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, 2022

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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2022, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $76.0 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 20, 2023, there were 48,144,924 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, 2022, are incorporated by reference in Part III of this Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. 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:

- our expectations with respect to our microbiome technology and related portfolio of intellectual property and microbiome assets, and our objectives to realize the value of our intellectual property estate through licensing our technology to collaboration partners and enforcing our patent rights against infringing technologies;
- the initiation, timing, progress and results of any current or future preclinical studies and clinical trials and related preparatory work of product candidates developed using our microbiome technology, including through academic collaborations;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the ability of our current or future partners or collaborators to obtain regulatory approval product candidates developed using our microbiome technology;
- the ability of our current or future partners or collaborators to advance product candidates into, and successfully complete, preclinical studies and clinical trials;
- the ability of our current or future partners or collaborators to contract with contract research organizations, contract manufacturing organizations, third-party suppliers and manufacturers and other third parties with which they do business and their ability to perform adequately;
- our expectations regarding the potential market size and the rate and degree of market acceptance for any product candidates developed using our microbiome technology;
- our ability to fund our working capital requirements and to service any debt obligations we may incur;
- our intellectual property position, including the scope of protection we are able to establish, maintain and enforce for intellectual property rights covering product candidates developed using our microbiome technology;
- our financial performance and our ability to effectively manage employee matters; and
- our ability to obtain additional funding for our operations.

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 have discontinued our PRISM4 Phase 3 trial of CP101 in recurrent *C. difficile* infection ("CDI") and shifted our strategic focus towards realizing the value of our intellectual property estate and other assets. This process may be costly, time consuming and complex, and we may not realize any additional value. If we fail to execute successfully on this reprioritized strategic focus, our Board may decide to pursue other options, including a dissolution and liquidation of the Company.
- We have a limited operating history, have incurred net losses in every year since our inception and may continue to incur net losses in the future.
- We may require additional funding to finance our operations. If we are unable to raise capital when needed, we could be forced to consider a dissolution and liquidation of the Company.
- We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern.
- Actions that we have taken to refocus our business, including the discontinuation of our clinical trial of CP101 and our workforce reduction, may not be as effective as anticipated at reducing our ongoing costs and maximizing shareholder value, and could have a negative impact on our results of operations.
- We may be unable to retain the services of the key remaining members of our management team or attract, retain and motivate the qualified personnel necessary to oversee and implement our strategic reprioritization and, as a result, we may be unable to fully monetize our intellectual property estate and other assets.
- Our intellectual property portfolio is based on microbiome therapeutics, which is a newly approved approach to therapeutic intervention.
- Clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of product candidates developed using our microbiome technology, which would prevent or delay or limit the scope of regulatory approval and commercialization and could harm the value and marketability of our intellectual property portfolio.
- The results of preclinical studies and early-stage clinical trials involving product candidates developed using our microbiome technology may not be predictive of the results of later-stage clinical trials. Initial success in third-party studies or clinical trials involving any product candidates that utilize our microbiome technology may not be indicative of results obtained when these trials are completed or in later-stage trials.
- Product candidates developed using our microbiome technology 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 product candidates developed using our microbiome technology, or are identified following approval of such product candidates, the development of such product candidates may be suspended or abandoned, the commercial profile of any approved label may be limited, or the developers of such product candidates may be subject to other significant negative consequences following marketing approval, which could harm the value of our intellectual property portfolio.
- Interim, topline and preliminary data from clinical trials involving product candidates developed using our microbiome technology 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.
- Preclinical development is uncertain. Preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect the ability of a developer of a product candidate developed using our microbiome technology to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business and our ability to realize the value of our microbiome technology intellectual property portfolio.

- Although we have discontinued the PRISM4 trial and withdrawn our IND for CP101, we remain subject to ongoing regulatory obligations, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with such regulatory requirements or experience unanticipated problems.
- The manufacture of product candidates developed using our microbiome technology is complex and developers of such product candidates may encounter difficulties in production, particularly with respect to process development or scaling-up of our manufacturing capabilities.
- We have relied on third-party donors of biological material to manufacture certain product candidates such as CP101, and if we did not detect all pathogens in donor material, there may be adverse reactions in persons who use or consume products that are derived from that material.
- Some of our product candidates may be studied in clinical trials sponsored by organizations or agencies other than us, or in investigator-sponsored clinical trials, which means we will have minimal or no control over the conduct of such trials.
- 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.
- If we are unable to obtain or protect intellectual property rights related to any of our technologies, product candidates, or that otherwise have value, we may not be able to compete effectively or leverage our intellectual property to generate value.
- Patent terms may be inadequate to protect the competitive position of the products of our future collaboration partners, if any, 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 product candidate, our business may be materially harmed.
- 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 may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.
- We or our collaboration partners may be unsuccessful in licensing or acquiring intellectual property from third parties that may be required to develop and commercialize our product candidates.
- Third parties may initiate legal proceedings alleging that we or a collaboration partner 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.
- We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.
- Intellectual property rights do not necessarily address all potential threats to our competitive advantage.
- Our shares of common stock could be delisted from the Nasdaq Global Select Market, which could result in, among other things, less liquidity for holders of shares of our common stock and a decline in the price of our common stock.

PART I

Item 1. Business.

Overview

We are a microbiome technology company with a portfolio of intellectual property and microbiome assets. Our objectives are to realize the value of our intellectual property estate through licensing our technology to collaboration partners and enforcing our patent rights against infringing parties and, in certain cases, to generate additional data on selected product candidates through academic collaborations. We have a robust intellectual property estate reflecting our pioneering role in the microbiome therapeutics field, including more than 70 issued U.S. and foreign patents with relevance for both donor-derived and donor-independent microbiome therapeutics in a range of potential indications. Our assets include CP101, an investigational, orally administered microbiome candidate designed for the prevention of recurrent *C. difficile* infection, or CDI, with positive clinical data from a Phase 2 randomized, placebo-controlled trial and a Phase 2 open-label trial, and pre-

clinical assets that are designed to target ulcerative colitis, Crohn's disease, and autism spectrum disorder. Additionally, we have developed a significant biorepository of strains and samples. In January 2023, we announced the decision to discontinue our Phase 3 clinical trial of CP101 in recurrent CDI and focus on realizing the value of our intellectual property estate and other assets. We are currently in the process of winding down our development efforts and significantly scaling back our expenses, including by terminating vendor contracts and reducing headcount.

Until January 2023, we were a clinical-stage microbiome therapeutics company using 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 microbiome disruption can increase susceptibility to immune disorders, infections, neurological conditions, cancer and other serious diseases. We developed our *Human-First Discovery* platform to use reverse translation to identify diseases of microbiome disruption and to design microbiome therapeutics that address them.

We were previously developing CP101 as an orally administered complete microbiome therapeutic designed for the prevention of recurrent 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, 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. On March 1, 2022, we announced that enrollment in our Phase 3 clinical trial of CP101 for the prevention of recurrent CDI, or the PRISM4 trial, was paused following receipt of a clinical hold letter from the U.S. Food and Drug Administration, or the FDA, in connection with our investigational new drug application for CP101, requesting additional information regarding our SARS-CoV-2 donor screening procedures and associated informed consent language. On April 27, 2022, the FDA removed the clinical hold and in October 2022, we proceeded with patient dosing in the PRISM4 trial. On January 24, 2023, we announced our decision to discontinue PRISM4. We believe that CP101 has therapeutic potential in both CDI and other indications.

We have also used our *Human-First Discovery* platform to develop FIN-211, an investigational microbiome candidate designed to address the gastrointestinal and behavioral symptoms of autism spectrum disorder, or ASD. Following a strategic review of our pipeline, on November 10, 2022, we announced the decision to suspend efforts to initiate our planned Phase 1 clinical trial of FIN-211 in ASD, or the AUSPIRE trial.

In January 2017, we entered into an agreement, which we refer to as the Takeda Agreement, with Takeda Pharmaceutical Company Limited, or Takeda, pursuant to which we granted Takeda a worldwide, exclusive license, with the right to grant sublicenses, under certain of our patents, patent applications and know-how to develop our microbiome therapeutic candidate, FIN-524, for the prevention, diagnosis, theragnosis or treatment of diseases in humans. We also partnered with Takeda on discovery efforts targeting the development of the microbiome therapeutic candidate FIN-525 for the treatment of Crohn's disease. In August 2022, Takeda elected to terminate the Takeda Agreement. Termination of the Takeda Agreement became effective on November 17, 2022, at which point the license rights granted to Takeda terminated and we regained full rights to pursue FIN-524 and FIN-525, and any other microbiome product candidates for inflammatory bowel disease, in all fields worldwide.

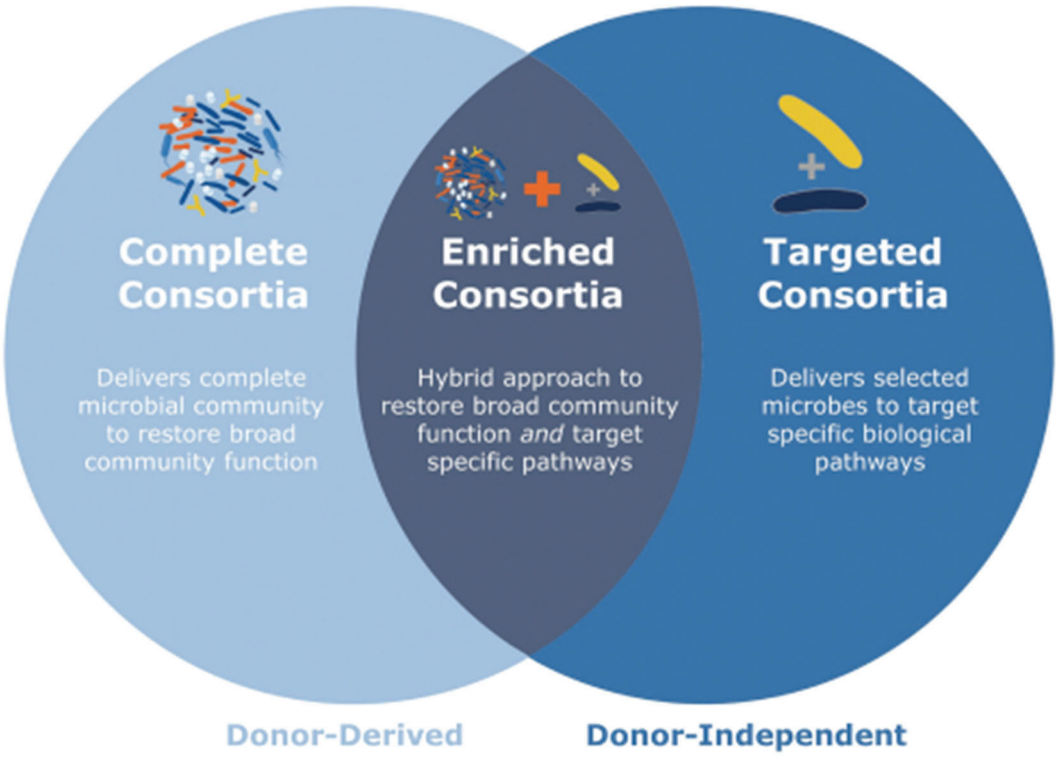
We will also continue to explore opportunities to realize the value of our intellectual property and microbiome assets through strategic partnerships and academic collaborations. These include our licensing relationship with the University of Minnesota, or UMN, pursuant to which UMN is conducting multiple investigator-sponsored clinical trials using a microbiome product candidate comprised of compositions to which we hold an exclusive license. In addition to our clinical and pre-clinical assets, we have developed a biorepository of samples and strains that can be used in a variety of research applications and may form the basis for future collaborations.

On each of April 19, 2022, September 1, 2022, and January 24, 2023, we announced the implementation of certain expense reduction measures, including reductions in our workforce. On January 24, 2023, we announced a decision to re-orient our business strategy to close our Phase 3 study of CP101 in CDI and focus on realizing the value of the Company's intellectual property and other assets. This decision came after an assessment by our management team and board of directors of multiple factors, including our outlook for identifying a commercial partner, slower than anticipated enrollment in the PRISM4 trial, the harmful impact of what we believe is the ongoing unauthorized use of our intellectual property, and broader sector trends in the biotechnology industry.

Targeted and Enriched Consortia Product Candidates

In addition to CP101, a Complete Consortia product candidate designed to address community-level dysbiosis, or disruption across many functional pathways and species, we also developed certain 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 enabled us to tailor our product candidates to the pathophysiology of each indication. This combination of capabilities also enabled us to pursue a third product strategy, Enriched Consortia, which is designed to address dysbiosis at both the community and pathway level. These product strategies are summarized in the schema below:



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: as of 2015, 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 inflammatory bowel disease, or 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 disruption of the microbiome. 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 microbiome disruption, we believe that only through the restoration of the critical physiological role of the microbiome organ can this be achieved.

Intellectual Property

As a core source of value at the Company, we believe that our intellectual property portfolio is foundational for the field of microbiome therapeutics. We believe that this portfolio may present attractive licensing opportunities as the field continues to mature and new applications for microbiome technology emerge. We have filed or in-licensed U.S. and foreign patents and patent applications related to this foundational technology. As a result, we have developed a significant portfolio of intellectual property assets.

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 relevant product candidates, or whether the claims of any issued patents will provide any competitive advantage or value for the enterprise.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months following their submission, 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, others may contend that 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.

We have a large and diverse patent portfolio consisting of more than 70 issued U.S. and foreign patents that we own or exclusively license from others. Our patent portfolio has broad applicability of specific inventions across the microbiome field, and provides protection for our product candidates CP101, FIN-211, FIN-524, FIN-525, as well as additional Complete, Enriched and Targeted Consortia product candidates that may be developed. For CP101 specifically, our patent portfolio includes more than ten U.S. patents that cover CP101 and specific methods of use and manufacture. These patents have expiration dates between 2031 and 2037.

Foundational Protection for Multiple Product Candidates

Many of our 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 twenty issued U.S. patents, one pending U.S. patent application, granted foreign patents in Australia, Brazil, Canada, China, Israel, Mexico, Republic of Korea, New Zealand and Japan, and two 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 specific approaches 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, three pending U.S. patent applications, 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 specific approaches to formulations comprising fecal bacteria, methods of increasing fecal microbiota diversity, and methods of decreasing the 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, Brazil, Japan and China, and eight pending foreign patent applications. These issued U.S. patents have claims directed to specific approaches 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 other Complete Consortia product candidates include:

- One owned issued U.S. patent (U.S. 10,617,724) covering specific approaches to 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 specific approaches to 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 specific approaches to 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 specific approaches to 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 specific approaches to room-temperature stable products containing human-derived bacteria.
- One in-licensed issued U.S. patent (U.S. 10,849,936) covering specific approaches to 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 patent protection that we expect will cover each of our Targeted Consortia product candidates, including FIN-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 specific approaches to 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 that we expect will cover 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 specific approaches to 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 specific approaches to 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 specific approaches to 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 specific approaches to 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 specific approaches to 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 specific approaches to 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 United States Patent and Trademark Office 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 product candidates developed using our intellectual property 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.

Our Collaborations and License Agreements

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, our affiliates or our sublicensees, 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. We are also currently engaging in discussions with Skysong regarding our recent strategic reprioritization and the potential implications of these changes on our ongoing obligations under the Arizona State Agreement.

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 for any reason or upon an uncured material breach of the agreement by Skysong. Skysong may terminate the Arizona State Agreement 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 the University of Minnesota

In March 2012, CIPAC Limited, an entity established under the laws of Malta, or CIPAC, entered into a license agreement, or the UMN Agreement, with Regents of 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. We are currently in discussions with UMN to amend the UMN Agreement with respect to the dates of specific deadlines for achieving milestones required as part of our obligation to use commercially reasonable efforts to commercialize the licensed inventions and to manufacture and sell licensed products, but we cannot guarantee that these efforts will be successful.

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 began 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 cover 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 upon an uncured material breach of the UMN Agreement by UMN. UMN may terminate the UMN Agreement 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.

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 other 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 not to 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 hepatitis B virus, 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 FIN-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. Although we have discontinued the PRISM4 trial and withdrawn our investigational new drug application, or IND, for CP101, as the sponsor of clinical trials and IND holder, we along with third-party contractors, remain subject to regulation. 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.

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 the Good Laboratory Practice 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 by a sponsor to administer an investigational product to humans and must become effective before human clinical trials may begin.

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 Good Clinical Practice, 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 institutional review board, or 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.

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 discontinue a clinical investigation under an IND must notify FDA and IRBs of the discontinuance. A sponsor may request that FDA inactivate or terminate its IND. If an IND is placed on inactive status, all investigators shall be so notified and all stocks of the drug shall be returned or otherwise disposed of in accordance with FDA regulations. A sponsor is not required to submit annual reports to an IND on inactive status. A sponsor who intends to resume clinical investigation under an IND placed on inactive status must submit a protocol amendment to FDA containing the proposed general investigational plan for the coming year and appropriate protocols. Clinical investigations under an IND on inactive status may only resume (1) 30 days after FDA receives the protocol amendment, unless FDA notifies the sponsor that the investigations described in the amendment are subject to a clinical hold, or (2) on earlier notification by FDA that the clinical investigations described in the protocol amendment may begin.

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.

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.

Employees and Human Capital Resources

As of March 20, 2023, we had 18 employees. Of these 18 employees, 6 are engaged in research and development activities and 12 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 retaining and incentivizing and our existing 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.

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 Shift in Strategic Focus, Financial Position and Capital Needs

We have discontinued our PRISM4 Phase 3 trial of CP101 in recurrent C. difficile infection ("CDI") and shifted our strategic focus towards realizing the value of our intellectual property estate and other assets. This process may be costly, time consuming and complex, and we may not realize any additional value. If we fail to execute successfully on this reprioritized strategic focus, our Board may decide to pursue other options, including a dissolution and liquidation of the Company.

We have discontinued our PRISM4 Phase 3 clinical trial of CP101 in recurrent CDI and shifted our focus towards realizing the value of our intellectual property estate and other assets. The process of reorienting our business strategy is costly, time consuming and complex, and we have incurred, and may in the future incur, significant costs related to this continued strategic shift. The strategic alternatives we are considering include the evolution into a microbiome technology and intellectual property company, focusing on the potential out-license of our technology, enforcement of our patent rights, the sale of certain of our assets, strategic partnerships, joint ventures, restructurings, divestitures, investments or other alternatives, as well as current and any potential new investigator-sponsored trials, to advance our microbiome assets and de-risk future development opportunities in the microbiome space. These activities, as well as our January 2023 reduction in force, which will result in the termination of approximately 95% of our employees, may also result in a loss of continuity, accumulated knowledge, know-how and efficiency. Further, our strategic reprioritization may result in unexpected expenses or liabilities and/or write-offs. There is no assurance that we will be successful at executing on our revised strategy or that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results.

If we are unable to execute successfully on our reprioritized strategic focus, our cash resources may not last as long as estimated and our business, results of operations and financial condition could be materially and adversely affected. Our Board may decide to pursue other options, including a dissolution and liquidation of the Company, which may result in our stockholders receiving little or no value in respect of their shares of common stock.

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

We have recently reprioritized our strategic operations and are focusing on realizing the value of our intellectual property estate and other assets. We have a limited operating history in both this capacity and as a clinical-stage microbiome therapeutics company. 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, and particularly due to our strategic reprioritization, 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. Although we may use our product candidates and microbiome technology to support third-party research, including investigator-sponsored trials, we do not currently expect to progress any product candidate through clinical trials or commercial approval and we do not currently expect to generate any revenue from product sales. We have incurred losses in each reporting period since our inception. For the years ended December 31, 2022 and 2021, we reported net losses of $114.6 million and $58.2 million, respectively. As of December 31, 2022, we had an accumulated deficit of $275.6 million. We expect to continue to incur significant losses for the foreseeable future as we attempt to realize the value of our intellectual property estate and other assets.

We may never succeed in realizing the full value of our intellectual property estate and other assets 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. 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 realizing the value of our intellectual property estate and other assets, 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 may require additional funding to finance our operations. If we are unable to raise capital when needed, we could be forced to consider a dissolution and liquidation of the Company.

To date, we have primarily funded our operations through the initial public offering (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 in an effort to maximize the value of our intellectual property estate and other assets, including through enforcement of our patents. We may require additional capital to do so, which we may raise through equity offerings, debt financings, and other collaborations, strategic alliances and licensing arrangements or other sources. 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 securities, 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 operational efforts. If we are unable to raise capital when needed or on acceptable terms, we would be forced to consider a dissolution and liquidation of the Company.

We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern.

In Note 1 to our consolidated financial statements, we disclose that there is substantial doubt about our ability to continue as a going concern. Although we currently forecast that our cash and cash equivalents of $71.0 million as of December 31, 2022 will be sufficient to fund our operating expenses and capital requirements for at least twelve months from the issuance of our annual consolidated financial statements for the year ended December 31, 2022, we have identified certain qualitative conditions and events that raise substantial doubt about our ability to continue as a going concern. On January 24, 2023, we announced the implementation of certain expense reduction measures, including reductions in our workforce, and the decision to re-orient our business strategy to discontinue our Phase 3 clinical trial of CP101 in recurrent CDI and focus on realizing the value of our intellectual property estate and other assets. While we believe strongly in the value of our pioneering intellectual property portfolio and the merits of our current litigation activities relating to those assets, we may never succeed in realizing the value of our intellectual property estate and other assets and even if we do, we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our ability to continue as a going concern. Further, we have suffered recurring losses from operations since our inception and expect to continue to incur operating losses for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern.

Based on our internal estimates and current operating plan, including giving effect to our recent changes to our business plan and reductions in force, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into 2025. However, this estimate is based on our current assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. We may not be able to limit expenses to the extent we predict, and adequate additional funding may not be available to us on acceptable terms, or at all. If we cannot continue as a viable entity, our shareholders may lose some or all of their investment in us.

Actions that we have taken to refocus our business, including the discontinuation of our clinical trial of CP101 and our workforce reductions, may not be as effective as anticipated at reducing our ongoing costs and maximizing shareholder value, and could have a negative impact on our results of operations.

As previously disclosed, in connection with our strategic reprioritization we implemented a workforce reduction and discontinued our clinical trial of CP101 for the prevention of recurrent CDI. We undertook these steps in an effort to refocus our business, reduce expenses and conserve cash. However, there can be no assurance that these efforts will result in the expected degree of cost-cutting and cash-savings, or otherwise create any shareholder value, particularly in light of the recent depletion of cash from the repayment of amounts outstanding under our loan agreement with Hercules and given our ongoing obligations with respect to our existing lease commitments. These undertakings were, and the reduction in our workforce may continue to be, disruptive to our limited operations, including by distracting management from our core business, affecting employee productivity and morale, or impacting our ability to hire or retain key personnel, any of which could, in turn materially and adversely impact our operations. In addition, such actions could impair our operations, could make it more difficult for us to deploy resources towards business development, or financial or other strategic, opportunities.

We may be unable to retain the services of the key remaining members of our management team or attract, retain and motivate the qualified personnel necessary to oversee and implement our strategic reprioritization and, as a result, we may be unable to fully monetize our intellectual property estate and other assets.

We are highly dependent on our management team, including Mark Smith, Ph.D., our Chief Executive Officer, as we implement our strategic reprioritization. Each member of our management team may terminate their employment with us at any time. The loss of the services of any of these key personnel, as a result of our strategic reprioritization or otherwise, could impede our ability to fully monetize our intellectual property and other assets. We do not currently maintain "key person" life insurance on the lives of our executives or any of our employees.

In January 2023, we implemented a restructuring that is expected to reduce our workforce by approximately 95% when it is complete in May 2023. By the end of March 2023, the majority of our key management team will no longer be employed with us. The uncertainty inherent in this ongoing restructuring may be difficult to manage, may cause concerns from third parties with whom we do business, and may make it difficult to attract new employees in the future who will be key to implementing and overseeing our new business strategy and operations. In addition, while we expect to engage in an orderly transition process as we reduce our key management team and look for qualified individuals to guide the Company through our strategic reprioritization, we face a variety of risks and uncertainties related to management transition, including potential diversion of management attention from critical business concerns, failure to retain key personnel, failure to attract qualified personnel to guide us through the strategic reprioritization, and loss of institutional knowledge.

If we lose one or more of our executive officers or key employees, or if we are unable to attract and retain new executive officers and employees key to the execution of our strategic reprioritization, our ability to implement our business strategy successfully could be seriously harmed. The loss of the services of our executive officers or other key employees could impede the achievement of our business objectives and adversely affect our ability to successfully implement our reprioritized business strategy. Additionally, our limited senior management team size may hamper our ability to effectively manage a publicly traded company while operating our business. Our management team realizes that it will take significant resources to meet the requirements of federal securities laws while simultaneously working on the strategic reprioritization.

Attracting and retaining qualified personnel to guide the Company through our strategic reprioritization and operate the Company once our new strategic focus has been implemented 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 implement our business strategy. 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.

Our liquidity position could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail.

We regularly maintain cash balances at third-party financial institutions, such as Silicon Valley Bank, in excess of the Federal Deposit Insurance Corporation (the "FDIC") insurance limit. Silicon Valley Bank's ongoing insolvency and receivership with the FDIC temporarily impacted access to our cash or cash equivalents. Similar failures of a depository institution to return our deposits or other adverse developments in financial or credit markets could further impair our liquidity position, including our ability to satisfy working capital needs, and create additional market and economic uncertainty.

Risks Related to the Development and Manufacture of Product Candidates Developed Using Our Microbiome Technology

Our intellectual property portfolio is based on microbiome therapeutics, which is a newly approved approach to therapeutic intervention.

Our intellectual property portfolio is based on microbiome therapy, a therapeutic approach that is designed to treat disease by restoring the function of a dysbiotic microbiome. At this time, we are aware of only one product that has received regulatory approval for a therapeutic based on this approach, and we are not yet aware of its degree of commercial success. With such limited precedent, we cannot be certain that this approach will lead to the development of additional approvable or marketable products. In addition, the efficacy potential of product candidates developed using microbiome technology may vary based on indication and use in different patient populations including geographical areas. Finally, the FDA or other regulatory agencies may have limited 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 expected development costs for developers of microbiome therapeutics and delay or prevent commercialization of product candidates developed using our microbiome technology. Regulatory requirements governing microbiome therapies are still developing and may change in the future. Regulatory authorities and advisory groups, and the new guidelines they promulgate, may lengthen the regulatory review process, require developers of microbiome therapeutics to perform additional preclinical studies or clinical trials, increase development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of product candidates developed using microbiome technology 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. The success of microbiome therapeutic product candidates, if approved, will depend upon physicians who specialize in the treatment of diseases targeted by product candidates developed using microbiome technology, prescribing potential treatments that involve the use of product candidates developed using microbiome technology in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. The success of microbiome therapeutic product candidates, if approved, will also depend on consumer acceptance and adoption of any such commercialized products. Adverse events in non-IND human clinical studies and clinical trials of product candidates developed using microbiome therapeutics, as well as any other adverse findings that may arise in connection with the continued research and development in the microbiome field, could result in negative publicity and a decrease in demand for any microbiome therapeutic product. 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 the ability of any of our current or future partners and collaborators, and the ability of others developing therapeutic candidates using our microbiome technology, to successfully 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 or demand for product candidates developed using microbiome technology.

Clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of product candidates developed using our microbiome technology, which would prevent or delay or limit the scope of regulatory approval and commercialization and could harm the value and marketability of our intellectual property portfolio.

To obtain the requisite regulatory approvals to market and sell any product candidates developed using our microbiome technology, any developers of such product candidates must demonstrate through extensive preclinical studies and clinical trials that the 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. For example, any developers of such product candidates may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful. Moreover, a clinical trial can fail at any stage of testing and most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. 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 any product candidates in the United States or abroad, the developer of such product candidate 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.

Clinical trials conducted by developers of product candidates that utilize our microbiome technology may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market such 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 any future clinical trials involving product candidates developed using our microbiome technology fail to demonstrate or are inconclusive with respect to safety and efficacy, if such product candidates do not meet the designated clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with such product candidates, the developers of such product candidates may be delayed in obtaining marketing approval, if at all, and the value and marketability of our intellectual property portfolio as a whole may be harmed. Any of these occurrences would have negative implications for the future development potential of product candidates developed with our microbiome technology and our intellectual property portfolio and may harm our business, financial condition and results of operations. Additionally, any safety concerns observed in any clinical trials involving product candidates developed using our microbiome technology could limit the prospects for regulatory approval of such product candidates in those and other indications and harm the value and marketability of our intellectual property portfolio as a whole.

Even if any clinical trials with respect to product candidates developed using our microbiome technology are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and the FDA or comparable foreign regulatory authorities may not interpret the results in the same manner as the proponent of the product candidate. More trials could be required before such product candidates are submitted for approval, especially for indications for which clinical endpoints are not well-established. The FDA or comparable foreign regulatory authorities may not view such product candidates as being efficacious 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 any other current or future product candidates may be significantly delayed, or significant additional resources may be required to conduct additional trials in support of potential approval of such 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 involving product candidates developed using our microbiome technology may not be predictive of the results of later-stage clinical trials. Initial success in third-party studies or clinical trials involving any product candidates that utilize our microbiome technology 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. Accordingly, there can be no assurance that any clinical trials involving product candidates developed using our microbiome technology will ultimately be successful or support further clinical development. There is a high failure rate for all product candidates proceeding through clinical trials. Many companies in the biotechnology and pharmaceutical industries, including in the field of microbiome therapeutics, have suffered significant setbacks in late-stage clinical trials after achieving what appeared to be positive results in early-stage development and product candidates developed using our microbiome technology may 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. Additionally, microbiome therapeutic product candidates used in small early-stage studies may be derived 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 clinical development could have negative implications for the future development potential of product candidates developed using our microbiome technology or our intellectual property portfolio as a whole, and would have a material adverse effect on our business, financial condition and results of operations.

Product candidates developed using our microbiome technology 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 product candidates developed using our microbiome technology, or are identified following approval of such product candidates, the development of such product candidates may be suspended or abandoned, the commercial profile of any approved label may be limited, or the developers of such product candidates may be subject to other significant negative consequences following marketing approval, which could harm the value of our intellectual property portfolio.

Undesirable side effects that may be caused by product candidates developed using our microbiome technology could cause the developers of such product candidates 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. The results from future preclinical studies and clinical trials of product candidates developed using our microbiome technology may identify safety concerns or other undesirable properties of such product candidates. Additionally, if the development of such product candidates is expanded into new patient populations or disease areas, side effects or adverse events not seen in preclinical and clinical research conducted to date could emerge.

The results of clinical trials of product candidates developed using our microbiome technology may show that such product candidates cause undesirable or unacceptable side effects or even death. In such an event, the relevant clinical trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order the developers of such product candidates to cease further development of or deny approval of such 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 would have negative implications for the future development potential of product candidates developed with our microbiome technology and our intellectual property portfolio and would significantly harm our business, financial condition and results of operations.

Moreover, if product candidates developed using our microbiome technology are associated with undesirable side effects in preclinical studies or clinical trials or have characteristics that are unexpected, the developers of such product candidates 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 other companies or institutions or with commercial products offered by others may cause the FDA or other regulatory oversight bodies to suspend or terminate clinical trials of product candidates developed using our microbiome technology or change the requirements for approval of such product candidates or otherwise adversely impact the clinical and commercial development of such product candidates. Such adverse developments may cause the FDA to perceive such product candidates as unsafe and bring increased regulatory scrutiny to the clinical operations of the developers of such product candidates more broadly, may lead to decreased confidence by patients, physicians and contract research organizations, or CROs, in such product candidates, and may result in reduced demand for any product ultimately developed, if approved.

Additionally, if any product candidates developed using our microbiome technology receives marketing approval and undesirable or unacceptable side effects caused by such products are later identified, a number of potentially significant negative consequences could result, including:

- site institutional review boards 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 the removal of the approved product from 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 the implementation of a risk evaluation and mitigation strategy, or REMS, plan to ensure that the benefits of the product outweigh its risks;
- the developer of the applicable product candidate 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;
- the developer of the applicable product candidate may be subject to limitations on how the product may be promoted;
- sales of the product may decrease significantly;
- we or the developer of the product candidate may be subject to litigation or product liability claims; and
- our reputation and/or the reputation of the developer of the product candidate may suffer.

Any of these events could prevent the developers of any product candidate developed using our microbiome technology 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 the generation of significant revenue from the sale of such product candidate, if approved. Any such occurrence may have negative implications for the future development potential of product candidates developed with our microbiome technology and would have a material adverse effect on our business, financial condition and results of operations.

Interim, topline and preliminary data from clinical trials involving product candidates developed using our microbiome technology 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, the developers of product candidates developed using our microbiome technology may publish interim, topline or preliminary data from clinical trials. Preliminary and interim data from such clinical trials may change as more patient data become available. Preliminary or interim data from such 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 becomes available, and the final clinical trial report becomes available. 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 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 and the value of our microbiome technology intellectual property portfolio.

Further, others, including regulatory agencies, may not accept or agree with the assumptions, estimates, calculations, interpretations, conclusions or analyses of developers of product candidates developed using our microbiome technology 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 the value and future marketability of our microbiome technology intellectual property portfolio in general. For example, regulatory agencies may disagree with the inclusion or exclusion of certain trial subjects from clinical trial data or the interpretation of such data. In addition, you or others may not agree that the information disclosed is the material or otherwise appropriate information to include in the disclosure, and any information such developer determines not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, if any, or product candidate. If the preliminary and interim data reported by a developer of a product candidate developed using our microbiome technology differs from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, the ability of the applicable developer to obtain approval for, and commercialize, such product candidates may be harmed, which could have negative implications for the future development potential of product candidates developed with our microbiome technology and may harm our business, operating results, prospects or financial condition.

Preclinical development is uncertain. Preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect the ability of a developer of a product candidate developed using our microbiome technology to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business and our ability to realize the value of our microbiome technology intellectual property portfolio.

Before any developer of a product candidate developed using our microbiome technology can commence clinical trials for such product candidate, the developer 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 conducting preclinical testing and studies may cause the developer of such product candidate to incur additional operating expenses. The FDA may not accept proposed clinical programs involving product candidates developed using our microbiome technology, or the outcome of preclinical testing and foreign clinical trials involving product candidates developed using our microbiome technology may not support the further development of additional product candidates that may further our business strategy or allow us to achieve profitability. As a result, we cannot be sure that INDs or similar applications for preclinical programs related to product candidates developed using our microbiome technology will be submitted, 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. Unless clinical trials involving product candidates developed using our microbiome technology are initiated and, ultimately, successfully completed, and such product candidates achieve regulatory approval and are commercialized successfully, we may be unable to execute on our business strategy of maximizing the value of our intellectual property estate.

Although we have discontinued the PRISM4 trial and withdrawn our IND for CP101, we remain subject to ongoing regulatory obligations, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with such regulatory requirements or experience unanticipated problems.

Although we have discontinued the PRISM4 trial and withdrawn our IND application for CP101, as the sponsor of clinical trials and IND holder, we remain subject to regulation. Our failure or the failure of our third-party contractors to comply with the applicable regulatory requirements of the FDA or other applicable governmental authorities at any time, including requirements related to the manufacture, testing, labeling, distribution, promotion, import, or export, may subject us to administrative or judicial sanctions, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

Further, as product candidates developed using our microbiome technology are developed through early- to late-stage clinical trials towards approval and commercialization, the developers of such product candidates may make alterations to these product candidates and their method of manufacture and use, including changes to the 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 such 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 the developers of such product candidates conduct bridging comparability testing or other additional clinical studies to confirm the clinical relevance of prior data.

We have relied on third-party donors of biological material to manufacture certain product candidates such as CP101, and if we did not detect all pathogens in donor material, there may be adverse reactions in persons who use or consume products that are derived from that material.

While the stool donor program on which we relied to manufacture certain product candidates, including CP101, involved extensive screening of potential entrants, we can make no assurances that it successfully screened for, or was 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 have failed to identify certain existing diseases or conditions in the humans that we evaluated for entry into our donor program. In addition, while enrolled in our program, donors may have developed new diseases or conditions, or the worsening of pre-existing or underlying diseases or conditions, that we may have failed to identify. The use by a collaboration partner 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 if there are any adverse reactions in patients who use or consume products derived from that donor.

While our stool donor program was operating, we extensively tested the biological materials that we received from qualified third-party donors or suppliers for the presence of certain pathogens and other microorganisms; however, there can be no assurances that we detected all pathogens and other microorganisms in our product candidates, which could result in an adverse reaction in persons who use or consume our product candidates. Our testing processes may have failed to identify pathogens in the stool that we received 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. The presence of pathogens in the stool material that we received from third-party donors may also result in adverse reactions in persons who use or consume products that are derived from that material.

Even if product candidates developed using our microbiome technology obtain regulatory approval, the products may not gain market acceptance among physicians, patients, hospitals and others in the medical community, and they may not have the degree of commercial success necessary for us to generate significant revenue.

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 product candidates developed using our microbiome technology are accepted in the market, including:

- the clinical indications for which such product candidates are approved;
- physicians, hospitals and patients considering such product candidates as a safe and effective treatment;
- the potential and perceived advantages of such product candidates over current or future alternative treatments;
- the ability of the developers of such product candidates to demonstrate their advantages 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 such product candidates as well as competitive products;
- the cost of treatment and the availability of testing for patient selection;
- the pricing of such 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 sales and marketing efforts for such product candidates.

If product candidates developed using our microbiome technology 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, serious adverse events or deaths in other clinical trials involving the microbiome, or in clinical trials involving similar therapeutic approaches, even if not ultimately attributable to products developed using our microbiome technology, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of such product candidates, stricter labeling requirements for those product candidates that are licensed, and a decrease in demand for any such product candidates.

Even if products developed using our microbiome technology achieve market acceptance, the developers of such products may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received, are more cost effective or render such products obsolete.

We may become exposed to costly and damaging liability claims, either when our product candidates are tested 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, our product candidates have been used in clinical trials, and from 2017 to 2019, we manufactured FMT materials, produced to specifications defined by OpenBiome, that were 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 any future use of product candidates by our collaborators and partners, including through investigator-sponsored trials with academic institutions, 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 or have used our products and product candidates, 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. Although we have discontinued the PRISM4 trial and withdrawn our IND for CP101, if any of our product candidates were to have caused adverse side effects during clinical trials, we may be exposed to substantial liabilities. Regardless of the merits or eventual outcome, liability claims may result in:

- injury to our reputation;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management's time and our resources; and

- substantial monetary awards to trial participants or patients.

Although we believe we maintain adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. 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

Healthcare legislative or regulatory reform measures may have a negative impact on our ability to realize revenue from our intellectual property assets.

In the United States and some foreign jurisdictions, there has been significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality of life and/or expanding access. In the United States, the pharmaceutical industry continues to be a particular focus of these efforts and has been significantly affected by health care reform initiatives at the federal and state level, a number of which have been implemented. The commercial success of a drug product depends in large part on whether government authorities and health care programs, such as Medicare and Medicaid, and private health insurance cover the product and provide adequate reimbursement for the product. Health care reform efforts that adversely affect coverage and reimbursement or restrict the prices that companies can set for their products would likely adversely affect the ability of a company to commercialize successfully any new product. If challenges to the successful commercialization of drug products increase as the result of health care reform, our ability to license or sell our intellectual property assets and the value of those assets may be adversely affected.

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.

Our activities have historically implicated 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 involved the use of biological and hazardous materials and produce hazardous waste products. We generally contracted with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination to the environment or other injury from these materials, which could cause 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 complied 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 are not aware of any current or ongoing violations, we cannot be certain that our past activities will not be subject to challenge in the future.

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, or the FCPA. 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 to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees may be considered foreign officials. 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 or regulations could also have an adverse impact on our reputation, our business, results of operations and financial condition.

Risks Related to Our Relationships with and Dependence on Third Parties

Some of our product candidates may be studied in clinical trials sponsored by organizations or agencies other than us, or in investigator-sponsored clinical trials, which means we will have minimal or no control over the conduct of such trials.

We have in the past supplied, and expect to continue to supply, and otherwise support, third-party research, including investigator-sponsored clinical trials with academic and private non-academic institutions, such as our licensing relationship with the University of Minnesota, or UMN, pursuant to which UMN is conducting multiple investigator-sponsored clinical trials using a microbiome product candidate comprised of compositions to which we hold an exclusive license. Because we will not be the sponsors of these investigator-sponsored trials, we have less control over the protocols, administration or conduct of these trials, including any follow-up with patients and ongoing collection of data after treatment. The conduct or findings of these trials may have a negative impact on the value of our intellectual property portfolio, notwithstanding that we have little involvement or control over these trials. As a result, we are subject to additional risks associated with the way investigator-sponsored trials are conducted. In particular, we may be named in lawsuits that could lead to increased costs associated with legal defense. Additional risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues and difficulties or differences in interpreting data. Third-party investigators may design clinical trials with clinical endpoints that are more difficult to achieve, or in other ways that increase the risk of negative clinical trial results. Negative results in investigator-sponsored clinical trials could have a material adverse effect on the public perception of our product candidates. As a result, our lack of control over the conduct and timing of and communications with the FDA and other regulatory authorities regarding investigator-sponsored trials may expose us to additional risks and uncertainties, many of which are outside our control.

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 evaluate and, as deemed appropriate, enter into partnerships in the future when strategically attractive, including potentially with major biotechnology or pharmaceutical companies. We do not currently have capabilities for product development or any capability for commercialization. Accordingly, we may enter into collaborations with other companies to advance our product candidates or the therapeutic potential of our microbiome technology intellectual property portfolio. If we fail to enter into or maintain collaborations on reasonable terms or at all, the commercial potential of our microbiome technology intellectual property portfolio could be adversely affected.

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 current and future strategic collaborations or academic partnerships, if any, do not result in the successful discovery, development and commercialization of product candidates or if one of our collaborators terminates its agreement with us, the commercial potential of our microbiome technology intellectual property portfolio could be adversely affected. 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 collaboration partners.

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.

Risks Related to Our Intellectual Property

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 UMN and Skysong Innovations LLC, or Skysong. 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, may lose rights to sub-license certain patents, and may face other penalties. Such an occurrence would materially adversely affect our business prospects. Further, a licensor's decision to terminate a patent license could have a material adverse impact on the likelihood of success in any litigation involving such patents, including any ongoing litigation.

In particular, if we fail to comply with our development obligations under our license agreements, including as a result of our decision to discontinue our PRISM4 Phase 3 clinical trial of CP101 in recurrent CDI and shift our focus towards realizing the value of our intellectual property estate and other assets, we may lose our patent rights with respect to such agreement on a territory-by-territory basis, which would affect our patent rights worldwide. We are currently in discussions with UMN to amend the UMN Agreement with respect to these obligations, but we cannot guarantee that these negotiations will be successful. We are also currently engaging in discussions with Skysong regarding our recent strategic reprioritization and the potential implications of these changes on our ongoing obligations under our license agreement with Skysong.

In addition, 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 and UMN, 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.

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.

If we are unable to obtain or protect intellectual property rights related to any of our technologies, product candidates, or that otherwise have value, we may not be able to compete effectively or leverage our intellectual property to generate value.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and technologies. 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 technologies 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 relates to our patented technologies or 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 to leverage our intellectual property to generate value. Further, if a collaboration partner encounters delays in regulatory approvals, the period of time during which they 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 or yet subject 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 without authorization. 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 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 the competitive position of the products of our future collaboration partners, if any, 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 product candidate, or upon the lapse of patent terms covering products of our future collaboration partners, 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 or collaboration partner 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 or our future collaboration partners 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. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business. In addition, our ability to pursue our business strategy of enforcing our patent rights against infringing parties will be negatively impacted by the lapse of the patent term for any of our intellectual property and microbiome assets, which may negatively impact our ability to realize the value of our intellectual property estate.

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, directly or via a licensor or collaboration partner, 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, directly or via a licensor or collaboration partner, initiate legal proceedings against a third party to enforce a patent, the defendant could counterclaim that the patent 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 UMN, alleged infringement by Rebiotix of three United States Patents owned by UMN and exclusively licensed to us. On January 23, 2023, we filed a second amended answer and counterclaims, in which we alleged infringement of two additional patents owned by Finch. Rebiotix has filed claims asserting non-infringement and invalidity of the UMN patents and two additional patents owned by Finch. 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, including amendments unfavorable to us, our licensors or a collaboration partner. 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 that is valuable to our business or otherwise relates to our microbiome assets. 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. We are focused on monetizing our microbiome assets, including through licensing transactions to collaboration partners and other third parties. An adverse outcome in any proceedings to enforce or defend our patent rights could diminish the value of our microbiome assets, could discourage third parties from entering into collaboration or other licensing agreements with us and could have a material adverse impact on our ability to generate revenue from our intellectual property and other microbiome assets.

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 or our collaboration partners 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 or a collaboration partner 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 collaborators, if any, to develop, manufacture, market and sell 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 or our collaboration partners may become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and our 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 or our collaboration partners 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 technology, 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 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 or our collaboration partners 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 us, including by increasing the cost of, or otherwise burdening, the ability of a collaboration partner to commercialize 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 U.S., Japan and China that may impact our competitive position with respect to one of our preclinical product candidates. We are also aware of an issued U.S. patent containing claims which, if valid and enforceable, could be construed to cover CP101. While we believe that the granted claims within these third party patents may not be valid, may not be construed to cover our products and/or that they may be reasonably challenged for validity, there can be no assurance that any such challenge would be successful. If we or a collaboration partner 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 or a collaboration partner from manufacturing and commercializing certain product candidates, 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 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 or were involved in developing our microbiome assets or 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 in the future may require 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 technologies or product candidates or those of our collaboration partners, and our future patents or other intellectual property rights may not be effective or sufficient to 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 expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions which may be attractive and commercially valuable to us or to a collaboration partner. 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 leverage our microbiome assets in all of the 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. As we operate with a significantly reduced workforce and otherwise reduce costs, the risk of inadvertent non-compliance may increase or we may decide to forego payment of necessary fees. Regardless of the circumstances, in such an event, potential competitors might be able to enter the market, which could have a material adverse effect on our business. Moreover, as we seek to monetize our patents and other microbiome technology through strategic collaborations, any such event could diminish the value of our portfolio of intellectual property and microbiome assets, expose liability to a strategic collaboration partner or otherwise 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.

Risks Related to Our Business Operations and Employee Matters

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

Our internal computer systems and those of any of our current or future collaborators and strategic partners 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 business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. 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 collaborators, 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.

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 or future collaborators and strategic partners 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 data, that are subject to privacy and

security requirements under the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or 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 gathered 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 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, 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, 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

Our shares of common stock could be delisted from the Nasdaq Global Select Market, which could result in, among other things, less liquidity for holders of shares of our common stock and a decline in the price of our common stock.

Our common stock is listed on the Nasdaq Global Select Market ("Nasdaq GSM"), which imposes, among other requirements, a minimum $1.00 per share bid price requirement for continued inclusion on the Nasdaq GSM pursuant to Nasdaq Listing Rule 5450(a)(1) (the "Bid Price Requirement"). On December 30, 2022 we received a deficiency letter (the "Notice") from the Listing Qualifications Department of the Nasdaq Stock Market, LLC ("Nasdaq") notifying us that, for the preceding 30 consecutive trading days, the closing bid price of our common stock was below the Bid Price Requirement. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have until June 28, 2023 (the "Compliance Date") to regain compliance with the Bid Price Requirement. According to the Notice, if at any time before the Compliance Date the closing bid price of our common stock is at least $1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written notification that we have achieved compliance with the Bid Price Requirement and our common stock will continue to be eligible for listing on the Nasdaq GSM. If we do not regain compliance with the Bid Price Requirement by the Compliance Date, we may be eligible for an additional 180-day compliance period. To qualify, we would need to transfer the listing of the common stock to the Nasdaq Capital Market, provided that we meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards, with the exception of the Bid Price Requirement. To effect such a transfer, we would also need to pay an application fee to Nasdaq and would need to provide written notice to Nasdaq of our intention to cure the deficiency during the additional compliance period by effecting a reverse stock split, if necessary. As part of its review process, Nasdaq would make a determination of whether it believes we will be able to cure this deficiency.

We may not be able to keep the closing bid price above $1.00 per share for the required 10 consecutive trading days by the Compliance Date. There is no guarantee that a reverse stock split would be approved by the stockholders or that a reverse stock split would allow us to regain compliance with the Bid Price Requirement. If Nasdaq concludes that we will not be able to cure the deficiency, or if we do not cure the deficiency within such additional 180-day compliance period, Nasdaq will provide written notification to us that our common stock will be subject to delisting. At that time, we may appeal Nasdaq's delisting determination to a Nasdaq Listing Qualifications Panel (the "Panel"). However, there can be no assurance that, if we receive a delisting notice and appeal the delisting determination by Nasdaq to the Panel, such appeal would be successful. Delisting from the Nasdaq GSM could make trading our common stock more difficult for investors, potentially leading to declines in our liquidity and share price. If our common stock is delisted by the Nasdaq GSM, our common stock may be eligible to trade on the Nasdaq Capital Market or an over-the-counter quotation system, where an investor may find it more difficult to sell our stock or obtain accurate quotations as to the market value of our common stock. We cannot assure you that our common stock, if delisted from the Nasdaq GSM, will be listed on another national securities exchange or quoted on an over-the counter quotation system.

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 GSM, 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, 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 updates related to our efforts to realize value from our intellectual property estate and other assets, as well as numerous other factors, many of which are beyond our control, including the factors listed below and other factors described in this "Risk Factors" section:

- 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;
- 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, and any adverse ruling which may arise;
- changes in the structure of healthcare payment systems;
- general political and economic conditions; 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. To date, we have only limited research coverage by equity research analysts. Certain equity research analysts who were previously providing research coverage of our common stock have elected not to continue such coverage, and we may never again obtain such coverage. If no or few analysts commence coverage of us, the market price of our common stock may be adversely affected. 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. 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, 2022, 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.

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 $1.235 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 the necessary 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 or maintain 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. We cannot be certain that director and officer liability insurance will continue to be available to us on economically reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large retention, or deductible, or co-insurance requirements, could have an adverse effect on our business, financial condition and results of operations. 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.

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with 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, the rules and regulations of Nasdaq and the rules and regulations of the Commission. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting.

We must provide a management certification of our internal control over financial reporting, as required by Section 404(a) of the Sarbanes-Oxley Act. This certification states the responsibility of our management to establish and maintain an adequate internal control structure and procedures for financial reporting and also contains an assessment of the effectiveness of our internal control over financial reporting. The process of building our accounting and financial functions and infrastructure has required and will continue to require significant professional fees, internal costs and management efforts. For example, we expect that we will need to outsource our financial reporting functions, and we plan to rely on consultants or external service providers to assist with our financial reporting, and to provide services related to our finance function to supplement our internal staff, including with respect to the evaluation and documentation of our system of internal controls functions. Any disruptions or difficulties in maintaining our internal financial staff or the services provided by outside consultants or financial service providers, or in implementing or using our accounting and financial functions and infrastructure, could adversely affect our system of internal controls and harm our business. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention.

In addition, 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 successfully identify and remediate any material weaknesses in our internal control over financial reporting or 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 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 also needs 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.

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 have generated and expect to generate significant federal and state net operating loss, or NOL, carryforwards in the future. To the extent that our federal NOL carryforwards were generated prior to 2018, these NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. To the extent that our federal NOL carryforwards were generated after 2017, these federal NOL carryforwards may be carried forward indefinitely, but such federal NOL carryforwards cannot offset more than 80% of the federal taxable income that we would have in any future taxable year beginning with our 2021 taxable year before taking into account such federal NOL carryforwards. Similar rules may apply

under state tax laws. 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 or eliminated, including, in our case, because we might not be considered to have continued our business enterprise. The completion of our IPO in March 2021, together with private placements and other transactions that have occurred since our inception, may have triggered 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 or eliminated, such limitations or elimination could result in increased future tax liability to us and our future cash flows could be adversely affected.

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, which commenced in May 2022 for approximately 61,139 square feet of office and laboratory space in Charlestown, Massachusetts, which we are currently subleasing out to two subtenants for three-year terms (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., or, collectively, Rebiotix, filed a complaint against us in the U.S. District Court for the District of Delaware, or the Court. 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, or the '309 Patent; 10,463,702, or the ‘702 Patent; 10,328,107, or the ‘107 Patent; 10,064,899; 10,022,406, or the ’406 Patent; 9,962,413, or the ’413 Patent; and 9,308,226. On February 7, 2022, we filed an answer and counterclaims against Rebiotix for infringement of the ’107 Patent, the ’702 Patent, and the ’309 Patent. In June 2022, we alleged infringement of the ’406 Patent and ’413 Patent by Rebiotix. On March 7, 2022, we filed an amended answer and counterclaims, in which we, together with the Regents of the University of Minnesota, or 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, or, collectively, the UMN Patents. On April 4, 2022, Rebiotix filed counterclaims for declaratory judgment of non-infringement and invalidity of the UMN Patents. On May 2, 2022, the Company and UMN responded, denying such counterclaims. The Court set a trial date for a five-day trial beginning on May 20, 2024. On January 23, 2023, we filed a second amended answer and counterclaims, in which we alleged infringement by Rebiotix of two additional U.S. Patents owned by us: U.S. Patent Nos. 11,541,080, or the '080 Patent; and 11,491,193, or the '193 Patent. On February 7, 2023, Rebiotix filed counterclaims for declaratory judgment of non-infringement and invalidity of the ’080 Patent and the ’193 Patent. The Court issued a claim construction order on February 28, 2023.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 20, 2023, the closing price of our common stock on The Nasdaq Global Select Market was $0.40 per share.

Holders of Our Common Stock

As of March 20, 2023, there were approximately 70 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 microbiome technology company with a portfolio of intellectual property and microbiome assets. Our objectives are to realize the value of our intellectual property estate through licensing our technology to collaboration partners and enforcing our patent rights against infringing parties and, in certain cases, to generate additional data on selected product candidates through academic collaborations. We have a robust intellectual property estate reflecting our pioneering role in the microbiome therapeutics field, including more than 70 issued U.S. and foreign patents with relevance for both donor-derived and donor-independent microbiome therapeutics in a range of potential indications. Our assets include CP101, an investigational, orally administered microbiome candidate designed for the prevention of recurrent *C. difficile* infection, or CDI, with positive clinical data from a Phase 2 randomized, placebo-controlled trial and a Phase 2 open-label trial, and pre-clinical assets that are designed to target ulcerative colitis, Crohn's disease, and autism spectrum disorder. Additionally, we have developed a significant biorepository of strains and samples. In January 2023, we announced the decision to discontinue our Phase 3 clinical trial of CP101 in recurrent CDI and focus on realizing the value of our intellectual property estate and other assets. We are currently in the process of winding down our development efforts and significantly scaling back our expenses, including by terminating vendor contracts and reducing headcount.

Until January 2023, we were a clinical-stage microbiome therapeutics company using 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 microbiome disruption can increase susceptibility to immune disorders, infections, neurological conditions, cancer and other serious diseases. We developed our *Human-First Discovery* platform to use reverse translation to identify diseases of microbiome disruption and to design microbiome therapeutics that address them.

We were previously developing CP101 as an orally administered complete microbiome therapeutic designed for the prevention of recurrent 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, 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. On March 1, 2022, we announced that enrollment in our Phase 3 clinical trial of CP101 for the prevention of recurrent CDI, or the PRISM4 trial, was paused following receipt of a clinical hold letter from the U.S. Food and Drug Administration, or the FDA, in connection with our investigational new drug application for CP101, requesting additional information regarding our SARS-CoV-2 donor screening procedures and associated informed consent language. On April 27, 2022, the FDA removed the clinical hold and in October 2022, we proceeded with patient dosing in the PRISM4 trial. On January 24, 2023, we announced our decision to discontinue PRISM4. We believe that CP101 has therapeutic potential in both CDI and other indications.

We have also used our *Human-First Discovery* platform to develop FIN-211, an investigational microbiome candidate designed to address the gastrointestinal and behavioral symptoms of autism spectrum disorder, or ASD. Following a strategic review of our pipeline, on November 10, 2022, we announced the decision to suspend efforts to initiate our planned Phase 1 clinical trial of FIN-211 in ASD, or the AUSPIRE trial.

In January 2017, we entered into an agreement, which we refer to as the Takeda Agreement, with Takeda Pharmaceutical Company Limited, or Takeda, pursuant to which we granted Takeda a worldwide, exclusive license, with the right to grant sublicenses, under certain of our patents, patent applications and know-how to develop our microbiome therapeutic candidate, FIN-524, for the prevention, diagnosis, theragnosis or treatment of diseases in humans. We also partnered with Takeda on discovery efforts targeting the development of the microbiome therapeutic candidate FIN-525 for the treatment of Crohn's disease. In August 2022, Takeda elected to terminate the Takeda Agreement. Termination of the Takeda Agreement

became effective on November 17, 2022, at which point the license rights granted to Takeda terminated and we regained full rights to pursue FIN-524 and FIN-525, and any other microbiome product candidates for inflammatory bowel disease, in all fields worldwide.

We will also continue to explore opportunities to realize the value of our intellectual property and microbiome assets through strategic partnerships and academic collaborations. These include our licensing relationship with the University of Minnesota, or UMN, pursuant to which UMN is conducting multiple investigator-sponsored clinical trials using a microbiome product candidate comprised of compositions to which we hold an exclusive license. In addition to our clinical and pre-clinical assets, we have developed a biorepository of samples and strains that can be used in a variety of research applications and may form the basis for future collaborations.

On each of April 19, 2022, September 1, 2022, and January 24, 2023, we announced the implementation of certain expense reduction measures, including reductions in our workforce. On January 24, 2023, we announced a decision to re-orient our business strategy to close our Phase 3 study of CP101 in CDI and focus on realizing the value of the Company's intellectual property and other assets. This decision came after an assessment by our management team and board of directors of multiple factors, including our outlook for identifying a commercial partner, slower than anticipated enrollment in the PRISM4 trial, the harmful impact of what we believe is the ongoing unauthorized use of our intellectual property, and broader sector trends in the biotechnology industry.

Our recent business initiatives have been focused primarily on organizing and staffing our company and establishing and protecting our intellectual property portfolio. Until January 2023, we also focused on developing and progressing our product candidates through clinical development, and research and development activities. We do not currently expect to be able to progress any product candidate through clinical trials or commercial approval and we do not currently expect to generate 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, our loan agreement with Hercules Capital and from collaboration revenue.

Since our inception, we have incurred significant operating losses. Our net losses were $114.6 million and $58.2 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $275.6 million. We expect to continue to generate operating losses and negative operating cash flows for the foreseeable future as we attempt to realize the value of our intellectual property estate and other assets.

Although we believe strongly in the value of our pioneering intellectual property portfolio and the merits of our current litigation activities relating to those assets, we may never succeed in realizing the value of our intellectual property estate and other assets and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability.

As a result, we may need additional funding to support our operating activities as we seek to realize value from our intellectual property estate and other assets. Until such time, if ever, that we can generate substantial 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 as needed, we may decide to pursue a dissolution and liquidation.

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, if any, will be derived from enforcement and out-licensing of our intellectual property estate. Additionally, we will continue to earn royalties under our Asset Purchase Agreement, dated as of November 19, 2020, or the OpenBiome Agreement, with Microbiome Health Research Institute, Inc., doing business as OpenBiome, or OpenBiome, based on sales of fecal microbiota transplantation, or FMT, materials, which we receive as reimbursement for the payment of third-party license fees.

Collaboration and License Agreement with Takeda

In January 2017, we entered into a research collaboration and exclusive license agreement, or as amended and restated, 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 FIN-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 FIN-524 from us to Takeda in accordance with a transition plan, with Takeda to assume sole responsibility for regulatory matters with respect to FIN-524. In November 2021, we amended the Takeda Agreement to enable us to carry out certain FIN-525 preliminary evaluation activities.

In August 2022, we received written notice from Takeda that, following a review of its pipeline, Takeda had elected to exercise its right to terminate the Takeda Agreement. In accordance with the terms of the Takeda Agreement, the termination became effective on November 17, 2022, or the Termination Effective Date. Pursuant to a further amendment to the Takeda Agreement, dated October 19, 2022, we are in the process of winding down and transitioning activities under the Takeda Agreement. As of the Termination Effective Date, the license rights granted to Takeda terminated and Takeda ceased to accrue any financial obligations to us. Revenue earned to date 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.

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 an aggregate of $4.0 million in additional payments upon the achievement of certain development milestones for FIN-524 therapeutic products. Since the Termination Effective Date, we are no longer eligible to receive future milestones under the Takeda Agreement.

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.

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, 2022 and 2021, as there are currently no products available for sale.

Also on November 19, 2020, we entered into an asset purchase agreement, or the OpenBiome Agreement, with Microbiome Health Research Institute, Inc., or OpenBiome. The OpenBiome Agreement effectively terminated certain existing agreements with OpenBiome and internalized certain functions for which we 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 on March 1, 2021, we acquired certain additional assets, including biological samples, a commercial lease, intellectual property, capital equipment and contracts. As of December 31, 2022, 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. We will continue to earn royalties under the OpenBiome Agreement, which serve as reimbursement for third party license fees, based on sales of fecal microbiota transplantation, or FMT, materials.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for research activities, including discovery and development efforts. 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 engaged in research and development functions, including their fees and related travel expenses

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. 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 and, as such, are classified as costs of our platform research.

Until January 2023, research and development activities were central to our business model. We expect that our research and development expenses will decrease in the foreseeable future due to our reduced headcount and our decisions to discontinue our Phase 3 clinical trial of CP101 and to focus on realizing the value of our intellectual property estate and other assets. This decision came after an assessment by our management team and board of directors of multiple factors, including our outlook for identifying a commercial partner, slower than anticipated enrollment in the PRISM4 trial, the harmful impact of what we believe is the ongoing unauthorized use of our intellectual property, and broader sector trends in the biotechnology industry. Our research and development expenses have been primarily focused on supporting clinical trials for CP101.

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 decrease in the foreseeable future due to our reduced headcount. We expect to continue to incur 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.

Impairment of Goodwill

Goodwill and Acquired In Process Research and Development, or 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 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 an acquired asset or the strategy for our 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 our 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.

Restructuring Expense

Restructuring expense consists of costs directly incurred as a result of restructuring initiatives, and includes one-time severance payments, healthcare coverage, outplacement services and related expenses.

Total Other Income (Expense), Net

Other Income (Expense), Net

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

Interest Income (Expense)

Interest income primarily consists of interest earned on our cash and cash equivalents. Interest expense consists primarily of interest on borrowings under our Loan and Security Agreement, dated as of May 11, 2022, with Hercules Capital, Inc., or the Loan Agreement.

(Loss) Gain on Disposal of Fixed Assets

(Loss) Gain on disposal of fixed assets relates to the gain we realized when we sold certain lab equipment during the years ended December 31, 2022 and 2021.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021 (in thousands):

	YEAR ENDED DECEMBER 31,	
	2022	2021
REVENUE:		
Collaboration revenue	$ 861	$ 18,532
Total revenue	861	18,532
OPERATING EXPENSES:		
Research and development	(57,893)	(57,279)
General and administrative	(38,088)	(21,238)
Impairment of goodwill	(18,057)	—
Restructuring expense	(2,416)	—
Total operating expenses	(116,454)	(78,517)
Net operating loss	(115,593)	(59,985)
OTHER INCOME (EXPENSE), NET:		
Gain on extinguishment of PPP Loan	—	1,827
Interest (expense) income, net	252	22
(Loss) gain on disposal of fixed assets, net	(7)	28
Other income (expense), net	702	(52)
Total other income, net	947	1,825
Net loss	$ (114,646)	$ (58,160)

Revenue

Revenue of $0.9 million and $18.5 million for the years ended December 31, 2022 and 2021, respectively, primarily consisted of collaboration revenue earned under the Takeda Agreement. Our collaboration revenue decreased by $17.7 million due to the November 2021 amendment to the Takeda Agreement, pursuant to which we transitioned primary responsibilities with respect to FIN-524 to Takeda in the third quarter of 2021, resulting in a decrease in collaboration

revenue in 2022, in addition to Takeda's election in August 2022 to terminate the agreement, which terminated in November 2022.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2022 and 2021 (in thousands):

	YEAR ENDED DECEMBER 31,		
	2022	2021	Increase (Decrease)
CDI	$ 16,524	$ 16,779	$ (255)
Inflammatory Bowel Diseases (IBD)	1,157	6,328	(5,171)
Autism Spectrum Disorder (ASD)	5,038	6,842	(1,804)
Hepatitis B (HBV)	260	3,172	(2,912)
Platform	25,490	21,593	3,897
Unallocated	9,424	2,565	6,859
	$ 57,893	$ 57,279	$ 614

Research and development expenses for the year ended December 31, 2022, were $57.9 million, as compared to $57.3 million for the year ended December 31, 2021. The increase of $0.6 million reflected a $6.9 million increase in unallocated costs, driven by a $5.0 million charge in the fourth quarter of 2022 for the partial impairment of the right-of-use asset associated with the Hood Lease and a $1.7 million increase in stock-based compensation expense, in addition to an increase of $3.9 million in platform-related expenses. These increases were partially offset by a $5.2 million decrease in IBD program expenses due to the termination of our collaboration with Takeda, which was completed in the fourth quarter of 2022. Additionally, program expenses related to HBV decreased by $2.9 million, while costs related to our ASD program decreased by $1.8 million in connection with our decision to suspend our HBV program, announced on March 31, 2022, and our subsequent decision, announced on September 1, 2022, to suspend our Phase 1 clinical trial in ASD. Additionally, there was a $0.3 million decrease in costs related to our CDI program, primarily due to a decrease in external clinical research organization costs.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2022 and 2021 (in thousands):

	YEAR ENDED DECEMBER 31,		
	2022	2021	Increase
Personnel expenses (including stock-based compensation)	$ 11,969	$ 11,729	$ 240
Facilities and supplies	3,946	327	3,619
Professional fees	13,517	5,459	8,058
Other expenses	8,656	3,723	4,933
	$ 38,088	$ 21,238	$ 16,850

General and administrative expenses were $38.1 million for the year ended December 31, 2022, as compared to $21.2 million for the year ended December 31, 2021. The increase of $16.9 million for fiscal year 2022 was due to a $8.1 million increase in professional fees, a $3.6 million increase in facilities and supplies, driven by the addition of $3.7 million in rent expense under the Hood Lease, which was entered into in 2022, a $4.9 million increase in other expenses, and a $0.2 million increase in personnel expenses. The increase in professional fees was primarily related to $9.5 million increase in legal expenses, partially offset by a $0.8 million decrease in audit and tax services and a $0.6 million decrease in consulting expenses. The increase in other expenses was primarily related to a $1.9 million charge in the fourth quarter of 2022 for the partial impairment of the right-of-use asset associated with the Hood Lease, an increase of $1.6 million in state excise taxes, and an increase of $1.1 million in business insurance costs.

Other Income, Net

Total other income, net was $0.9 million for the year ended December 31, 2022, compared to $1.8 million for the year ended December 31, 2021. The increase of $0.9 million was primarily due to the forgiveness of the loan we received under the

Paycheck Protection Program of the CARES Act, or the PPP Loan, in full in the amount of $1.8 million in 2021, offset by sublease income of $0.7 million earned during the year ended December 31, 2022.

Impairment of Goodwill

For the year ended December 31, 2022, we recognized a goodwill impairment charge of $18.1 million, as the fair value of the Company's reporting unit was determined to be less than its carrying value, primarily due to a sustained decline in market conditions that drove our market capitalization below our net book value. We also performed a valuation of our CP101 IPR&D asset, which resulted in no impairment, as the fair value of the asset exceeded the carrying value as of December 31, 2022. No impairment charge to goodwill or IPR&D was recognized for the year ended December 31, 2021.

Restructuring Expense

Restructuring expense for the year ended December 31, 2022 was $2.4 million, compared to zero for the year ended December 31, 2021. The increase is due to the costs associated with the implementation of certain expense reduction measures in both April and September 2022. Refer to Note 8 within the consolidated financial statements for further information.

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 do not currently expect to progress any product candidate through clinical trials or commercial approval and we do not currently expect to generate any revenue from product sales. We expect that our revenue for the next several years, if any, will be derived from enforcement and out-licensing of our intellectual property estate. We have funded our operations primarily through equity financings, the Loan Agreement, 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 with Takeda which was terminated in 2022. In May 2022, we borrowed $15.0 million under the Loan Agreement, and subsequently, in January 2023, we voluntarily paid off all outstanding amounts under the Loan Agreement. In March 2021, we completed our initial public offering ("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.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2022 and 2021 (in thousands):

	YEAR ENDED DECEMBER 31,	
	2022	2021
Net cash used in operating activities	$ (74,851)	$ (67,133)
Net cash used in investing activities	(2,182)	(15,921)
Net cash provided by financing activities	14,873	119,110
Net (decrease) increase in cash and cash equivalents, and restricted cash	$ (62,160)	$ 36,056

Operating Activities

During the year ended December 31, 2022, cash used in operating activities was $74.9 million, which was primarily related to our net loss of $114.6 million. The cash outflow included an $18.1 million charge for goodwill impairment, $7.8 million in stock-based compensation expense, a $6.9 million charge for the partial impairment of the right-of-use asset associated with the Hood Lease, and $5.5 million in non-cash depreciation and amortization. The outflow was also impacted by a net decrease in our operating assets and liabilities of $1.6 million. The change in operating assets and liabilities includes a $2.5 million decrease in prepaid expenses and other current assets and a $2.3 million decrease in accounts payable. This was offset by a $1.9 million increase in operating lease liabilities, a $0.7 million increase in other non-current assets, a $0.4 million increase in accounts receivable, and a $0.2 million increase in accrued expenses and other current liabilities.

During the year ended December 31, 2021, cash used in operating activities was $67.1 million, which 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 a $1.8 million gain on extinguishment of the 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.

Investing Activities

During the years ended December 31, 2022 and 2021, we used $2.2 million and $15.9 million, respectively, of cash in investing activities. The $2.2 million used during the year ended December 31, 2022 and the $15.9 million used during the year ended December 31, 2021 was related to the purchases of property and equipment.

Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities of $14.9 million was due to proceeds from borrowings under the Loan Agreement and the exercise of company stock options and was partially offset by principal payments on finance lease obligations and payments of debt issuance costs.

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.

Funding Requirements

As of December 31, 2022, our cash and cash equivalents were $71.0 million. We believe that our existing cash on hand will enable us to fund our operating expenses and capital expenditure requirements into 2025. 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 to continue to incur significant losses for the foreseeable future as we attempt to realize the value of our intellectual property estate and other assets.

Material Cash Requirements

The following table summarizes our contractual obligations as of December 31, 2022, and the effects 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	$ 52,582	$ 6,109	$ 12,682	$ 11,401	$ 22,390
Loan payable	15,000	—	15,000	—	—
License agreements	565	25	140	135	265
Total	$ 68,147	$ 6,134	$ 27,822	$ 11,536	$ 22,655

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.

Loan Payable

In May 2022, we entered into the Loan Agreement, under which we previously borrowed $15.0 million. In January 2023, we voluntarily paid off all outstanding principal, accrued and unpaid interest, fees, costs and expenses under the Loan Agreement.

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 the 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 through 2023, which increases to $20,000 in 2024. Future minimum payments through 2031 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 11 to our annual consolidated financial statements appearing elsewhere in this Annual Report for a description of our license agreements.

Purchase and Other Obligations

We have entered 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 generally 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 Annual 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, which was terminated in 2022. 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. 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 on October 1, 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.

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.

In connection with the preparation of the financial statements for the third quarter of 2022, management identified factors that could trigger impairment including a sustained decline in the Company's stock price throughout the third quarter of 2022, resulting in a reduction of the Company's market capitalization below net book value. As a result of the triggering event identified, management concluded that this impairment indicator required the Company to perform an interim impairment test of goodwill and IPR&D as of September 30, 2022. Management's assessment for the impairment of goodwill indicated that the fair value of the Company's reporting unit was less than its carrying value at September 30, 2022, resulting in a full goodwill impairment charge of $18.1 million. Management's assessment for the impairment of IPR&D indicated that the fair value of the Company's IPR&D asset at September 30, 2022 exceeded its carrying value, resulting in no impairment to IPR&D as of September 30, 2022.

In connection with its preparation of the financial statements for the year ended December 31, 2022, management identified factors that could trigger impairment, including the Company's decision to discontinue its Phase 3 clinical trial of CP101 in recurrent CDI, which was announced in January 2023. As a result of the triggering event identified, management concluded that this impairment indicator required the Company to perform an interim impairment test of IPR&D as of December 31, 2022. Management's assessment for the impairment of IPR&D indicated that the fair value of the Company's IPR&D asset at December 31, 2022 exceeded its carrying value, resulting in no impairment to IPR&D as of December 31, 2022.

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 triggering event assessment as of December 31, 2022, and annual impairment assessment as of October 1, 2021, respectively, indicated that the fair value of our IPR&D asset exceeded its carrying value, resulting in no impairment.

We expect given management's decision to discontinue our Phase 3 clinical trial of CP101 in recurrent CDI and focus on realizing the value of our intellectual property estate and other assets, that the value of our IPR&D asset will be impaired in the first quarter of 2023, as the value of the asset is derived from the estimated future cash flows associated with CP101.

The assumptions related to the development of fair value for IPR&D could deviate materially from actual results and forecasts used to support the asset's carrying value and may change in the future, which could result in impairment charges that would adversely affect financial results of operations. There can be no assurance that, at the time future impairment tests are completed, a material impairment charge to IPR&D 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 Annual 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 $1.235 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, 2022, we had cash and cash equivalents of $71.0 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.

We have been affected by market risk exposure primarily through the effect of changes in interest rates on amounts payable under the Loan Agreement. As of December 31, 2022, borrowings under the Loan Agreement totaled $15.0 million with an average interest rate of 8.71%. On January 25, 2023, we voluntarily prepaid all outstanding principal, accrued and unpaid interest, fees, costs and expenses under the Loan Agreement. As of December 31, 2021, we had no debt outstanding that is subject to interest rate variability. See “Note 7. Loan Payable” in the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information regarding our borrowings.

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, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's recurring losses from operations incurred since inception, the expectation of continuing operating losses for the foreseeable future, and uncertainty around the shift in business strategy, raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 23, 2023

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, 2022	DECEMBER 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 71,038	$ 133,481
Accounts receivable	144	494
Prepaid expenses and other current assets	3,369	8,576
Total current assets	74,551	142,551
Property and equipment, net	15,936	19,635
Operating right-of-use assets	32,752	5,053
In-process research and development	32,900	32,900
Goodwill	—	18,057
Restricted cash, non-current	2,568	2,268
Other assets	4,232	4,905
TOTAL ASSETS	$ 162,939	$ 225,369
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 1,097	$ 3,737
Accrued expenses and other current liabilities	10,161	9,925
Operating lease liabilities, current	3,431	1,128
Total current liabilities	14,689	14,790
Deferred tax liability	3,461	3,461
Loan payable, non-current	14,653	—
Operating lease liabilities, non-current	34,255	4,887
Other liabilities	170	7
Total liabilities	67,228	23,145
COMMITMENTS AND CONTINGENCIES (Note 11)		
Preferred stock (undesignated), $0.001 par value; 10,000,000 shares authorized and no shares issued and outstanding as of December 31, 2022 and December 31, 2021	—	—
STOCKHOLDERS' EQUITY:		
Common stock, $0.001 par value; 200,000,000 shares authorized as of December 31, 2022 and December 31, 2021; 48,053,596 and 47,512,182 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	48	47
Additional paid-in capital	371,304	363,172
Accumulated deficit	(275,641)	(160,995)
Total stockholders' equity	95,711	202,224
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 162,939	$ 225,369

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,	
	2022	2021
REVENUE:		
Collaboration revenue	$ 861	$ 18,532
Total revenue	861	18,532
OPERATING EXPENSES:		
Research and development	(57,893)	(57,279)
General and administrative	(38,088)	(21,238)
Impairment of goodwill	(18,057)	—
Restructuring expense	(2,416)	—
Total operating expenses	(116,454)	(78,517)
Net loss from operations	(115,593)	(59,985)
OTHER INCOME (EXPENSE), NET:		
Gain on extinguishment of PPP Loan	—	1,827
Interest income, net	252	22
(Loss) gain on disposal of fixed assets, net	(7)	28
Other income (expense), net	702	(52)
Total other income, net	947	1,825
Loss before income taxes	(114,646)	(58,160)
Income tax provision	—	—
Net loss	$ (114,646)	$ (58,160)
Net loss attributable to common stockholders—basic and diluted (Note 16)	$ (114,646)	$ (58,160)
Net loss per share attributable to common stockholders—basic and diluted	$ (2.40)	$ (1.48)
Weighted-average common stock outstanding—basic and diluted	47,691,632	39,202,086

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, 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
Exercise of common stock options	—	—	—	—	—	—	—	—	188,338	1	140	—	141
Issuance of common stock under employee stock purchase plan	—	—	—	—	—	—	—	—	100,645	—	148	—	148
Vesting of restricted stock units	—	—	—	—	—	—	—	—	252,431	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	7,844	—	7,844
Net loss	—	—	—	—	—	—	—	—	—	—	—	(114,646)	(114,646)
BALANCE December 31, 2022	—	$ —	—	$ —	—	$ —	—	$ —	48,053,596	$ 48	$ 371,304	$ (275,641)	$ 95,711

See notes to consolidated financial statements.

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

	YEAR ENDED DECEMBER 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (114,646)	$ (58,160)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	5,507	2,301
Stock-based compensation expense	7,844	4,161
Impairment of goodwill	18,057	—
Impairment of long lived assets	6,926	—
Gain on extinguishment of PPP Loan	—	(1,808)
Non-cash interest expense	167	—
Loss (gain) on sale of property and equipment	7	(28)
Other non-cash operating lease cost	2,851	913
Changes in operating assets and liabilities:		
Accounts receivable	350	540
Due from related party	—	61
Prepaid expenses and other current assets	(2,529)	(3,217)
Other non-current assets	656	(4,689)
Accounts payable	(2,259)	2,261
Accrued expenses and other current liabilities	237	5,435
Other non-current liabilities	50	—
Due to related party	—	(266)
Deferred revenue	—	(13,631)
Operating lease liabilities	1,931	(1,006)
Net cash used in operating activities	(74,851)	(67,133)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(2,182)	(15,983)
Proceeds from sale of property and equipment	—	62
Net cash used in investing activities	(2,182)	(15,921)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from initial public offering, net of underwriting discounts, commissions and offering costs	—	118,576
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	(22)	(27)
Proceeds from exercise of stock options and issuance of common stock under employee stock purchase plan	289	171
Proceeds from borrowings under loan agreement, net	14,738	—
Payment of deferred offering costs	(132)	(2,659)
Net cash provided by financing activities	14,873	119,110
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(62,160)	36,056
Cash, cash equivalents and restricted cash at beginning of year	135,965	99,909
Cash, cash equivalents and restricted cash at end of year	$ 73,805	$ 135,965
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for interest	$ 741	$ 9
Cash paid in connection with operating lease liabilities	$ (268)	$ (1,434)
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Property and equipment in accounts payable and accrued liabilities	$ 14	$ 381
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
Remeasurement of right-of-use asset	$ 382	$ —
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 37,094	$ —
Prepaid rent reclassified to right-of-use assets	$ 7,736	$ —

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,	
	2022	2021
Cash and cash equivalents	$ 71,038	$ 133,481
Restricted cash	2,767	2,484
Total cash, cash equivalents and restricted cash	$ 73,805	$ 135,965

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 microbiome technology company with a portfolio of intellectual property and microbiome assets. The Company's objectives are to realize the value of its intellectual property estate through licensing its technology to collaboration partners and enforcing its patents rights against infringing parties and, in certain cases, to generate additional data on selected product candidates through academic collaborations. The Company has an intellectual property estate including more than 70 issued U.S. and foreign patents with relevance for both donor-derived and donor-independent microbiome therapeutics in a range of potential indications. The Company's assets include CP101, an investigational, orally administered microbiome candidate designed for the prevention of recurrent *C. difficile* infection ("CDI"), with positive clinical data from a Phase 2 randomized, placebo-controlled trial and a Phase 2 open-label trial, and pre-clinical assets that are designed to target ulcerative colitis, Crohn's disease, and autism spectrum disorder. Additionally, the Company has developed a biorepository of strains and samples. In January 2023, the Company announced the decision to discontinue its Phase 3 trial of CP101 in recurrent CDI and focus on realizing the value of its intellectual property estate and other assets. This decision came after an assessment by the Company's management team and board of directors of multiple factors, including the Company's outlook for identifying a commercial partner, slower than anticipated enrollment in the PRISM4 trial, and broader sector trends in the biotechnology industry. The Company is currently in the process of winding down its development efforts and significantly scaling back its expenses, including by terminating vendor contracts and reducing headcount.

Until January 2023, the Company was a clinical-stage microbiome therapeutics company using its *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 microbiome disruption can increase susceptibility to immune disorders, infections, neurological conditions, cancer and other serious diseases. The Company developed its *Human-First Discovery* platform to use reverse translation to identify diseases of microbiome disruption and to design microbiome therapeutics that address them.

Risks and Uncertainties

The Company is subject to a number of risks, including risks related to government regulation, intellectual property and dependence on key personnel.

Liquidity

The Company has incurred recurring losses since its inception, including net losses of $114.6 million and $58.2 million for the years ended December 31, 2022 and 2021, respectively. In addition, as of December 31, 2022, the Company had an accumulated deficit of $275.6 million. The Company expects to continue to generate operating losses for the foreseeable future as it attempts to realize the value of its intellectual property estate and other assets.

On January 24, 2023, the Company announced its decision to discontinue its Phase 3 clinical trial of CP101 in recurrent CDI. As a result of this decision, the Company approved and implemented a restructuring plan (the "January 2023 Restructuring") (see Note 17). Also on January 24, 2023, the Company announced its decision to shift the Company's business strategy to focus on realizing the value of the Company's intellectual property estate and other assets.

The Company currently forecasts that its cash and cash equivalents of $71.0 million as of December 31, 2022, will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months beyond the date of issuance of the annual consolidated financial statements. However, due to the consideration of certain qualitative factors,

including the Company's recurring losses from operations incurred since inception, the expectation of continuing operating losses for the foreseeable future, and uncertainty around its ability to successfully realize the full value of its intellectual property estate and other assets, the Company has concluded that there is substantial doubt regarding the Company's ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company does not currently expect to progress any product candidate through clinical trials or commercial approval and it does not currently expect to generate any revenue from product sales. The Company may never succeed in realizing the value of its intellectual property estate and other assets and, even if it does, it may never generate revenue that is significant or large enough to achieve profitability.

As a result, the Company may need additional funding to support its operating activities as it seeks to realize value from its intellectual property estate and other assets. Until such time, if ever, that the Company can generate substantial revenue, the Company expects to finance its cash needs through equity offerings, debt financings or other capital sources, including collaborations, licenses or similar arrangements. However, the Company may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. If the Company is unable to obtain funding as needed, it may decide to pursue a dissolution and liquidation.

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, 2022 and 2021.

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 $71.0 million and $133.5 million as of December 31, 2022 and 2021, 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 $2.8 million and $2.5 million as of December 31, 2022 and 2021, respectively, primarily related to security deposits on its operating leases for its offices in Somerville and Charlestown, Massachusetts for each of years ended December 31, 2022 and 2021. 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 creditworthy and the Company has not experienced any losses on these deposits. As of December 31, 2022 and 2021, 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, 2022 and 2021.

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.

In connection with its preparation of the financial statements for the third quarter of 2022, management identified factors that could trigger impairment, including a sustained decline in the Company's stock price throughout the third quarter of 2022, resulting in a reduction of the Company's market capitalization below net book value. As a result of the triggering event identified, management concluded that this impairment indicator required the Company to perform an interim impairment test of goodwill and IPR&D as of September 30, 2022.

As of September 30, 2022, the Company's assessment for the impairment of goodwill indicated that the fair value of the Company's reporting unit was less than its carrying value at September 30, 2022, resulting in a full impairment charge of $18.1 million included as impairment of goodwill on the Company's statement of operations.

In connection with its preparation of the financial statements for the year ended December 31, 2022, management identified factors that could trigger impairment including management's decision to discontinue the Company's Phase 3 clinical trial of CP101 in recurrent CDI, which was announced in January 2023. As a result of the triggering event identified, management concluded that this impairment indicator required the Company to perform an impairment test of IPR&D as of December 31, 2022.

Management utilized the discounted cash flow ("DCF") to derive the fair value of the Company as of September 30, 2022, and utilized the multi-period excess earnings method ("MPEEM"), to derive the fair value of the CP101 IPR&D asset as of September 30, 2022 and December 31, 2022. Both methods are variations of the income approach. The DCF method was leveraged to calculate the fair value of the Company on an equity level basis for management's use in goodwill impairment testing procedures. The MPEEM was leveraged to calculate the fair value of the CP101 IPR&D for management's use in IPR&D impairment testing procedures. The MPEEM approach calculates the fair value of an asset or entity by estimating the after-tax cash-flows attributable to an asset or entity, applying contributory asset charges to reflect other tangible and intangible assets being in place to help achieve the subject item's future cash flows, and then discounting the net cash flows to a present value using a risk-adjusted discount rate.

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 cash flow projections in these fair value analyses for the Company and the CP101 IPR&D consist of management's estimates of revenue growth rates and operating margins, taking into consideration historical results in addition to applicable industry and market conditions. The discount rate used in the fair value analysis for the Company is based on a weighted average cost of capital, which represents the weighted average rate a business must pay its providers of debt and equity. The

discount rate used in the fair value analysis for the CP101 IPR&D is based on the weighted average cost of capital in addition to consideration of various industry resources for venture capital rates of return.

The Company's triggering event assessment as of December 31, 2022 for impairment of IPR&D and annual assessment as of October 1, 2021 indicated that the fair value of its IPR&D asset 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 as a separate charge within operating expenses on the Company's consolidated statements of operations.

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 initial public offering (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. There were no deferred offering costs as of December 31, 2022.

Leases

The Company follows the provisions of ASC Topic 842, *Leases* ("ASC 842"), for all contracts and agreements that are within its scope. Under ASC 842, 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 is 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.

Debt Issuance Costs

Costs associated with the issuance of debt instruments are capitalized and amortized over the term of the respective financing arrangement using the effective interest method through the maturity date of the related debt instrument. These costs represent legal fees and other costs related to the Company's term loan.

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 and restricted stock units. 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, 2022 and 2021, 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 9) and (2) royalty revenue from OpenBiome's sales of a licensed product under the Asset Purchase and License Agreement with OpenBiome (see Note 9).

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 it expects 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,	
	2022	2021
Transferred over time	$ 861	$ 18,532
Total	$ 861	$ 18,532

Net Loss Per Share

Subsequent to the closing of its IPO, the Company has had one class of shares outstanding and basic net loss per common share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock awards. 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 stock options, restricted stock unit ("RSU") awards and shares issuable under the employee stock purchase plan. 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, 2022 and 2021.

Recently Issued and Adopted Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board or other accounting standard setting bodies that the Company adopts as of the specified effective date. There have been no new accounting pronouncements or changes to accounting pronouncements that, if adopted, would have or may have a material impact on the Company's consolidated statements or disclosures.

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, 2022	QUOTED PRICES IN ACTIVE MARKETS FOR IDENTICAL ASSETS (LEVEL 1)	SIGNIFICANT OBSERVABLE INPUTS (LEVEL 2)	SIGNIFICANT OBSERVABLE INPUTS (LEVEL 3)
Asset				
Money market funds	$ 69,991	$ 69,991	$ —	$ —
Total financial assets	$ 69,991	$ 69,991	$ —	$ —

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	$ —	$ —

There have been no transfers between fair value levels during the years ended December 31, 2022 and 2021. 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, 2022 and 2021 (in thousands):

	DECEMBER 31, 2022	DECEMBER 31, 2021
Lab equipment	$ 4,146	$ 3,850
Office furniture and fixtures	1,406	537
Leasehold improvements	13,972	13,894
Construction work-in-progress	316	329
Software	4,883	4,883
Computer equipment	499	368
Total	$ 25,222	$ 23,861
Less: Accumulated depreciation	(9,286)	(4,226)
Property and equipment, net	$ 15,936	$ 19,635

Depreciation and amortization expense was $5.5 million and $2.3 million for the years ended December 31, 2022 and 2021, respectively. During the year ended December 31, 2021, the Company purchased $3.9 million of software, property, and equipment from Microbiome Health Research Institute Inc. doing business as OpenBiome ("OpenBiome"), under the Asset Purchase Agreement, dated as of November 19, 2020 between the Company and OpenBiome (the “OpenBiome Agreement”). As of December 31, 2022, the Company held $1.9 million of the assets purchased from OpenBiome. For additional information on the OpenBiome Agreement, see Note 9 and Note 14.

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 14), 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, 2022 and 2021. The Company recognized sublease income under the sublease to OpenBiome as rent was received over the sublease term. Gross lease income under the sublease to OpenBiome for the year ended December 31, 2021 was $0.1 million 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, as assumed, was from March 2021 through February 2023. The Company’s lease expense under the Cherry Street Lease was $0.1 million for each of the years ended December 31, 2022 and 2021.

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, 2022 and 2021 was $0.1 million and $0.2 million, 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, Finch entered into a 10-year lease agreement (the "Hood Lease") with Hood Park LLC, pursuant to which Finch will lease approximately 61,139 square feet of office and laboratory space (the "Premises"). 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 started at approximately $4.5 million, and the lease contains annual rent escalations. Finch became responsible for paying rent under the Hood Lease on January 1, 2022 and commenced business operations in the Premises in the second quarter of 2022, which triggered recognition of the lease for accounting purposes. The Company recognized a right-of-use asset totaling $37.1 million and lease liability of $29.4 million upon the commencement of the lease. Lease expense related to the Hood Lease of $3.7 million was recorded for the year ended December 31, 2022.

The Hood Lease provided for a tenant improvement allowance of approximately $14.8 million for the cost of Finch’s work on the Premises. As of December 31, 2022, $14.8 million of lessor owned tenant improvements were completed by the Company, which was fully paid by the lessor to the Company as of December 31, 2022.

Finch 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, 2022 and 2021.

In the third quarter of 2022, Finch entered into a sublease agreement to sublet approximately one third of its leased space under the Hood Lease, which commenced on August 10, 2022, for an initial term of two years, with an option for Finch to extend the sublease for up to one additional year, which Finch exercised in the fourth quarter of 2022. Additionally, in the fourth quarter of 2022, Finch entered into a second sublease agreement to sublet the remainder of its leased space under the Hood Lease for a three-year term, which commenced on December 15, 2022. For the year ended December 31, 2022, Finch recognized sublease income of $0.7 million which is presented as other income in the consolidated statements of operations.

In connection with the preparation of the financial statements for the year ended December 31, 2022, due to the execution of the subleases of the leased space under the Hood Lease, Finch identified a triggering event with regards to the fair value of the Hood right-of-use asset. Therefore, Finch performed a discounted cash flow analysis that considered market-based rent assumptions, which resulted in an impairment of the right-of-use asset of $6.9 million which was recognized in general and administrative and research and development expense on the consolidated statement of operations for the year ended December 31, 2022.

The following table presents the classification of right-of-use assets and lease liabilities as of December 31, 2022 and 2021:

	BALANCE SHEET CLASSIFICATION	DECEMBER 31, 2022	DECEMBER 31, 2021
ASSETS			
Operating lease assets	Operating right-of-use assets	$ 32,752	$ 5,053
Finance lease assets	Property and equipment, net	1	22
Total lease assets		32,753	5,075
Liabilities			
Current			
Operating lease liabilities	Operating lease liabilities, current	$ 3,431	$ 1,128
Finance lease liabilities	Other current liabilities	6	19
Noncurrent			
Operating lease liabilities	Operating lease liabilities, non-current	34,255	4,887
Finance lease liabilities	Other liabilities	—	7
Total lease liabilities		$ 37,692	$ 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 years ended December 31, 2022 and 2021:

	YEAR ENDED DECEMBER 31,	
LEASE COST	**2022**	**2021**
Finance lease cost:		
Amortization of right-of-use assets	$ 22	$ 27
Interest on lease liabilities	4	10
Operating lease cost	5,230	1,336
Short-term lease cost	173	254
Variable lease cost	1,949	525
Sublease income	(702)	(88)
Total lease cost	$ 6,676	$ 2,064

The weighted-average remaining lease term and discount rate for the years ended December 31, 2022 and 2021 were as follows:

LEASE TERM AND DISCOUNT RATE	DECEMBER 31, 2022	DECEMBER 31, 2021
Weighted-average remaining lease term (years)		
Operating leases	8.5	4.6
Finance Leases	0.2	1.2
Weighted-average discount rate		
Operating leases	8.3%	6.7%
Finance Leases	30.6%	30.6%

Supplemental disclosure of cash flow information for the years ended December 31, 2022 and 2021 related to leases were as follows:

	YEAR ENDED DECEMBER 31,	
SUPPLEMENTAL CASH FLOW INFORMATION	**2022**	**2021**
Cash paid for amounts included in measurement of lease liabilities		
Operating cash flows (used in) from operating leases	$ (1,931)	$ 1,006
Financing cash flows from finance leases	22	27

The following table represents a summary of the Company's future lease payments required as of December 31, 2022:

	OPERATING LEASE OBLIGATIONS	FINANCE LEASE OBLIGATIONS	TOTAL LEASE OBLIGATIONS
2023	$ 6,103	$ 6	$ 6,109
2024	6,255	—	6,255
2025	6,427	—	6,427
2026	6,186	—	6,186
2027	5,215	—	5,215
Thereafter	22,390	—	22,390
Total future minimum lease payments	$ 52,576	$ 6	$ 52,582
Less: amount representing interest	(14,890)	—	(14,890)
Present value of future minimum lease payments	$ 37,686	$ 6	$ 37,692

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following as of December 31, 2022 and 2021 (in thousands):

	DECEMBER 31, 2022	DECEMBER 31, 2021
Accrued research and development	$ 1,967	$ 1,345
Accrued legal and professional fees	5,852	1,117
Accrued compensation and benefits	880	4,401
Accrued other	1,462	3,062
Total accrued expenses and other current liabilities	$ 10,161	$ 9,925

7. LOAN PAYABLE

Hercules Loan and Security Agreement

On May 11, 2022 (the "Closing Date") the Company entered into a loan and security agreement (the "Loan Agreement") with Hercules Capital, Inc., providing for a term loan with aggregate maximum borrowings of up to $55.0 million (the "Term Loan"). On January 25, 2023 (the "Payoff Date"), the Company voluntarily paid off all outstanding principal, accrued and unpaid interest, fees, costs and expenses under the Loan Agreement, equal to $16.2 million in the aggregate. Following the Payoff Date, all obligations, covenants, debts and liabilities of the Company under the Loan Agreement were satisfied and discharged in full, and the Loan Agreement and all other documents entered into in connection with the Loan Agreement were terminated.

Under the Loan Agreement, the Company borrowed an initial amount of $15.0 million, and, subject to the terms of the Loan Agreement and conditioned upon the Company's compliance with certain operating covenants contained therein, the Loan Agreement provided for an additional $20.0 million under the first tranche of the Term Loan, and an additional $20.0 million from the second tranche subject to the achievement of certain milestones and conditions.

The Term Loan bore interest at a variable annual rate equal to the greater of (i)(a) 4.05% plus (b) the Prime Rate (as reported in the Wall Street Journal) and (ii) 7.55%. Borrowings under the Loan Agreement were repayable in monthly interest-only payments through December 1, 2024, or December 1, 2025 if certain conditions had been achieved prior to December 1, 2024. After the interest-only payment period, borrowings under the Loan Agreement were repayable in equal monthly payments of principal and accrued interest until November 1, 2026. At the Company's option, the Company could prepay all or a portion of the outstanding borrowings, subject to a prepayment fee of 3.0% of the principal amount if prepayment occurred during the 12 months following the Closing Date, 2.0% after 12 months following the Closing Date and 1.0% after 24 months but on or prior to 36 months following the Closing Date.

The Company paid a $0.3 million facility charge upon closing and would have paid a facility charge in connection with a draw under the second tranche of the Term Loan equal to 0.75% of the amount drawn. The Loan Agreement also provided for a final payment, payable upon maturity or the repayment of the obligations in full or in part (on a pro rata basis), equal to

5.50% of the aggregate principal amount of Term Loans advanced to the Company and repaid on such date, which was accrued to other liabilities. The Loan Agreement included a minimum cash covenant of $12.5 million that would have applied commencing on the date the principal amount borrowed under the Term Loan exceeded $25.0 million, subject to waiver upon satisfaction of certain conditions as set forth in the Loan Agreement. Borrowings under the Loan Agreement were collateralized by substantially all of the Company's personal property and other assets, other than its intellectual property. In addition, the Loan Agreement included certain customary affirmative and restrictive covenants, representations and warranties, and required the Company to maintain its cash in controlled deposit accounts.

The loan payable balance as of December 31, 2022 consisted of the following (in thousands):

	DECEMBER 31, 2022
Principal amount of loan payable	$ 15,000
Less: current portion of loan payable	—
Loan payable, net of current portion	15,000
Facility charge	(231)
Unamortized issuance costs	(116)
Loan payable, including accretion, net of current portion	$ 14,653

The estimated future principal payments as of December 31, 2022 were due as follows (in thousands):

	DECEMBER 31, 2022
2023	$ —
2024	574
2025	7,210
2026	7,216
Total	$ 15,000

8. RESTRUCTURING

During the year ended December 31, 2022 the Company recognized restructuring charges of $2.4 million, consisting of one-time severance payments, healthcare coverage, outplacement services and related expenses in connection with the Company's April 2022 restructuring action (the "April Restructuring") and September 2022 restructuring action (the "September Restructuring"). The April Restructuring was substantially completed by the end of the second quarter of 2022 and the remaining charges were incurred in the third quarter of 2022.

The September Restructuring began in the third quarter of 2022 and was substantially completed in the fourth quarter of 2022, and the Company expects to incur approximately $0.2 million in future periods related to this restructuring action. The accrued restructuring liability is included in accrued compensation and benefits as of December 31, 2022.

The following table summarizes the restructuring accrual activity for the year ended December 31, 2022 (in thousands):

	SEVERANCE AND RELATED BENEFITS
Accrued restructuring liability as of December 31, 2021	$ —
Restructuring charges	2,416
Cash payments	(2,215)
Accrued restructuring liability as of December 31, 2022	$ 201

9. REVENUE

Takeda Pharmaceutical Company Limited

In January 2017, the Company entered into an agreement (as amended, 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 (formerly 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 FIN-524 from the Company to Takeda in accordance with a transition plan, and Takeda assumed sole responsibility for regulatory matters with respect to FIN-524. In November 2021, the Takeda Agreement was amended again to enable the Company to carry out certain preliminary evaluation activities with respect to FIN-525. In August of 2022, Takeda elected to terminate the Takeda Agreement and in October of 2022, the Takeda Agreement was amended to reflect the parties' transition plans.

Under the terms of the Takeda Agreement, the Company agreed to design FIN-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, *Revenue from Contracts with Customers,* 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 committee and joint development committee. 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 included the upfront payment and the estimable reimbursable R&D costs in the transaction price and recognized revenue associated with it over the period it expected 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 FIN-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 Takeda Agreement ("Amendment #2"). Pursuant to Amendment #2, Finch was obligated to perform 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 Amendment #2, Takeda paid Finch for pass-through costs incurred and research services performed at the agreed-upon full-time equivalent rate. The additional feasibility work was completed in the second quarter of 2022.

In August 2022, the Company received written notice from Takeda that, following a review of its pipeline, Takeda had elected to exercise its right to terminate the Takeda Agreement, including the associated amendments. In accordance with the terms of the Takeda Agreement, the termination became effective on November 17, 2022 (the "Termination Effective Date"). Pursuant to a further amendment to the Takeda Agreement, dated October 19, 2022, the Company is in the process of winding down and transitioning activities under the Takeda Agreement. As of the Termination Effective Date, the license rights granted to Takeda terminated and Takeda ceased to accrue any financial obligations to the Company.

The Company recognized revenue related to the Takeda Agreement of $0.9 million and $18.5 million in the years ended December 31, 2022 and 2021, respectively, which is included under collaboration revenue in the consolidated statements of operations.

Takeda reimbursed the Company for certain R&D costs on a quarterly basis. The Company recorded accounts receivable of less than $0.1 million and $0.5 million on its consolidated balance sheets as of December 31, 2022, and 2021, respectively. As of December 31, 2022, there is no remaining deferred revenue due to the Company's satisfaction of the performance obligation.

The Takeda Agreement contained various milestone payments associated with development and commercialization efforts that provided for a maximum available amount of $180.0 million had all of the milestones been achieved. Upon the Termination Effective Date, the Company was no longer eligible to receive future milestones. As of December 31, 2022, the Company has earned and received $4.0 million in milestone payments.

The Company was previously eligible to receive royalties under the Amendment and Takeda was 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, 2022 and 2021.

OpenBiome

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 OpenBiome Agreement (see Note 14) 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 had not earned any of these royalty payments pursuant to the LMIC Agreement as of December 31, 2022.

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, 2022 and 2021, as there are currently no marketable OpenBiome Royalty Products.

10. INCOME TAXES

For the years ended December 31, 2022 and 2021, 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,	
	2022	2021
Federal income taxes at 21%	21.00%	21.00%
State income taxes, net of federal benefit and tax credits	5.00	6.90
Permanent differences	(3.88)	(0.19)
Research and development credit	0.00	2.12
Change in valuation allowance	(22.12)	(29.30)
Other adjustments	0.00	(0.53)
	0.00%	0.00%

Significant components of the Company's net deferred tax assets and liabilities as of December 31, 2022 and 2021 are as follows (in thousands):

	YEAR ENDED DECEMBER 31,	
	2022	2021
Deferred Tax Assets:		
Net operating losses	$ 61,782	$ 48,419
Tax credits	6,033	4,376
Accrued expenses	17	859
Right of Use Liabilities	10,225	1,633
Section 174 R&D Expenditures	9,898	—
Other	1,310	548
Total deferred tax assets	89,265	55,835
Valuation allowance	(75,627)	(49,079)
Total net deferred tax assets	13,638	6,756
Deferred Tax Liabilities:		
Intangibles assets	8,057	7,952
Fixed assets	121	563
Right of Use Assets	8,639	1,372
Other	282	330
Total deferred tax liabilities	17,099	10,217
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, the Company's 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, 2022 and 2021, 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, 2022 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 $26.5 million during 2022 related to a full valuation allowance recorded against additional net operating losses and tax credits generated in the period.

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures immediately in the year incurred and requires taxpayers to capitalize and amortize them over five years pursuant to IRC Section 174. The mandatory capitalization requirement had no impact to the overall deferred tax assets due to the Company's loss position and full valuation allowance.

As of December 31, 2022, the Company had federal net operating losses of $230.9 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, $193.7 million, can be carried forward indefinitely. 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, 2022, the Company had post-apportioned state net operating losses of $13.3 million that can generally be carried forward 20 years. 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, 2022, the Company had $4.9 million and $1.1 million of federal and state research and development credits, respectively, which will expire at various dates through 2041. 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.

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, 2022 and 2021, 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,	
	2022	2021
Balance, beginning of year	$ 1,822	$ 1,318
Additions for tax positions of current year	651	507
Additions for tax positions of prior years	—	(3)
Balance, end of year	$ 2,473	$ 1,822

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, 2022 and 2021, 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.

11. 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 "Court"). 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 (the "'406 Patent"); 9,962,413 (the "'413 Patent"); 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. In June 2022, Finch alleged infringement of the '406 and '413 Patents by Rebiotix. 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, (collectively, the "UMN Patents"). On April 4, 2022, Rebiotix filed counterclaims for declaratory judgment of non-infringement and invalidity of the UMN Patents. On May 2, 2022, the Company and UMN responded, denying such counterclaims. The Court set a trial date for a five-day trial beginning on May 20, 2024. On January 23, 2023, the Company filed a second amended answer and counterclaims, in which the Company alleged infringement by Rebiotix of two additional U.S. Patents owned by Finch: U.S. Patent Nos. 11,541,080 (the "'080 Patent") and 11,491,193 (the "'193 Patent"). On February 7, 2023 Rebiotix filed counterclaims for declaratory judgment of non-infringement and invalidity of the '080 and '193 patents. The Court issued a claim construction order on February 28, 2023. 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 that there is no probable or estimable loss contingency that is required to be recorded as of December 31, 2022.

License and royalty payments

The Company has also entered into license agreements under which it is obligated to make milestone and royalty payments and incur annual maintenance fees. The Company owes an annual maintenance fee of $5,000 under the agreement with the University of Minnesota, as well as escalating minimum royalty amounts. The Company is also required to pay minimum royalties under the agreement with Arizona State University of $5,000 annually through 2023, which increases to $20,000 in 2024. The minimum payments continue in perpetuity for the University of Minnesota until the agreement is terminated. The Company entered into the OpenBiome Agreement in November 2020 (see Note 9 and Note 14) and the closing of the OpenBiome Agreement occurred on March 1, 2021. Under the terms of the OpenBiome Agreement, the Company was 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 chemistry, manufacturing, and controls ("CMC") process used to manufacture materials for its clinical trials. The Company is obligated to pay to OpenBiome a low single digit royalty on net sales of licensed natural products by the Company and its 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.

Purchase and other obligations

The Company has entered 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 the Company's 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.

Leases

The Company's commitments under its lease agreements are described in Note 5.

12. 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 the Company's common stock, diluting the voting power of the Company's common stock,

impairing the liquidation rights of the Company's common stock, or delaying or preventing a change in control. As of December 31, 2022, 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, 2022, no cash dividends have been declared or paid.

As of December 31, 2022 and 2021, the Company has reserved the following shares of common stock for the exercise of stock options, vesting of restricted stock, and shares under the employee stock purchase plan:

	YEAR ENDED DECEMBER 31,	
	2022	2021
Options to purchase common stock	3,289,383	3,264,770
Unvested restricted stock units	270,996	—
Shares issuable under employee stock purchase plan	92	45,195
	3,560,471	3,309,965

13. 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.

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 the Company's 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.

On January 1, 2022, the number of shares of common stock reserved and available for issuance under the 2021 Plan automatically increased by 2,375,609 shares pursuant to the provisions of the 2021 Plan.

As of December 31, 2022, there were 3,289,383 shares of common stock issuable upon the exercise of outstanding options and there were 1,846,333 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 under the 2021 ESPP commenced on December 1, 2021.

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, participants in the 2021 ESPP will purchase shares of common stock 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 2021 ESPP are subject to the determinations of the compensation committee of the Board. On January 1, 2022, the number of shares of common stock reserved and available for issuance under the 2021 ESPP automatically increased by 475,121 shares pursuant to the provisions of the 2021 ESPP. As of December 31, 2022, 100,645 shares were issued under the 2021 ESPP in 2021 and 874,476 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, 2022 and 2021 were as follows:

	2022	2021
Risk-free interest rate	2.26%	0.88%
Expected term (in years)	5.88	5.1 - 6.3
Expected volatility	95.7%	77.7% - 93.0%
Expected dividend yield	0.0%	0.0%

The following table summarizes the activity of the Company's stock options under the 2017 Plan and 2021 Plan for the year ended December 31, 2022:

	SHARES	WEIGHTED-AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL TERM (in years)	AGGREGATE INTRINSIC VALUE (in thousands)
Outstanding as of December 31, 2021	3,264,770	$ 11.04	8.4	$ 7,228
Granted	2,185,894	6.92		
Exercised	(188,338)	0.74		
Cancelled or forfeited	(1,500,529)	10.47		
Expired	(472,414)	6.56		
Outstanding as of December 31, 2022	3,289,383	$ 9.79	6.9	$ —
Options exercisable as of December 31, 2022	1,349,144	$ 9.51	5.0	$ —
Options vested or expected to vest as of December 31, 2022	3,289,383	$ 9.79	6.9	$ —

The options granted during the years ended December 31, 2022 and 2021 were granted to employees and consultants of the Company. As of December 31, 2022, there was approximately $12.1 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 2.43 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 2022 and 2021 was $0.4 million and $1.7 million, respectively. The weighted-average grant date fair value of stock options granted in the years ended December 31, 2022 and 2021 under the Black-Scholes option pricing model was $6.92 per option and $9.87 per option, respectively.

Restricted Stock Unit Awards

In June 2022 the Company issued RSU awards with time-based vesting conditions to employees. The fair value of an RSU award is equal to the fair market value of the Company's ordinary shares on the date of grant and the expense is recognized on a straight-line basis over the requisite service period. The RSUs primarily vest over one year from the grant date.

The following table summarizes the activity of the Company's RSUs under the 2021 Plan for the year ended December 31, 2022:

	RSUs	WEIGHTED-AVERAGE GRANT DATE FAIR VALUE	AGGREGATE INTRINSIC VALUE (in thousands)
Outstanding as of December 31, 2021	—	$ —	$ —
Granted	623,260	2.79	
Vested and distributed	(252,431)	2.79	
Forfeited	(99,833)	2.79	
Unvested as of December 31, 2022	270,996	$ 2.79	$ 131

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, 2022 and 2021 is as follows (in thousands):

	YEAR ENDED DECEMBER 31,	
	2022	2021
Research and development	$ 3,265	$ 1,605
General and administrative	4,579	2,556
Total	$ 7,844	$ 4,161

14. RELATED PARTY TRANSACTIONS

Master Strategic Affiliation Agreement

Under the 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. The Strategic Agreement was amended and restated in its entirety upon execution of the OpenBiome Agreement in November 2020 (as amended, the "A&R Strategic Agreement").

The Company did not record any reimbursements to or from OpenBiome under the A&R Strategic Agreement during the year ended December 31, 2022. For the year ended December 31, 2021, the Company reimbursed OpenBiome $0.1 million, and OpenBiome reimbursed the Company $0.1 million under the A&R Strategic Agreement. As of December 31, 2022 and December 31, 2021, the Company recorded zero payable balance due to OpenBiome.

OpenBiome subleased office and lab space from the Company through December 31, 2021 (see Note 5). The Company's rent income under the sublease was $0.1 million for the year ended December 31, 2021.

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 OpenBiome $1.1 million under the CSA for the year ended December 31, 2021.

OpenBiome Agreement

On November 19, 2020, the Company entered into the OpenBiome Agreement in order to obtain OpenBiome's CMC manufacturing process to enhance the Company's then current manufacturing capabilities for CP101; the OpenBiome Agreement was fully executed and closed on March 1, 2021. Simultaneously with entering into the OpenBiome Agreement, the Company terminated the Material Access License Agreement, the CSA and the Asset Purchase and License Agreement, as well as certain subject matter agreements, and executed 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.

Under the OpenBiome Agreement, the Company is also required to pay certain milestones of 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 will continue to earn royalties under the OpenBiome Agreement, which serve as reimbursement for third party license fees, based on sales of fecal microbiota transplantation ("FMT") materials.

15. 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 $0.7 million and $0.8 million in the years ended December 31, 2022 and 2021, respectively.

16. 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,	
	2022	2021
Numerator:		
Net loss	$ (114,646)	$ (58,160)
Net loss attributable to common stockholders—basic and diluted	(114,646)	(58,160)
Denominator:		
Weighted-average common stock outstanding—basic and diluted	47,691,632	39,202,086
Net loss per share attributable to common stockholders—basic and diluted	$ (2.40)	$ (1.48)

The Company's potentially dilutive securities, which include stock options, restricted stock, and shares issuable under the employee stock purchase plan, 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, 2022 and 2021 because including them would have had an anti-dilutive effect:

	YEAR ENDED DECEMBER 31,	
	2022	2021
Options to purchase common stock	3,289,383	3,264,770
Unvested restricted stock units	270,996	—
Shares issuable under employee stock purchase plan	92	45,195
	3,560,471	3,309,965

17. SUBSEQUENT EVENTS

January Restructuring

On January 24, 2023, the Company announced decisions to discontinue its Phase 3 clinical trial of CP101 in recurrent CDI and to focus on realizing the value of its intellectual property estate and other assets. In connection with these decisions, on January 23, 2023, the Board approved certain expense reduction measures, including a reduction of the Company's workforce by 77 full-time employees, or approximately 95% of the Company's then current employee base (the "January 2023 Restructuring"). The Company initiated the January 2023 Restructuring on January 24, 2023, with the majority of impacted positions ending in February 2023 and a small number of positions maintained into May 2023.

As a result of the January 2023 Restructuring, the Company estimates that it will incur approximately $4.1 million in costs resulting from cash expenditures consisting of one-time severance payments, outplacement services and related expenses. The Company expects to record a significant portion of these charges in the first half of 2023. The January 2023 Restructuring is expected to be substantially complete by the end of the second quarter of 2023. The estimates of costs that the Company expects to incur, and the timing thereof, are subject to a number of assumptions and actual results may differ. The Company may also incur other charges or cash expenditures not currently contemplated in connection with the Restructuring.

Hercules Loan Agreement Payoff

On January 25, 2023, the Company voluntarily paid off all outstanding principal, accrued and unpaid interest, fees, costs and expenses, equal to $16.2 million in the aggregate (the "Payoff Amount"), under the Loan Agreement. The Payoff Amount included a prepayment charge of $330,000, equal to 2.2% of the outstanding principal, and an end of term fee of $825,000. Upon receipt by the lender of the Payoff Amount on January 25, 2023, all obligations, covenants, debts and liabilities of the Company under the Loan Agreement were satisfied and discharged in full, and the Loan Agreement and all other documents entered into in connection with the Loan Agreement were terminated.

IPR&D Asset

As a result of management's decision to discontinue the Company's Phase 3 clinical trial of CP101 in recurrent CDI and focus on realizing the value of the Company's intellectual property estate and other assets, the value of the Company's IPR&D asset will be impaired in the first quarter of 2023, as the value of the asset is derived from the estimated future cash flows associated with CP101.

Silicon Valley Bank

On March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. The Company received full access to its cash at SVB on March 13, 2023.

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 principal executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022. Based on the evaluation of our disclosure controls and procedures as of December 31, 2022, our principal executive officer and our principal 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

Management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management of the Company has assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2022. In making its assessment of internal control over financial reporting, management used the criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2022.

This annual report does not include an audit report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to audit by the Company's registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

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 year ended December 31, 2022, 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 principal executive officer and our principal 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.

On March 23, 2023, Jo Viney, Ph.D. informed us of her intent to resign as a member of the Board of Directors, effective as of March 28, 2023. Dr. Viney's decision to resign was not the result of any disagreement between Dr. Viney and us on any matters relating to our operations, policies or practices.

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 2023 annual meeting of stockholders, or the 2023 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, 2022.

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 2023 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 2023 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 2023 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 2023 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 (incorporated by reference to Exhibit 4.3 of the Registrant's Annual Report on Form 10-K, filed March 31, 2022).
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 (incorporated by reference to Exhibit 10.3 of the Registrant's Annual Report on Form 10-K, filed March 31, 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#	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).
10.6#	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).
10.7+	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).
10.8+	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).
10.9+	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).
10.10†	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).
10.11†	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).
10.12†	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).

10.13†	Executive Employment Agreement by and between Finch Therapeutics Group, Inc. and Marc Blaustein, dated as of September 8, 2021 (incorporated by reference to Exhibit 10.19 of the Registrant's Annual Report on Form 10-K, filed March 31, 2022).
10.14*†	Amendment No. 1 to the Executive Employment Agreement by and between Finch Therapeutics Group, Inc. and Marc Blaustein, dated as of December 7, 2022.
10.15*†+	Retention Bonus Agreement by and between Finch Therapeutics Group, Inc. and Marc Blaustein, dated as December 7, 2022.
10.16†	Amended and Restated Executive Employment Agreement by and between Finch Therapeutics Group, Inc. and Joseph Vittiglio, dated as of March 12, 2021 (incorporated by reference to Exhibit 10.20 of the Registrant's Annual Report on Form 10-K, filed March 31, 2022).
10.17†	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 (incorporated by reference to Exhibit 10.21 of the Registrant's Annual Report on Form 10-K, filed March 31, 2022).
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)

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* 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 23, 2023

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 23, 2023
/s/ Marc Blaustein Marc Blaustein	Chief Operating Officer *(Principal Financial Officer and Principal Accounting Officer*)	March 23, 2023
/s/ Susan Graf Susan Graf	Chairman of the Board of Directors	March 23, 2023
/s/ Domenic Ferrante Domenic Ferrante	Director	March 23, 2023
/s/ Chris Shumway Chris Shumway	Director	March 23, 2023
/s/ Nicholas Haft Nicholas Haft	Director	March 23, 2023
/s/ Christian Lange Christian Lange	Director	March 23, 2023
/s/ Jeffery Smisek Jeffery Smisek	Director	March 23, 2023
/s/ Jo Viney Jo Viney, Ph.D.	Director	March 23, 2023