECHNICAL INFORMATION**	☐ None ☒ Yes. Description is attached as Exhibit A
6	**FEDERAL GOVERNMENT RIGHTS**	The inventions described in the following Licensed Patents and Licensed Patent Applications claiming priority to [***] were developed with federal funding and contain Federal Government Rights.
7	**PATENT RELATED EXPENSES** **Include all that apply**	Licensee shall either pay on University's behalf or reimburse University for any Patent-Related Expenses paid by University within [***] from receipt of invoice from University.
8	**SUBLICENSE RIGHTS**	Yes
9	**PERFORMANCE MILESTONES**	Provided that the United States Food and Drug Administration ("FDA") does not recommend or require unanticipated studies or prerequisites, including, without limitation, detailed characterization of control material for clinical trial use, as part of the regulatory approval process for obtaining a Licensed Product to treat [***], Licensee shall perform the following milestones. If the FDA does recommend or require such unanticipated studies or prerequisites, the parties will negotiate in good faith extensions to the milestones to reflect additional time that may be needed to achieve the following: (a) [***] (b) [***] [***]
10	**PAYMENTS**	
10.1	**UPFRONT PAYMENT**	No upfront fee shall be payable.
10.2	**LICENSE MAINTENANCE FEE**	Beginning on the Effective Date and each year thereafter in which Licensee, an Affiliate, or a Sublicensee does not sell Licensed Product, Licensee will pay to University a yearly maintenance fee of $[***] USD, payable on each anniversary of the Original Effective Date.

10.3	**RUNNING ROYALTIES ON NET SALES**	Licensee shall pay to University on a Licensed Product-by-Licensed Product and country-by-country basis royalties on Net Sales of Licensed Products, whether the sales are made by Licensee, an Affiliate of Licensee, or a Sublicensee, such royalties being equal to: • [***] • [***] • [***] determined and payable as provided in Section 4.4 of the General Terms, except as otherwise determined in Section 10.4 of the Business Terms. For clarity, a Licensed Product shall not be deemed to "infringe" a Valid Claim under this Section 10.3 where its manufacture, use, sale, offer for sale, import or export is deemed not infringing pursuant to 35 U.S.C. § 271(e)(1).
10.4	**ANNUAL MINIMUM AMOUNT OF RUNNING ROYALTIES**	Beginning in the calendar year 2021 and for each year thereafter during the Term, if the total royalties payable by the Licensee to the University pursuant to Section 10.3 of the Business Terms do not meet the Minimum Royalty Payment for that year, then Licensee shall pay to University, within [***] after the conclusion of such year, such additional amount to ensure that the total royalties paid by the Licensee to the University during such year is at least equal to the Minimum Royalty Payment. Year(s) Minimum Royalty Payment [***] [***] The annual Minimum Royalty Payment is not available for carryforward or carryback against royalties for years other than the applicable year or for other payments due under this Agreement.
10.5	**SUBLICENSE NON-ROYALTY CONSIDERATION**	Licensee shall pay to University [***]% of all Non-Royalty Consideration it receives from a Sublicensee within [***]. With respect to any Sublicense of the Licensed Patent Rights, Licensee will, as part of the negotiation with a Sublicensee, allocate the various categories of payments required from a Sublicensee on a commercially reasonable basis and not with a view to undermine the fees that are due to University under this Section 10.5. If University has a good faith objection to the allocation made by Licensee and a Sublicensee, then University will give prompt notice to Licensee and the parties shall meet and attempt to agree on which portion of the total payments received by Licensee pursuant to such sublicense would constitute Sublicense Non-Royalty Consideration. [***]
10.6	**TRANSFER FEE**	Within [***] after the closing of a Transfer or Change of Control, Licensee shall pay to University, as a Transfer Fee, $[***] USD. For clarity, Licensee shall not be obligated to pay a Transfer Fee to the extent it assigns this Agreement to an Affiliate of Licensee existing as of the Effective Date.

10.7	**MILESTONE PAYMENTS**	Not applicable/none required.
10.8	**EARLY TERMINATION FEE**	Unless waived by University in writing, Licensee shall pay to University a fee of $[***] USD in the event it terminates the Agreement early for convenience under Section 10.3(b) of the General Terms.
11	**LICENSEE'S ADDRESS FOR NOTICE**	Contact: [***] Address: Finch Therapeutics, Inc. 200 Inner Belt Road Suite 400 Somerville, MA 02143 Phone [***] Email: [***]
12	**LICENSEE'S CONTACT FOR PATENT PROSECUTION CONSULTATION**	Contact: [***] Address: [***] Phone [***] Email: [***]
13	**LICENSEE'S CONTACT FOR BILLING AND FINANCE**	Contact: [***] Address: Finch Therapeutics, Inc. 200 Inner Belt Road Suite 400 Somerville, MA 02143 Phone [***] Email: [***]

THE PARTIES HEREBY EXECUTE THIS AGREEMENT

Regents of the University of Minnesota	**Finch Therapeutics Holdings LLC**
By: /s/ Rick Huebsch	**By:** /s/ Mark Smith
Rick Huebsch **Executive Director** Technology Commercialization	**Mark Smith** **CEO**
Date: January 19, 2022	**Date:** 1/28/2022
The signatory warrants that they are authorized to execute this agreement on behalf of the Regents of the University of Minnesota.	The signatory warrants that they are authorized to execute this agreement on behalf of Licensee

GENERAL TERMS

1. DEFINITIONS AND INTERPRETATION

1.1 Definitions

In this Agreement:

"**Affiliate**" means an entity that controls Licensee or the Sublicensee, as the case may be, is controlled by Licensee or Sublicensee, or along with Licensee or Sublicensee, is under the common control of a Third Party. An entity shall be deemed to have control of the controlled entity if it: (a) owns, directly or indirectly, fifty percent (50%) or more of the outstanding voting securities of the controlled entity, or (b) has the right, power or authority, directly or indirectly, to direct or cause the direction of the policy decisions of the controlled entity, whether by ownership of securities, by representation on the controlled entity's governing body, by contract, or otherwise.

"**Change of Control**" means (a) the acquisition by a person or group of beneficial ownership of the capital stock of Licensee if after the acquisition the person or group beneficially owns [***]% or more of either (i) the total number of the then outstanding shares of common stock of Licensee or (ii) the total number of the then outstanding shares of voting securities of Licensee; (b) a change in the composition of Licensee's board of directors such that less than a majority of individuals who serve as such directors as of the Effective Date or who were nominated for election to the board of directors by at least three quarters of directors in office as of the Effective Date or whose nomination and election to the board of directors was similarly approved, are serving on Licensee's board of directors; or (c) irrespective of whether Licensee is a surviving entity, the consummation of a merger, consolidation, reorganization involving Licensee or other exchange of shares of Licensee in one or a series of related transactions.

"**Early Termination**" means the termination of this Agreement permitted under Section 10.3 (b) of the General Terms.

"**Effective Date**" means the date of the last signature on this Agreement.

"Enforcement Litigation" means any litigation involving the enforcement of Licensed Intellectual Property against a Third Party.

"**Field of Use**" means the field(s) of use described in Section 3 of the Business Terms.

"**Licensed Patent**" means: (i) a patent described in Section 5.1 of the Business Terms and (ii) a patent held by University that arose out of and/or claimed priority to a Licensed Patent Application. "Licensed Patent" also means any reissues or reexaminations or post-issuance certificates of a Licensed Patent that contain one or more Valid Claims.

"**Licensed Patent Application**" means a patent application described in Section 5.2 of the Business Terms along with continuations, continuations-in-part (but only to the extent the claims are supported by a patent application pending as of the Original Effective Date) and divisionals of such a patent application.

"**Licensed Product**" means a product or service or part of a product or service in the Field of Use: (a) the making, using, importing, selling, or providing of which, absent this license, infringes, induces infringement, or contributes to infringement of a Licensed Patent or is otherwise covered by a claim in a Licensed Patent Application; or (b) which is made with, uses, was derived from, identified or validated by, incorporates, or was developed in whole or in part using any Licensed Technical Information.

"**Licensed Intellectual Property**" means the Licensed Patents, Licensed Patent Applications and Licensed Technical Information, as set forth in Section 5.

"Licensed Technical Information" means the information identified in Appendix A, as referenced at Section 5.3 of the Business Terms.

"**Licensee**" means the entity identified in Section 1 of the Business Terms.

"Minimum Royalty Payment" means the minimum royalty payments as set forth in Section 10.4 of the Business Terms.

"**Net Sales**" means [***].

"**Non-Royalty Consideration**" means [***].

"**Patent-Related Expenses**" means costs and expenses (including out-of-pocket attorneys' fees, patent agent fees and governmental fees) that University incurs in filing, prosecuting and maintaining the Licensed Patents.

"**Performance Milestone**" means an act or event specified described in Section 9 of the Business Terms.

"**Royalty Consideration**" means any royalty payment received by Licensee from a Sublicensee based on the Sublicensee's sales of Licensed Products.

"Running Royalties" means the running royalties as set forth in Section 10.3 of the Business Terms.

"**Sublicense**" when used as a noun, means any agreement between Licensee or an Affiliate of Licensee and a Third Party that contains a grant by Licensee or an Affiliate of Licensee to such Third Party to all or a portion of University's Licensed Intellectual Property regardless of the name given to the agreement by the parties; when used as a verb, means Licensee's act of entering into any agreement with a Third Party that contains a grant by Licensee to such Third Party to all or a portion of University's Licensed Intellectual Property, regardless of the name given to the agreement by the parties.

"**Sublicensee**" means the Third Party in a Sublicense.

"**Territory**" means the geographical area described in Section 2 of the Business Terms.

"**Third Party"** means any party other than University or Licensee or its Affiliates.

"Transfer" means the assignment of this License to a Third Party other than in connection with a Change of Control.

"Transfer Fee" means the fee set forth in Section 10.6 of the Business Terms.

"**University Indemnitees**" means University, its respective regents, officers, employees, students, agents, faculty, representatives and volunteers.

"Valid Claim" means [***].

"Year" means a calendar year during the term of this Agreement.

1.2 Rules of Interpretation and Convention

In this Agreement, unless the context requires otherwise:

(a) headings are for convenience only and do not affect interpretation;

(b) the singular includes the plural and conversely;

(c) a reference to any statute, rule, regulation or policy includes any amendment, and any statute, rule, regulation or policy replacing it;

(d) all computations and payments made under this Agreement shall be in United States dollars. To determine the U.S. dollar value of transactions conducted in non-United States currencies on any particular day, the parties shall use the exchange rate for that currency as reported in the Wall Street Journal in the most recently published edition prior to the date of the transaction; and

(e) all notices, reports, and other documents and instruments that a party elects or is required to deliver to the other party must be in English.

2. LICENSE

2.1 Grant of License

(a) Subject to the terms and conditions of this Agreement, University hereby grants to Licensee, and Licensee hereby accepts, an exclusive license under University's rights in the Licensed Patents and Licensed Patent Applications to make, have made, use, sell, offer for sale, import, have imported, or otherwise dispose or have disposed a Licensed Product in the Territory and in the Field of Use;

(b) a non-exclusive license under University's interest in the Licensed Technical Information to use in conjunction with its exercise of rights under 2.1 (a);

(c) Except as provided in this section, no other rights or licenses, express or implied, are granted to Licensee.

2.2 Retained Rights

Notwithstanding any provision of this Agreement, University retains on behalf of itself and all other non-profit research institutions, the right to practice the Licensed Intellectual Property for research, teaching, and education. The University shall have the specific right to use the Licensed Technology in commercial research projects sponsored by for-profit entities, provided that the for-profit entity that wishes to sponsor such a commercial research project is informed of the Licensee's rights hereunder and the need to negotiate with the Licensee with respect to commercial access to the Licensed Technology. The University shall have the right to sublicense its rights under this section to one or more non-profit academic or research institutions, provided that the non-profit academic or research institutions are informed of the Licensee's rights hereunder and the need to negotiate with the Licensee with respect to the commercial access to the Licensed Technology.

3. SUBLICENSING

3.1 Sublicense Requirements

Licensee may sublicense its rights under this Agreement, in whole or in part, through multiple tiers of sublicensees and to Third Parties and Affiliates; provided that, with respect to any sublicense to a Third Party, the Licensee shall deliver to the University a true and correct copy of the sublicense agreement or other agreement under which the Licensee purports or intends to grant such sublicense rights within [***] of the execution of such agreement, which copy may be redacted to exclude confidential information of the Licensee or the applicable sublicensee, but such copy shall not be redacted to the extent that it impairs the University's ability to ensure compliance with this Agreement. The Licensee shall not enter into such agreement if the terms of the agreement are inconsistent in any respect with the terms of this Agreement.

3.2 Copy of Sublicenses and Sublicense Royalty Reports

Licensee shall submit to University within [***] of the effective date of a Sublicense a copy of such Sublicense in accordance with the terms of Section 3.1 of the General Terms, any subsequent amendments of the Sublicense and all copies of Sublicensee's royalty reports.

4. PAYMENT, RECORDS, AND AUDIT

4.1 Licensee's Payment Obligation

Licensee shall pay all amounts under Sections 7 and 10 of the Business Terms by the dates indicated therein. Licensee shall pay such amounts by wire transfer, check (payable to the "Regents of the University of Minnesota" and sent to: Regents of the University of Minnesota, NW 5960, PO Box 1450, Minneapolis, MN 55485-5960; reference agreement number on check), or any other method of payment specified by University.

4.2 Licensee Responsible for Non-U.S. Taxes

Licensee shall pay all non-U.S. taxes related to payments made to University and invoiced to Licensee under this Agreement.

4.3 Interest

All amounts due under this Agreement will bear compound interest at [***]% per annum on the entire unpaid balance computed from the payment due date of such amount (not to be fewer than [***] following receipt of an invoice) until the amount is paid.

4.4 Royalty Payments/Sales Reports

Within [***] after the last day of the [***] beginning in the calendar year in which Licensee first sells a Licensed Product, Licensee shall provide to University a written report (even if there are no sales for the calendar quarter) that sets forth the amount of Net Sales for each Licensed Product within the Territory during such calendar quarter. The Licensee shall deliver along with such written report its payment for royalties (if any) accrued during such calendar quarter calculated in accordance with Section 10.3 and Section 10.4 of the Business Terms.

Notwithstanding the foregoing, if the Licensee, in its reasonable judgment, elects to pay royalties or similar payments to one or more Third Parties for a license to intellectual property rights owned or controlled by such Third Part(ies) that are reasonably useful or necessary for the manufacture, use, sale, offer for sale, import, or export of Licensed Products (whether to one or more Third Parties, the "Third Party Royalty Payment"), then Licensee may deduct an amount equal to [***] of any Third Party Royalty Payments, provided that in no event shall the royalties otherwise due University be less than [***] of the royalties that would be payable to University absent the effects of this Section 4.4. [***]

4.5 No Refund

With the exception of an undisputed overpayment made by Licensee to University, all amounts paid to University by Licensee under this Agreement are non-refundable.

4.6 Termination Report

Licensee shall pay to University all amounts due under this Agreement and submit to University a written report to include contact information for any Sublicensees within [***] after the Agreement terminates. Licensee will continue to submit any applicable royalty payments and/or reports after the license terminates, until all Licensed Products made or imported during the Term of the Agreement have been sold.

4.7 Accounting

Licensee shall maintain (and shall cause each Sublicensee to maintain) records showing manufacture, importation, sale, use, and provision of a Licensed Product for [***] from the date of sale of that Licensed Product. Records will

include information in sufficient detail to enable University or its representative to determine the royalties owed under this Agreement. Upon request by University, Licensee shall deliver to University or its representative, copies of all documents and materials (including electronic records) reasonably relevant to Licensee's and Sublicensee's performance of this Agreement, including, without limitation, copies of all Sublicenses in accordance with the terms of Section 3.1 of the General Terms.

4.8 Audit

No more than [***] during the Term, and during the Licensee's normal business hours, Licensee shall allow (and shall cause each Sublicensee to allow) University or its designee to examine Licensee's records to verify payments made by Licensee under this Agreement. In connection with such audit, Licensee shall provide (and shall cause each Sublicensee to provide) commodious space at no cost to conduct the audit.

4.9 Paying for Audit

University will pay for any audit done under Section 4.8 of the General Terms. But if the audit reveals an underreporting of royalties due University of [***] or more for the period being audited, Licensee shall pay the audit costs.

5. GOVERNMENT RIGHTS AND REGULATIONS

5.1 Bayh-Dole Requirements

This Agreement is subject to Title 35, Sections 200-204 of the United States Code. Among other things, these provisions provide the United States Government with nonexclusive rights in the Licensed Patents. They also impose the obligation that any Licensed Products sold or produced in the United States be "manufactured substantially in the United States." Licensee shall ensure all obligations of these provisions are met.

5.2 Compliance with Laws

Licensee shall ensure that the manufacture, use, sale, or transfer of Licensed Products comply with all applicable laws and regulations.

5.3 Export Control

Licensee agrees to comply with U.S. export laws and regulations pertaining to the export of technical data, services and commodities, including the International Traffic in Arms Regulations (22 C.F.R., parts 120-130), the Export Administration Regulations (15 C.F.R., parts 730-744), the regulations administered by the Treasury Department's Office of Foreign Assets Control (31 C.F.R., parts 501-598) and the Anti-Boycott Regulations (15 C.F.R 760). Licensee shall obtain any necessary U.S. government license or other authorization required pursuant to the U.S. export control laws and regulations for the export or re-export of any commodity, service or technical data covered by this Agreement.

5.4 Cooperation with Governmental Requests

Licensee shall comply upon reasonable notice from University with all governmental requests relevant to the Licensed Intellectual Property directed to either University or Licensee and provide all information and assistance necessary to comply with the governmental requests.

5.5 Patent Marking

Licensee and each Sublicensee shall mark all Licensed Products in a manner consistent with their current patent marking practices for their own products provided appropriate notice is given by such marking in accordance with

35 USC 287 or other relevant statutes. Where marking is to be performed but the Licensed Product cannot be marked, the patent notice shall be placed on associated tags, labels, packaging, or accompanying documentation either electronic or paper as appropriate.

6. PATENT PROSECUTION AND MAINTENANCE

6.1 Patent Prosecution and Maintenance

The University, in consultation with the Licensee, shall control the preparation, filing, prosecution, and maintenance of the Licensed Intellectual Property. University will consult with Licensee in connection with the foregoing; however, if Licensee is unresponsive to University's requests for input, University may proceed in the exercise of its best judgment without prior consultation. In no event shall Licensee file a patent application with respect to the Licensed Intellectual Property without first consulting with the University. To facilitate consultation with Licensee, University will:

(a) keep Licensee reasonably informed as to the filing, prosecution, and maintenance of the Licensed Patents and Licensed Patent Applications;

(b) furnish to Licensee copies of material documents relevant to such filing, prosecution and maintenance; and

(c) allow Licensee a reasonable opportunity to comment on material documents related to the Licensed Patents or Patent Applications prior to filing such documents at a patent office.

6.2 Licensee Assistance and Contact

At University's request, Licensee shall provide all information and assistance to University in the filing and prosecution of all Licensed Patents. In furtherance of the foregoing, Licensee designates the person identified in Section 12 of the Business Terms to respond to University's request for consultation and cooperation on a pending matter within [***] or sooner as may be required under the circumstances. If Licensee's contact fails to respond in such time period, University, exercising its own judgment and discretion, may respond to the matter as it deems appropriate.

6.3 Patent-Related Expenses

Licensee shall pay on behalf of or reimburse University for Patent-Related Expenses in accordance with Section 7 of the Business Terms, unless otherwise provided in this Agreement.

7. COMMERCIALIZATION

7.1 Diligence

Licensee shall use its commercially reasonable efforts, consistent with sound and reasonable business practices and judgment, to commercialize the Licensed Intellectual Property and to manufacture and offer to sell and sell Licensed Products [***].

7.2 Performance Milestones

Licensee shall perform, or cause to happen or be performed, as the case may be, all the performance milestones described in Section 9 of the Business Terms.

7.3 Commercialization Reports

By [***] of each year, Licensee will submit a written annual report to University covering the preceding calendar year if applicable. Each report will describe Licensee's [***] Licensee will specifically describe how each Licensed Product is related to each Licensed Patent.

8. INFRINGEMENT

8.1 Notification to University

Licensee shall notify University if it believes a third party is infringing a Licensed Patent and provide University with all credible evidence that is has to support this belief. Subject to Section 8.2 of these General Terms, Licensee shall have the first right to initiate, control, defend and/or settle any proceedings involving the validity, enforceability or infringement of any Licensed Patent when in its sole judgment such action may be necessary, proper, and justified. If Licensee elects not to initiate, control, or defend any proceedings described above, Licensee shall promptly notify University, and University may defend or bring such action at its own expense, in its own name and entirely under its own direction and control.

8.2 Good Faith Negotiations with University Prior to Commencing Infringement Action

Prior to commencing any action to enforce a Licensed Patent, Licensee shall enter into good faith negotiations with University on the desirability of bringing suit, the parties to the action, the selection of counsel, and such other matters. University may not be named (nor is Licensee authorized to name University) as a party in any such action without its prior written consent. Unless otherwise agreed upon by the parties, and subject to Section 8.3 of the General Terms, the party initiating the enforcement shall bear any out-of-pocket expenses associated with the litigation (including but not limited to attorneys' fees, e-discovery costs, court costs).

8.3 Enforcement Litigation

Settlement of any Enforcement Litigation requires the written consent of the University. Further, any recovery in any Enforcement Litigation will be shared with University as follows:

(a) any recovery shall be first used to reimburse the party initiating the Enforcement Litigation for its actual fees, costs, and expenses incurred in the Enforcement Litigation;

(b) [***]

(c) [***].

8.4 Infringement by Licensee

If any suit, action or proceeding is brought or commenced against Licensee alleging the infringement of a patent or other intellectual property right owned by a Third Party by reason of the manufacture, use or sale of Licensed Products, Licensee shall give University prompt notice thereof. If the validity of a Licensed Patent is questioned in such suit, action or proceeding, Licensee shall have no right to make any settlement or compromise which affects the scope, validity, enforceability or otherwise of a Licensed Patent without University’s prior written approval.

9. UNIVERSITY NAME AND MARKS; LICENSEE NAME

9.1 No Use of University Name or Marks

No provision of this Agreement grants Licensee or Sublicensee any right or license to use the name, logo, or any marks owned by or associated with University or the names, or identities of any member of the faculty, staff, or student body of University. Licensee shall not use and shall not permit a Sublicensee to use any such logos, marks, names, or identities without University’s prior written approval. The foregoing notwithstanding, without the consent of University, Licensee may indicate that it is licensed by the University under the Licensed Intellectual Property and identify the inventors of the Licensed Patents or Licensed Patent Applications, their affiliation with the University, and their relationship to Licensee, and further, Licensee may comply with disclosure requirements of all applicable laws relating to its business, including, without limitation, United States and securities laws.

9.2 No use of Licensee Name

University shall not use the name of Licensee or its Affiliates or Sublicensees in any promotional material or other public announcement without the prior written consent of Licensee or its Affiliates or Sublicensees (as applicable).

10. TERMINATION

10.1 University's Right to Terminate for Breach

Subject to Section 10.2 of the General Terms, University may terminate this Agreement if Licensee:

(a) is delinquent on any report or payment;

(b) misses a milestone under Section 9 of the Business Terms, subject to the parties performing the obligations set forth in section 9 with respect to unanticipated studies or prerequisites required by the FDA;

(c) is in breach of any material provision of this Agreement; or

(d) provides any materially false report.

10.2 Licensee's Right to Remedy Breach

Termination under Section 10.1 of the General Terms takes effect (without any further action by University) [***] after receipt by Licensee of written notice by University of any default under Section 10.1 of the General Terms, unless within that [***] period Licensee remedies the default and notifies University of the same.

10.3 Licensee's Right to Terminate

Licensee may terminate this Agreement:

(a) if University is in default of any material provision of this Agreement and fails to remedy the default within [***] of Licensee's written notice; or

(b) for convenience ("Early Termination") by delivering to University a written notice of termination at least [***] prior to the date of termination and upon payment of the Early Termination Fee as described in Section 10.8 of the Business Terms, if applicable.

10.4 Effect of Termination.

Upon Termination:

(a) The grant of rights under Section 2.1 of the General Terms terminates. Licensee may, however, sell or dispose of Licensed Products manufactured prior to termination for [***] thereafter, provided that Licensee continue to pay royalties on the sale of Licensed Products; and

(b) Upon request, University may grant a license to any Sublicensees on financial terms substantially similar to such terms in Sublicense provided Sublicensee has performed when due all of its obligations under the Sublicense.

(c) Sublicenses granted by Licensee shall be assigned to University upon request and at University's discretion; provided that University's obligations under such Sublicense shall be consistent with and not exceed University's obligations to Licensee under this Agreement and provided that such Sublicensee agrees in a writing sent to University to assume all obligations of this Agreement for the benefit of University, including the obligations to make all payments and provide all reports due under this Agreement.

10.5 Sections of the Agreement Surviving Termination.

Surviving any termination or expiration are:

(a) Licensee's payment obligations for payments accrued prior to termination; and

(b) the provisions of Sections 4.7, 8, 9, 11,12, 13, 14.1, 14.3, 14.4, 14.8, 14.9, 14.10, 14.11, 14.12 and 14.13 of the General Terms, and any other provision that by its nature is intended to survive.

11. INDEMNIFICATION AND INSURANCE

11.1 Indemnification

Licensee shall indemnify, hold harmless, and defend all University Indemnitees against any Third Party claim of any kind arising out of or related to the exercise of any rights granted Licensee under this Agreement or Licensee's breach of any provision of this Agreement.

11.2 Insurance

Licensee warrants that it now maintains and will continue to maintain liability insurance coverage appropriate to the risk involved in marketing and selling Licensed Products subject to this Agreement and that the insurance coverage lists University of Minnesota as an additional insured. Upon University's request, Licensee shall present evidence to University that this coverage is being maintained.

12. DISCLAIMER OF WARRANTIES

12.1 Warranties

University warrants that to the best of its actual knowledge as of the date of execution of this Agreement it has the right to grant the licenses to the Licensed Intellectual Property contained in this Agreement.

12.2 Disclaimer of all Other Warranties

UNIVERSITY PROVIDES LICENSEE THE RIGHTS GRANTED IN THIS AGREEMENT AS IS AND WITH ALL FAULTS, IF ANY. UNIVERSITY MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED CONCERNING THE LICENSED INTELLECTUAL PROPERTY.

AMONG OTHER THINGS, UNIVERSITY EXPRESSLY DISCLAIMS ANY WARRANTIES CONCERNING AND MAKES NO REPRESENTATIONS:

(a) that each Licensed Patent Application will be allowed or granted or that a patent will issue from a Licensed Patent Application;

(b) concerning the validity, enforceability, interpretation of claims or scope of any Licensed Patent;

(c) that the exercise of the rights or licenses granted to Licensee or a Sublicensee under this Agreement will not infringe or violate a third party's intellectual property rights; or

(d) that the exploitation of the Licensed Patents or Licensed Intellectual Property will be successful.

13. LIMITATION ON TYPE AND AMOUNT DAMAGES

13.1 Limitation on Type of Damages

University is not liable for any special, consequential, lost profit, loss of business opportunity, expectation, punitive or other indirect damages in connection with any claim arising out of or related to this Agreement.

13.2 Limitation on Amount of Damages.

With the exception of the University's gross negligence or willful misconduct, or an overpayment made by Licensee to University, in no event shall University's liability to Licensee exceed the payments made to University by Licensee during the [***] prior to the event that gave rise to the claim.

14. MISCELLANEOUS

14.1 Choice of Law and Jurisdiction

The internal laws of the state of Minnesota, without giving effect to its conflict of laws principles, govern the validity, construction, and enforceability of this Agreement. A suit, claim, or other action to enforce the terms of this Agreement may be brought only in the state courts of Hennepin County, Minnesota. Licensee hereby submits to the jurisdiction of that court and waives any objections it may have to that court asserting jurisdiction over Licensee or its assets and property and to venue in that jurisdiction.

14.2 Amendment and Waiver

The Agreement may be amended from time to time only by a written instrument signed by the parties. No term or provision of this Agreement may be waived, and no breach excused unless such waiver or consent is in writing and signed by the party claimed to have waived or consented. No waiver of a breach is to be deemed a waiver of a different or subsequent breach.

14.3 Data Practices Act

The parties acknowledge that University is subject to the terms and provisions of the Minnesota Government Data Practices Act, Minnesota Statutes §13.01 et seq. (the "Act"), and that the Act requires, with certain exceptions, University to permit the public to inspect and copy any information that University collects, creates, receives, maintains, or disseminates, including the existence of and the terms of this Agreement.

14.4 Confidentiality

To the extent permitted by law, including as provided in the Act, University shall hold in confidence and disclose only to University employees, agents and contractors who need to know:

(a) the reports described in Sections 3.2, 4.4, and 7.3 of the General Terms;

(b) the records inspected in accordance with Sections 4.7 and 4.8 of the General Terms. No provision of this Agreement is to be construed to further prohibit, limit, or condition University's right to use and disclose any information in connection with enforcing this Agreement, in court or elsewhere.

14.5 Assignment

Except as provided in Section 14.6 of the General Terms or with University's prior written consent, Licensee shall not effect a Transfer of its interest under this Agreement. Any Transfer attempted to be made in violation of this section is void. Absent the consent of all the parties, an assignment or delegation will not release the assigning or delegating party from its obligations.

14.6 Change of Control

Licensee may assign this Agreement to an Affiliate or as part of a Change of Control upon prior and complete performance of the following conditions:

(a) Licensee must give University [***] prior written notice of the assignment, including the new assignee's contact information;

(b) the new assignee must agree in writing to University to be bound by this Agreement; and

(c) University must have received the full Transfer Fee if applicable.

Notwithstanding the foregoing in this Section 14.6, University hereby approves the Transfer of this Agreement to Licensee (i.e. Finch Therapeutics Holdings LLC) and hereby waives any Transfer Fee (solely in connection there with) otherwise payable hereunder.

14.7 Consent and Approvals

Except as otherwise expressly provided, in order to be effective, all consents or approvals required under this Agreement must be in writing.

14.8 Entire Agreement

The parties intend this Agreement (including all attachments, exhibits, and amendments hereto) to be the final and binding expression of their contract and agreement and the complete and exclusive statement of the terms thereof. The Agreement cancels, supersedes, and revokes all prior negotiations, representations and agreements among the parties, whether oral or written, relating to the subject matter of this Agreement. No representations or statements of any kind made by either party, which are not expressly stated herein, will be binding on such party.

14.9 Enforceability

If a court of competent jurisdiction adjudges a provision of this Agreement to be unenforceable, invalid, or void, such determination is not to be construed as impairing the enforceability of any of the remaining provisions hereof and such provisions will remain in full force and effect.

14.10 No Third-Party Beneficiaries

No provision of this Agreement, express or implied, is intended to confer upon any person other than the parties to this Agreement any rights, remedies, obligations, or liabilities hereunder. No Sublicensee may enforce or seek damages under this Agreement.

14.11 Relationship of Parties

In entering into, and performing their duties under this Agreement, the parties are acting as independent contractors and independent employers. No provision of this Agreement creates or is to be construed as creating a partnership, joint venture, or agency relationship between the parties. No party has the authority to act for or bind the other party in any respect.

14.12 Notices

In order to be effective, all notices, requests, and other communications that a party is required or elects to deliver must be in writing and must be delivered personally, or by facsimile or electronic mail (provided such delivery is confirmed), or by a recognized overnight courier service or by United States mail, first-class, certified or registered, postage prepaid, return receipt requested, to the other party at its address set forth below or to such other address as such party may designate by notice given under this Section:

If to University: University of Minnesota
Technology Commercialization
200 Oak Street, SE
Suite 280
Minneapolis, MN 55455
Fax: [***]
E-mail: [***]

For notices sent under Section 8, with a copy to:

University of Minnesota
Office of the General Counsel
Attn: [***]
360 McNamara Alumni Center
200 Oak Street S.E.
Minneapolis, MN 55455-2006
Facsimile No.: [***]
Email: [***]

If to Licensee: As indicated in Section 11 of the Business Terms.

14.13 Security Interest

In no event may Licensee grant, or permit any person to assert or perfect, a security interest in Licensee's rights under this Agreement.

14.14 Execution in Counterparts

This Agreement may be executed in counterparts and by facsimile or electronic transmission.

EXHIBIT A

Technical Information

[***]

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE FINCH THERAPEUTICS GROUP, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO FINCH THERAPEUTICS GROUP, INC. IF PUBLICLY DISCLOSED.

Exhibit 10.7

AMENDMENT #2 TO AMENDED AND RESTATED AGREEMENT

This Amendment to Amended and Restated Agreement (this "***Amendment***") is entered into as of November 12, 2021 (the "***Amendment #2 Effective Date***") by and between **Finch Therapeutics, Inc.**, a Delaware corporation having its principal office at 200 Inner Belt Road, 4th Floor, Somerville, Massachusetts 02143 ("***Finch***"), and **Takeda Development Center Americas, Inc.**, a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, having its principal office at 95 Hayden Avenue, Lexington, MA 02421 ("***Takeda***").

Background

Finch and Takeda are the parties to the Amended and Restated Agreement dated October 21, 2019, as amended by the Amendment to the Amended and Restated Agreement dated August 9, 2021 (the "***Agreement***").

As a result of the parties' discussion on the results obtained from the FIN-524 Crohn Feasibility Study performed by Finch under the Agreement, the parties have agreed for Finch to perform certain additional preliminary research activities with respect to combinations of some microbial isolates included in Optimal FIN-524 and one or more microbial isolates that are not included in Optimal FIN-524 and have been identified as relevant to Crohn's Disease by Finch ("***FIN-525 Preliminary Evaluation***") such that Takeda can evaluate the results and determine whether to initiate the full FIN-525 Development Program, and desire to memorialize such agreement in this Amendment.

NOW THEREFORE, in consideration of mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Finch and Takeda agree as follow:

1. Definitions. Unless otherwise specifically set forth herein, all capitalized terms in this Amendment, including the Background stated above, shall have the same meaning as set forth in the Agreement.

2. Amendments. The Agreement is hereby amended as follows:

(1) Performance of FIN-525 Preliminary Evaluation. Finch shall have responsibility for performance of the FIN-525 Preliminary Evaluation in accordance with the relevant Development Plan attached to this Amendment as **Exhibit A**. The Parties hereby confirm and agree that the FIN-525 Preliminary Evaluation shall constitute part of the FIN-525 Development Program; *provided*, for the purpose of Section 8.2(a-1), initiation of the FIN-525 Preliminary Evaluation shall not be construed as determination by Takeda of initiation of the full FIN-525 Development Program, *provided further* that Takeda shall use commercially reasonable efforts following receipt of all the

results of the FIN-525 Preliminary Evaluation to either make such determination or determine to not initiate the FIN-525 Development Program, and in either case to provide to Finch prompt written notice of Takeda's determination. In the event that such notice indicates Takeda's determination to not initiate the FIN-525 Development Program, upon Finch's receipt of the notice the FIN-525 Development Program shall be deemed terminated in accordance with Section 13 of the Agreement.

(2) Development Funding. Notwithstanding Section 4.4(a)-(d) of the Agreement, Finch will be responsible for all costs incurred by or on behalf of Finch in performing the FIN-525 Preliminary Evaluation; *provided*, subject to the payment schedule below, Takeda shall pay Finch a total of US$[***] in support of the FIN-525 Preliminary Evaluation, all as detailed in the Budget included in **Exhibit A** of this Amendment. Finch shall issue an invoice in accordance with the payment schedule below and Takeda shall pay such invoiced amount within [***] after the receipt of relevant invoice from Finch.
Payment Schedule:
[***]

(3) Milestone Event 1 for FIN-525. Milestone Event 1 for FIN-525 set forth in Section 8.2(a-1) is hereby deleted in its entirety and replaced with the following:
[***]

3. Agreements and Acknowledgement by the Parties.

(1) Amendment #2 Effective Date. This Amendment shall be effective as of the Amendment #2 Effective Date and shall apply with respect to any performance by Finch of the FIN-525 Preliminary Evaluation prior to the Amendment #2 Effective Date. This Amendment shall remain effective during the Term of the Agreement, unless terminated in accordance with the provisions of the Agreement.

(2) Reaffirmation. The parties hereby confirm all of the terms and covenants, and provisions of the Agreement, and except as provided or modified herein, the Agreement remains unmodified and in full force and effect.

(3) Governing Law. This Amendment shall be governed by and construed in accordance with laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different jurisdiction.

(4) Incorporation of Terms and Provision of Original Agreement. The terms and conditions of the Agreement are hereby incorporated by reference and shall be applicable to this Amendment and the matters addressed herein as if set forth herein in full.

(5) Entire Agreement. This Amendment, along with the Agreement, sets forth the complete, final, and exclusive agreement, and all the covenants, promises, agreements, warranties, representations, conditions, and understandings between the parties with respect to the subject matter hereof, and

supersedes, as of the Amendment #2 Effective Date, all prior and contemporaneous agreements and understandings between the parties with respect to the subject matter hereof.

(6) Further Assistance. Each party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments, and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other party may reasonably request in connection with this Amendment or to carry out more effectively the provisions and purposes hereof.

(7) Severability. If any one or more of the provisions of this Amendment is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Amendment and shall not serve to invalidate any remaining provisions hereof, and the invalid or unenforceable provision shall be replaced with the most nearly coextensive valid and enforceable provision that is acceptable to the court of competent jurisdiction, or otherwise, the parties shall engage in good-faith efforts to replace such invalid or unenforceable provision with a valid and enforceable provision as closely as possible commensurate with the objectives completed by the parties when entering this Amendment.

(8) Counterparts. This Amendment may be executed simultaneously in two counterparts, by facsimile or PDF copy, each of which shall be deemed an original, but all of which together shall constitute on and the same instrument.

INWITNESS WHEREOF, the parties have caused this Amendment to be executed on their behalf by their duly authorized representatives as of the Amendment #2 Effective Date.

FINCH THERAPEUTICS, INC.

By: /s/ Mark Smith

Name: Mark Smith

Title: Chief Executive Officer

TAKEDA DEVELOPMENT CENTER AMERICAS, INC.

By: /s/ Chinweike Ukomadu

Print name: Chinweike Ukomadu

Title: Head of Gastroenterology Therapeutic Area Unit

Exhibit A

[***]
4

Exhibit 10.17

Release Agreement

I, Zain Kassam, understand and agree completely to the terms set forth in this Release Agreement (the "Release") and in the Amended and Restated Executive Employment Agreement (the "Employment Agreement") dated March 12, 2021, by and between Finch Therapeutics Group, Inc. ("Company") and me, as a result of my voluntary resignation without Good Reason effective on November 5, 2021 (the "Termination Date"). I understand that I am not entitled to any payments set forth in Section 1 below if I do not sign this Release and return it to Company pursuant to the terms set forth herein. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in the Employment Agreement.

Section 1.**Payments Upon Termination**. On the Termination Date, I shall be paid an amount equal to (i) Forty-Three Thousand Six Hundred Dollars ($43,600), less lawful deductions (which is an amount equal to thirty percent (30%) the pro-rated amount of my Target Bonus for the period of time worked in 2021 through the Termination Date), plus (ii) Two Hundred and Eighteen Thousand Dollars ($218,000.00), less lawful deductions (which is an amount equal to the sum of six (6) times my monthly base salary as of the Termination Date).

Section 2.**General Release and Knowing Waiver of Employment-Related Claims**. For and in consideration of the payment described in Section 1, I, on my own behalf and on behalf of my successors and assigns (collectively referred to as "Releasor"), hereby release and forever discharge the Company, its affiliates, and their respective stockholders, members, predecessors, successors, officers, directors, agents, representatives, employees, consultants and advisors (collectively referred to as "Releasee"), from any and all claims, counterclaims, demands, debts, actions, causes of action, suits, expenses, costs, attorneys' fees, damages, indemnities, obligations and/or liabilities of any nature whatsoever (collectively, "Claims"), whether known or unknown, which Releasor ever had, now has or hereafter can, shall or may have against Releasee, for, upon or by reason of any matter, cause or thing whatsoever from the beginning of the time to the day of the date of this Release, including, but not limited to, the following:

(a)all such Claims and demands directly or indirectly arising out of or in any way connected with my employment with Company, including but not limited to providing services to the Company, or the termination of that employment and provision of services;

(b)all such Claims and demands related to salary, bonuses, commissions, stock, stock options, units, profits interests or any other ownership interests in the Company, vacation pay, fringe benefits, expense reimbursements, separation pay and/or any other form of compensation or wages to which I may be entitled whether under common law, the Massachusetts Payment of Wages Act, (M,G.L. c. 149, sections 148, 148A, 148B, 148C, 149, 150, 150A-150C, 151, 152, 152A, et seq.), or otherwise;

(c)any Claims arising under any federal, state or local law, statute or ordinance, including, without limitation, Title VII of the Civil Rights Act of 1964, , the Americans With Disabilities Act, the Civil Rights Act of 1991, the Fair Labor Standards Act, the Equal Pay Act, the Employee Retirement Income Security Act of 1974, the Family and Medical Leave Act of 1993, and the Consolidated Omnibus Budget Reconciliation Act of 1985, the anti-retaliation provisions of any federal or state statute, including state workers' compensation statutes, and any other applicable state or local statutes, including the Massachusetts Fair Employment Practices Act (M.G.L. c. 151B), the Massachusetts Equal Rights Act, the Massachusetts Equal Pay Act, the Massachusetts Privacy Statute, the Massachusetts Sick Leave Law, the Massachusetts Civil Rights Act, all as amended, the Massachusetts Payment of Wages Act (M.G.L. c. 149 sections 148 and 150), the Massachusetts Overtime regulations (M.G.L. c. 151 sections 1A and 1B), the Massachusetts Meal Break regulations (M.G.L. c. 149 sections 100 and 101); the Massachusetts Parental Leave Law (M.G.L. c. 149, section 105D); the Massachusetts Family and Medical Leave Law (M.G.L. c. 175M);

(d)any Claims for breach of contract, express or implied, including any claim for breach of any implied covenant of good faith and fair dealing; and

(e)any Claims of constructive discharge, discrimination, harassment, retaliation, fraud, defamation, intentional tort, emotional distress and negligence; and

Nothing in this Release shall prevent me from enforcing my rights, if any (i) to my non-forfeitable accrued benefits (within the meaning of Sections 203 and 204 of ERISA) under any tax-qualified retirement plan maintained by the Company, (ii) to receive continuation coverage pursuant to COBRA, (iii) to indemnification conferred upon me as an officer of the Company pursuant to the Company's governing documents, under any applicable insurance policies or in accordance with applicable law or (iv) that cannot be waived under applicable law. Further, nothing in this Release affects my rights to provide information to, participate in an investigation by or file an administrative charge or complaint with any Governmental Authorities (defined below), including, but not limited to, the Equal Employment Opportunity Commission or similar administrative agency. However, I agree not to accept any monetary relief or recovery from any charge or complaint filed against any Releasee with any such administrative agency except where authorized by applicable law.

Also, Releasor does not release any Claims against Releasee that may arise after this Release has become effective.

Section 3.**Representation by Counsel and Review Period**. I have been advised to consult independent legal counsel before signing this Release, and I hereby represent that I have executed this Release after having the opportunity to consult independent counsel and after considering the terms of this Release. I further represent and warrant that I have read this Release carefully, that I have discussed it or have had reasonable opportunity to discuss it with my counsel, that I fully understand its terms, and that I am signing it voluntarily and of my own free will.

Section 4.**Consideration for Release**. I acknowledge that the consideration for this Release is consideration to which I would not otherwise be entitled and is in lieu of any rights or claims that I may have with respect to any other remuneration from the Company.

Section 5.**Representation Concerning Filing of Legal Actions**. I represent that, as of the date of this Release, I have not filed any lawsuits, charges, complaints, petitions, claims or other accusatory pleadings against Company or any of the other Releasees in any court or with any governmental agency.

Section 6.**Continuing Obligations Concerning Confidential Information and Company Property.** I acknowledge and agree that I remain subject to the restrictive covenants contained in Section 3 of the Employment Agreement and the covenants related to Confidentiality & Proprietary Information contained in Section 4 of the Employment Agreement, each of which survives the termination of my employment. I further acknowledge that I am obligated to return to the Company by November [8], 2021, all Company documents, originals and copies, whether in hard or electronic form, and all Company property, including without limitation keys, computers, computer disks, pagers, phones and credit cards.

Section 7.**Non-disparagement**. Subject to the provisions of Section 8, I will not make any statements, whether verbally or in writing (including in electronic communications) that are professionally or personally disparaging of, or adverse to the interests of, the Company or its officers, directors, managers or employees. This includes, but is not limited to, any statements that disparage the products, services, finances, financial condition, capability or any other aspect of the business of the Company. I further agree not to engage in any conduct which is intended to harm, professionally or personally, the reputation of the Company or its officers, directors, managers or employees. For its part, the Company shall direct those of its executives that know of this Release not to make any statements, whether verbally or in writing (including in electronic communications) that are professionally or personally disparaging of you, or adverse to your interests.

Section 8.**Disclosure Exceptions**. Nothing in this Release shall prohibit the Releasor from lawfully (A) initiating communications directly with, cooperating with, providing information to, causing information to be provided to, or otherwise assisting in an investigation by any governmental or regulatory agency, entity, or official(s) (collectively, "Governmental Authorities") regarding a possible violation of any law; (B) responding to any inquiry or legal process directed to the Releasor individually (and not directed to the Company and/or its subsidiaries) from any such Governmental Authorities; (C) testifying, participating or otherwise assisting in an action or proceeding by any such

Governmental Authorities relating to a possible violation of law; or (D) making any other disclosures that are protected under the whistleblower provisions of any applicable law. Additionally, pursuant to the federal Defend Trade Secrets Act of 2016, the Releasor shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made to the Releasor's attorney in relation to a lawsuit for retaliation against the Releasor for reporting a suspected violation of law; or (c) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Nor does this Agreement require the Releasor to obtain prior authorization from the Company before engaging in any conduct described in this Section 8, or to notify the Company that he has engaged in any such conduct.

Section 9.**Tax Provision**. All payments and benefits provided under the Employment Agreement are intended to be exempt from, or to comply with, the requirements of section 409A of the Code and this Release shall be interpreted and administered in accordance with these intentions. The Severance Benefits and rights to COBRA Reimbursement under the Employment Agreement are intended to be exempt from section 409A of the Code under the "short-term deferral" exception of Treas. Reg. Section 1.409A-1(b)(4), to the maximum extent applicable, and then under the "separation pay" exception of Treas. Reg. Section 1.409A-1(b)(9)(iii), to the maximum extent applicable. All payments that are subject to Section 409A that are to be made upon a termination of the Releasee's employment may only be made upon the Releasee's "separation from service," as defined in Treas. Reg. Section 1.409A-1(h), from the Company. For purposes of section 409A of the Code, the right to a series of installment payments under this Agreement shall be treated as a right to a series of separate payments and each such installment shall be treated as a separate payment. With respect to any payments that are subject to section 409A of the Code, in no event shall the Releasee, directly or indirectly, designate the calendar year of a payment. Any reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of Treas. Reg. Section 1.409A- 3(i)(1)(iv). Notwithstanding the foregoing, the Releasee acknowledges that he has been advised to seek the advice of a tax advisor with respect to the tax consequences of all payments pursuant to the Employment Agreement, including any adverse tax consequence under section 409A and applicable State tax law, and neither the Company nor any of its members, officers, employees, agents or affiliates shall be responsible for any such adverse tax consequences or guarantees any particular tax consequences to the Releasee with respect to payments and benefits under the Employment Agreement.

Section 10.**Amendment of Release**. This Release may not be amended or modified except by a writing signed by Joseph Vittiglio, SVP and General Counsel, on behalf of Company and by me.

Section 11.**Governing Law**. This Release shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without regard to principles of conflicts of laws thereunder.

Section 12.**Neutral Interpretation**. This Release shall be interpreted in a neutral manner, and not more strongly for or against any party based upon the source of the draftsmanship of the Release.

Section 13.**Headings**. The various headings in this Release are inserted for convenience only and are not part of the Release.

Section 14.**No Admission of Liability.** Releasee agrees that this Release, and performance of the acts required by it, does not constitute an admission of liability, culpability, negligence or wrongdoing on the part of anyone, and will not be construed for any purpose as an admission of liability, culpability, negligence or wrongdoing by any party and/or by any party's current, former or future parents, subsidiaries, related entities, predecessors, successors, officers, directors, stockholders, agents, employees and assigns

Section 15.**Waiver of Notice Period.** The Company hereby waives the thirty (30)-day period for advance notice of the Executive's termination of employment required pursuant to Section 6 of the Employment Agreement.

Dated: This 4th day of November, 2021.

/s/ Zain Kassam
Name: Zain Kassam

` /s/ Mark Smith
Finch Therapeutics Group, Inc.
By: Mark Smith
Title: CEO

Exhibit 10.19

EXECUTIVE EMPLOYMENT AGREEMENT

This AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT, dated as of September 8, 2021 (this "Agreement"), is made by and between Finch Therapeutics Group, Inc., a Delaware corporation ("FTG", together with all subsidiaries and affiliates hereinafter referred to as the "Company"), and Marc Blaustein (the "Executive").

WHEREAS, the Company desires to employ the Executive as its Chief Operating Officer;

WHEREAS, the Executive desires to be employed by the Company as Chief Operating Officer and to perform his duties to the Company on the terms and conditions hereinafter set forth; and

WHEREAS, the Company and the Executive wish to enter into this Agreement to set forth the terms and conditions of the Executive's employment with the Company effective as of [the date hereof] (the "Effective Date").

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Company and the Executive agree as follows:

1. Employment.

1.1 **Term of Employment**. The Company agrees to employ Executive on an at-will basis, and Executive agrees to accept such employment and serve the Company, in accordance with the terms and conditions set forth herein. The Executive's term of employment under this Agreement (the "Term") shall be for the period commencing on the date of this Agreement (the "Start Date") and ending when the Executive's employment is terminated pursuant to Section 6 hereof.

1.2 **Position, Duties, and Responsibilities**. During the Term, Executive shall be employed and serve as Chief Operating Officer of the Company (together with such other position or positions consistent with Executive's title as the Company shall specify from time to time) and shall have such duties and responsibilities commensurate therewith, and such other duties as may be assigned and/or prescribed from time to time by the Chief Executive Officer (the "CEO") and/or the Board of Directors of FTG (the "Board"). Executive shall report to the CEO.

1.3 **Performance**. Executive shall devote his full business time, attention, skill, and best efforts to the performance of his duties under this Agreement and shall not engage in any other paid work during the Term that (a) conflicts with the interests of the Company, (b) interferes with the proper and efficient performance of Executive's duties for the Company, or (c) interferes with Executive's exercise of judgment in the Company's best interests. Executive may not serve on any for-profit board of directors or board of any educational, social, religious or civic organizations without the prior written approval of the Board. Executive affirms that he has no contractual commitments or other legal obligations that would prohibit him from fully performing his duties for the Company.

2. Compensation. As full compensation for all services to be rendered by the Executive to the Company in all capacities, the Executive shall receive the following compensation and benefits:

2.1 **Salary**. The Executive shall be entitled to receive an annual base salary of $400,000 USD (the "Base Salary"). The Base Salary, which will be reviewed annually, will be paid periodically in accordance with the Company's normal payroll practices and be subject to applicable withholdings.

2.2 **Bonus**. Executive will be eligible to receive an annual bonus of forty percent (40%) of Executive's Base Salary, less applicable withholdings (the "Target Bonus"). The amount of any bonus shall be determined by the Board or the Compensation Committee of the Board in their sole discretion. Except as provided in Section 7, Executive must be employed by Company at the time of any such bonus payment in order to be eligible for any such payment. Except as set forth in Section 7.3 below, the Target Bonus is not earned until paid and no pro-rated amount will be paid if Executive's employment terminates for any reason prior to the payment date.

2.3 **Equity**. Subject to approval by the Board, Executive shall be granted an option to purchase 150,000 shares of the Company's common stock (the "Option"), with an exercise price equal to the fair market value of a share of common stock as determined by the closing price of a share of the Company's common stock as reported on the Nasdaq Global Select Market at the close of business on the date of grant, pursuant to the terms of the Company's 2021 Equity Incentive Plan (the "Plan") and individual stock option grant notice and agreements as applicable. The Option will be subject to the terms and conditions of the Plan and the Executive's grant agreement and will vest 25% on the one-year anniversary of the date of grant, and thereafter over the ensuing 3 years in a series of thirty-six (36) successive equal monthly installments, subject to Executive's continuous service as of each such date. The Option shall be an incentive stock option under Section 422 of the Internal Revenue Code of 1986, as amended to the maximum extent permissible.

2.4 **Benefits**. Executive is entitled, during the Term, to participate in all employee benefits plans customarily granted to other executives of the Company, including medical, dental and disability insurance, life insurance and a 401(k) plan, subject to plan terms and applicable Company policies. Further, Executive shall be entitled to paid vacation in accordance with then-applicable Company policy for full- time, exempt employees, or any subsequent policy approved by the Board. The Company reserves the right to cancel or change the benefit plans or programs it offers to its employees at any time.

2.5 **Indemnification**. The Company agrees to indemnify Executive to the maximum extent allowable under the terms and conditions of its certificate of incorporation, bylaws, under applicable law, and under the indemnification agreement signed herewith. Further, Executive will be covered by the Company's directors' and officers' liability insurance coverage as in effect from time to time and that certain Indemnification Agreement by and between the Company and the Executive dated the date hereof.

3. Restrictive Covenants.

3.1 **Acknowledgement**. Executive understands that the nature of Executive's position gives him access to and knowledge of confidential, proprietary and/or trade secret, and customer information and places him in a position of trust and confidence with the Company. Executive understands and acknowledges that the intellectual services he provides to the Company are unique, special, or extraordinary. Executive further understands and acknowledges that the Company's ability to reserve these for the exclusive knowledge and use of the Company is of great competitive importance and commercial value to the Company, and that improper use or disclosure by Executive is likely to result in unfair or unlawful competitive activity. Executive represents and warrants that he is not in breach of any agreement requiring him to preserve the confidentiality of any information, client lists, trade secrets or other

confidential information or any agreement not to compete or interfere with any prior employer, and that neither the execution of this Agreement nor the performance by Executive of his obligations hereunder will conflict with, result in a breach of, or constitute a default under, any agreement to which he is a party or to which he may be subject. Executive further represents that he has not taken and will not take any confidential or proprietary information from any prior employer or other person and will not use or disclose any such information in performing his obligations hereunder but instead will rely on his generalized knowledge and skill in performing his services hereunder.

3.2 **Non-Competition**. Because of the Company's legitimate business interest as described herein, and the good and valuable consideration offered to Executive in this Agreement (including the mutually agreed-to consideration in accordance with Sections 7.2, 7.3 and 7.4), during the period of Executive's employment with Company and for a period of twelve (12) months from termination of Executive's employment for any reason (other than as set forth in Section 6.4) (the "Non-Compete Period"), without the prior written consent of the Company, Executive shall not, in any capacity (whether as an employee, director, officer, partner, interest holder, investor, consultant, advisor or otherwise, except as the holder of not more than 1% of the outstanding stock of a publicly-held company), directly or indirectly engage in any activity on behalf of any other individual or enterprise (other than the Company) that is pursuing, or is planning to pursue, activities related to microbiome therapies and diagnostics ("Competitive Activity") anywhere in the United States, Canada, Europe or any other country in which the Company is either doing business or actively planning to do business as of the date of Executive's termination of employment or two years prior. For the avoidance of doubt, engagement in any respect with Seres Therapeutics, Rebiotix, Symbiotic Health, Assembly Biosciences, Monarch Laboratories, Vedanta, ViThera, Second Genome, Synthetic Biologics, Intrexon/Actogenix, Evelo Thereapeutics, Enterome, Axial Biotherapeutics, Kallyope and/or Kaleido (so long as any of those companies pursue activities related to microbiome therapies), constitutes Competitive Activity. The Company may waive the provisions of this Section 3.2 by providing written notice to Executive upon termination of Executive's employment.

3.3 **Non-Solicitation of Employees**. During the Non-Compete Period, Executive will not, and will not attempt to, directly or indirectly hire, interview, solicit, recruit, induce, procure, encourage, work with, retain or engage for employment, consulting services or otherwise any present or former employee of the Company unless such person shall have voluntarily ceased to be employed by the Company or any subsidiary or affiliate for a period of at least six (6) months.

3.4 **Non-Disparagement**. Subject to Section 5, below, Executive agrees that he shall not at any time, during or after his employment with Company, directly or indirectly, (a) make any public comments about (including, without limitation, by way of news interviews or the expression of personal views, opinions or judgments to the media or any other entity or person outside the Company) the Company (other than factual information or other publicly available information about the Company) without prior consultation with the Board, or any disparaging comments about any constituent entity of the Company or any of their respective officers, directors, members, partners, investors, consultants, advisors or other employees (collectively, the "Company Group") or (b) disparage, criticize, ridicule or make any negative comments about the Company Group (or any constituent thereof) to any person or entity within the Company Group or any other individual or entity with whom the Company Group has or may have a business or personal relationship, including any current, former or prospective vendor, vendee, investor or employee. This Section 3.4 does not, in any way, restrict or impede Executive from exercising protected rights to the extent that such rights cannot be waived by agreement or from complying with any applicable law or regulation or a valid order of a court of competent jurisdiction or an authorized government agency,

provided that such compliance does not exceed that required by the law, regulation or order. Executive shall promptly provide written notice of any such order to the Board.

3.5 **Injunctive Relief**. Executive recognizes that irreparable injury will result to the Company in the event of any breach of any of the terms or provisions of this Section 3. Therefore, Executive agrees that in the event of such a breach, FTG and other members of the Company Group will be entitled to seek, in addition to other remedies and damages available, an injunction to restrain any such breach and all persons acting for and/or in concert with Executive. The restricted periods described in Section 3 will not expire, and will be tolled, during any period in which Executive is in violation of Section 3.2 and/or Section 3.3, as applicable, and the restriction will automatically be extended by the time period that Executive is in violation of such restriction.

4. Confidential & Proprietary Information.

4.1 **Confidentiality**. Executive understands that all confidential and/or proprietary information concerning the Company, whether written or oral, which is or has been communicated to him by any person working for or on behalf of the Company or an entity affiliated with the Company, and all confidential and/or proprietary information that he generates as a result of services performed for the Company, including but not limited to trade secrets, regulatory strategy, intellectual property strategy, research and clinical strategies, technologies, procedures, models, testing systems, research, assays, compounds, molecules, organisms, gene sequences, cell lines, complement inhibitors and other re-agents (including the composition thereof), formulas, methods, processes, test and experimental data and results, specifications, invention disclosures, patent claims, laboratory notebooks, schematics and drawings (collectively referred to as "Confidential Information"), is proprietary and confidential to the Company. Subject to Section 5, Executive agrees that he shall not at any time (whether during or after the term of his employment with Company or until such time as such Confidential Information has become public knowledge), without the prior written consent of the Company, directly or indirectly, use or disclose any Confidential Information except as is necessary to fulfill his obligations hereunder or as is required to be disclosed by law, court order, or similar compulsion (provided that he shall promptly give the Company written notice of a court order or similar compulsion that would require the disclosure of Confidential Information in order to permit the Company to seek an appropriate protective order). Executive's obligations with respect to Confidential Information will cease when the Confidential Information: (i) becomes part of the public domain through no wrongful act of Executive, or (ii) is approved for release by prior written authorization of the Company. Executive agrees to destroy or return (at Company's request) any and all Confidential Information to the Company upon any termination of this Agreement.

4.2 **Intellectual Property; Works Made for Hire**. The Company shall own all right, title and interest (including without limitation patent rights and copyrights) to all tangible and intangible property, products, developments, discoveries and inventions ("Inventions") conceived, created or produced directly or indirectly by or through Executive during the term of Executive's employment with the Company, which relate to the actual or anticipated business, research and development of the Company, including, but not limited to, all documents, reports, and electronic or written materials, and all computer software and biological materials, and all related patent, know-how and other intellectual property rights, including, without limitation, all technical information, records, data, reports, tests or trial results and other results, and tangible manifestations and embodiments of work ("Work"), and Executive shall provide the Company with the originals and/or all copies of any such Inventions upon request of the Company. Executive hereby assigns to the Company all right, title and interest in any Invention or discovery, whether in finished or

incomplete form, made during the term of his employment with the Company, and in any patent application, related documents and any patent relating to such invention or discovery. To the extent that any copyrighted work produced by the Executive hereunder is not deemed a "work made for hire" for purposes of the copyright laws of the United States, Executive hereby assigns to Company all right, title and interest in the copyright of such work, including without limitation the right to reproduce, distribute, sublicense, perform and display the work and to create and use derivative works therefrom in any medium throughout the world. The term "derivative works" as used in this Agreement has the same meaning as used in the Copyright Act of the United States. Executive shall complete and execute such assignments, certificates or other instruments as the Company may from time to time deem necessary or desirable to evidence, establish, maintain, perfect, protect, enforce or defend its or any of its affiliates' right, title and interest in or to any of the foregoing. Executive shall retain no rights in or to any work product produced hereunder.

5. **Disclosure Exceptions**. Nothing in this Agreement shall prohibit or restrict Executive from lawfully (A) initiating communications directly with, cooperating with, providing information to, causing information to be provided to, or otherwise assisting in an investigation by any governmental or regulatory agency, entity, or official(s) (collectively, "Governmental Authorities") regarding a possible violation of any law; (B) responding to any inquiry or legal process directed to Executive individually (and not directed to the Company and/or its subsidiaries) from any such Governmental Authorities; (C) testifying, participating or otherwise assisting in an action or proceeding by any such Governmental Authorities relating to a possible violation of law; or (D) making any other disclosures that are protected under the whistleblower provisions of any applicable law. Additionally, pursuant to the federal Defend Trade Secrets Act of 2016, Executive shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made to Executive's attorney in relation to a lawsuit for retaliation against Executive for reporting a suspected violation of law; or (c) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Nor does this Agreement require Executive to obtain prior authorization from the Company before engaging in any conduct described in this Paragraph, or to notify the Company that he has engaged in any such conduct.

6. **Termination of Employment**. Executive is an employee-at-will, such that the Term and Executive's employment hereunder may be terminated by either the Company or Executive at any time and for any reason; provided that, unless otherwise provided herein, either party shall be required to give the other party at least thirty (30) calendar days advance written notice of any termination of Executive's employment; provided, however, that the Company may cease accepting services from the Executive or otherwise disallow the Executive's access to Company facilities, computer systems, or personnel during the thirty days' notice period. Upon termination of Executive's employment during the Term, Executive shall be entitled to the compensation and benefits further described in Section 7 below and shall have no further rights to any compensation or any other benefits from the Company or any of its affiliates. Should the Company elect to forego the aforementioned notice provision, it shall remit to Executive payment in lieu of notice equal to the salary he would have received during the notice period.

6.1 **Termination upon Death**. The Term shall terminate as of the date of Executive's

death.

6.2 **Termination upon Disability**. If Executive suffers from a Disability during the Term, the Company may terminate the Term by written notice to Executive, in which event the Term shall terminate ten (10) days after the date upon which the Company has given written notice to Executive of its determination to terminate the Executive's employment under this Agreement.

6.3 **Termination by the Company for Cause**. The Company may immediately terminate Executive for Cause (as defined in Section 8.2 below).

6.4 **Termination by the Company without Cause**. The Company may terminate the Term at any time, without Cause.

6.5 **Termination by Executive without Good Reason**. Executive may terminate the Term at any time, without Good Reason (as defined in Section 8.3 hereof).

6.6 **Termination by Executive for Good Reason**. Executive may terminate the Term for Good Reason (such termination to comply with the notice, cure and termination provisions of the definition of Good Reason in Section 8.3 hereof) upon thirty (30) days' written notice from Executive to the Company and the Board.

7. Severance Payments.

7.1 **Accrued Obligations**. Upon Executive's employment termination, for any reason, the Company shall pay to Executive in a lump sum, within ten (10) business days following the termination date of his employment (or such earlier date as is required under applicable law), (i) all unpaid salary accrued prior to the termination date of his employment, (ii) accrued but unused vacation through the termination date of his employment if available in accordance with then-applicable Company policy for full-time, exempt employees, and (iii) any unreimbursed business expenses for which Executive is entitled to be reimbursed by the Company pursuant to the Company's then-existing reimbursement policy.

7.2 **Termination by the Company without Cause or by Executive for Good Reason Not in Connection with a Change in Control**. If the Company terminates Executive's employment with the Company for a reason other than Cause, death or Disability, or Executive terminates Executive's employment with the Company for Good Reason at any time other than within the 12-month period following a Change in Control (as defined in the Plan), the Company shall:

(a) **Cash Payment**. Pay to Executive an aggregate amount (paid in nine (9) monthly installments in accordance with the Company's regular payroll practices), following the effective date of a Release (as defined in Section 8.1 below) and commencing on the payroll date that next follows the 65th day after the termination date, equal to the sum of nine (9) times his monthly base salary (at the monthly base salary rate in effect for Executive immediately prior to the termination of his employment). On the 65th day following Executive's termination date, the Company will pay Executive in a lump sum the Severance that Executive would have received on or prior to such date under the standard payroll schedule but for the delay while waiting for the 65th day in compliance with Code Section 409A, with the balance of the Severance being paid as originally scheduled; and

(b) **Benefits**. Provide Executive and his dependents with the same life, accident, health and dental insurance benefits, if any, that Executive was receiving immediately prior to the termination of employment until the earlier of: (i) the date which is twelve (12) months following the date of Executive's termination; or (ii) the date Executive commences subsequent employment (such period, the "Pre-Change

Continuation Period"); provided, that if the Executive's continued participation is not possible under the terms of any one or more of those insurance plans or results in adverse taxes to the Company or Executive, and if Executive was participating in the Company's group health plan immediately prior to the date of termination and timely elects COBRA health continuation, then the Company shall pay to Executive a monthly payment in a gross amount equal to the COBRA premium for the earlier of twelve (12) months following Executive's termination or (B) until Executive becomes eligible for coverage under another employer's group coverage ("Benefits Continuation Period"), and Executive agrees to notify the Company promptly and in writing should that eligibility occur. Subject to Executive's timely presentment of receipts, the reimbursements will commence within sixty-five (65) days following Executive's termination and will be made on a monthly basis for the duration of the Benefits Continuation Period. If such payments would violate any applicable law, then the Company shall instead pay Executive taxable monthly payments of equal value on the same schedule, which amounts may be used for such purpose as Executive may determine; and

(c) **Bonus**. Pay to Executive any unpaid Target Bonus that is earned and payable and approved by the Board, payable when bonuses are paid to similarly situated executives and no later than March 15 of the year following the performance year.

7.3 **Termination by the Company without Cause or by Executive for Good Reason in Connection with a Change in Control**. If the Company terminates Executive's employment with the Company for a reason other than Cause, death or Disability, or Executive terminates Executive's employment with the Company for Good Reason during the 12-month period following a Change in Control, the Company shall, in lieu of the benefits set forth in Section 7.2 above:

(a) **Cash Payment**. Pay to the Executive an aggregate amount (paid in twelve (12) monthly installments in accordance with the Company's regular payroll practices), following the effective date of a Release (as defined in Section 8.1 below) and commencing on the payroll date that next follows the 65th day after the termination date, equal to the sum of twelve (12) times his monthly base salary (at the monthly base salary rate in effect for Executive immediately prior to the termination of his employment). On the 65th day following Executive's termination date, the Company will pay Executive in a lump sum the Severance that Executive would have received on or prior to such date under the standard payroll schedule but for the delay while waiting for the 65th day in compliance with Code Section 409A, with the balance of the Severance being paid as originally scheduled; and

(b) **Benefits**. Provide Executive and his dependents with the same life, accident, health and dental insurance benefits, if any, that Executive was receiving immediately prior to the termination of employment until the earlier of: (i) the date which is twelve (12) months following the date of Executive's termination; or (ii) the date Executive commences subsequent employment (such period, the "Change in Control Pre-Change Continuation Period"); provided, that if Executive's continued participation is not possible under the terms of any one or more of those insurance plans or results in adverse taxes to the Company or Executive, and if Executive was participating in the Company's group health plan immediately prior to the date of termination and timely elects COBRA health continuation, then the Company shall pay to Executive a monthly payment in a gross amount equal to the COBRA premium for the earlier of twelve
(12) months following Executive's termination or (B) until Executive becomes eligible for coverage under another employer's group coverage ("Change in Control Benefits Continuation Period"), and Executive agrees to notify the Company promptly and in writing should that eligibility occur. Subject to Executive's timely presentment of receipts, the reimbursements will commence within sixty-five (65) days following Executive's termination and will be made on a monthly basis for the duration of the Change in Control Benefits Continuation Period. If such payments would violate any applicable law, then the Company shall

instead pay Executive taxable monthly payments of equal value on the same schedule, which amounts may be used for such purpose as Executive may determine; and

(c) **Bonus**. Pay to Executive any unpaid Target Bonus that is earned and payable and approved by the Board, payable when bonuses are paid to similarly situated executives and no later than March 15 of the year following the performance year.

(d) **Bonus Severance**. Pay to Executive an amount equal to Executive's pro rata Target Bonus for the calendar year in which Executive's termination occurs, payable subject to standard federal and state payroll withholding requirements on the Company's first regularly scheduled payroll date following the effective date of a Release that next follows the 65th day after the termination date; and

(e) **Equity Awards**. Any equity awards with respect to Company stock then held by Executive which vest based on continued service shall become fully vested and exercisable as of the date of such termination. Any equity awards that vest based upon the achievement of performance goals shall be subject to the terms of such awards.

7.4 **Termination for Cause**. In the event Executive's employment with the Company is terminated by the Company for Cause, or Executive terminates his employment with the Company for any reason other than Good Reason (including his death or Disability), Executive shall not be entitled to the severance benefits or other considerations described herein by virtue of this Agreement; provided that, if the Company does not waive the provisions of Section 3.2 in connection with such termination, the Company will pay Executive an amount equal to the sum of six (6) times his monthly base salary (at the monthly base salary rate in effect for Executive immediately prior to the termination of his employment), except to the extent such termination arises from Executive's breach of his fiduciary duty or theft of Company property (whether physical or electronic). Such amount shall be paid in monthly installments in accordance with the Company's regular payroll practices following the effective date of the termination.

8. General.

8.1 **Release**. Notwithstanding any other provision of this Agreement to the contrary, benefits, including, but not limited to severance payments under Section 7 hereof, shall be payable under this paragraph only if Executive enters into a final and binding agreement in favor of the Company, its affiliates and their respective officers and directors in a form provided by the Company, substantially in the form attached hereto as Exhibit A (the "Release"), which has not been revoked within sixty-five (65) days of his termination of employment whereby Executive releases the Company and its subsidiaries (and those affiliated with the Company and its subsidiaries) from all claims that Executive may otherwise have against them, to the extent that the basis for such claims arose on or before the date the Release is signed by Executive; except that such Release shall not adversely affect Executive's rights to enforce the terms of this Agreement, and shall not adversely affect Executive's right to vested benefits, right to indemnification or right to reimbursement of expenses by the Company to which Executive would otherwise be entitled to under, without limitation, any charter document or Company insurance policy, by reason of services he rendered for the Company or any of its subsidiaries as an officer and/or an employee thereof.

8.2 **Definition of Cause**. For purposes of this Agreement, "Cause" shall mean: (i) the conviction of Executive by a court of competent jurisdiction of, or the pleading of guilty or nolo contendere to, any felony or any crime involving moral turpitude; (ii) gross negligence, breach of fiduciary duty, or breach of any confidentiality, non-competition or developments agreement by Executive in favor of the

Company that (A) cannot be cured or (B) has not been cured or corrected by Executive within thirty (30) days prior written notice of such breach or failure; (iii) Executive shall have willfully and continually failed to substantially perform Executive's duties with the Company after a written demand for substantial performance is delivered by the Company, which demand specifically identifies the manner in which the Company believes that Executive has not substantially performed Executive's duties pursuant to the disciplinary procedures of the Company, and such failure of substantial performance shall have continued for a period of thirty (30) days after such written demand; (iv) Executive has been chronically absent from work (excluding vacations, illnesses or leaves of absences); (v) the commission by Executive of an act of fraud, embezzlement or misappropriation against the Company; (vi) Executive shall have refused, after explicit notice, to obey any lawful resolution or direction by the Board which is consistent with his duties as an officer of the Company or FTG, as applicable; or (vii) a material breach or failure to follow any written policy or rule adopted by the Company or any of its subsidiaries that (A) cannot be cured or (B) has not been cured or corrected by Executive within thirty (30) days prior written notice of such breach or failure.

8.3 **Definition of Good Reason**. For purposes of this Agreement, "Good Reason" shall mean one or more of the following events, as the case may be: (i) a material diminution in Executive's authority, duties or responsibilities; (ii) a material diminution in Executive's base salary (other than a reduction of not more than 10% that is applicable to similarly situated executives of the Company); (iii) a material change in the geographic location of Executive's place of business (provided, however, that travel for business purposes consistent with past practices shall not be considered a change in the place of business for the purpose of this clause; and provided, further, that a relocation of less than 50 miles from Executive's then present location will not be considered a material change in geographic location); (iv) a material breach by the Company of this Agreement or any agreement under which Executive provides services to the Company; and/or; provided, that the occurrence of any of the events listed in clauses (i) though (iv) shall not constitute Good Reason (x) unless Executive shall have given written notice of the event to the Company within thirty (30) days after it first existed and the Company shall have failed to remedy the condition within thirty (30) days after the written notice, in which case Executive's employment shall terminate thirty-one (31) days after written notice of the event to the Company, or (y) if the event follows an event or action by Executive that would constitute Cause (as defined herein) for termination.

8.4 **Definition of Disability**. For purposes of this Agreement, "Disability" means an independent medical doctor (selected by the Company's health or disability insurer) has certified that Executive has, for six (6) months consecutive or nonconsecutive in any 12-month period been disabled in a manner that materially interferes with his ability to perform his responsibilities as an employee of Company. Any refusal by Executive to submit to a medical examination for the purpose of certifying disability shall be deemed to constitute conclusive evidence of the Executive's disability. Notwithstanding the foregoing, nothing herein shall abrogate Employee's rights under state or federal law.

8.5 **Certain Tax Matters**.

(a) This Agreement is intended to comply with section 409A of the Internal Revenue Code of 1986, as amended (the "Code") and its corresponding regulations, or an exemption, and payments may only be made under this Agreement upon an event and in a manner permitted by section 409A, to the extent applicable. Severance benefits under the Agreement are intended to be exempt from section 409A of the Code under the "short-term deferral" exception, to the maximum extent applicable, and then under the "separation pay" exception, to the maximum extent applicable. For purposes of section 409A of the

Code, all payments to be made upon a termination of employment under this Agreement may only be made upon a "separation from service" within the meaning of such term under section 409A of the Code, each payment made under this Agreement shall be treated as a separate payment and the right to a series of installment payments under this Agreement is to be treated as a right to a series of separate payments. In no event shall the Executive, directly or indirectly, designate the calendar year of payment. Notwithstanding any provision of this Agreement to the contrary, in no event shall the timing of Executive's execution of the Release, directly or indirectly, result in Executive designating the calendar year of payment, and if a payment that is deferred compensation subject to section 409A of the Code and subject to execution of the Release could be made in more than one taxable year, payment shall be made in the later taxable year. All reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of section 409A of the Code, including, where applicable, the requirement that (i) any reimbursement is for expenses incurred during Executive's lifetime (or during a shorter period of time specified in this Agreement), (ii) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during a calendar year may not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred, and
(iv) the right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(b) Notwithstanding any provision in this Agreement to the contrary, if at the time of Executive's separation from service with the Company, the Company (or a company that is aggregated with the Company for this purpose under section 409A of the Code) has securities which are publicly-traded on an established securities market and Executive is a "specified employee" (as defined in section 409A of the Code) and it is necessary to postpone the commencement of any severance payments otherwise payable pursuant to this Agreement as a result of such separation from service to prevent any accelerated or additional tax under section 409A of the Code, then Company will postpone the commencement of the payment of any such payments hereunder (without any reduction in such payments ultimately paid or provided to Executive) that are not otherwise exempt from section 409A of the Code, until the first payroll date that occurs after the date that is six (6) months following Executive's separation from service with Company. If any payments are postponed due to such requirements, such postponed amounts will be paid in a lump sum to Executive on the first payroll date that occurs after the date that is six (6) months following Executive's separation from service with Company. If Executive dies during the postponement period prior to the payment of the postponed amount, the amounts withheld on account of section 409A of the Code shall be paid to the personal representative of Executive's estate within sixty (60) days after the date of Executive's death.

(c) The Company makes no representation or warranty and shall have no liability to Executive or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

8.6 **Excise Tax Adjustment**.

(a) If any payment or benefit Executive will or may receive from the Company or otherwise (a "280G Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this Section, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then any such 280G Payment provided pursuant to this Agreement (a "Payment") shall be equal to the Reduced Amount. The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax,

or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state, foreign and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "Reduction Method") that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "Pro Rata Reduction Method").

(b) Notwithstanding any provision of this Section 8.6 to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Executive as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

(c) The Company shall appoint a nationally-recognized accounting, consulting or law firm to make the determinations required by this Section 8.6. The Company shall bear all expenses with respect to the determinations by such firm required to be made hereunder.

(d) If Executive receives a Payment for which the Reduced Amount was determined pursuant to clause (x) of Section 8.6.(a) and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, Executive agrees (after any appeals related to the IRS's determination have been exhausted) to promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of Section 8.6.(a)) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of Section 8.6.(a), Executive shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

8.7 **Binding Effect**. Except as otherwise provided herein, this Agreement shall be binding upon the Company and inure to the benefit of the Company and any successor or assign (whether direct or indirect, by purchase, merger, consolidation, reorganization or otherwise) of the Company. The Company shall require any such successor to assume this Agreement expressly and to be bound by the provisions of this Agreement as if such successor or assign were the Company and for purposes of this Agreement, any such successor or assign of the Company shall be deemed to be the Company for all purposes.

8.8 **Effect on Other Agreements**. Nothing herein shall in any way limit Executive's obligations under any other non-competition, confidentiality, option or similar agreement between Company or any of its affiliates and Executive currently in effect or which may be entered into in the future.

8.9 **Withholding; No Gross-Up**. All payments required to be made by the Company hereunder to Executive shall be subject to the withholding of such amounts, if any, relating to tax and other payroll deductions as the Company may reasonably determine it must withhold pursuant to any applicable law or regulation. For the avoidance of doubt, the Company shall have no obligation under this Agreement to make

any tax gross-up payments in respect of any tax imposed on Executive and all taxes, penalty or otherwise, imposed on Executive shall be Executive's sole responsibility.

8.10 **Advice of Counsel**. EXECUTIVE ACKNOWLEDGES THAT, IN EXECUTING THIS AGREEMENT, EXECUTIVE HAS THE RIGHT AND HAD THE OPPORTUNITY TO SEEK THE ADVICE OF INDEPENDENT LEGAL COUNSEL, AND HAS READ AND UNDERSTOOD ALL OF THE TERMS AND PROVISIONS OF THIS AGREEMENT. THIS AGREEMENT SHALL NOT BE CONSTRUED AGAINST ANY PARTY BY REASON OF THE DRAFTING OR PREPARATION HEREOF.

8.11 **Arbitration**. Except for claims arising from a breach of Section 3.2, all claims or disputes arising out of or relating to this Agreement shall be resolved by binding arbitration. Such agreement includes all claims, whether based on tort, contract, or statute, including, but not limited to, any claims of discrimination, harassment, or retaliation, whether based on Title VII of the Civil Rights Act of 1964, as amended, or any other local, state or Federal law (including, but not limited to, the Massachusetts Fair Employment Practices Law – Mass. Gen. Laws Chapter 151B) and other state and federal laws., claims for wages or compensation, claims based in equity, or otherwise. The claim or dispute will be arbitrated in accordance with the rules of the American Arbitration Association ("AAA") under its existing Arbitration Rules. These rules may be found at https://www.adr.org/Rules. The Company shall pay the arbitration administrative costs and the arbitrator's fees subject to applicable law and the AAA Rules. Each party in the arbitration shall bear his/its own attorneys' fees and legal costs. The Parties agree to file any demand for arbitration within the time limit established by the applicable statute of limitations for the asserted claims. Failure to demand arbitration within the prescribed time period shall result in waiver of said claims. The Parties agree that the arbitration will be in Boston, Massachusetts. EXECUTIVE UNDERSTANDS AND AGREES THAT HE IS WAIVING HIS RIGHTS TO BRING SUCH CLAIMS OR DISPUTES TO COURT, INCLUDING THE RIGHT TO A JURY TRIAL. Notwithstanding the foregoing, this Agreement expressly does not prohibit either party from seeking, exclusively in a court of competent jurisdiction located within Massachusetts, an application for a provisional remedy or other equitable or injunctive relief to prevent actual or threatened irreparable harm, or from pursuing therein any claim that cannot by law be subject to mandatory arbitration. In the event of any procedural matter not covered by the aforesaid AAA rules, the procedural law of the Commonwealth of Massachusetts shall govern.

8.12 **Governing Law**. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without regard to conflicts of laws principles.

8.13 **Entire Agreement**. This Agreement, along with equity agreements referenced in Section 2.3 above or other agreements referenced in Section 2.5 above, constitutes the entire Agreement between Executive and the Company concerning the subject matter hereof and supersedes any prior negotiations, understandings, or agreements concerning the subject matter hereof, whether oral or written, and may be amended or rescinded only upon the written consent of Company and the Executive.

8.14 **Modification & Waiver**. No provision of this Agreement may be amended or modified unless such amendment or modification is agreed to in writing and signed by Executive and an authorized representative of the Company. No waiver by either of the parties of any breach by the other party hereto of any condition or provision of this Agreement to be performed by the other party hereto shall be deemed a waiver of any similar or dissimilar provision or condition at the same or any prior or subsequent time, nor shall the failure of or delay by either of the parties in exercising any right, power or privilege hereunder operate as a waiver thereof to preclude any other or further exercise thereof or the exercise of any other such right, power or privilege.

8.15 **Severability**. The invalidity or unenforceability of any provision of this Agreement shall not affect the other provisions of this Agreement and this Agreement shall be construed and reformed to the fullest extent possible.

8.16 **Captions**. Captions and headings of the sections and paragraphs of this Agreement are intended solely for convenience and no provision of this Agreement is to be construed by reference to the caption or heading of any section or paragraph.

8.17 **Successors and Assigns**. Executive may not assign any of his rights or obligations under this Agreement; the rights and obligations of the Company under this Agreement shall inure to the benefit of, and shall be binding upon, the successors and assigns of the Company.

8.18 **Survival**. Upon the expiration or other termination of this Agreement, the respective rights and obligations of the parties hereto shall survive such expiration or other termination to the extent necessary to carry out the intentions of the parties under this Agreement. For the avoidance of doubt, the covenants in Section 3 and Section 4 of this Agreement shall survive any termination or expiration of this Agreement and termination of Executive's employment for any reason.

8.19 **Counterparts**. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and both of which taken together shall constitute one and the same instrument. Facsimile or scanned and e-mailed signatures shall be deemed valid and binding for such purposes.

[*Remainder of Page Intentionally Left Blank*]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first written above, to be effective as of the Effective Date.

FINCH THERAPEUTICS GROUP, INC.

By : /s/ Mark Smith

Name: Mark Smith

Title: CEO

EXECUTIVE:

By : /s/ Marc B. Blaustein

Name: Marc B. Blaustein

EXHIBIT A

Form of Release

I understand and agree completely to the separation payment terms set forth in the Amended and Restated Executive Employment Agreement (the "Employment Agreement") dated__, by and between Finch Therapeutics Group, Inc. (the "Company") and me. I understand that I am not entitled to any separation payments if I do not sign this Release and return it to the Company on or before **[DATE – to be inserted by the Company at the time of termination]** pursuant to the terms set forth herein or if I revoke this Release as set forth in Section 3 below. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in the Employment Agreement.

Section 1. **General Release and Knowing Waiver of Employment-Related Claims**. For and in consideration of the separation payments and any other benefits I am eligible to receive from the Company, I, on my own behalf and on behalf of my successors and assigns (collectively referred to as "Releasor"), hereby release and forever discharge the Company, its affiliates, and their respective stockholders, members, predecessors, successors, officers, directors, agents, representatives, employees, consultants and advisors (collectively referred to as "Releasee"), from any and all claims, counterclaims, demands, debts, actions, causes of action, suits, expenses, costs, attorneys' fees, damages, indemnities, obligations and/or liabilities of any nature whatsoever (collectively, "Claims"), whether known or unknown, which Releasor ever had, now has or hereafter can, shall or may have against Releasee, for, upon or by reason of any matter, cause or thing whatsoever from the beginning of the time to the day of the date of this Release, including, but not limited to, the following:

(a) all such Claims and demands directly or indirectly arising out of or in any way connected with my employment with the Company, including but not limited to providing services to the Company, or the termination of that employment and provision of services;

(b) all such Claims and demands related to salary, bonuses, commissions, stock, stock options, units, profits interests or any other ownership interests in the Company, vacation pay, fringe benefits, expense reimbursements, separation pay and/or any other form of compensation;

(c) any Claims arising under any federal, state or local law, statute or ordinance, including, without limitation, Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, the Older Workers Benefit Protection Act, the Americans With Disabilities Act, the Civil Rights Act of 1991, the Fair Labor Standards Act, the Equal Pay Act, the Employee Retirement Income Security Act of 1974, the Family and Medical Leave Act of 1993, and the Consolidated Omnibus Budget Reconciliation Act of 1985, the anti- retaliation provisions of any federal or state statute, including state workers' compensation statutes, and any other applicable state or local statutes, including the Massachusetts Fair Employment Practices Act (M.G.L.c. 151B), the Massachusetts Equal Rights Act, the Massachusetts Equal Pay Act, the Massachusetts Privacy Statute, the Massachusetts Sick Leave Law, the Massachusetts Civil Rights Act, all as amended, the Massachusetts Payment of Wages Act (M.G.L. c. 149 sections 148 and 150), the Massachusetts Overtime regulations (M.G.L. c. 151 sections 1A and 1B), the Massachusetts Meal Break regulations (M.G.L. c. 149 sections 100 and 101) **[additional state statutes to be inserted at the time of termination as applicable]**;

(d) any Claims for breach of contract, express or implied, including any claim for breach of any implied covenant of good faith and fair dealing; and

(e) any Claims of constructive discharge, discrimination, harassment, retaliation, fraud, defamation, intentional tort, emotional distress and negligence; and

Notwithstanding the foregoing, nothing herein releases any claim Releasor has or may have against Releasee regarding the performance or non-performance of obligations arising under the Employment Agreement, and nothing in this Release shall prevent me from enforcing my rights, if any (i) to my non-forfeitable accrued benefits (within the meaning of Sections 203 and 204 of ERISA) under any tax-qualified retirement plan maintained by the Company, (ii) to receive continuation coverage pursuant to COBRA, (iii) to indemnification conferred upon me as an officer of the Company pursuant to the Company's governing documents, under any applicable insurance policies or in accordance with applicable law or (iv) that cannot be waived under applicable law. Further, nothing in this Release affects my rights to provide information to, participate in an investigation by or file an administrative charge or complaint with any Governmental Authorities (as defined below), including, but not limited to, the Equal Employment Opportunity Commission or similar administrative agency. However, I agree not to accept any monetary relief or recovery from any charge or complaint filed against any Releasee with any such administrative agency except where authorized by applicable law.

Also, Releasor does not release any Claims against Releasee that may arise after this Release has become effective.

Section 2. **Representation by Counsel and Review Period**. I have been advised to consult independent legal counsel before signing this Release, and I hereby represent that I have executed this Release after having the opportunity to consult independent counsel and after considering the terms of this Release for **[if over 40][twenty- one (21) [applies if no reduction in force]/forty-five (45) [applies if there is a reduction in force]]** days (although I may choose to voluntarily execute this Release earlier). I further represent and warrant that I have read this Release carefully, that I have discussed it or have had reasonable opportunity to discuss it with my counsel, that I fully understand its terms, and that I am signing it voluntarily and of my own free will.

Section 3. **Right to Revoke Release**. This Release shall not become effective until the eighth (8^{th}) day following the date on which I have executed it, provided that I have not revoked it, and I may at any time prior to that effective date revoke this Release by delivering written notice of revocation to **[Name and contact information to be inserted at the time of termination]**.

Section 4. **Consideration for Release**. I acknowledge that the consideration for this Release is consideration to which I would not otherwise be entitled and is in lieu of any rights or claims that I may have with respect to any other remuneration from the Company.

Section 5. **Representation Concerning Filing of Legal Actions**. I represent that, as of the date of this Release, I have not filed any lawsuits, charges, complaints, petitions, claims or other accusatory pleadings against Company or any of the other Releasees in any court or with any Governmental Authority.

Section 6. **Continuing Obligations Concerning Confidential Information and Company Property**. I acknowledge and agree that I remain subject to the restrictive covenants contained in Section 3 of the Employment Agreement and the covenants related to Confidentiality & Proprietary Information contained in Section 4 of the Employment Agreement, each of which survives the termination of my

employment. I further acknowledge that I am obligated to return to the Company by **[DATE]**, all Company documents, originals and copies, whether in hard or electronic form, and all Company property, including without limitation keys, computers, computer disks, pagers, phones and credit cards.

Section 7. **Nondisparagement**. Subject to the provisions of Section 8, I will not make any statements, whether verbally or in writing (including in electronic communications) that are professionally or personally disparaging of, or adverse to the interests of, the Company or its officers, directors, managers or employees. This includes, but is not limited to, any statements that disparage the products, services, finances, financial condition, capability or any other aspect of the business of the Company. I further agree not to engage in any conduct which is intended to harm, professionally or personally, the reputation of the Company or its officers, directors, managers or employees. For its part, the Company shall direct those of its executives that know of this Release not to make any statements, whether verbally or in writing (including in electronic communications) that are professionally or personally disparaging of you, or adverse to your interests.

Section 8. **Disclosure Exceptions**. Nothing in this Release shall prohibit the Releasor from lawfully (A) initiating communications directly with, cooperating with, providing information to, causing information to be provided to, or otherwise assisting in an investigation by any governmental or regulatory agency, entity, or official(s) (collectively, "Governmental Authorities") regarding a possible violation of any law; (B) responding to any inquiry or legal process directed to the Releasor individually (and not directed to the Company and/or its subsidiaries) from any such Governmental Authorities; (C) testifying, participating or otherwise assisting in an action or proceeding by any such Governmental Authorities relating to a possible violation of law; or (D) making any other disclosures that are protected under the whistleblower provisions of any applicable law. Additionally, pursuant to the federal Defend Trade Secrets Act of 2016, the Releasor shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made to the Releasor's attorney in relation to a lawsuit for retaliation against the Releasor for reporting a suspected violation of law; or (c) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Nor does this Agreement require the Releasor to obtain prior authorization from the Company before engaging in any conduct described in this Section 8, or to notify the Company that he has engaged in any such conduct.

Section 9. **Tax Provision**. All payments and benefits provided under the Employment Agreement are intended to be exempt from, or to comply with, the requirements of section 409A of the Code and this Release shall be interpreted and administered in accordance with these intentions. The severance benefits and rights to COBRA reimbursement under the Employment Agreement are intended to be exempt from section 409A of the Code under the "short-term deferral" exception of Treas. Reg. Section 1.409A-1(b)(4), to the maximum extent applicable, and then under the "separation pay" exception of Treas. Reg. Section 1.409A-1(b)(9)(iii), to the maximum extent applicable. All payments that are subject to Section 409A that are to be made upon a termination of the Releasee's employment may only be made upon the Releasee's "separation from service," as defined in Treas. Reg. Section 1.409A-1(h), from the Company. For purposes of section 409A of the Code, the right to a series of installment payments under this Agreement shall be treated as a right to a series of separate payments and each such installment shall be treated as a separate payment. With respect to any payments that are subject to section 409A of the Code, in no event shall the Releasee, directly or indirectly, designate the calendar year of a payment. Any reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of

Treas. Reg. Section 1.409A- 3(i)(1)(iv). Notwithstanding the foregoing, the Releasee acknowledges that he has been advised to seek the advice of a tax advisor with respect to the tax consequences of all payments pursuant to the Employment Agreement, including any adverse tax consequence under section 409A and applicable State tax law, and neither the Company nor any of its members, officers, employees, agents or affiliates shall be responsible for any such adverse tax consequences or guarantees any particular tax consequences to the Releasee with respect to payments and benefits under the Employment Agreement.

Section 10. **Amendment of Release**. This Release may not be amended or modified except by a writing signed on behalf of the Company and by me.

Section 11. **Governing Law**. This Release shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without regard to principles of conflicts of laws thereunder.

Section 12. **Neutral Interpretation**. This Release shall be interpreted in a neutral manner, and not more strongly for or against any party based upon the source of the draftsmanship of the Release.

Section 13. **Headings**. The various headings in this Release are inserted for convenience only and are not part of the Release.

Section 14. **No Admission of Liability**. Releasee agrees that this Release, and performance of the acts required by it, does not constitute an admission of liability, culpability, negligence or wrongdoing on the part of anyone, and will not be construed for any purpose as an admission of liability, culpability, negligence or wrongdoing by any party and/or by any party's current, former or future parents, subsidiaries, related entities, predecessors, successors, officers, directors, stockholders, agents, employees and assigns.

Dated: This_____day of____, 20__.

WITNESSES:

Exhibit 10.20

AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT

This AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT, dated as of March 12, 2021 (this "Agreement"), is made by and between Finch Therapeutics Group, Inc., a Delaware corporation ("FTG", together with all subsidiaries and affiliates hereinafter referred to as the "Company"), and Joseph Vittiglio (the "Executive").

WHEREAS, the Company desires to continue to employ the Executive as its General Counsel;

WHEREAS, the Company and the Executive previously entered into an employment agreement dated as of December 7, 2020 pursuant to which the Executive served as General Counsel and Senior Vice President of Legal Affairs of the Company (the "Prior Agreement");

WHEREAS, the Executive desires to continue to be employed by the Company as General Counsel and to perform his duties to the Company on the terms and conditions hereinafter set forth;

WHEREAS, the Parties wish to amend and restate the terms of the Prior Agreement as set forth in this Agreement; and

WHEREAS, the Company and the Executive wish to enter into this Agreement to set forth the terms and conditions of the Executive's continued employment with the Company effective and conditional on the pricing date of the initial public offering of the common stock of the Company (the "Effective Date").

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Company and the Executive agree as follows:

1. Employment.

1.1 **Term of Employment**. The Company agrees to employ Executive on an at-will basis, and Executive agrees to accept such employment and serve the Company, in accordance with the terms and conditions set forth herein. The Executive's term of employment under this Agreement (the "Term") shall be for the period commencing on the date of this Agreement (the "Start Date") and ending when the Executive's employment is terminated pursuant to Section 6 hereof.

1.2 **Position, Duties, and Responsibilities**. During the Term, Executive shall be employed and serve as General Counsel and Senior Vice President of Legal Affairs of the Company (together with such other position or positions consistent with Executive's title as the Company shall specify from time to time) and shall have such duties and responsibilities commensurate therewith, and such other duties as may be assigned and/or prescribed from time to time by the Chief Executive Officer (the "CEO") and/or the Board of Directors of FTG (the "Board"). The Executive shall report to the CEO.

1.3 **Performance**. Executive shall devote his full business time, attention, skill, and best efforts to the performance of his duties under this Agreement and shall not engage in any other paid work during the Term that (a) conflicts with the interests of the Company, (b) interferes with the proper and efficient performance of Executive's duties for the Company, or (c) interferes with Executive's exercise of judgment in the Company's best interests. Executive may not serve on any for-profit board of directors or board of any educational, social, religious and civic organizations without the prior written approval of the Board. The Executive reaffirms that he has no contractual commitments or other legal obligations that would prohibit him from fully performing his duties for the Company.

2. Compensation. As full compensation for all services to be rendered by the Executive to the Company in all capacities, the Executive shall receive the following compensation and benefits:

2.1 **Salary**. The Executive shall be entitled to receive an annual base salary of $389,000 USD (the "Base Salary"). The Base Salary, which will be reviewed annually, will be paid periodically in accordance with the Company's normal payroll practices and be subject to applicable withholdings.

2.2 **Bonus**. Executive will be eligible to receive an annual bonus of forty percent (40%) of Executive's Base Salary, less applicable withholdings (the "Target Bonus"). The amount of any bonus shall be determined by the Board or the Compensation Committee of the Board in their sole discretion. Except as provided in Section 7, Executive must be employed by Company at the time of any such bonus payment in order to be eligible for any such payment. Except as set forth in Section 7.3 below, the Target Bonus is not earned until paid and no pro-rated amount will be paid if Executive's employment terminates for any reason prior to the payment date.

2.3 **Equity**. Any existing equity awards will remain subject to the terms thereof, except as set forth in Section 7.3(e). In addition, subject to approval by the Board, Executive shall be eligible for the following additional equity grant:

(a) Subject to approval by the Board, Executive shall be granted on the Effective Date an option to purchase 60,578 shares of Common Stock (the "Option") of FTG. The Option is intended to qualify as an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code") to the extent permissible under applicable laws. Except as otherwise provided herein, subject to Executive's continuous service to the Company (as defined in the Plan (as defined below)) through each applicable vesting date, the Option will vest and become exercisable as follows:

The shares covered by the Option shall be granted with an exercise price equal to the price per share of common stock at which the Company's shares are first sold to the public in the proposed initial public offering ("IPO"), as specified in the final prospectus for the IPO, in accordance with the terms of the Finch Therapeutics Group, Inc.
2021 Equity Incentive Plan (the "Plan") and form of agreement issued thereunder. The Option will vest and become exercisable over five (5) years, with 20% of the shares covered by the Option vesting and becoming exercisable on the first year anniversary of the Effective Date, and the remaining shares covered by the Option vesting and becoming exercisable in forty-eight (48) equal monthly installments thereafter, subject to Executive's continuous service as of each such date.

(b) Subject to approval by the Board, Executive shall be granted an option to purchase 34,616 shares of the Company's common stock (the "Additional Option"), with all of the same terms (including grant date and exercise price) as the Option; provided, however that the Additional Option will vest 25% on the one-year anniversary of the date of grant, and thereafter over the ensuing 3 years in a series of thirty-six (36) successive equal monthly installments, subject to Executive's continuous service as of each such date. The Additional Option shall be an incentive stock option under Section 422 of the Code to the maximum extent permissible

2.4 **Benefits**. Executive is entitled, during the Term, to participate in all employee benefits plans customarily granted to other executives of the Company, including medical, dental and disability insurance, life insurance and a 401(k) plan, subject to plan terms and applicable Company policies. Further, Executive shall be entitled to paid vacation in accordance with then applicable Company policy for full-time, exempt employees, or any subsequent policy approved by the Board. The Company reserves the right to cancel or change the benefit plans or programs it offers to its employees at any time.

2.5 **Indemnification**. The Company agrees to indemnify Executive to the maximum extent allowable under the terms and conditions of its certificate of incorporation, bylaws under applicable law, and under the indemnification agreement signed herewith. Further, Executive will be covered by the Company's directors' and officers' liability insurance coverage as in effect from time to time and that certain Indemnification Agreement by and between the Company and the Executive dated the date hereof.

3. Restrictive Covenants.

3.1 **Acknowledgement.** The Executive understands that the nature of the Executive's position gives him access to and knowledge of confidential, proprietary and/or trade secret, and customer information and places him in a position of trust and confidence with the Company. The Executive understands and acknowledges that the intellectual services he provides to the Company are unique, special, or extraordinary. The Executive further understands and acknowledges that the Company's ability to reserve these for the exclusive knowledge and use of the Company is of great competitive importance and commercial value to the Company, and that improper use or disclosure by the Executive is likely to result in unfair or unlawful competitive activity. The Executive represents and warrants that he is not in breach of any agreement requiring him to preserve the confidentiality of any information, client lists, trade secrets or other confidential information or any agreement not to compete or interfere with any prior employer, and that neither the execution of this Agreement nor the performance by the Executive of his obligations hereunder will conflict with, result in a breach of, or constitute a default under, any agreement to which he is a party or to which he may be subject. The Executive further represents that he has not taken and will not take any confidential or proprietary information from any prior employer or other person and will not use or disclose any such information in performing his obligations hereunder but instead will rely on his generalized knowledge and skill in performing his services hereunder.

3.2 **Non-Competition.** Because of the Company's legitimate business interest as described herein, and the good and valuable increased consideration offered to the Executive in this Agreement (including the mutually agreed-to consideration in accordance with Sections 7.2, 7.3 and 7.4), during the period of the Executive's employment with Company and for a period of twelve (12) months from termination of Executive's employment for any reason (other than as set forth in Section 6.4) (the "Non-Compete Period"), without the prior written consent of the Company, the Executive shall not, in any capacity (whether as an employee, director, officer, partner, interest holder, investor, consultant, advisor or otherwise, except as the holder of not more than 1% of the outstanding stock of a publicly- held company), directly or indirectly engage in any activity on behalf of any other individual or enterprise (other than the Company) that is pursuing, or is planning to pursue, activities related to microbiome therapies and diagnostics ("Competitive Activity") anywhere in the United States, Canada, Europe or any other country in which the Company is either doing business or actively planning to do business as of the date of the Executive's termination of employment or two years prior. For the avoidance of doubt, engagement in any respect with Seres Therapeutics, Rebiotix, Symbiotic Health, Assembly Biosciences, Monarch Laboratories, Vedanta, ViThera, Second Genome, Synthetic Biologics, Intrexon/Actogenix, Evelo Thereapeutics, Enterome, Axial Biotherapeutics, Kallyope and/or Kaleido (so long as any of those companies pursue activities related to microbiome therapies), constitutes Competitive Activity. Company may waive the provisions of this Section 3.2 by providing written notice to Executive upon termination of Executive's employment.

3.3 **Non-Solicitation of Employees**. During the Non-Compete Period, the Executive will not, and will not attempt to, directly or indirectly hire, interview, solicit, recruit, induce, procure, encourage, work with, retain or engage for employment, consulting services or otherwise any present or former employee of the Company unless such person shall have voluntarily ceased to be employed by the Company or any subsidiary or affiliate for a period of at least six (6) months.

3.4 **Non-Disparagement.** Subject to Section 5, below, the Executive agrees that he shall not at any time, during or after his employment with Company, directly or indirectly, (a) make any public comments about (including, without limitation, by way of news interviews or the expression of personal views, opinions or judgments to the media or any other entity or person outside the Company) the Company (other than factual information or other publicly available information about the Company) without prior consultation with the Board, or any disparaging comments about any constituent entity of the Company or any of their respective officers, directors, members, partners, investors, consultants, advisors or other employees (collectively, the "Company Group") or (b) disparage, criticize, ridicule or make any negative comments about the Company Group (or any constituent thereof) to any person or entity within the Company Group or any other individual or entity with whom the Company Group has or may have a business or personal relationship, including any current, former or prospective vendor, vendee, investor or employee. This Section 3.4 does not, in any way, restrict or impede the Executive from exercising protected rights to the extent that such rights cannot be waived by

agreement or from complying with any applicable law or regulation or a valid order of a court of competent jurisdiction or an authorized government agency, provided that such compliance does not exceed that required by the law, regulation or order. The Executive shall promptly provide written notice of any such order to the Board.

3.5 **Injunctive Relief**. The Executive recognizes that irreparable injury will result to the Company in the event of any breach of any of the terms or provisions of this Section 3. Therefore, the Executive agrees that in the event of such a breach, FTG and other members of the Company will be entitled to seek, in addition to other remedies and damages available, an injunction to restrain any such breach and all persons acting for and/or in concert with the Executive. The restricted periods described in Section 3 will not expire, and will be tolled, during any period in which the Executive is in violation of Section 3.2 and/or Section 3.3, as applicable, and the restriction will automatically be extended by the time period that the Executive is in violation of such restriction.

4. Confidential & Proprietary Information.

4.1 **Confidentiality**. The Executive understands that all confidential and/or proprietary information concerning the Company, whether written or oral, which is or has been communicated to him by any person working for or on behalf of the Company or an entity affiliated with the Company, and all confidential and/or proprietary information which he generates as a result of services performed for the Company, including but not limited to trade secrets, regulatory strategy, intellectual property strategy, research and clinical strategies, technologies, procedures, models, testing systems, research, assays, compounds, molecules, organisms, gene sequences, cell lines, complement inhibitors and other re-agents (including the composition thereof), formulas, methods, processes, test and experimental data and results, specifications, invention disclosures, patent claims, laboratory notebooks, schematics and drawings (collectively referred to as "Confidential Information"), is proprietary and confidential to the Company. Subject to Section 5, the Executive agrees that he shall not at any time (whether during or after the term of his employment with Company or until such time as such Confidential Information has become public knowledge), without the prior written consent of Company, directly or indirectly, use or disclose any Confidential Information except as is necessary to fulfill his obligations hereunder or as is required to be disclosed by law, court order, or similar compulsion (provided that he shall promptly give Company written notice of a court order or similar compulsion that would require the disclosure of Confidential Information in order to permit Company to seek an appropriate protective order). Executive's obligations with respect to Confidential Information will cease when the Confidential Information: (i) becomes part of the public domain through no wrongful act of Executive, or (ii) is approved for release by prior written authorization of the Company. The Executive agrees to destroy or return (at Company's request) any and all of Confidential Information to Company upon any termination of this Agreement.

4.2 **Intellectual Property; Works Made for Hire.** Company shall own all right, title and interest (including without limitation patent rights and copyrights) to all tangible and intangible property, products, developments, discoveries and inventions ("Inventions") conceived, created or produced directly or indirectly by or through the Executive during the term of Executive's employment with Company which relate to the actual or anticipated business, research and development of the Company, including, but not limited to, all documents, reports, and electronic or written materials, and all computer software and biological materials, and all related patent, know-how and other intellectual property rights, including, without limitation, all technical information, records, data, reports, tests or trial results and other results, and tangible manifestations and embodiments of work ("Work"), and the Executive shall provide Company with the originals and/or all copies of any such Inventions upon request of Company. The Executive hereby assigns to Company all right, title and interest in any Invention or discovery, whether in finished or incomplete form, made during the term of his employment with Company, and in any patent application, related documents and any patent relating to such invention or discovery. To the extent that any copyrighted work produced by Company hereunder is not deemed a "work made for hire" for purposes of the copyright laws of the United States, the Executive hereby assigns to Company all right, title and interest in the copyright of such work, including without limitation the right to reproduce, distribute, sublicense, perform and display the work and to create and use derivative works therefrom in any medium throughout the world. The term "derivative works" as used in this Agreement has the same meaning as used in the Copyright Act of the United States. The Executive shall complete and execute such assignments, certificates or other instruments as Company may from time to time deem necessary or desirable

to evidence, establish, maintain, perfect, protect, enforce or defend its or any of its affiliate's right, title and interest in or to any of the foregoing. The Executive shall retain no rights in or to any work product produced hereunder.

5. Disclosure Exceptions. Nothing in this Agreement shall prohibit or restrict Executive from lawfully (A) initiating communications directly with, cooperating with, providing information to, causing information to be provided to, or otherwise assisting in an investigation by any governmental or regulatory agency, entity, or official(s) (collectively, "Governmental Authorities") regarding a possible violation of any law; (B) responding to any inquiry or legal process directed to Executive individually (and not directed to the Company and/or its subsidiaries) from any such Governmental Authorities; (C) testifying, participating or otherwise assisting in an action or proceeding by any such Governmental Authorities relating to a possible violation of law; or (D) making any other disclosures that are protected under the whistleblower provisions of any applicable law. Additionally, pursuant to the federal Defend Trade Secrets Act of 2016, Executive shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made to Executive's attorney in relation to a lawsuit for retaliation against Executive for reporting a suspected violation of law; or (c) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Nor does this Agreement require Executive to obtain prior authorization from the Company before engaging in any conduct described in this Paragraph, or to notify the Company that he has engaged in any such conduct.

6. Termination of Employment. The Executive is an employee-at-will such that the Term and the Executive's employment hereunder may be terminated by either Company or the Executive at any time and for any reason; provided that, unless otherwise provided herein, either party shall be required to give the other party at least thirty (30) calendar days advance written notice of any termination of the Executive's employment; provided, however, that the Company may cease accepting services from the Executive or otherwise allow the Executive's access to Company facilities, computer systems, or personnel during the thirty days' notice period. Upon termination of the Executive's employment during the Term, the Executive shall be entitled to the compensation and benefits further described in Section 7 below and shall have no further rights to any compensation or any other benefits from the Company or any of its affiliates. Should Company elect to forego the aforementioned notice provision, it shall remit to the Executive payment in lieu of notice equal to the salary he would have received during the notice period.

6.1 **Termination upon Death**. The Term shall terminate as of the date of the Executive's death.

6.2 **Termination upon Disability**. If the Executive suffers from a Disability during the Term, Company may terminate the Term by written notice to the Executive, in which event the Term shall terminate ten (10) days after the date upon which Company has given written notice to the Executive of its determination to terminate the Executive's employment under this Agreement.

6.3 **Termination by Company for Cause**. Company may immediately terminate the Executive for Cause (as defined in Section 8.2 below).

6.4 **Termination by Company without Cause**. Company may terminate the Term at any time, without Cause.

6.5 **Termination by the Executive without Good Reason**. The Executive may terminate the Term at any time, without Good Reason (as defined in Section 8.3 hereof).

6.6 **Termination by the Executive for Good Reason**. The Executive may terminate the Term for Good Reason (such termination to comply with the notice, cure and termination provisions of the definition of Good Reason in Section 8.3 hereof) upon thirty (30) days' written notice from the Executive to Company and the Board.

7. Severance Payments.

7.1 **Accrued Obligations**. Upon the Executive's employment termination, for any reason, Company shall pay to the Executive in a lump sum, within ten (10) business days following the termination date of his/her employment (or such earlier date as is required under applicable law), (i) all unpaid salary accrued prior to the termination date of his/her employment, (ii) accrued but unused vacation through the termination date of his/her employment if available in accordance with then applicable Company policy for full-time, exempt employees, and (iii) any unreimbursed business expenses for which the Executive is entitled to be reimbursed by Company pursuant Company's then-existing reimbursement policy.

7.2 **Termination by the Company without Cause or by the Executive for Good Reason Not in Connection with a Change in Control**. If Company terminates the Executive's employment with Company for a reason other than Cause, death or Disability, or the Executive terminates the Executive's employment with Company for Good Reason at any time other than within the 12-month period following a Change in Control (as defined in the Company's 2021 Equity Incentive Plan (the "Plan"), the Company shall:

(a) **Cash Payment**. Pay to the Executive an aggregate amount (paid in nine (9) monthly installments in accordance with Company's regular payroll practices), following the effective date of a Release (as defined in Section 8.1 below) and commencing on the payroll date that next follows the 65th day after the termination date, equal to the sum of nine (9) times his/her monthly base salary (at the monthly base salary rate in effect for the Executive immediately prior to the termination of his/her employment). On the 65th day following Executive's termination date, the Company will pay Executive in a lump sum the Severance that Executive would have received on or prior to such date under the standard payroll schedule but for the delay while waiting for the 65th day in compliance with Code Section 409A, with the balance of the Severance being paid as originally scheduled; and

(b) **Benefits**. Provide the Executive and his/her dependents with the same life, accident, health and dental insurance benefits, if any, that the Executive was receiving immediately prior to the termination of employment until the earlier of: (i) the date which is twelve (12) months following the date of the Executive's termination; or (ii) the date the Executive commences subsequent employment (such period, the "Pre-Change Continuation Period"; provided, that if the Executive's continued participation is not possible under the terms of any one or more of those insurance plans or results in adverse taxes to the Company or Executive, and if the Executive was participating in Company's group health plan immediately prior to the date of termination and timely elects COBRA health continuation, then Company shall pay to the Executive a monthly payment in a gross amount equal to the COBRA premium for the earlier of twelve (12) months following the Executive's termination or (B) until the Executive becomes eligible for coverage under another employer's group coverage ("Benefits Continuation Period"), and the Executive agrees to notify Company promptly and in writing should that eligibility occur. Subject to Executive's timely presentment of receipts, the reimbursements will commence within sixty (65) days following the Executive's termination and will be made on a monthly basis for the duration of the Benefits Continuation Period. If such payments would violate any applicable law, then the Company shall instead pay the Executive taxable monthly payments of equal value on the same schedule, which amounts may be used for such purpose as the Executive may determine; and

(c) **Bonus**. Pay to Executive any unpaid Annual Bonus that is earned and payable and approved by the Board, payable when bonuses are paid to similarly situated executives and no later than March 15 of the year following the performance year.

7.3 **Termination by the Company without Cause or by the Executive for Good Reason in Connection with a Change in Control**. If Company terminates the Executive's employment with Company for a reason other than Cause, death or Disability, or the Executive terminates the Executive's employment with Company for Good Reason during the 12-month period following a Change in Control, the Company shall, in *lieu* of the benefits set forth in Section 7.2 above:

(a) **Cash Payment**. Pay to the Executive an aggregate amount (paid in twelve (12) monthly installments in accordance with Company's regular payroll practices), following the effective date

of a Release (as defined in Section 8.1 below) and commencing on the payroll date that next follows the 65th day after the termination date, equal to the sum of twelve (12) times his/her monthly base salary (at the monthly base salary rate in effect for the Executive immediately prior to the termination of his/her employment). On the 65th day following Executive's termination date, the Company will pay Executive in a lump sum the Severance that Executive would have received on or prior to such date under the standard payroll schedule but for the delay while waiting for the 65th day in compliance with Code Section 409A, with the balance of the Severance being paid as originally scheduled; and

(b) **Benefits**. Provide the Executive and his/her dependents with the same life, accident, health and dental insurance benefits, if any, that the Executive was receiving immediately prior to the termination of employment until the earlier of: (i) the date which is twelve (12) months following the date of the Executive's termination; or (ii) the date the Executive commences subsequent employment (such period, the "Change in Control Pre-Change Continuation Period"; provided, that if the Executive's continued participation is not possible under the terms of any one or more of those insurance plans, and if the Executive was participating in Company's group health plan immediately prior to the date of termination and timely elects COBRA health continuation, then Company shall pay to the Executive a monthly payment in a gross amount equal to the COBRA premium for the earlier of twelve (12) months following the Executive's termination or (B) until the Executive becomes eligible for coverage under another employer's group coverage ("Change in Control Benefits Continuation Period"), and the Executive agrees to notify Company promptly and in writing should that eligibility occur. Subject to Executive's timely presentment of receipts, the reimbursements will commence within sixty (65) days following the Executive's termination and will be made on a monthly basis for the duration of the Change in Control Benefits Continuation Period;

(c) **Bonus**. Pay to Executive any unpaid Annual Bonus that is earned and payable and approved by the Board, payable when bonuses are paid to similarly situated executives and no later than March 15 of the year following the performance year.

(d) **Bonus Severance**. Pay to the Executive an amount equal to the Executive's pro rata Target Bonus for the calendar year in which the Executive's termination occurs, payable subject to standard federal and state payroll withholding requirements on the Company's first regularly scheduled payroll date following the effective date of a Release that next follows the 65th day after the termination date; and

(e) **Equity Awards.** Any equity awards with respect to Company stock then held by the Executive which vest based on continued service shall become fully vested and exercisable as of the date of such termination. Any equity awards that vest based upon the achievement of performance goals shall be subject to the terms of such awards.

7.4 **Termination for Cause.** In the event the Executive's employment with Company is terminated by Company for Cause, or the Executive terminates his employment with Company for any reason other than Good Reason (including his death or Disability), the Executive shall not be entitled to the severance benefits or other considerations described herein by virtue of this Agreement; provided that, if Company does not waive the provisions of Section 3.2 in connection with such termination, Company will pay Executive an amount equal to the sum of six (6) times his/her monthly base salary (at the monthly base salary rate in effect for the Executive immediately prior to the termination of his/her employment), except to the extent such termination arises from Executive's breach of his fiduciary duty or theft of Company property (whether physical or electronic). Such amount shall be paid in monthly installments in accordance with Company's regular payroll practices following the effective date of the termination.

8. General.

8.1 **Release.** Notwithstanding any other provision of this Agreement to the contrary, benefits, including, but not limited to severance payments under Section 7 hereof, shall be payable under this paragraph only if the Executive enters into a final and binding agreement in favor of the Company, its affiliates and their respective officers and directors in a form provided by the Company, substantially in the form attached hereto as Exhibit A (the "Release") which has not been revoked within sixty (65) days of his termination of

employment whereby the Executive releases the Company and its subsidiaries (and those affiliated with the Company and its subsidiaries) from all claims that the Executive may otherwise have against them, to the extent that the basis for such claims arose on or before the date the Release is signed by the Executive; except that such Release shall not adversely affect the Executive's rights to enforce the terms of this Agreement, and shall not adversely affect the Executive's right to vested benefits, right to indemnification or right to reimbursement of expenses by the Company to which the Executive would otherwise be entitled to under, without limitation, any charter document or Company insurance policy, by reason of services he rendered for the Company or any of its subsidiaries as an officer and/or an employee thereof.

8.2 **Definition of Cause.** For purposes of this Agreement, "Cause" shall mean: (i) the conviction of the Executive by a court of competent jurisdiction of, or the pleading of guilty or nolo contendere to, any felony or any crime involving moral turpitude; (ii) gross negligence, breach of fiduciary duty or breach of any confidentiality, non-competition or developments agreement by the Executive in favor of the Company that (A) cannot be cured or (B) has not been cured or corrected by Executive within thirty (30) days prior written notice of such breach or failure; (iii) the Executive shall have willfully and continually failed to substantially perform the Executive's duties with the Company after a written demand for substantial performance is delivered by the Company, which demand specifically identifies the manner in which the Company believes that the Executive has not substantially performed the Executive's duties pursuant to the disciplinary procedures of Company, and such failure of substantial performance shall have continued for a period of thirty (30) days after such written demand; (iv) the Executive has been chronically absent from work (excluding vacations, illnesses or leaves of absences); (v) the commission by the Executive of an act of fraud, embezzlement or misappropriation against the Company; (vi) the Executive shall have refused, after explicit notice, to obey any lawful resolution or direction by the Board which is consistent with his/her duties as an officer of the Company or FTG, as applicable; or (vii) a material breach or failure to follow any written policy or rule adopted by the Company or any of its subsidiaries that (A) cannot be cured or (B) has not been cured or corrected by Executive within thirty

(30) days prior written notice of such breach or failure.

8.3 **Definition of Good Reason.** For purposes of this Agreement, "Good Reason" shall mean one or more of the following events, as the case may be: (i) a material diminution in the Executive's authority, duties or responsibilities; (ii) a material diminution in the Executive's base salary (other than a reduction of not more than 10% that is applicable to similarly situated executives of the Company); (iii) a material change in the geographic location of the Executive's place of business (provided, however, that travel for business purposes consistent with past practices shall not be considered a change in the place of business for the purpose of this clause; and provided, further, that a relocation of less than 50 miles from Executive's then present location will not be considered a material change in geographic location); and/or (iv) a material breach by the Company of this Agreement or any agreement under which the Executive provides services to the Company; provided, that the occurrence of any of the events listed in clauses (i) though (iv) shall not constitute Good Reason (x) unless the Executive shall have given written notice of the event to the Company within thirty

(30) days after it first existed and the Company shall have failed to remedy the condition within thirty (30) days after the written notice, in which case the Executive's employment shall terminate thirty-one (31) days after written notice of the event to the Company, or (y) if the event follows an event or action by the Executive that would constitute Cause (as defined herein) for termination.

8.4 **Definition of Disability.** For purposes of this Agreement, "Disability" means an independent medical doctor (selected by the Company's health or disability insurer) has certified that the Executive has, for six (6) months consecutive or nonconsecutive in any 12 month period been disabled in a manner that materially interferes with his/her ability to perform his/her responsibilities as an employee of Company. Any refusal by the Executive to submit to a medical examination for the purpose of certifying disability shall be deemed to constitute conclusive evidence of the Executive's disability. Notwithstanding the foregoing, nothing herein shall abrogate Employee's rights under state or federal law.

8.5 **Certain Tax Matters**.

(a) This Agreement is intended to comply with section 409A of the Internal Revenue Code of 1986, as amended (the "Code") and its corresponding regulations, or an exemption, and payments may only be made under this Agreement upon an event and in a manner permitted by section 409A,

to the extent applicable. Severance benefits under the Agreement are intended to be exempt from section 409A of the Code under the "short-term deferral" exception, to the maximum extent applicable, and then under the "separation pay" exception, to the maximum extent applicable. For purposes of section 409A of the Code, all payments to be made upon a termination of employment under this Agreement may only be made upon a "separation from service" within the meaning of such term under section 409A of the Code, each payment made under this Agreement shall be treated as a separate payment and the right to a series of installment payments under this Agreement is to be treated as a right to a series of separate payments. In no event shall the Executive, directly or indirectly, designate the calendar year of payment. Notwithstanding any provision of this Agreement to the contrary, in no event shall the timing of the Executive's execution of the Release, directly or indirectly, result in the Executive designating the calendar year of payment, and if a payment that is deferred compensation subject to section 409A of the Code and subject to execution of the Release could be made in more than one taxable year, payment shall be made in the later taxable year. All reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of section 409A of the Code, including, where applicable, the requirement that (i) any reimbursement is for expenses incurred during the Executive's lifetime (or during a shorter period of time specified in this Agreement), (ii) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during a calendar year may not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred, and (iv) the right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(b) Notwithstanding any provision in this Agreement to the contrary, if at the time of the Executive's separation from service with Company, Company (or a company that is aggregated with the Company for this purpose under section 409A of the Code) has securities which are publicly-traded on an established securities market and the Executive is a "specified employee" (as defined in section 409A of the Code) and it is necessary to postpone the commencement of any severance payments otherwise payable pursuant to this Agreement as a result of such separation from service to prevent any accelerated or additional tax under section 409A of the Code, then Company will postpone the commencement of the payment of any such payments hereunder (without any reduction in such payments ultimately paid or provided to the Executive) that are not otherwise exempt from section 409A of the Code, until the first payroll date that occurs after the date that is six

(6) months following the Executive's separation from service with Company. If any payments are postponed due to such requirements, such postponed amounts will be paid in a lump sum to the Executive on the first payroll date that occurs after the date that is six (6) months following the Executive's separation from service with Company. If the Executive dies during the postponement period prior to the payment of the postponed amount, the amounts withheld on account of section 409A of the Code shall be paid to the personal representative of the Executive's estate within sixty (60) days after the date of the Executive's death.

(c) Company makes no representation or warranty and shall have no liability to the Executive or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

8.6 **Excise Tax Adjustment,**

(a) If any payment or benefit Executive will or may receive from the Company or otherwise (a "280G Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this Section, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then any such 280G Payment provided pursuant to this Agreement (a "Payment") shall be equal to the Reduced Amount. The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax, or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state, foreign and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "Reduction Method") that results

in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "Pro Rata Reduction Method").

(b) Notwithstanding any provision of this Section 8.6 to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Executive as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

(c) The Company shall appoint a nationally-recognized accounting, consulting or law firm to make the determinations required by this Section 8.6. The Company shall bear all expenses with respect to the determinations by such firm required to be made hereunder.

(d) If Executive receives a Payment for which the Reduced Amount was determined pursuant to clause (x) of Section 8.6.(a) and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, Executive agrees (after any appeals related to the IRS's determination have been exhausted) to promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of Section 8.6.(a)) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of Section 8.6.(a), Executive shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

8.7 **Binding Effect.** Except as otherwise provided herein, this Agreement shall be binding upon Company and inure to the benefit of the Company and any successor or assign (whether direct or indirect, by purchase, merger, consolidation, reorganization or otherwise) of the Company. Company shall require any such successor to assume this Agreement expressly and to be bound by the provisions of this Agreement as if such successor or assign were Company and for purposes of this Agreement, any such successor or assign of Company shall be deemed to be Company for all purposes.

8.8 **No Employment Agreement; Effect on Other Agreements.** Nothing herein shall in any way limit the Executive's obligations under any other non-competition, confidentiality, option or similar agreement between Company or any of its affiliates and the Executive currently in effect or which may be entered into in the future.

8.9 **Withholding; No Gross-Up.** All payments required to be made by Company hereunder to the Executive shall be subject to the withholding of such amounts, if any, relating to tax and other payroll deductions as Company may reasonably determine it must withhold pursuant to any applicable law or regulation. For the avoidance of doubt, Company shall have no obligation under this Agreement to make any tax gross-up payments in respect of any tax imposed on the Executive and all taxes, penalty or otherwise, imposed on the Executive shall be the Executive's sole responsibility.

8.10 **Advice of Counsel**. EXECUTIVE ACKNOWLEDGES THAT, IN EXECUTING THIS AGREEMENT, EXECUTIVE HAS THE RIGHT AND HAD THE OPPORTUNITY TO SEEK THE ADVICE OF INDEPENDENT LEGAL COUNSEL, AND HAS READ AND UNDERSTOOD ALL OF THE TERMS AND PROVISIONS OF THIS AGREEMENT. THIS AGREEMENT SHALL NOT BE CONSTRUED AGAINST ANY PARTY BY REASON OF THE DRAFTING OR PREPARATION HEREOF.

8.11 **Arbitration.** Except for claims arising from a breach of Section 3.2, all claims or disputes arising out of or relating to this Agreement shall be resolved by binding arbitration. Such agreement includes all claims, whether based on tort, contract, or statute, including, but not limited to, any claims of discrimination, harassment, or retaliation, whether based on Title VII of the Civil Rights Act of 1964, as

amended, or any other local, state or Federal law (including, but not limited to, the Massachusetts Fair Employment Practices Law – Mass. Gen. Laws Chapter 151B) and other state and federal laws., claims for wages or compensation, claims based in equity, or otherwise. The claim or dispute will be arbitrated in accordance with the rules of the American Arbitration Association ("AAA") under its existing Arbitration Rules. These rules may be found at https://www.adr.org/Rules. The Company shall pay the arbitration administrative costs and the arbitrator's fees subject to applicable law and the AAA Rules. Each party in the arbitration shall bear his/its own attorneys' fees and legal costs. The Parties agree to file any demand for arbitration within the time limit established by the applicable statute of limitations for the asserted claims. Failure to demand arbitration within the prescribed time period shall result in waiver of said claims. The Parties agree that the arbitration will be in Boston, Massachusetts. EXECUTIVE UNDERSTANDS AND AGREES THAT HE IS WAIVING HIS RIGHTS TO BRING SUCH CLAIMS OR DISPUTES TO COURT, INCLUDING THE RIGHT TO A JURY
TRIAL. Notwithstanding the foregoing, this Agreement expressly does not prohibit either party from seeking, exclusively in a court of competent jurisdiction located within Massachusetts, an application for a provisional remedy or other equitable or injunctive relief to prevent actual or threatened irreparable harm, or from pursuing therein any claim that cannot by law be subject to mandatory arbitration. In the event of any procedural matter not covered by the aforesaid AAA rules, the procedural law of the Commonwealth of Massachusetts shall govern.

8.12 **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without regard to conflicts of laws principles.

8.13 **Entire Agreement.** This Agreement, along with equity agreements referenced in Section 2.3 above or other agreements referenced in Section 2.5 above, constitutes the entire Agreement between the Executive and Company concerning the subject matter hereof and supersedes any prior negotiations, understandings, or agreements concerning the subject matter hereof, whether oral or written, and may be amended or rescinded only upon the written consent of Company and the Executive.

8.14 **Modification & Waiver**. No provision of this Agreement may be amended or modified unless such amendment or modification is agreed to in writing and signed by the Executive and an authorized representative of Company. No waiver by either of the parties of any breach by the other party hereto of any condition or provision of this Agreement to be performed by the other party hereto shall be deemed a waiver of any similar or dissimilar provision or condition at the same or any prior or subsequent time, nor shall the failure of or delay by either of the parties in exercising any right, power or privilege hereunder operate as a waiver thereof to preclude any other or further exercise thereof or the exercise of any other such right, power or privilege.

8.15 **Severability.** The invalidity or unenforceability of any provision of this Agreement shall not affect the other provisions of this Agreement and this Agreement shall be construed and reformed to the fullest extent possible.

8.16 **Captions**. Captions and headings of the sections and paragraphs of this Agreement are intended solely for convenience and no provision of this Agreement is to be construed by reference to the caption or heading of any section or paragraph.

8.17 **Successors and Assigns.** The Executive may not assign any of his/her rights or obligations under this Agreement; the rights and obligations of Company under this Agreement shall inure to the benefit of, and shall be binding upon, the successors and assigns of Company.

8.18 **Survival.** Upon the expiration or other termination of this Agreement, the respective rights and obligations of the parties hereto shall survive such expiration or other termination to the extent necessary to carry out the intentions of the parties under this Agreement. For the avoidance of doubt, the covenants in Section 3 and Section 4 of this Agreement shall survive any termination or expiration of this Agreement and termination of the Executive's employment for any reason.

8.19 **Counterparts.** This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and both of which taken together shall constitute one and the same instrument. Facsimile or scanned and e-mailed signatures shall be deemed valid and binding for such purposes.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first written above, to be effective as of the Effective Date.

FINCH THERAPEUTICS GROUP, INC.

By: /s/ Mark Smith
Name: Mark Smith
Title: CEO

EXECUTIVE:
/s/ Joseph Vittiglio
Joseph Vittiglio

EXHIBIT A

Form of Release

I understand and agree completely to the separation payment terms set forth in the Amended and Restated Executive Employment Agreement (the "Employment Agreement") dated__, by and between Finch Therapeutics Group, Inc. ("Company") and me. I understand that I am not entitled to any separation payments if I do not sign this Release and return it to Company on or before **[DATE – to be inserted by Company at the time of termination]** pursuant to the terms set forth herein or if I revoke this Release as set forth in Section 3 below. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in the Employment Agreement.

Section 1. **General Release and Knowing Waiver of Employment-Related Claims**. For and in consideration of the separation payments and any other benefits I am eligible to receive from the Company, I, on my own behalf and on behalf of my successors and assigns (collectively referred to as "Releasor"), hereby release and forever discharge the Company, its affiliates, and their respective stockholders, members, predecessors, successors, officers, directors, agents, representatives, employees, consultants and advisors (collectively referred to as "Releasee"), from any and all claims, counterclaims, demands, debts, actions, causes of action, suits, expenses, costs, attorneys' fees, damages, indemnities, obligations and/or liabilities of any nature whatsoever (collectively, "Claims"), whether known or unknown, which Releasor ever had, now has or hereafter can, shall or may have against Releasee, for, upon or by reason of any matter, cause or thing whatsoever from the beginning of the time to the day of the date of this Release, including, but not limited to, the following:

(a) all such Claims and demands directly or indirectly arising out of or in any way connected with my employment with Company, including but not limited to providing services to the Company, or the termination of that employment and provision of services;

(b) all such Claims and demands related to salary, bonuses, commissions, stock, stock options, units, profits interests or any other ownership interests in the Company, vacation pay, fringe benefits, expense reimbursements, separation pay and/or any other form of compensation;

(c) any Claims arising under any federal, state or local law, statute or ordinance, including, without limitation, Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, the Older Workers Benefit Protection Act, the Americans With Disabilities Act, the Civil Rights Act of 1991, the Fair Labor Standards Act, the Equal Pay Act, the Employee Retirement Income Security Act of 1974, the Family and Medical Leave Act of 1993, and the Consolidated Omnibus Budget Reconciliation Act of 1985, the anti- retaliation provisions of any federal or state statute, including state workers' compensation statutes, and any other applicable state or local statutes, including the Massachusetts Fair Employment Practices Act (M.G.L.
c. 151B), the Massachusetts Equal Rights Act, the Massachusetts Equal Pay Act, the Massachusetts Privacy Statute, the Massachusetts Sick Leave Law, the Massachusetts Civil Rights Act, all as amended, the Massachusetts Payment of Wages Act (M.G.L. c. 149 sections 148 and 150), the Massachusetts Overtime regulations (M.G.L. c. 151 sections 1A and 1B), the Massachusetts Meal Break regulations (M.G.L. c. 149 sections 100 and 101) **[additional state statutes to be inserted at the time of termination]**;

(d) any Claims for breach of contract, express or implied, including any claim for breach of any implied covenant of good faith and fair dealing; and

(e) any Claims of constructive discharge, discrimination, harassment, retaliation, fraud, defamation, intentional tort, emotional distress and negligence; and

Notwithstanding the foregoing, nothing herein releases any claim Releasor has or may have against Releasee regarding the performance or non-performance of obligations arising under the Employment Agreement, and nothing in this Release shall prevent me from enforcing my rights, if any (i) to my non-forfeitable accrued benefits (within the meaning of Sections 203 and 204 of ERISA) under any tax-qualified retirement plan maintained by the Company, (ii) to receive continuation coverage pursuant to COBRA (iii) to indemnification

conferred upon me as an officer of the Company pursuant to the Company's governing documents, under any applicable insurance policies, or in accordance with applicable law or (iv) that cannot be waived under applicable law. Further, nothing in this Release affects my rights to provide information to, participate in an investigation by or file an administrative charge or complaint with any Governmental Agencies (defined below), including, but not limited to, the Equal Employment Opportunity Commission or similar administrative agency. However, I agree not to accept any monetary relief or recovery from any charge or complaint filed against any Releasee with any such administrative agency except where authorized by applicable law.

Also, Releasor does not release any Claims against Releasee that may arise after this Release has become effective.

Section 2. **Representation by Counsel and Review Period**. I have been advised to consult independent legal counsel before signing this Release, and I hereby represent that I have executed this Release after having the opportunity to consult independent counsel and after considering the terms of this Release for **[if over 40][twenty- one (21) [applies if no reduction in force]/forty-five (45) [applies if there is a reduction in force]]** days (although I may choose to voluntarily execute this Release earlier). I further represent and warrant that I have read this Release carefully, that I have discussed it or have had reasonable opportunity to discuss it with my counsel, that I fully understand its terms, and that I am signing it voluntarily and of my own free will.

Section 3. **Right to Revoke Release**. This Release shall not become effective until the eighth day following the date on which I have executed it, **provided** that I have not revoked it, and I may at any time prior to that effective date revoke this Release by delivering written notice of revocation to **[Name and contact information to be inserted at the time of termination]**.

Section 4. **Consideration for Release**. I acknowledge that the consideration for this Release is consideration to which I would not otherwise be entitled and is in lieu of any rights or claims that I may have with respect to any other remuneration from the Company.

Section 5. **Representation Concerning Filing of Legal Actions**. I represent that, as of the date of this Release, I have not filed any lawsuits, charges, complaints, petitions, claims or other accusatory pleadings against Company or any of the other Releasees in any court or with any governmental agency.

Section 6. **Continuing Obligations Concerning Confidential Information and Company Property.** I acknowledge and agree that I remain subject to the restrictive covenants contained in Section 3 of the Employment Agreement and the covenants related to Confidentiality & Proprietary Information contained in Section 4 of the Employment Agreement, each of which survives the termination of my employment. I further acknowledge that I am obligated to return to the Company by [DATE], all Company documents, originals and copies, whether in hard or electronic form, and all Company property, including without limitation keys, computers, computer disks, pagers, phones and credit cards.

Section 7. **Nondisparagement**. Subject to the provisions of Section 8, I will not make any statements, whether verbally or in writing (including in electronic communications) that are professionally or personally disparaging of, or adverse to the interests of, the Company or its officers, directors, managers or employees. This includes, but is not limited to, any statements that disparage the products, services, finances, financial condition, capability or any other aspect of the business of the Company. I further agree not to engage in any conduct which is intended to harm, professionally or personally, the reputation of the Company or its officers, directors, managers or employees. For its part, the Company shall direct those of its executives that know of this Release not to make any statements, whether verbally or in writing (including in electronic communications) that are professionally or personally disparaging of you, or adverse to your interests.

Section 8. **Disclosure Exceptions**. Nothing in this Release shall prohibit the Releasor from lawfully (A) initiating communications directly with, cooperating with, providing information to, causing information to be provided to, or otherwise assisting in an investigation by any governmental or regulatory agency, entity, or official(s) (collectively, "Governmental Authorities") regarding a possible violation of any law; (B) responding to any inquiry or legal process directed to the Releasor individually (and not directed to the Company and/or its subsidiaries) from

any such Governmental Authorities; (C) testifying, participating or otherwise assisting in an action or proceeding by any such Governmental Authorities relating to a possible violation of law; or (D) making any other disclosures that are protected under the whistleblower provisions of any applicable law. Additionally, pursuant to the federal Defend Trade Secrets Act of 2016, the Releasor shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made to the Releasor's attorney in relation to a lawsuit for retaliation against the Releasor for reporting a suspected violation of law; or (c) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Nor does this Agreement require the Releasor to obtain prior authorization from the Company before engaging in any conduct described in this Section 8, or to notify the Company that he has engaged in any such conduct.

Section 9. **Tax Provision**. All payments and benefits provided under the Employment Agreement are intended to be exempt from, or to comply with, the requirements of section 409A of the Code and this Release shall be interpreted and administered in accordance with these intentions. The Severance Benefits and rights to COBRA Reimbursement under the Employment Agreement are intended to be exempt from section 409A of the Code under the "short-term deferral" exception of Treas. Reg. Section 1.409A-1(b)(4), to the maximum extent applicable, and then under the "separation pay" exception of Treas. Reg. Section 1.409A-1(b)(9)(iii), to the maximum extent applicable. All payments that are subject to Section 409A that are to be made upon a termination of the Releasee's employment may only be made upon the Releasee's "separation from service," as defined in Treas. Reg. Section 1.409A-1(h), from the Company. For purposes of section 409A of the Code, the right to a series of installment payments under this Agreement shall be treated as a right to a series of separate payments and each such installment shall be treated as a separate payment. With respect to any payments that are subject to section 409A of the Code, in no event shall the Releasee, directly or indirectly, designate the calendar year of a payment. Any reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of Treas. Reg. Section 1.409A- 3(i)(1)(iv). Notwithstanding the foregoing, the Releasee acknowledges that he has been advised to seek the advice of a tax advisor with respect to the tax consequences of all payments pursuant to the Employment Agreement, including any adverse tax consequence under section 409A and applicable State tax law, and neither the Company nor any of its members, officers, employees, agents or affiliates shall be responsible for any such adverse tax consequences or guarantees any particular tax consequences to the Releasee with respect to payments and benefits under the Employment Agreement.

Section 10. **Amendment of Release**. This Release may not be amended or modified except by a writing signed by , on behalf of Company and by me.

Section 11. **Governing Law**. This Release shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without regard to principles of conflicts of laws thereunder.

Section 12. **Neutral Interpretation**. This Release shall be interpreted in a neutral manner, and not more strongly for or against any party based upon the source of the draftsmanship of the Release.

Section 13. **Headings**. The various headings in this Release are inserted for convenience only and are not part of the Release.

Section 14. **No Admission of Liability.** Releasee agrees that this Release, and performance of the acts required by it, does not constitute an admission of liability, culpability, negligence or wrongdoing on the part of anyone, and will not be construed for any purpose as an admission of liability, culpability, negligence or wrongdoing by any party and/or by any party's current, former or future parents, subsidiaries, related entities, predecessors, successors, officers, directors, stockholders, agents, employees and assigns.

Dated: This ___day of___, 20___.

WITNESSES:

17

Exhibit 10.21

AMENDMENT NO. 1
TO AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT

This AMENDMENT NO. 1 TO AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT (this "New Amendment") is made as of March 18, 2021, by and between Finch Therapeutics Group, Inc., a Delaware corporation ("FTG", together with all subsidiaries and affiliates hereinafter referred to as the "Company"), and Joseph Vittiglio (the "Executive") This New Amendment shall amend that certain AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT, dated as of March 12, 2021 (the "Prior Amendment"), by and between the Company and the Executive.

RECITALS

WHEREAS, the Prior Amendment amended that certain Employment Agreement, dated on or about December 7, 2020, by and between the Company and the Executive (the "Employment Agreement"); and

WHEREAS, the vesting commencement date set forth in the Prior Amendment was mis-stated due to an administrative error; and

WHEREAS, the parties desire to amend the Prior Amendment to reflect the true intention of the Company and the Executive, as set forth herein.

NOW, THEREFORE, for good and valuable consideration, the sufficiency of which is hereby acknowledged, the parties hereto hereby agree as follows:

1. **AMENDMENT OF SECTION 2.3(a) OF THE PRIOR AMENDMENT.** The vesting commencement date for the Option referenced in Section 2.3(a) of the Prior Agreement shall be amended such that the vesting commencement date shall be on the first year anniversary of December 7, 2020, and the remaining shares covered by the Option vesting and becoming exercisable in forty-eight (48) equal monthly installments thereafter, subject to Executive's continuous service as of each such date.

2. **COUNTERPARTS**. This New Amendment may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

3. **GOVERNING LAW**. All issues and questions concerning the construction, validity, enforcement and interpretation of this New Amendment shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without regard to conflicts of laws principles.

4. **NO OTHER AMENDMENT**. Except as specifically amended by this New Amendment, all other terms and conditions of the Prior Amendment shall remain in full force and effect in accordance with their terms without modification.

IN WITNESS WHEREOF, the undersigned hereby executes this New Amendment as of the date first above written.

FINCH THERAPEUTICS GROUP, INC.

By: /s/ Mark Smith
Name: Mark Smith Title: CEO

EXECUTIVE:

/s/ Joseph Vittiglio
Name: Joseph Vittiglio

Exhibit 21.1

SUBSIDIARIES

Name	Jurisdiction of Formation
Finch Therapeutics, Inc.	Delaware
Finch Therapeutics Holdings, LLC	Delaware
Finch Research and Development, LLC	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-254773 on Form S-8 of our report dated March 31, 2022, relating to the consolidated financial statements of Finch Therapeutics Group, Inc. and its subsidiaries appearing in this Annual Report on Form 10-K of Finch Therapeutics Group, Inc. and its subsidiaries for the year ended December 31, 2021.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 31, 2022

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark Smith, certify that:

1. I have reviewed this Annual Report on Form 10-K of Finch Therapeutics Group, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2022

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

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gregory D. Perry, certify that:

1. I have reviewed this Annual Report on Form 10-K of Finch Therapeutics Group, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2022

By: /s/ Gregory D. Perry
Gregory D. Perry
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Finch Therapeutics Group, Inc. (the "Company") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the company, hereby certifies, pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to his or her knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Exchange Act; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

Date: March 31, 2022

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

Date: March 31, 2022

By: /s/ Gregory D. Perry
Gregory D. Perry
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)