As filed with the Securities and Exchange Commission on March 18, 2021

Registration Statement No. 333-253622

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

AMENDMENT NO. 2
TO
FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

FINCH THERAPEUTICS GROUP, INC.

(Exact name of registrant as specified in its charter)

Delaware	**2836**	**82-3433558**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

200 Inner Belt Road, Suite 400
Somerville, Massachusetts 02143
Tel: (617) 229-6499
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Mark Smith, Ph.D.
Chief Executive Officer
Finch Therapeutics Group, Inc.
200 Inner Belt Road, Suite 400
Somerville, Massachusetts 02143
Tel: (617) 229-6499
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Divakar Gupta **Ryan S. Sansom** **Courtney T. Thorne** **Cooley LLP** **500 Boylston Street** **Boston, Massachusetts 02116** **(617) 937-2300**	**Joseph D. Vittiglio** **General Counsel and Corporate Secretary** **Finch Therapeutics Group, Inc.** **200 Inner Belt Road, Suite 400** **Somerville, Massachusetts 02143** **Tel: (617) 229-6499**	**Edwin M. O'Connor** **Seo Salimi** **Goodwin Procter LLP** **620 Eighth Avenue** **New York, New York 10018** **(212) 813-8000**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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 in Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	**Amount to be Registered(1)**	**Proposed Maximum Offering Price Per Share(2)**	**Proposed Maximum Aggregate Offering Price(1)(2)**	**Amount of Registration Fee(3)**
Common Stock, $0.001 par value per share	7,187,500	$17.00	$122,187,500	$13,331

(1) Includes 937,500 additional shares that the underwriters have the option to purchase.
(2) Estimated solely for purposes of computing the amount of the registration fee pursuant to Rule 457(a) under the Securities Act of 1933, as amended. Includes the offering price of additional shares that the underwriters have the option to purchase.
(3) The registration fee includes $12,547 that was previously paid by the Registrant in connection with the filing of its Registration Statement.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion
Preliminary Prospectus dated March 18, 2021

PROSPECTUS

6,250,000 Shares

Common Stock

This is the initial public offering of Finch Therapeutics Group, Inc. We are selling 6,250,000 shares of our common stock.

We expect the public offering price to be between $15.00 and $17.00 per share. Currently, no public market exists for the shares. We have applied to list our common stock on the Nasdaq Global Market under the symbol “FNCH.”

Investing in the common stock involves risks that are described in the “Risk Factors” section beginning on page 13 of this prospectus.

	Per Share	Total
Public offering price	$	$
Underwriting discount	$	$
Proceeds, before expenses, to us	$	$

The underwriters may also exercise their option to purchase up to an additional 937,500 shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about , 2021.

BofA Securities **Jefferies** **Evercore ISI**

The date of this prospectus is , 2021.

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We own various U.S. federal trademark applications and unregistered trademarks, including our company name and our logo, appearing in this prospectus. All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for your convenience, trade names, trademarks and service marks contained in this prospectus may appear without the "®" or "™" symbols. Such references are not intended to indicate, in any way, that we will not assert, to the fullest extent possible under applicable law, our rights or the rights of the applicable licensor to those trade names, trademarks and service marks.

We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus, any amendment or supplement to this prospectus or any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus, any amendment or supplement to this prospectus or any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

PROSPECTUS SUMMARY

This summary highlights, and is qualified in its entirety by, the more detailed information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, especially the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus. Unless the context otherwise requires, the terms "Finch," "Finch Therapeutics," "the company," "we," "us," "our" and similar references in this prospectus refer to Finch Therapeutics Group, Inc. and its consolidated subsidiaries.

Overview

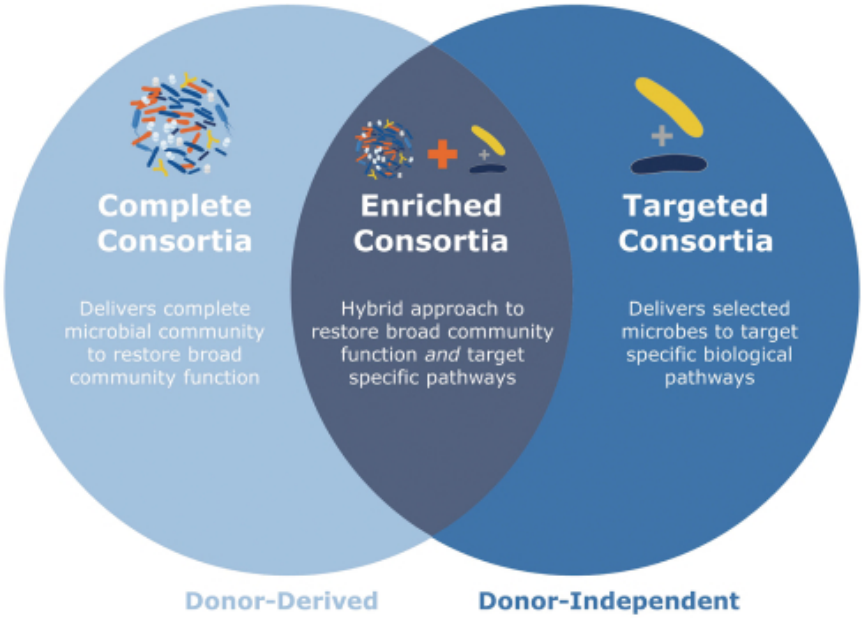
We are a clinical-stage microbiome therapeutics company leveraging our Human-First Discovery platform to develop a novel class of orally administered biological drugs. The microbiome consists of trillions of microbes that live symbiotically in and on every human and are essential to our health. When key microbes are lost, the resulting dysbiosis can increase susceptibility to immune disorders, infections, neurological conditions, cancer and other serious diseases. We are developing novel therapeutics designed to deliver missing microbes and their clinically relevant biochemical functions to correct dysbiosis and the diseases that emerge from it. Our Human-First Discovery platform uses reverse translation to identify diseases of dysbiosis and to design microbiome therapeutics that address them. Our lead product candidate, CP101, delivers a complete microbiome and is being developed initially for the treatment of patients with recurrent *Clostridioides difficile* infection, or CDI. In June 2020, we reported positive topline data from our first of two pivotal trials in recurrent CDI, and we plan to initiate a Phase 3 clinical trial, which we refer to as PRISM4, as our second pivotal trial of CP101 for recurrent CDI in mid-2021. Although we need to generate additional data confirming safety and efficacy to support regulatory approval of CP101 for the treatment of recurrent CDI, we believe data from our pivotal, Phase 2 clinical trial with CP101 validates our platform, positioning us to initiate new clinical trials in at least three new indications over the next 18 months, including chronic hepatitis B virus, or HBV, autism spectrum disorder, or ASD, and ulcerative colitis. We believe that our differentiated platform, rich pipeline and the broad therapeutic potential of this new field of medicine position us to transform care for a wide range of unmet medical needs.

Microbes and humans have evolved together over millions of years, developing an intricate and mutually beneficial relationship. It is only through the application of recent breakthroughs in genomic sequencing and computational analysis that the depth of this symbiotic partnership has become clear. Enabled by the genomic revolution, researchers have discovered that humans carry over a 1,000-fold more microbial genes than host genes and that the biochemistry of the microbiome is fundamentally intertwined with many aspects of human physiology leading some to consider the microbiome to be a new organ system. Unsurprisingly given the criticality of this system, disruptions to our microbiome, like the introduction of broad-spectrum antibiotics, have been tied to a wide range of diseases. We are developing therapeutics that restore missing microbes, enabling us to engage a fundamental aspect of human biology that has been inaccessible to drug developers until now.

Our lead candidate, CP101, consists of a lyophilized, intact microbial community harvested from rigorously screened healthy donors and formulated in orally administered capsules designed to release at the appropriate location in the gastrointestinal tract. CP101 is designed to deliver a complete microbiome, addressing the community-level dysbiosis that characterizes CDI. Patients with CDI suffer from severe diarrhea, which can progress to toxic megacolon and death, with more than 44,000 CDI-attributable deaths annually in the United States. In addition to the human cost, the economic impact of CDI is significant, with 2.4 million in-patient days and more than $5.0 billion in direct treatment costs each year in the United States alone. CDI often returns after cessation of antibiotic treatment because antibiotics do not address the dysbiosis that underlies this disease. We estimate there are approximately 200,000 cases of recurrent CDI annually in the United States.

In June 2020, we announced that CP101 met its primary efficacy endpoint in PRISM3, a randomized, placebo-controlled, multi-center, pivotal, Phase 2 clinical trial in recurrent CDI. Overall, 74.5% of participants who received a single administration of CP101 achieved a sustained clinical cure, defined as the absence of CDI through week 8, achieving statistical significance for the primary efficacy endpoint, with a clinically meaningful 33.8% relative risk reduction for CDI recurrence compared to placebo. In PRISM3, the prevalence of adverse events were similar across CP101 and placebo arms, with no treatment-related serious adverse events in the CP101 arm. We plan to initiate a Phase 3 clinical trial as our second pivotal trial of CP101 for recurrent CDI in mid-2021 to build on the results of PRISM3. Further, based on the clinical validation of CP101 for recurrent CDI, we plan to develop CP101 in other diseases of dysbiosis, including the treatment of chronic HBV. We plan to initiate our first clinical trial of CP101 in chronic HBV in mid-2021, with an initial safety review in the second half of 2021 and topline data in the second half of 2022.

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



Our Human-First Discovery platform informs each of these product strategies using clinical interventional data, through a process of reverse translation. Core to this strategy is our ability to deploy our proprietary machine learning algorithms to mine clinical data generated internally and by third parties, including experience with fecal microbiota transplantation, or FMT, a procedure that has been used to restore the gut microbiome and address community-level dysbiosis. FMT is a procedure, not a product. It is not approved by the U.S. Food and Drug Administration, or the FDA, and there are no standards for testing, processing and delivery of FMT, though it typically requires a colonoscopy. Despite these limitations, FMT has been used to treat more than 50,000 patients, with hundreds of clinical studies ongoing across a range of disease areas. We believe that

this data can be used to (1) identify diseases where addressing dysbiosis provides therapeutic benefit, (2) reveal the mechanisms that underlie these results and (3) uncover key microbes and functional pathways that drive these clinical outcomes. We believe this reverse translation strategy is the optimal approach to developing microbiome therapeutics, providing causal insights that cannot be gleaned from preclinical *in vitro* or *in vivo* experiments alone. We further believe that we are uniquely positioned to execute on this strategy because of our proprietary FMT database and biorepository, our broad network of collaborators that supports the rapid growth of our data assets and our proprietary machine learning algorithms that enable the efficient translation of clinical data into therapeutic insights.

We have used our Human-First Discovery platform to develop FIN-211, an Enriched Consortia product candidate that we are advancing for the treatment of the gastrointestinal and behavioral symptoms of ASD. Scientific research in human and animal models have highlighted the "gut-brain axis" linking dysbiosis to neurological and neurobehavioral conditions, as the microbiome impacts the enteric nervous system and the production of neurotransmitters. This basic research is supported by a growing body of third-party clinical research. In an open-label, proof-of-concept FMT trial conducted by one of our collaborators, it was observed that, two years after treatment, 33% of the study participants who had previously been diagnosed with ASD were below the ASD diagnostic cutoff score for the Childhood Autism Rating Scale (CARS), a commonly used ASD diagnostic tool. Additionally, in a third-party, open-label randomized, controlled trial, children with ASD receiving FMT and behavioral therapy showed a statistically significant improvement in their behavioral symptoms compared to those receiving behavioral therapy alone. Both studies also observed marked improvements in the gastrointestinal symptoms that many autistic children suffer from. There are no FDA-approved therapies for the core symptoms of ASD and the total financial burden of care for this condition is estimated to exceed $100 billion in the United States annually. We have received feedback from the FDA that demonstrating benefit for either the gastrointestinal or behavioral symptoms of ASD could support a biologics license application. Building on our discussions with the FDA, we aim to continue to validate behavioral instruments as part of our clinical development plans. We have designed FIN-211 to address both aspects of ASD and plan to initiate a Phase 1 clinical trial of FIN-211 in ASD in the second half of 2021, with topline data in the second half of 2022. We believe FIN-211 has the potential to transform care for patients with ASD.

We are also advancing FIN-524 and FIN-525 as Targeted Consortia product candidates for the treatment of ulcerative colitis and Crohn's disease, the most common types of inflammatory bowel diseases. We are partnering with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Limited, to develop these assets. FIN-524 was discovered through the computational and molecular analysis of data from 147 patients treated with FMT and 19 observational studies of an additional 2,210 patients. We plan to initiate our first clinical trial of FIN-524 in ulcerative colitis in the first half of 2022. In addition, we are conducting initial discovery efforts on FIN-525, and pending Takeda's review, we could initiate IND-enabling studies for FIN-525 in Crohn's disease in the second half of 2021.

Key Advantages of Our Platform

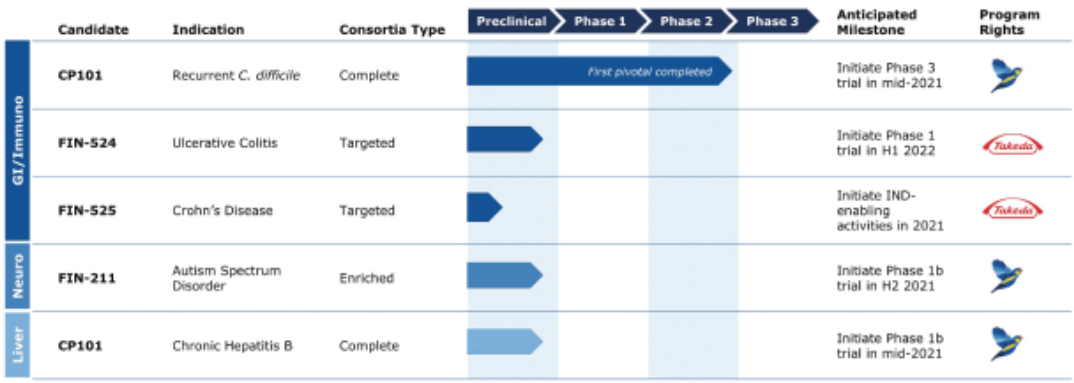
- ***Our Human-First Discovery platform leverages clinical data to significantly reduce drug development time and translational risk.*** Given the distinct biology of the human microbiome, developing products by relying on laboratory and animal models alone is challenging. However, with our Human-First Discovery platform, we have deployed powerful machine learning capabilities to integrate our proprietary FMT data with information from our human strain library. We believe this strategy reduces translational risk, because we only commence programs where clinical data already exists, thereby limiting the risk that effects seen in the laboratory will not translate to the clinic. Further, in the many indications like chronic HBV where we believe a Complete Consortia product strategy is attractive, we are able to enter the clinic directly with CP101, avoiding the time, costs and translational risks associated with traditional preclinical development. We believe that this approach is enabled by the favorable tolerability profile we have observed to date with CP101.

- ***We have differentiated capabilities to develop both complete and targeted microbiome therapeutics***. We have product candidates that address the distinct types of dysbiosis that lead to microbiome-mediated diseases. We have an orally administered Complete Consortia product candidate, which we believe enables both a potential near-term commercial opportunity in recurrent CDI, if approved, and the ability to expand into new therapeutic areas linked to community-level dysbiosis. We are also developing Targeted Consortia and Enriched Consortia product candidates that engage selected biological pathways to address more specific functional defects. This combination of capabilities enables us to develop product candidates that address each of the distinct types of dysbiosis that lead to microbiome-mediated diseases.

- ***We have exclusive access to certain data and thousands of samples from the largest providers of FMT in the world.*** We have developed strategic partnerships with groups that we believe are the largest providers of FMT in the United States, China and Australia, feeding our proprietary database of clinical data. One of these groups, OpenBiome, has delivered treatments to more than 50,000 patients across a network of more than 1,000 clinics. We have obtained exclusive access to a library of more than 10,000 microbiome samples from certain donors that have been administered to patients. We have demonstrated the ability to cryo-revive strains from these samples, enabling isolation of specific strains demonstrating promising results in FMT directly from the relevant source material, rather than generic bacteria captured from samples without clinical history or murine isolates that may not exhibit clinical activity in humans. We have developed a large and growing database and biorepository which we are continually mining to develop new product candidates.

- ***We have built multi-layered patent protection with significant longevity***. We have a large and diverse patent portfolio that embodies pioneering work in the microbiome field. Our patent portfolio consists of over 50 issued U.S. and foreign patents, as well as over 130 patent applications, that have broad relevance for the industry and provide multi-layered protection for our product candidates, including key product composition claims that extend through 2031 and other relevant patents that extend through 2036.

Our Pipeline



Our Team

We are led by an energetic team of experienced biotechnology executives and recognized leaders in the microbiome therapeutics space. Our co-founder and Chief Executive Officer, Mark Smith, Ph.D., has been a pioneer in microbiome research, authoring over 50 peer-reviewed publications in the field. Dr. Smith founded OpenBiome, establishing the universal donor model for microbiota transplantation as a new standard of care for CDI. Gregory D. Perry, our Chief Financial Officer, has more than 20 years of experience managing teams at leading biotechs such as Transkaryotic Therapies, Inc., Eleven Biotherapeutics, Inc. and ImmunoGen, Inc. Our co-founder and Chief Medical Officer, Zain Kassam, M.D., M.P.H., is a world-class clinical researcher in the microbiome field and has authored over 150 peer-reviewed abstracts and papers. Dr. Kassam has collaborated on dozens of clinical studies investigating applications of the microbiome to treat disease. Our senior management team combines decades of experience in microbiology, data science, clinical research and the manufacture and commercialization of complex biologics, collectively developing more than 40 approved therapies across a wide range of modalities and therapeutic areas. We have assembled an exceptional team, including 34 individuals who hold a Ph.D. or M.D. degree.

Our Strategy

We believe that the human microbiome represents an untapped opportunity for therapeutic intervention. We have designed our Human-First Discovery platform to scale across multiple therapeutic areas, producing orally administered microbiome therapeutics that can correct dysbiosis and the many diseases that we believe emerge from it. Our goal is to transform patient care by becoming the leading biopharmaceutical platform company developing and commercializing microbiome therapeutics. The key elements of our strategy to achieve this goal are to:

- ***Drive CP101 for recurrent CDI toward regulatory approval and commercialization.***
- ***Advance CP101 into additional indications where FMT demonstrates compelling clinical outcomes.***
- ***Leverage our Enriched Consortia product strategy to drive clinical development of FIN-211 for the treatment of ASD and other high value indications.***
- ***Continue to use our Human-First Discovery platform to translate clinical data into a pipeline of differentiated product candidates, including Targeted Consortia.***
- ***Selectively enter into strategic collaborations to maximize the value of our platform and pipeline.***

Risks Associated with Our Business

Our business is subject to a number of risks. These risks are discussed more fully in the section titled “Risk Factors” immediately following this prospectus summary. You should read these risks before you invest in our common stock. In particular, risks associated with our business include, but are not limited to, the following:

- We face substantial competition which may result in others developing or commercializing drugs before or more successfully than us, particularly since we are aware of a number of companies focused on developing microbiome therapeutics in various indications, including three competitors that have a product candidate being evaluated in clinical trials for recurrent CDI.
- We have a limited operating history, have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.

- Even if we consummate this offering, we will require substantial additional funding to finance our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our product development programs or other operations.
- We believe our current cash and cash equivalents will be sufficient to fund our business only for a limited amount of time, and if we are not able to raise additional funds, we may be unable to continue as a going concern.
- We are heavily dependent on the success of our product candidates, which are in clinical development. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.
- Our product candidates are based on microbiome therapeutics, which is an unproven approach to therapeutic intervention.
- Our relationship with OpenBiome may adversely affect our ability to develop our product candidates and subject us to increased liability.
- Our business and operations may be adversely affected by the evolving and ongoing COVID-19 global pandemic.
- Our product candidates may be associated with serious adverse, undesirable or unacceptable side effects or other properties or safety risks, which may delay or halt their clinical development, or prevent marketing approval.
- The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- The manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-up of our manufacturing capabilities.
- We rely on third-party donors of biological material to manufacture certain product candidates such as CP101, and if we do not obtain an adequate supply of acceptable material from those qualified donors, the clinical and commercial supply of these product candidates may be adversely impacted.
- We intend to operate our own manufacturing facility for certain product candidates, which will require significant resources and we may fail to successfully operate our facility, which could adversely affect our clinical trials and the commercial viability of our product candidates.
- We have never commercialized a product candidate and may experience delays or unexpected difficulties in obtaining regulatory approval for our current or future product candidates for our initial or potential additional indications.
- We rely on third parties to supply and manufacture our product candidates, and we expect to continue to rely on third parties to manufacture our products, if approved.
- If we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market.

- In preparation for this offering, we identified a material weakness in our internal control over financial reporting. If we are not able to remediate the material weakness or if we otherwise 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.

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, dated September 21, 2017, 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, (i) Project C. Merger Sub Inc., a Delaware corporation and subsidiary of Finch Therapeutics Group, Inc., merged with and into Finch Therapeutics, Inc. and (ii) Crestovo Merger Sub LLC merged with and into Crestovo Holdings LLC, a Delaware limited liability company and subsidiary of Finch Therapeutics Group, Inc., with each of Finch Therapeutics, Inc. and Crestovo Holdings LLC surviving the merger as a wholly-owned subsidiary of Finch Therapeutics Group, Inc.

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 prospectus.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- being permitted to present in this prospectus only two years of audited financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- reduced disclosure obligations regarding the executive compensation in our periodic reports and proxy statements;
- not being required to submit to our stockholders advisory votes on executive compensation or golden parachute arrangements;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act; and
- an exemption from new or revised financial accounting standards until they would apply to private companies and from compliance with any new requirements adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation.

We may take advantage of these exemptions for up to the last day of the fiscal year ending after the fifth anniversary of this offering or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (1) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (2) the last day of our fiscal year following

the fifth anniversary of the date of the closing of this offering; (3) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (4) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of certain reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

We have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies which may make comparison of our financials to those of other public companies more difficult. We have also elected to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of these elections, the information that we provide in this prospectus may be different than the information you may receive from other public companies in which you hold equity interests. In addition, it is possible that some investors will find our common stock less attractive as a result of these elections, which may result in a less active trading market for our common stock and higher volatility in our stock price.

We are also a “smaller reporting company,” meaning that the market value of our shares held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, 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 emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

THE OFFERING

Common stock offered by us	6,250,000 shares.
Common stock to be outstanding immediately after this offering	45,895,402 shares (or 46,832,902 shares if the underwriters exercise in full their option to purchase additional shares).
Option to purchase additional shares	We have granted the underwriters an option, exercisable for 30 days after the date of this prospectus, to purchase up to an additional 937,500 shares from us.
Use of proceeds	We estimate that we will receive net proceeds of approximately $90.3 million (or approximately $104.3 million if the underwriters exercise in full their option to purchase additional shares), based on an assumed initial public offering price of $16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds of this offering, together with our existing cash and cash equivalents, as follows: • approximately $50.0 million to advance the clinical development of CP101 for the treatment of recurrent CDI, our lead product candidate, through the receipt of topline data from our planned Phase 3 clinical trial; • approximately $20.0 million to advance the clinical development of FIN-211 for the treatment of ASD, an Enriched Consortia product candidate, through the receipt of topline data from our planned Phase 1 clinical trial; • approximately $10.0 million to fund the advancement of CP101 in additional indications, including chronic HBV through the receipt of topline data from our planned Phase 1 clinical trial; • approximately $60.0 million for investment in our Human-First Discovery platform, including the development of commercial-ready manufacturing capabilities; and • the remaining proceeds for working capital and general corporate purposes. See “Use of Proceeds” for additional information.
Risk factors	You should carefully read the section titled “Risk Factors” on page 13 in this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.
Proposed Nasdaq Global Market symbol	“FNCH”

The number of shares of our common stock to be outstanding after the closing of this offering is based on 39,645,402 shares of our common stock outstanding as of December 31, 2020, which gives effect to the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 31,253,609 shares of our common stock, and excludes:

- 1,053,874 shares of our common stock issuable upon the exercise of options outstanding as of December 31, 2020 under our 2017 Equity Incentive Plan, as amended, or the 2017 Plan, at a weighted-average exercise price of $1.51 per share;
- 251,810 shares of our common stock issuable on the exercise of options granted subsequent to December 31, 2020 under our 2017 Plan, with a weighted-average exercise price of $13.00 per share;
- 815,214 shares of our common stock issuable upon the exercise of options approved subsequent to December 31, 2020 to be granted to our named executive officers and certain of our other employees under our 2021 Equity Incentive Plan, or 2021 Plan, contingent and effective upon the execution of the underwriting agreement for this offering, at an exercise price equal to the initial public offering price per share;
- 19,346 shares of our common stock issuable upon the exercise of warrants outstanding as of December 31, 2020, at a weighted-average exercise price of $0.03 per share; and
- 698,601 shares of our common stock reserved for future issuance under our 2017 Plan as of December 31, 2020, which shares will cease to be available for future issuance immediately prior to the time that our 2021 Plan becomes effective;
- 4,700,000 shares of our common stock reserved for future issuance pursuant to our 2021 Plan (which does not give effect to the grant of 815,214 shares of common stock issuable upon the exercise of stock options that will be granted contingent and effective upon the execution of the underwriting agreement for this offering), which will become effective upon the execution of the underwriting agreement related to this offering, as well as any shares reserved pursuant to provisions in our 2021 Plan that automatically increase the number of shares of common stock reserved for issuance under the 2021 Plan; and
- 500,000 shares of our common stock reserved for future issuance under our 2021 Employee Stock Purchase Plan, or ESPP, which will become effective upon the execution of the underwriting agreement related to this offering, as well as any shares reserved pursuant to provisions in the ESPP that automatically increase the number of shares of common stock reserved for issuance under the ESPP.

Unless otherwise indicated, this prospectus reflects and assumes the following:

- a one-for-14.444 reverse stock split of our common stock effected on March 12, 2021;
- the automatic conversion of all of our outstanding shares of convertible preferred stock into an aggregate of 31,253,609 shares of our common stock upon the closing of this offering;
- the filing and effectiveness of our amended and restated certificate of incorporation in Delaware and the adoption of our amended and restated bylaws, each of which will occur in connection with the closing of this offering;
- no exercise of the outstanding options referred to above after December 31, 2020; and
- no exercise by the underwriters of their option to purchase additional shares of our common stock.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth our summary consolidated financial data. We derived the summary statement of operations data for the years ended December 31, 2019 and 2020 and the summary balance sheet data as of December 31, 2020 from our audited consolidated financial statements included elsewhere in this prospectus.

When you read this summary consolidated financial data, it is important that you read it together with the historical consolidated financial statements and related notes to those statements, as well as the section of this prospectus titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of the results to be expected in any future period.

	YEAR ENDED DECEMBER 31,	
	2019	2020
REVENUE:		
Collaboration revenue	$ 9,083	$ 7,376
Contract manufacturing revenue from related party	435	—
Royalties revenue from related party	587	343
Services revenue from related party	49	—
Total revenue	10,154	7,719
OPERATING EXPENSES:		
Cost of contract manufacturing revenue from related party	(314)	—
Research and development	(23,543)	(33,144)
General and administrative	(7,439)	(14,011)
Total operating expenses	(31,296)	(47,155)
Net operating loss	(21,142)	(39,436)
OTHER INCOME, NET:		
Interest income, net	488	106
Loss on sale of assets to related party	(140)	—
Loss on disposal of fixed assets	—	(13)
Other income, net	40	2
Total other income, net	388	95
Net loss	$ (20,754)	$ (39,341)
Net loss attributable to common stockholders—basic and diluted	$ (20,754)	$ (39,341)
Net loss per share attributable to common stockholders—basic and diluted(1)	$ (2.84)	(4.83)
Weighted-average common stock outstanding—basic and diluted(1)	7,295,751	8,144,555
Pro forma net loss per share attributable to common stockholders—basic and diluted(2)		$ (1.13)
Pro forma weighted average common stock outstanding—basic and diluted(2)		34,691,996

(1) See Note 15 of the notes to our consolidated financial statements appearing at the end of this prospectus for further details on the calculation of basic and diluted net loss per share attributable to common stockholders. The unaudited pro forma basic and diluted weighted-average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2020 have been prepared to give effect, upon a qualified initial public offering, to the automatic conversion of all outstanding shares of preferred stock into common stock as if the proposed initial public offering had occurred on the later of the beginning of each period or the issuance date of the preferred stock.

(2) The unaudited pro forma weighted average number of shares outstanding used to determine pro forma basic and diluted net income per share attributable to common stockholders for the year ended December 31, 2020 was 34,691,996 and included the impact of the automatic conversion of all outstanding shares of redeemable convertible preferred stock into an aggregate of 31,253,609 shares of common stock.

The following table presents our summary consolidated balance sheet data:

- on an actual basis as of December 31, 2020;
- on a pro forma basis to reflect the automatic conversion of all outstanding shares of convertible preferred stock into an aggregate of 31,253,609 shares of our common stock upon the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our sale of 6,250,000 shares of common stock in this offering at an assumed initial public offering price of $16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	As of December 31, 2020		
	Actual	Pro Forma	Pro Forma As Adjusted
		(in thousands)	
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 99,710	$ 99,710	$ 190,259
Working capital(1)	94,678	94,678	185,991
Total assets	165,338	165,338	254,874
Total liabilities	28,002	28,002	27,238
Convertible preferred stock	233,054	—	—
Total stockholders' (deficit) equity	(95,718)	137,336	227,636

(1) Working capital is defined as current assets less current liabilities.

The pro forma as adjusted information discussed above is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase or decrease in the assumed initial public offering price of $16.00 per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase or decrease each of cash and cash equivalents, working capital, total assets and total stockholders' equity by $5.8 million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions. We may also increase or decrease the number of shares of common stock we are offering. Each increase or decrease of 1.0 million in the number of shares of common stock offered by us would increase or decrease each of cash and cash equivalents, working capital, total assets and total stockholders' equity by $14.9 million, assuming that the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The risks described below are not the only ones we face. Additional risks and uncertainties that we are currently unaware of, or that we currently believe are not material, may also adversely impact our business. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment.

Risks Related to Our Financial Position and Capital Needs

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

We are a clinical-stage biopharmaceutical company with a limited operating history. Since our inception, we have focused primarily on developing and progressing our product candidates through clinical development, organizing and staffing our company, research and development activities, establishing and protecting our intellectual property portfolio including for our Human-First Discovery platform, and raising capital. Consequently, we have no meaningful operations upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drug products. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have not yet demonstrated the ability to progress any product candidate through clinical trials, we have no products approved for commercial sale and we have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. For the years ended December 31, 2019 and 2020, we reported net losses of $20.8 million and $39.3 million, respectively. As of December 31, 2020, we had an accumulated deficit of $102.8 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our lead therapeutic product candidate, CP101, for the treatment of recurrent *Clostridioides difficile* infection, or CDI, and any future product candidates we may develop.

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

- continue our ongoing and planned development of CP101 for the treatment of recurrent CDI, including our planned Phase 3 clinical trial of CP101;
- initiate preclinical studies and clinical trials for any additional product candidates that we may pursue in the future, including our earlier-stage programs such as our planned Phase 1 clinical trials of FIN-211 for the treatment of autism spectrum disorder, or ASD, and CP101 for the treatment of chronic hepatitis B virus, or HBV;
- develop, optimize and scale our manufacturing processes and capabilities, including constructing facilities to support the commercial scale production of CP101 and, in the future, our other drug candidates;
- establish and expand a donor program to support our clinical supply for trial and initial commercial needs;

- increase the amount of research and development activities to identify and develop product candidates using our proprietary discovery approach;
- make milestone, royalty or other payments under in-license or collaboration agreements;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing, quality systems and commercialization efforts and our operations as a public company;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties;
- invest in or in-license other technologies; and
- experience any delays or encounter any issues with any of the above, including, but not limited to, failed studies, complex results, manufacturing challenges, quality issues, safety issues or other regulatory challenges, or as a result of the ongoing COVID-19 pandemic.

To become and remain profitable, we, our collaborators and any potential future collaborators must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

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

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

To date, we have primarily funded our operations through private placements of equity securities and upfront and milestone payments received pursuant to our collaboration agreement with Millennium Pharmaceuticals, Inc., or Takeda. We expect to spend substantial amounts to advance our product candidates into clinical development and to complete the clinical development of, seek regulatory approvals for and commercialize our product candidates, if approved. We will require additional capital beyond the proceeds of this offering, which we may raise through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources to enable us to complete the development and potential commercialization of our product candidates. Furthermore, upon

the closing of this offering, we expect to incur additional costs associated with operating as a public company. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate certain of our research and development programs.

As of December 31, 2020, our cash and cash equivalents were $99.7 million. We believe that the net proceeds from this offering, together with our existing cash on hand, will enable us to fund our operating expenses and capital expenditure requirements into mid-2023. However, we will need to obtain substantial additional funding in connection with our continuing operations and planned activities. Our future capital requirements will depend on many factors, including:

- the timing, costs, progress and results of our planned clinical trials of CP101 and other product candidates;
- the progress of preclinical development and possible clinical trials of our current earlier-stage programs;
- the scope, progress, results and costs of our research programs and preclinical development of other product candidates that we may pursue;
- the development requirements of other product candidates that we may pursue;
- any possible delays or interruptions with our clinical trials, our receipt of services from our third-party service producers on whom we rely, our supply chain or other regulatory challenges, including those due to the COVID-19 pandemic or to other unforeseen global events;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the timing and amount of milestone and royalty payments that we are required to make or eligible to receive under our current or future licensing and collaboration agreements;
- the cost of establishing a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration, or the FDA, and any comparable foreign regulatory authority;
- the costs and timing of future commercialization activities, including product manufacturing and related quality systems implementation, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs associated with building our commercial scale manufacturing facility;
- the cost of expanding, maintaining and enforcing our intellectual property portfolio, including filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our product candidates;

- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the extent to which we partner our programs, acquire or in-license other product candidates and technologies or enter into additional strategic collaborations;
- the revenue, if any, received from commercial sales of CP101 and any future product candidates for which we receive marketing approval;
- the cost of equipment and physical infrastructure to support our research and development; and
- the costs of operating as a public company.

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

We believe our current cash and cash equivalents will be sufficient to fund our business only for a limited amount of time, and if we are not able to raise additional funds, we may be unable 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. Based on our current operating plan, not including the proceeds of the offering, we believe that cash and cash equivalents of $99.7 million as of December 31, 2020 will not be sufficient to fund our operating expenses and capital expenditure requirements for twelve months from the issuance date of our annual consolidated financial statements for the year ended December 31, 2020. 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. In addition, the expected net proceeds of this offering will not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates. We will continue to seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms, or at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. Further, if we cannot continue as a viable entity, our shareholders may lose some or all of their investment in us.

Raising additional capital will cause dilution to our stockholders, including purchasers of our common stock in this offering, restrict our operations or require us to relinquish rights to our product candidates.

Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We do not have any committed external source of funds. To the extent that we raise

additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights.

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

Risks Related to the Development of Our Product Candidates

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

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

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

- successful and timely completion of clinical trials and preclinical studies for which the FDA or any comparable foreign regulatory authority agree with the design, endpoints or implementation;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receiving regulatory approvals or authorizations for conducting our planned clinical trials or future clinical trials;
- initiation and successful patient enrollment in, and completion of, additional clinical trials on a timely basis;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate is safe and effective as a treatment for our targeted indications or, in the case of an applicable product candidates that is regulated as a biological product, that the applicable product is safe, pure, and potent for our targeted indications;

- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate's risk-benefit ratio for its proposed indication is acceptable;
- timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishing and scaling up, either alone or with third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing that meet current Good Manufacturing Practices, or cGMP, and other legal and regulatory requirements, if any of our product candidates are approved;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates, both in the United States and internationally;
- successfully scaling a sales and marketing organization and launching commercial sales of our product candidates, if approved;
- acceptance of our product candidates' benefits and uses, if approved, by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety profile of our product candidates following approval, including long-term safety;
- effectively competing with companies developing and commercializing other therapies in the indications that our product candidates target;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors; and
- enforcing and defending against intellectual property rights and claims.

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

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

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

All of our product candidates are based on microbiome therapy, a therapeutic approach that is designed to treat disease by restoring the function of a dysbiotic microbiome. We have not, nor to our knowledge, has any other company, received regulatory approval for a therapeutic based on this approach. We cannot be certain that

our approach will lead to the development of approvable or marketable products. In addition, the efficacy potential of our microbiome therapeutics may vary based on indication and use in different patient populations including geographical areas. Finally, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of products based on microbiome therapeutics, which could result in a longer than expected regulatory review process or evolving FDA standards and guidance, increase our expected development costs and delay or prevent commercialization of our product candidates. Regulatory requirements governing microbiome therapies are still developing and may change in the future. Regulatory authorities and advisory groups, and the new guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our current or future product candidates or lead to significant post-approval limitations or restrictions.

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

Our microbiome therapeutics platform relies on third parties for biological materials, including human stool. Some biological materials have not always met our expectations or requirements, and any disruption in the supply of these biological materials could materially adversely affect our business. For example, if any supplied biological materials are contaminated with pathogens or disease organisms, we would not be able to use such biological materials. Although we have control processes and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. While we screen for a broad set of pathogens as a part of our manufacturing process, the donated human stool may contain organisms of which we are not aware and that could have an adverse effect on the safety of our product candidates and on the outcomes of our preclinical studies or clinical trials. Improper storage of these materials, by us or any third-party suppliers, may require us to destroy some of our raw materials or products which could create supply shortages, interruptions or other delays or require identification and contracting of additional third-party suppliers which we may not be able to do in a timely manner or on favorable terms.

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

The Microbiome Health Research Institute, Inc., or OpenBiome, is a non-profit organization that was co-founded in 2012 by our Chief Executive Officer and member of our board of directors, Mark Smith, Ph.D. OpenBiome operates a stool bank and manufactures, sells, and distributes fecal microbiota transplant products, or OpenBiome FMT Materials, for clinical research and for use in treating CDI not responding to standard therapy under its interpretation of the FDA's policy of enforcement discretion. In July 2013, the FDA issued guidance stating that it intended to exercise a policy of enforcement discretion regarding the IND regulatory requirements

for the use of FMT used to treat CDI not responding to standard therapies, provided that the treating physician obtains appropriate informed consent from the patient or his or her legally authorized representative. We have historically had a close relationship with OpenBiome and are currently and have previously been party to several agreements with OpenBiome related to, among other things, the license of various technology and intellectual property rights. In addition, Carolyn Edelstein, the Executive Director and co-founder of OpenBiome, is married to Dr. Smith. Although we believe our agreements with OpenBiome have been negotiated at an arms-length basis, there may be a perception that the terms of any such agreements have not been fairly negotiated, which could increase regulatory scrutiny, adversely impact our reputation or otherwise impair our ability to operate effectively.

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

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

OpenBiome has also supplied us with biological materials derived from human stool, which we intend to use as raw materials, subject to additional testing, screening and processing, in the manufacture of our product candidates, such as CP101, for use in our planned clinical trials. During the time we engaged OpenBiome to supply us with such human stool material, OpenBiome received a clinical hold from the FDA with respect to the need for new screening measures to mitigate the risk of transmission of SARS-CoV-2 from donor to recipient of its OpenBiome FMT materials, and the need for additional information regarding OpenBiome's quality systems. This clinical hold was removed in January 2021. Although the OpenBiome clinical hold did not preclude us from receiving OpenBiome-supplied biological materials for our manufacturing activities, given that some materials were received while OpenBiome was under clinical hold, we may not be able to use these materials for such purposes if we determine they fail to meet our quality standards, or if the FDA or other parties perceive such materials to be unsafe. For example, the FDA or other regulatory agencies may determine that they should not be used for the same reasons underlying the clinical hold, or different reasons. In addition, while we intend to test these materials to ensure they meet our quality standards, we plan to use an assay to screen for COVID-19 that is still in development, and has not been reviewed or approved by the FDA. If we are unable to use the biological

materials we have received from OpenBiome, or are delayed in our use of those materials, our planned clinical trials could be significantly delayed and adversely affected. In addition, we may not be able to recoup the costs associate with acquiring these biological materials from OpenBiome.

In connection with the closing of the transactions contemplated by the OpenBiome Agreement, we acquired certain capital equipment and assumed the contracts with certain service providers to which OpenBiome was a party. We may encounter difficulties assimilating or integrating the personnel, technologies and equipment contemplated by the OpenBiome Agreement, particularly if such personnel choose not to work for us. This transaction may also disrupt our business and require management attention that would otherwise be available for development of our existing business. If the resulting benefits from the consummation of the transactions contemplated by the OpenBiome Agreement fail to meet our expectations, our business, results of operations and financial condition may be harmed. In addition, although the OpenBiome Agreement is structured to exclude the assumption of any liabilities of OpenBiome, we may be subject to unknown liabilities with respect to the assets we have acquired or contracts we have assumed.

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. We cannot guarantee that any of our ongoing and planned clinical trials will be conducted as planned or completed on schedule, if at all. Moreover, even if these trials are initiated or conducted on a timely basis, issues may arise that could result in the suspension or termination of such clinical trials.

Although we have completed the topline readout in connection with PRISM3, our Phase 2 clinical trial of CP101, we may experience delays in our ongoing clinical trials or preclinical studies and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or in sufficient numbers, have sufficient drug supply for our product candidates on a timely basis or be completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing, and our ongoing and future clinical trials may not be successful. We also may experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize CP101 or any future product candidates, including:

- delays in or failure to obtain regulatory authorizations to commence clinical trials;
- delays in reaching a consensus with regulatory agencies as to the design or implementation of our clinical trials; for example, we plan to have further discussions with the FDA regarding the size and make-up of the safety database for CP101 which could result in the need for additional studies or delays in our development timelines;
- delays in or failure to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in or failure to obtain institutional review board, or IRB, approval at each site;
- delays in or failure to recruit a sufficient number of suitable patients to participate in a trial;
- failure to have patients complete a trial or return for post-treatment follow-up;

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

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

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

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

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

In connection with the COVID-19 pandemic, we experienced a slowdown to enrollment in our PRISM-EXT clinical trial. We may experience additional COVID-19 related disruptions in the future that could severely impact our clinical trials, including:

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

Known or unanticipated impacts of the COVID-19 pandemic may have a material adverse effect on our business. While the ultimate economic impact brought by, and the duration of, the COVID-19 pandemic are difficult to assess or predict, the pandemic has resulted, and could further result, in significant disruption of

global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the COVID-19 pandemic could materially affect our business and the value of our common stock.

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

Two vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020, and more are likely to be authorized in the coming months. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials.

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

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

To obtain the requisite regulatory approvals to market and sell any of our product candidates, including CP101 and any other future product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our investigational drug products are safe and effective for use in each targeted indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. Further, the process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications, patient population and regulatory agency. Prior to obtaining approval to commercialize CP101 and any future product candidates in the United States or abroad, we, our collaborators or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. For example, we plan to have further discussions with the FDA regarding the size and make-up of the safety database for CP101 which could result in the need for additional studies or delays in our development timelines.

Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial

participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.

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

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

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

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

Additionally, some of the clinical trials we conduct may include open-label trials conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the

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

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

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

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

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

Additionally, adverse developments in clinical trials of pharmaceutical and biopharmaceutical products conducted by others or with commercial products offered by others may cause the FDA or other regulatory oversight bodies to suspend or terminate our clinical trials or change the requirements for approval of any of our product candidates or otherwise adversely impact the clinical and commercial development of our product candidates. Such adverse developments may cause the FDA to perceive CP101 as unsafe and bring increased regulatory scrutiny to our clinical operations more broadly, lead to decreased confidence by patients, physicians and contract research organizations, or CROs, in our product candidates, and result in reduced demand for any product that we may develop if approved. For example, in June 2019, the FDA issued a safety alert regarding the risk of serious adverse reactions due to the transmission of multi-drug resistant organisms in connection with

FMT treatment provided by a local, hospital-based FMT program. Two immunocompromised adults, one of whom later died, received FMT treatment from this hospital-based FMT program and subsequently developed infections caused by extended-spectrum beta-lactamase-producing E. coli. Additionally, in March 2020, the FDA issued another safety alert regarding the potential of serious or life-threatening infections with the use of FMT treatment after OpenBiome reported occurrences of enteropathogenic E. coli and shigatoxin-producing E. coli in FMT recipients.

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

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

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

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

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timely completion of our clinical trials in accordance with their protocols depends, among other things, on our ability to recruit a sufficient number of eligible patients to participate and remain in the trial until its conclusion. Patients may be unwilling to participate in our clinical trials because of negative publicity from adverse events related to novel therapeutic approaches, competitive clinical trials for similar patient populations, the existence of current treatments, such as FMT, or for other reasons, including the ongoing COVID-19 pandemic and negative perceptions of our product candidates. Any delays related to patient enrollment could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of the clinical trials altogether. We may not be able to identify, recruit and

enroll a sufficient number of patients, or those with the required or desired characteristics, to complete our clinical trials in a timely manner. Patient enrollment and trial completion is affected by many factors, including the:

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

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

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

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

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

From time to time, we may publish interim, topline or preliminary data from our clinical trials. Preliminary and interim data from our clinical trials may change as more patient data become available. Preliminary or interim data from our clinical trials are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available and we issue our final clinical trial report. Interim, topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary, topline and interim data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects. In addition, certain patient and product samples from our clinical trials are or will be retained by third parties and used by them for further research and studies, and the data from such studies may be inconsistent or contrary to the results from our earlier clinical trials.

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

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

Before we can commence clinical trials for any product candidate, we may be required to complete extensive preclinical studies that support any future Investigational New Drug, or IND, applications in the United States, or similar applications in other jurisdictions. Conducting preclinical testing is a lengthy, time-consuming and expensive process and delays associated with product candidates for which we are directly conducting preclinical testing and studies may cause us to incur additional operating expenses. While we have conducted a pivotal, Phase 2 clinical trial of CP101 for recurrent CDI, and plan to initiate a Phase 3 clinical trial as our second pivotal trial in mid-2021, we cannot be certain of the timely completion or outcome of our preclinical testing and studies for our other product candidates and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and foreign clinical trials will ultimately support the further development of our other product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or comparable foreign regulatory authorities allowing clinical trials to begin.

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, including requiring us to enroll more patients than originally expected, including with respect to the anticipated size of the safety database to be collected to support a biologics license application, or BLA, filing and possible approval;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective as a treatment for our targeted indications, or, in the case of a product candidate regulated as a biological product, that the product candidate is safe, pure and potent for its proposed indication;
- the population studied may not be sufficiently broad or representative to assure safety or efficacy in the population for which we seek approval, including as a result of our agreement with the FDA prior to unblinding to exclude certain patients enrolled at two GCP-non-compliant trial sites from adjudication and inclusion in our efficacy analysis;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including whether our statistical analysis plan meets FDA expectations;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the FDA or comparable foreign regulatory authorities may require additional preclinical studies or clinical trials beyond those that we currently anticipate;
- the FDA may conclude that our product candidate is the "same drug" as a competitor product that has been approved and has received orphan drug exclusivity for the same intended use;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA to the FDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes, testing regime or facilities operated by us or third-party manufacturers with which we contract for clinical and commercial supplies, including with certain technology transfer initiatives; and

- the approval policies or regulations of the FDA or any comparable foreign regulatory authorities or the laws they enforce may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

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

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or

frequency, or with our third-party manufacturers or manufacturing and testing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

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

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

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

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

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

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

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

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

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

clinical trials, including the emergence of serious adverse effects, may delay or prevent the development and approval of our product candidates.

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

Risks Related to the Manufacture of Our Product Candidates

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

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

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

Historically, early versions of CP101 were manufactured using unoptimized processes by third-party research collaborators that we have not used, or do not intend to use, in more advanced clinical trials or commercialization. We have, and may continue to, alter our manufacturing processes, product release criteria, dose strength or dosing regimen, and other aspects of CP101 to optimize it for late-stage clinical trials or commercialization. Although we are working to develop commercially viable processes, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials. As a result of these challenges, we may experience delays in our clinical development and/or commercialization plans.

We are still in the process of developing and scaling-up our manufacturing processes and quality systems for certain of our other product candidates, including FIN-524. These products contain proprietary bacterial strains that have never been manufactured in a scale sufficient for use in a clinical trial or for commercialization. We can make no assurances that we will be able to manufacture these products, or components of these products, in a cost effective manner or at the level required for clinical trials or commercialization.

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

We use human stool from extensively-screened third-party donors as starting material in the manufacture of several of our product candidates, including CP101. The stool that is received from these third-

party donors is tested for certain pathogens and processed without the use of replication or culturing to form an active ingredient in our products. Our ability to manufacture CP101 and other product candidates using donor-derived materials at clinical and commercial scale depends on obtaining a consistent and adequate supply of stool material. There are, in general, relatively few alternative sources of supply that would be sufficient to meet our clinical and commercial needs.

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

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

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

While we will extensively test the biological materials that we receive from qualified third-party donors or suppliers for the presence of certain pathogens and other microorganisms, there can be no assurances that we will detect all pathogens and other microorganisms in our products, which could result in an adverse reaction in persons who use or consume our products. Our testing processes may fail to identify pathogens in the stool that we receive from donors within our donor program. In addition, the emergence of new pathogens could affect the availability of stool donors, or require us to develop new testing processes to test both new and existing material and product, either of which could cause delays or shortage in the manufacture and distribution of our products. The presence of pathogens in the stool material that we receive from third-party donors may also result in adverse reactions in persons who use or consume products that are derived from that material. Additionally, regulatory or industry pathogen testing requirements may change over time, possibly making it more challenging to locate qualified donors, or requiring the development and validation of new test methods, which could adversely affect our ability to collect adequate supply and increase costs related to product manufacturing.

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

We are in the process of building out our manufacturing facility to support the manufacture of our product candidates, including CP101, for use in clinical development or for potential commercial sale, and anticipate completing construction in the second half of 2021. We may not be able to manufacture enough product at this facility to meet the clinical and commercial demand for our product candidates. We also cannot be sure that the manufacturing processes employed by us will result in products that will be safe and effective. Moreover, we may run into delays or cost overruns in connection with the development of our manufacturing facility, including the transfer of technology from our manufacturing operations at the University of Minnesota, which would increase our net losses and have an adverse effect on our stockholders' equity and working capital. For example, the FDA may find deficiencies in our technology transfer process or require one or more comparability studies of our drug product using test methods that we would need to develop. The actual cost to manufacture and process our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates, if approved. There are a lack of third-party CMOs willing or able to manufacture whole community product candidates like CP101. If we are unable to successfully manufacture and process our product candidates, we might not be able to produce some of our products at a level that would be sufficient to meet our clinical and commercial needs.

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

Our operations will remain subject to review and oversight by the FDA and the FDA could object to our use of our manufacturing facility. Prior to licensure to manufacture our product candidates, we must first receive approval from the FDA, which we may never obtain. Such approval may be contingent on a pre-approval inspection of our manufacturing facility. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel on account of the COVID-19 pandemic, the FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, the FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. Even if approved, we would be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations. Our license to manufacture product candidates will be subject to continued regulatory review.

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

Risks Related to the Commercialization of Our Product Candidates

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

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

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

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

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue arrangements with third-party sales, marketing, and distribution collaborators regarding the sales and marketing of our products, if approved. However, there can be no assurance that we will be able to establish or maintain such arrangements on favorable terms or if at all, or if we are able to do so, that these third-party arrangements will provide effective sales forces or marketing and distribution capabilities. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

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

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

We have received Fast Track designation for CP101 for the prevention of recurrent CDI, and we may seek Fast Track designation for our other product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs

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

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

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

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

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

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable

opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the biopharmaceutical industry, in particular for our lead product candidate, our business, financial condition and results of operations could be materially adversely affected and may cause us to reprioritize our planned trials and use of funds for planned trials.

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

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

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

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

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

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

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

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

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

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

We face competition from segments of the pharmaceutical, biotechnology and other related markets that pursue the development of microbiome therapies. We are aware of a number of companies focused on

developing microbiome therapeutics in various indications. For CP101, we are aware that Seres Therapeutics, Inc., Rebiotix, Inc. and Vedanta Biosciences, Inc. each have a product candidate being evaluated in clinical trials for recurrent CDI. In addition, we face competition from other therapies which are designed to treat the indications targeted by our product candidates.

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

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

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

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

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

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

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

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

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

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

reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

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

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

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

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of biopharmaceutical products. While we currently have no products that have been approved for commercial sale, from 2017 to 2019, we manufactured FMT materials, produced to specifications defined by OpenBiome, that were and may still be distributed and sold by OpenBiome for use under its interpretation of the FDA's policy of enforcement discretion for CDI not responding to standard therapies and for use in clinical research. This past use, as well as the current and future use of product candidates by us and our collaborators in clinical trials, and the potential sale of any approved products in the future, may expose us to liability claims. The FDA may not agree with OpenBiome's interpretation or application of the FDA's enforcement discretion policy to its product distribution activities, including its distributions to clinical sites without an IND in place with the FDA. These claims might be made by

patients who use the product, healthcare providers, pharmaceutical companies, our collaborators or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a product, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

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

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

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

Risks Related to Government Regulation

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

Healthcare providers, including physicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws and

other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations promulgated under such laws. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs, and other interactions with healthcare professionals. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for, or to induce, either the referral of an individual for, or the purchase, lease, order or arrangement for or recommendation of the purchase, lease, order or arrangement for any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers, and formulary managers, on the other. The term “remuneration” has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. A person does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, signed into law in 2010, provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- the federal civil and criminal false claims laws, including, without limitation, the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and the federal civil monetary penalty laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from the federal government, including Medicare, Medicaid and other government payors, that are false or fraudulent or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes “any request or demand” for money or property presented to the United States federal government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of products for unapproved, and thus non-reimbursable, uses;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), or knowingly and willfully falsifying, concealing or covering up, by any trick or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does

not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which impose, among other things, requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information on health plans, healthcare clearinghouses and certain healthcare providers, known as "covered entities", and their respective HIPAA "business associates", which are independent contractors that perform certain services for or on behalf of covered entities involving the use or disclosure of individually identifiable health information and their subcontractors that use, disclose or otherwise process individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal transparency laws, including the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to: (i) payments or other "transfers of value'' made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include information related to payments and other transfers of value provided in the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse midwives; and

- analogous state and foreign laws and regulations; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or that otherwise restrict payments that may be made to healthcare providers; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

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

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

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

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

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

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

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due

to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of litigation. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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

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

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

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

There remain judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and

medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole."

Further, since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. In December 2018, CMS published a new final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. On April 27, 2020, the United States Supreme Court reversed a Federal Circuit decision that previously upheld Congress' denial of $12 billion in "risk corridor" and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula. On December 14, 2018, a Texas United States District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the United States Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and held oral arguments on November 10, 2020. It is unclear how such ruling, other litigation and the healthcare reform efforts of the Biden Administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030, unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, and subsequent legislation, suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021, and extended the sequester by one year, through 2030. Proposed legislation, if passed, would extend this suspension until the end of the pandemic. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the former Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance (over a period of time) to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and

biosimilar drugs. On March 10, 2020, the former Trump administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the former Trump administration previously released a plan to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. However, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions after January 20, 2021. On July 24, 2020 and September 13, 2020, former President Trump announced several executive orders related to prescription drug pricing that sought to implement several of the former administration’s proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. However, in response to a lawsuit filed by several industry groups, on December 28, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction enjoining government defendants from implementing the MFN Rule pending completion of notice-and-comment procedures under the Administrative Procedure Act. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Interim Final Rule shall not commence earlier than 60 days after publication of that regulation in the Federal Register. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our product candidates. Additionally, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to an order entered by the U.S. District Court for the District of Columbia, the portion of the rule eliminating safe harbor protection for certain rebates related to the sale or purchase of a pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D has been delayed to January 1, 2023. Further, implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. It is also possible that additional governmental action is taken to address the COVID-19 pandemic.

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

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

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

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

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

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

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products while local, national and international conditions warrant. Since March 2020, foreign and domestic inspections by the FDA have largely been on hold with the FDA announcing plans in July 2020 to resume prioritized domestic inspections. The FDA

developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. Should the FDA determine that a pre-approval inspection is necessary for approval of any of our product candidates and an inspection cannot be completed during the review cycle due to restrictions on travel on account of the COVID-19 pandemic, the FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, the FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

If any of our relationships with these third-party laboratories, CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative laboratories, CROs or investigators or to do so in

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

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

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

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

We do not currently have the infrastructure or capability internally to manufacture all our product candidates for use in the conduct of our preclinical studies and clinical trials or for commercial supply, if our products are approved. We rely on, and expect to continue to rely on, contract manufacturing organizations, or CMOs. Any replacement of our CMOs could require significant effort and expertise because there may be a limited number of qualified CMOs. This could be particularly problematic where we rely on a single-source supplier. For example, to date we have identified only one CMO that appears to be capable of manufacturing certain of the proprietary bacterial strains within FIN-524 with the yields and quality necessary to support our clinical development efforts. Reliance on third-party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We are dependent on our CMOs for the production of our product candidates in accordance with relevant regulations, such as cGMP, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation. Moreover, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting product development activities that could harm our competitive position.

Our third-party manufacturers may be subject to damage or interruption from, among other things, fire, natural or man-made disaster, disease outbreaks or public health pandemics, power loss, telecommunications failure, unauthorized entry, computer viruses, denial-of-service attacks, acts of terrorism, human error, vandalism

or sabotage, financial insolvency, bankruptcy and similar events. For example, the extent to which COVID-19 may impact our manufacturing and supply chain will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

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

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

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

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

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

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;

- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;

- collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;

- if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and

- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

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

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

We face significant competition in seeking appropriate collaborative partners. Our ability to reach a definitive agreement for a partnership will depend, among other things, upon an assessment of the collaborator's resources and expertise, the terms and conditions of the proposed partnership and the proposed collaborator's evaluation of a number of factors. These factors may include the design or results of preclinical studies or clinical trials, the likelihood of regulatory approval, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of any uncertainty with respect to our ownership of technology (which can exist if there is a challenge to such ownership regardless of the merits of the challenge) and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a partnership could be more attractive than the one with us.

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

Termination of our current or any future license agreements would reduce or eliminate our rights under these agreements and may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Any of the foregoing could prevent us from commercializing our other product candidates, which could have a material adverse effect on our operating results and overall financial condition.

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

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

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

The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain

situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States Congress, the federal courts and the United States Patent and Trademark Office, or USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have owned or licensed or that we might obtain in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

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

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

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

If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. In an infringement proceeding, a court may decide that the patent claims we are asserting are invalid and/or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover the technology in question. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose some, and perhaps all, of the patent protection on our product candidates. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could have a material adverse impact on our business. Moreover, even if we are successful in any litigation, we may incur significant expense in connection with such proceedings, and the amount of any monetary damages may be inadequate to compensate us for damage as a result of the infringement and the proceedings.

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

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

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

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

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

Our commercial success depends, in part, upon our ability and the ability of future collaborators, if any, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including interference proceedings, post grant review and *inter partes* review before the USPTO or equivalent foreign regulatory authority. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Numerous patents and pending applications are owned by third parties in the fields in which we are developing product candidates, both in the United States and elsewhere. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that

would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products.

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

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

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

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

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

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

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

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

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

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

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

In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology. For example, certain jurisdictions do not allow for patent protection with respect to method of treatment.

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

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

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the

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

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

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

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

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

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

- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

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

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

We are highly dependent on our management team, including Mark Smith, Ph.D., our Chief Executive Officer, and Zain Kassam, M.D., M.P.H., our Chief Medical Officer. Each of them may currently terminate their employment with us at any time and will continue to be able to do so after the closing of this offering. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. We do not currently maintain "key person" life insurance on the lives of our executives or any of our employees.

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

We expect to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2020, we had 131 full-time employees, including 103 employees engaged in research and development. As our clinical development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect we will need additional managerial, operational, sales, marketing, financial, legal and other personnel. Future growth would impose significant added responsibilities on members of management, including:

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

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

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

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

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

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

While we have not experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials by us or our CROs could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, cause us not to comply with federal and/or state breach notification laws and foreign law equivalents and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, such measures may not prevent service interruptions or security breaches that could adversely affect our business and to the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or

inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

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

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

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

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

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

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

We maintain a large quantity of sensitive information, including confidential business and personal information in connection with the conduct of our clinical trials and related to our employees, and we are subject to laws and regulations governing the privacy and security of such information. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. Each of these laws, the

requirements of which sometimes evolve with amendments, regulations and case law, can be subject to varying interpretations. In addition, new laws regulating privacy and data security continue to be passed in jurisdictions all over the world. In May 2018, a new privacy regime, the General Data Protection Regulation, or the GDPR, took effect in the European Economic Area, or the EEA. The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of European persons. Among other things, the GDPR imposes requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing authorities, changes the lawful bases on which personal data can be processed, expands the definition of personal data and requires changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws, and imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our consolidated annual worldwide gross revenue). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

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

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

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

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is

not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

Risks Related to This Offering and Ownership of Our Common Stock

An active trading market for our common stock may not develop and you may not be able to resell your shares of our common stock at or above the initial offering price, if at all.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock was determined through negotiations with the underwriters and may not be indicative of the price at which our common stock will trade after the closing of this offering. Although we have applied for the listing of our common stock on The Nasdaq Global Market, if approved, an active trading market for our shares may never develop or be sustained following this offering. 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 in this offering at an attractive price or at all.

The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price may be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- the results of our clinical trials of CP101 or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for CP101 or any other product candidate we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results from, delays in or termination of clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- unanticipated serious safety concerns related to the use of CP101 or any other product candidate;
- unexpected regulatory actions related to the manufacture and testing of CP101 or any other product candidate;
- changes in financial estimates by us or by any equity research analysts who might cover our stock;

- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- our relationships with our collaborators;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- changes in the structure of healthcare payment systems;
- general political and economic conditions, including the effects of the ongoing COVID-19 pandemic; and
- other events or factors, many of which are beyond our control.

The stock market in general, and the Nasdaq Global Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this section, could have a significant and material adverse impact on the market price of our common stock.

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 you purchase shares of our common stock in this offering, you will suffer immediate dilution of your investment.

The initial public offering price of our common stock is substantially higher than the net tangible book value (deficit) per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our pro forma as adjusted net tangible book value per share after this offering. Based on the assumed initial public offering price of $16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of $12.15 per share, representing the difference between our pro forma as adjusted net tangible book value per share after this offering and the assumed initial public offering price.

In addition, as of December 31, 2020, we had outstanding stock options to purchase an aggregate of 1,053,874 shares of common stock at an exercise price of $1.51 per share. To the extent these outstanding options are exercised, there will be further dilution to investors in this offering.

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

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. As a newly public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will 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.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

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.

Upon the closing of this offering, we will have outstanding 39,645,402 shares of common stock, after giving effect to the automatic conversion of our outstanding convertible preferred stock into 31,253,609 shares of our common stock, and assuming no exercise of outstanding options to purchase shares of our convertible preferred stock. Of these shares, the shares sold in this offering will be freely tradable upon the closing of this offering and the remaining shares of common stock will be available for sale in the public market beginning 180 days after the date of this prospectus following the expiration of lock-up agreements between some of our stockholders and the underwriters. BofA Securities, Inc., Jefferies LLC and Evercore Group L.L.C. may release these stockholders from their lock-up agreements with the underwriters at any time and without notice, which would allow for earlier sales of shares in the public market.

In addition, following the closing of this offering, we intend to file one or more registration statements on Form S-8 under the Securities Act of 1933, as amended, or the Securities Act, registering the issuance of 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 2017 Plan, our 2021 Equity Incentive Plan, or 2021 Plan, and our 2021 Employee Stock Purchase Plan, or ESPP. Shares registered under these registration statements on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and the restrictions of Rule 144 in the case of our affiliates.

Additionally, after this offering, the holders of an aggregate of 31,665,929 and 39,330,184 shares of our common stock, or their transferees, will 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, respectively. 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.

Our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates beneficially own over 58.9% of our outstanding common stock prior to this offering and will continue to own a majority of our common stock following this offering. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions.

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

Participation in this offering by our existing stockholders and their affiliated entities may reduce the public float for our common stock.

To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors and principal stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of common stock purchased in this offering.

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

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

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

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

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

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

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

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

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

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

Commencing with our fiscal year ending December 31, 2022, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to this offering, we have never been required to test our internal control within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We may identify weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial

reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

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

In preparation for this offering, we identified a material weakness in our internal control over financial reporting. If we are not able to remediate the material weakness or if we otherwise 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.

Although we are not yet subject to the certification or attestation requirements of Section 404 of the Sarbanes-Oxley Act, in the course of reviewing our financial statements for this offering, management and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting as we did not design and maintain effective review and approval controls over certain transactions and accounts.

A material weakness is a deficiency, or a combination of control deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. This material weakness in our system of internal controls as of December 31, 2019 relates to (1) an ineffective control environment, including a lack of sufficient accounting personnel and personnel with financial reporting expertise; (2) ineffective controls over cutoff, recording and classification of certain accounts, and the valuation and recognition of intangible assets acquired in a business combination that occurred in 2017; (3) ineffective risk assessment controls, including those policies and practices that would identify changes in our business practices, which could significantly impact our consolidated financial statements and system of internal controls; and (4) ineffective monitoring of controls related to the financial close and reporting process. As a result, there were adjustments required in connection with closing our books and records and preparing our 2019 financial statements.

In an effort to remediate this material weakness, we intend to hire additional finance and accounting personnel with appropriate expertise to perform specific functions, and design and implement improved processes and internal controls, build out our financial management, risk assessment, and reporting infrastructure, and further develop and document our accounting policies and financial reporting procedures, including ongoing senior management review and audit committee oversight. We have also retained an accounting consulting firm to provide additional depth and breadth in our technical accounting and financial reporting capabilities and intend to continue this arrangement until permanent technical accounting resources are identified and hired.

There can be no assurance that we will be successful in pursuing these measures or that these measures will significantly improve or remediate the material weakness described above. There is also no assurance that we have identified all of our material weaknesses or that we will not in the future have additional material weaknesses. If we fail to remediate the material weakness or to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results, or report them within the timeframes required by law or Nasdaq. Failure to comply with Section 404 could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. There is no assurance that we will be able to remediate the material weakness in a timely manner, or

at all, or that in the future, additional material weaknesses will not exist or otherwise be discovered. If our efforts to remediate the material weakness identified are not successful, or if other material weaknesses or other deficiencies occur, our ability to accurately and timely report our financial position could be impaired, which could result in late filings of our required reports under the Exchange Act, restatements of our consolidated financial statements, a decline in the price of our common stock, suspension or delisting of our common stock from Nasdaq, and could adversely affect our reputation, results of operations and financial condition.

We will have broad discretion in the use of proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

We will have broad discretion over the use of proceeds from this offering. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. We could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Our failure to apply the net proceeds from this offering effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering. See the section titled "Use of Proceeds" for additional information.

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

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

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

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

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

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

We may not be entitled to forgiveness of our recently received PPP Loan, and our application for the PPP Loan could in the future be determined to have been impermissible or could result in damage to our reputation.

In April 2020, we received proceeds of $1.8 million from a loan, or the PPP Loan, under the Paycheck Protection Program, or the PPP, of the CARES Act, a portion of which may be forgiven, which we have used to retain current employees, maintain payroll and make lease and utility payments. The PPP Loan matures on April 23, 2022 and bears annual interest at a rate of 1.0%. Payments of principal and interest on the PPP Loan were originally deferred for the first six months of the term. Thereafter, we were required to pay the lender equal monthly payments of principal and interest. Under the PPP, we may apply for and be granted forgiveness for all or part of the PPP Loan. The amount of loan proceeds eligible for forgiveness was originally based on a formula that takes into account a number of factors, including the amount of loan proceeds used by us during the eight-week period after the loan origination for certain purposes, including payroll costs, interest on certain mortgage obligations, rent payments on certain leases, and certain qualified utility payments, provided that at least 75% of the loan amount was used for eligible payroll costs. Subject to the other requirements and limitations on loan forgiveness, only loan proceeds spent on payroll and other eligible costs during the covered eight-week period would have qualified for forgiveness. We will be required to repay any portion of the outstanding principal that is not forgiven, along with accrued interest, in accordance with the terms described above, and we cannot provide any assurance that we will be eligible for loan forgiveness or that any amount of the PPP Loan will ultimately be forgiven by the SBA. Furthermore, on April 28, 2020, the Secretary of the U.S. Department of the Treasury stated that the SBA will perform a full review of any PPP loan over $2.0 million before forgiving the loan. There can be no assurance that the U.S. Department of the Treasury will not expand the scope of its review to additional PPP loans.

In order to apply for the PPP Loan, we were required to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. We made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan is consistent with the broad objectives of the PPP. The certification described above does not contain any objective criteria and is subject to interpretation. If, despite our good-faith belief that given our Company's circumstances we satisfied all eligible requirements for the PPP Loan, we are later determined to have violated any of the laws or governmental regulations that apply to us in connection with the PPP Loan, such as the False Claims Act, or it is otherwise determined that we were ineligible to receive the PPP Loan, we may be subject to penalties, including significant civil, criminal and administrative penalties and could be required to repay the PPP Loan in its entirety. In addition, receipt of a PPP Loan may result in adverse publicity and damage to reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources.

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 to be in effect upon the closing of this offering 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, as will be in effect upon the completion of this offering, will provide 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. These forward-looking statements are contained principally in the sections of this prospectus titled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," but are also contained elsewhere in this prospectus. In some cases, you can identify forward-looking statements by the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "should," "will," or "would," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain.

These forward-looking statements include statements about:

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

We caution you that the foregoing list may not contain all of the forward-looking statements made in this prospectus.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions described under the section titled “Risk Factors” and elsewhere in this prospectus. We also operate in a very competitive and rapidly changing environment. New risks emerge from time to time and 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, or implied by, any forward-looking statements. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances described in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements contained in this prospectus.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, events, circumstances or achievements reflected in the forward-looking statements will ever be achieved or occur. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

INDUSTRY AND MARKET DATA

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties as well as our own estimates of potential market opportunities. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We believe that these third-party sources and estimates are reliable, but have not independently verified them. Our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

In addition, projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate is necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section of this prospectus titled “Risk Factors” and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately $90.3 million, or approximately $104.3 million if the underwriters exercise in full their option to purchase additional shares from us, in each case after deducting the underwriting discounts and commissions and estimated offering expenses payable by us and based on an assumed initial public offering price of $16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

Each $1.00 increase or decrease in the assumed initial public offering price of $16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the net proceeds to us from this offering by approximately $5.8 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions payable by us. We may also increase or decrease the number of shares we are offering. Each 1,000,000 share increase or decrease in the number of shares offered by us would increase or decrease the net proceeds to us from this offering by approximately $14.9 million, assuming that the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions payable by us.

We intend to use the net proceeds of this offering, together with our existing cash and cash equivalents, as follows:

- approximately $50.0 million to advance the clinical development of CP101 for the treatment of recurrent CDI, our lead product candidate, through the receipt of topline data from our planned Phase 3 clinical trial;
- approximately $20.0 million to advance the clinical development of FIN-211 for the treatment of ASD, an Enriched Consortia product candidate, through the receipt of topline data from our planned Phase 1 clinical trial;
- approximately $10.0 million to fund the advancement of CP101 in additional indications, including chronic HBV through the receipt of topline data from our planned Phase 1 clinical trial;
- approximately $60.0 million for investment in our Human-First Discovery platform, including the development of commercial-ready manufacturing capabilities; and
- the remaining proceeds for working capital and general corporate purposes.

We may also use a portion of the remaining net proceeds to in-license, acquire or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so.

Based on our planned use of the net proceeds from this offering and our existing cash and cash equivalents on hand, we believe that such funds will enable us to fund our operating expenses and capital expenditure requirements at least into mid-2023. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. The expected net proceeds from this offering, together with our existing cash, will not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise additional capital to complete the development and commercialization of our product candidates.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and prevailing business conditions, which could change in the future as such plans and conditions evolve. Predicting the cost necessary to develop product candidates can be difficult, and the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from preclinical studies and clinical trials, any collaborations that we may enter into with third parties and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

DIVIDEND POLICY

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.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of December 31, 2020:

- on an actual basis;
- on a pro forma basis, giving effect to (1) the automatic conversion of all of our outstanding shares of preferred stock into an aggregate of 31,253,609 shares of our common stock upon the closing of this offering and (2) the filing of our amended and restated certificate of incorporation, which will be filed in connection with this offering; and
- on a pro forma as adjusted basis to reflect (1) the pro forma items described immediately above and (2) the sale of 6,250,000 shares of common stock in this offering at an assumed initial public offering price of $16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The information below is illustrative only, and our capitalization following the closing of this offering will depend on the actual initial public offering price and other terms of the offering determined at the pricing of this offering.

You should read this table together with the section of this prospectus titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and the related notes appearing elsewhere in this prospectus.

	As of December 31, 2020		
	Actual	Pro Forma	Pro Forma As Adjusted(1)
	(in thousands, except share and per share data)		
Cash and cash equivalents	$ 99,710	$ 99,710	$ 190,259
Convertible preferred stock:			
Series A preferred stock, $0.001 par value per share; 167,496,750 shares authorized, 11,596,280 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	$ 53,593	$ —	$ —
Series B preferred stock, $0.001 par value per share; 74,620,739 shares authorized, 5,166,203 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	36,336	—	—
Series C preferred stock, $0.001 par value per share; 109,604,994 shares authorized, 7,588,254 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	53,221	—	—
Series D preferred stock, $0.001 par value per share; 99,705,359 shares authorized, 6,902,872 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	89,904	—	—
Stockholders’ (deficit) equity:			
Common stock, $0.001 par value per share; 598,232,153 shares authorized, 8,391,793 shares issued and outstanding, actual; 200,000,000 shares authorized, 39,645,402 shares issued and outstanding, pro forma and 45,895,402 shares issued and outstanding, pro forma as adjusted	8	40	46
Preferred stock, $0.001 par value per share; no shares authorized, issued or outstanding, actual; 10,000,000 shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Additional paid-in capital	7,109	240,131	330,425
Accumulated deficit	(102,835)	(102,835)	(102,835)
Total stockholders’ (deficit) equity	(95,718)	137,336	227,636
Total capitalization	$ 137,336	$ 137,336	$ 227,636

(1) The pro forma as adjusted information set forth above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase or decrease in the assumed initial public offering price of $16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately $5.8 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions payable by us. We may also increase or decrease the number of shares we are offering. Each 1,000,000 share increase or decrease in the number of shares offered by us would increase or decrease pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately $14.9 million, assuming that the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions payable by us.

The number of shares of our common stock shown as issued and outstanding in the table above is based on 39,645,402 shares of our common stock outstanding as of December 31, 2020, which gives effect to the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 31,253,609 shares of our common stock, and excludes:

- 1,053,874 shares of our common stock issuable upon the exercise of options outstanding as of December 31, 2020, at a weighted-average exercise price of $1.51 per share;
- 251,810 shares of our common stock issuable on the exercise of options granted subsequent to December 31, 2020 under our 2017 Plan, with a weighted-average exercise price of $13.00 per share;
- 815,214 shares of our common stock issuable upon the exercise of options approved subsequent to December 31, 2020 to be granted to our named executive officers and certain of our other employees under our 2021 Plan, contingent and effective upon the execution of the underwriting agreement for this offering, at an exercise price equal to the initial public offering price per share;
- 19,346 shares of our common stock issuable upon the exercise of warrants outstanding as of December 31, 2020, at a weighted-average exercise price of $0.03 per share; and
- 698,601 shares of our common stock reserved for future issuance under our 2017 Plan as of December 31, 2020, which shares will cease to be available for future issuance immediately prior to the time that our 2021 Equity Incentive Plan, or 2021 Plan, becomes effective;
- 4,700,000 shares of our common stock reserved for future issuance pursuant to our 2021 Plan (which does not give effect to the grant of 815,214 shares of common stock issuable upon the exercise of stock options that will be granted contingent and effective upon the execution of the underwriting agreement for this offering), which will become effective upon the execution of the underwriting agreement related to this offering, as well as any shares reserved pursuant to provisions in our 2021 Plan that automatically increase the number of shares of common stock reserved for issuance under the 2021 Plan; and
- 500,000 shares of our common stock reserved for future issuance under our ESPP, which will become effective upon the execution of the underwriting agreement related to this offering, as well as any shares reserved pursuant to provisions in the ESPP that automatically increase the number of shares of common stock reserved for issuance under the ESPP.

DILUTION

If you invest in our common stock, your interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after the closing of this offering.

Our historical net tangible book deficit as of December 31, 2020 was $(147.7) million, or $(17.60) per share of common stock. Our historical net tangible book deficit is the amount of our total tangible assets less our liabilities and preferred stock, which is not included within stockholders' deficit. Historical net tangible book deficit per share is our historical net tangible book deficit divided by the number of shares of common stock outstanding as of December 31, 2020.

Our pro forma net tangible book value as of December 31, 2020 was $85.4 million, or $2.15 per share of common stock. Pro forma net tangible book value per share is our pro forma net tangible book value divided by the total number of shares of common stock outstanding as of December 31, 2020, after giving effect to the automatic conversion of all of our outstanding shares of preferred stock into an aggregate of 31,253,609 shares of our common stock upon the closing of this offering.

Our pro forma as adjusted net tangible book value is our pro forma net tangible book value, after giving further effect to the sale of 6,250,000 shares of common stock in this offering at an assumed initial public offering price of $16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Our pro forma as adjusted net tangible book value as of December 31, 2020 was $176.7 million, or $3.85 per share of common stock. This amount represents an immediate increase in pro forma as adjusted net tangible book value of $1.70 per share to our existing stockholders and an immediate dilution of $12.15 per share to new investors participating in this offering. We determine dilution per share to new investors by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors.

The following table illustrates this dilution on a per share basis to new investors:

Assumed initial public offering price per share		$16.00
Historical net tangible book deficit per share as of December 31, 2020	$(17.60)	
Increase per share attributable to the pro forma adjustments described above	19.75	
Pro forma net tangible book value per share as of December 31, 2020	2.15	
Increase in pro forma net tangible book value per share attributed to new investors purchasing shares from us in this offering	1.70	
Pro forma as adjusted net tangible book value per share after giving effect to this offering		3.85
Dilution per share to new investors participating in this offering		$12.15

The dilution information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase or decrease in the assumed initial public offering price of $16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted net tangible book value per share by $0.13 per share and the dilution per share to investors participating in this offering by $0.87 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions payable by us. We may also increase or decrease the number of shares we are offering. Each 1,000,000 share increase in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase the pro forma as adjusted net tangible book value per share by $0.23 and decrease the dilution per share to investors participating in this offering by $0.23, assuming the assumed initial public offering price of $16.00 per share, which is the midpoint of the price range

set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions payable by us. Each 1,000,000 share decrease in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value per share after this offering by $0.25 and increase the dilution per share to new investors participating in this offering by $0.25, assuming the assumed initial public offering price of $16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions payable by us.

If the underwriters exercise in full their option to purchase an additional 937,500 shares of our common stock in this offering, the pro forma as adjusted net tangible book value would increase to $4.07 per share, representing an immediate increase to existing stockholders of $0.22 per share and the dilution per share to new investors participating in this offering would be $11.93 per share, assuming the assumed initial public offering price of $16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions payable by us.

The following table summarizes as of December 31, 2020, on the pro forma as adjusted basis described above, the number of shares of our common stock, the total consideration and the average price per share (1) paid to us by our existing stockholders and (2) to be paid by investors purchasing our common stock in this offering at an assumed initial public offering price of $16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	39,645,402	86.4%	$232,724,408	69.9%	$ 5.87
New investors	6,250,000	13.6	100,000,000	30.1	16.00
Total	45,895,402	100.0%	$332,724,408	100.0%	$ 7.25

Each $1.00 increase or decrease in the assumed initial public offering price of $16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the total consideration paid by investors in this offering by approximately $6.3 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions payable by us. We may also increase or decrease the number of shares we are offering. Each 1,000,000 share increase or decrease in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease the total consideration paid by investors in this offering by approximately $16.0 million, assuming the assumed initial public offering price of $16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions payable by us.

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters exercise in full their option to purchase 937,500 additional shares from us, the number of shares held by the existing stockholders after this offering would be reduced to 84.7% of the total number of shares of our common stock outstanding after this offering, and the number of shares held by new investors would increase to 13.3% of the total number of shares of our common stock outstanding after this offering.

The tables and calculations above are based on 39,645,402 shares of our common stock outstanding as of December 31, 2020, which gives effect to the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 31,253,609 shares of our common stock, and excludes:

- 1,053,874 shares of our common stock issuable upon the exercise of options outstanding as of December 31, 2020, at a weighted-average exercise price of $1.51 per share;

- 251,810 shares of our common stock issuable on the exercise of options granted subsequent to December 31, 2020 under our 2017 Plan, with a weighted-average exercise price of $13.00 per share;

- 815,214 shares of our common stock issuable upon the exercise of options approved subsequent to December 31, 2020 to be granted to our named executive officers and certain of our other employees under our 2021 Plan, contingent and effective upon the execution of the underwriting agreement for this offering, at an exercise price equal to the initial public offering price per share;

- 19,346 shares of our common stock issuable upon the exercise of warrants outstanding as of December 31, 2020, at a weighted-average exercise price of $0.03 per share; and

- 698,601 shares of our common stock reserved for future issuance under our 2017 Plan as of December 31, 2020, which shares will cease to be available for future issuance immediately prior to the time that our 2021 Equity Incentive Plan, or 2021 Plan, becomes effective;

- 4,700,000 shares of our common stock reserved for future issuance pursuant to our 2021 Plan (which does not give effect to the grant of 815,214 shares of common stock issuable upon the exercise of stock options that will be granted contingent and effective upon the execution of the underwriting agreement for this offering), which will become effective upon the execution of the underwriting agreement related to this offering, as well as any shares reserved pursuant to provisions in our 2021 Plan that automatically increase the number of shares of common stock reserved for issuance under the 2021 Plan; and

- 500,000 shares of our common stock reserved for future issuance under our ESPP, which will become effective upon the execution of the underwriting agreement related to this offering, as well as any shares reserved pursuant to provisions in the ESPP that automatically increase the number of shares of common stock reserved for issuance under the ESPP.

To the extent that any outstanding options are exercised, or new shares are issued under our equity plans at per share prices below the price to the public in this offering, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

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 prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements" and "Risk Factors" for a discussion of forward-looking statements and important factors that could cause actual results to differ materially from the results described in or implied by these forward-looking statements.

Overview

We are a clinical-stage microbiome therapeutics company leveraging our Human-First Discovery platform to develop a novel class of orally administered biological drugs. The microbiome consists of trillions of microbes that live symbiotically in and on every human and are essential to our health. When key microbes are lost, the resulting dysbiosis can increase susceptibility to immune disorders, infections, neurological conditions, cancer and other serious diseases. We are developing novel therapeutics designed to deliver missing microbes and their clinically relevant biochemical functions to correct dysbiosis and the diseases that emerge from it. Our Human-First Discovery platform uses reverse translation to identify diseases of dysbiosis and to design microbiome therapeutics that address them. Our lead product candidate, CP101, delivers a complete microbiome and is being developed initially for the treatment of patients with recurrent *Clostridioides difficile* infection, or CDI. In June 2020, we reported positive topline data from our first of two pivotal trials in recurrent CDI, and we plan to initiate a Phase 3 clinical trial, which we refer to as PRISM4, as our second pivotal trial of CP101 for recurrent CDI in mid-2021. Although we need to generate additional data confirming safety and efficacy to support regulatory approval of CP101 for the treatment of recurrent CDI, we believe data from our pivotal, Phase 2 clinical trial with CP101 validates our platform, positioning us to initiate new clinical trials in at least three new indications over the next 18 months, including chronic hepatitis B virus, or HBV, autism spectrum disorder, or ASD, and ulcerative colitis. We believe that our differentiated platform, rich pipeline and the broad therapeutic potential of this new field of medicine position us to transform care for a wide range of unmet medical needs.

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

Since our inception, we have incurred significant operating losses. Our net losses were $20.8 million and $39.3 million for the years ended December 31, 2019 and 2020, respectively. As of December 31, 2020, we had an accumulated deficit of $102.8 million. We expect to continue to generate operating losses and negative operating cash flows for the foreseeable future if and as we:

- continue the research and development of our product candidates;
- initiate clinical trials for, or additional preclinical development of, our product candidates;
- further develop and refine the manufacturing processes for our product candidates;
- seek regulatory and marketing authorizations for any of our product candidates that successfully complete development;

- seek to identify and validate additional product candidates;
- acquire or license other product candidates, technologies or biological materials;
- make milestone, royalty or other payments under any current or future license agreements;
- obtain, maintain, protect and enforce our intellectual property portfolio;
- seek to attract and retain new and existing skilled personnel;
- create additional infrastructure to support our operations as a public company and incur increased legal, accounting, investor relations and other expenses; and
- experience delays or encounter issues with any of the above.

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

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

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

We expect that our existing cash and cash equivalents of $99.7 million as of December 31, 2020 will not be sufficient to fund our operating expenses and capital expenditure requirements for twelve months from the issuance date of our annual consolidated financial statements for the year ended December 31, 2020. See “—Liquidity and Capital Resources.”

COVID-19 Business Update

In response to the ongoing global COVID-19 pandemic, we established a cross-functional task force and have implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on our employees and our business, including our clinical trials. Our operations are considered an essential business and we have been allowed to continue operating under current governmental restrictions during this period. We have taken measures to secure our research and development activities, while work in laboratories and facilities has been organized to reduce risk of COVID-19 transmission. The extent of the impact of the COVID-19 pandemic on our business, operations and clinical development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on our clinical trial enrollment, trial sites, contract research organizations, or CROs, contract manufacturing organizations, and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. While we are experiencing limited

financial impacts at this time, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, our business, financial condition and results of operations ultimately could be materially adversely affected. We continue to closely monitor the COVID-19 pandemic as we evolve our business continuity plans, clinical development plans and response strategy.

Recent Developments

In November 2020, we entered into the OpenBiome Agreement with Microbiome Health Research Institute, Inc., or OpenBiome, as further described below. Pursuant to the OpenBiome Agreement, upon signing, we acquired certain biological samples and obtained a license to certain OpenBiome technology. On March 1, 2021, the transaction under the OpenBiome Agreement closed, at which time we acquired certain additional assets, including biological samples, capital equipment and contracts. In connection with the closing, we paid $3.8 million in costs associated with the closing of the transaction. See “Business—Agreements with OpenBiome” for additional information.

Components of Our Results of Operations

Revenue

We have no products approved for commercial sale. We have not generated any revenue from product sales and do not expect to generate any revenue from the sale of licensed products for the foreseeable future. Our revenue to date has been generated primarily through collaboration and license agreements. We recognize revenue over our expected performance period under each agreement. We expect that our revenue for the next several years will be derived primarily from our current collaboration agreement and any additional collaborations that we may enter into in the future, and any collaboration revenue we generate will fluctuate from period to period as a result of the timing and amount of milestones and other payments. To date, we have not received any royalties under our collaboration agreement with Takeda Pharmaceutical Company Limited, or Takeda. However, in 2019 and 2020, we received royalties in the aggregate of $0.6 million and $0.3 million, respectively, pursuant to our 2019 Asset Purchase and License Agreement, or APL Agreement, with OpenBiome.

Collaboration and License Agreement with Takeda

In January 2017, we entered into a research collaboration and exclusive license agreement, or the Takeda Agreement, with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of 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, 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.

In connection with entry into the Takeda Agreement, we received a one-time, upfront payment from Takeda in the amount of $10.0 million. Additionally, we received $4.0 million in the aggregate for the achievement of certain development milestones for FIN-524 therapeutic products and are entitled to receive up to $176.0 million in the aggregate, for the achievement of specified development, regulatory and commercial sale milestones for FIN-524 therapeutic products. We are entitled to receive up to $177.7 million in the aggregate, for the achievement of specified development, regulatory and commercial sale milestones for FIN-525 therapeutic products, subject, to certain specified reductions based upon the nature of the FIN-525 product and certain additional milestones to be negotiated by the parties. We are also entitled to receive up to $10.0 million for the first diagnostic product for each of FIN-524 and FIN-525, subject to certain reductions in the event that Takeda uses a third party to develop such diagnostic products. Revenue under the Takeda Agreement is recognized as our research and development services are provided and is recorded as collaboration revenue on our consolidated statement of operations.

Agreements with OpenBiome

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

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

In February 2019, OpenBiome purchased manufacturing rights, manufacturing assets and existing inventory from us for total consideration of $3.3 million under the terms of the APL Agreement, with $2.4 million specifically related to the purchase of property, equipment and inventory. As of December 31, 2019, we do not owe OpenBiome any additional product or amounts under the APL Agreement, and we do not have inventory related to OpenBiome on our consolidated balance sheet. As of February 2019, we have no additional obligation to manufacture and transfer FMT materials to OpenBiome.

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 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 year ended December 31, 2020, as there are currently no products available for sale.

On November 19, 2020, we entered into an asset purchase agreement with OpenBiome, or the OpenBiome Agreement, the effect of which was to terminate certain existing agreements with OpenBiome and internalize some of functions for which we have previously relied on OpenBiome. Pursuant to the OpenBiome Agreement, we acquired certain biological samples and obtained a license to certain OpenBiome technology and, upon closing of the transaction, which is expected to occur in the first quarter of 2021, we will acquire certain additional assets, including biological samples, capital equipment and contracts. Through the closing of the transaction, we have agreed to make cash payments of approximately $5.0 million to OpenBiome. As of December 31, 2020, we have made payments of $1.2 million to OpenBiome related to the OpenBiome Agreement.

Operating Expenses

Cost of Contract Manufacturing Revenue from Related Party

Cost of contract manufacturing revenue consists of direct costs incurred to manufacture certain product for OpenBiome, a related party, pursuant to the terms of the QSS Agreement. We incurred $0.3 million in costs related to manufacturing efforts for OpenBiome in 2019. We did not incur any of these costs in 2020 and we will

not incur any of these costs going forward as we have fulfilled our obligation to manufacture materials for OpenBiome upon the signing of the APL Agreement. The QSS Agreement was terminated in November 2020 with the execution of the OpenBiome Agreement.

Research and Development Expenses

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

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

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

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase for the foreseeable future as we initiate clinical trials for our product candidates and continue to discover and develop additional product candidates. If any of our product candidates enter into later stages of clinical development, they will generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. There are numerous factors associated with the successful commercialization of any product candidates we may develop in the future, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development program and plans.

General and Administrative Expenses

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

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

Total Other Income, Net

Interest Income, Net

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

Loss on Sale of Assets to Related Party

Loss on sale of assets to related party relates to the loss we incurred when we sold the inventory and property and equipment to OpenBiome pursuant to the terms of the APL Agreement in February 2019.

Loss on Disposal of Fixed Assets

Loss on disposal of fixed assets relates to the loss we incurred when we disposed of certain lab equipment during the year ended December 31, 2020.

Other Income, Net

Other income, net primarily consists of insurance proceeds used to replace damaged furniture and fixtures as well as realized gains and losses on foreign exchange.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2020

The following table summarizes our results of operations for the years ended December 31, 2019 and 2020 (in thousands):

	YEAR ENDED DECEMBER 31,	
	2019	2020
REVENUE:		
Collaboration revenue	$ 9,083	$ 7,376
Contract manufacturing revenue from related party	435	—
Royalties revenue from related party	587	343
Services revenue from related party	49	—
Total revenue	10,154	7,719
OPERATING EXPENSES:		
Cost of contract manufacturing revenue from related party	(314)	—
Research and development	(23,543)	(33,144)
General and administrative	(7,439)	(14,011)
Total operating expenses	(31,296)	(47,155)
Net operating loss	(21,142)	(39,436)
OTHER INCOME, NET:		
Interest income, net	488	106
Loss on sale of assets to related party	(140)	—
Loss on disposal of fixed assets	—	(13)
Other income, net	40	2
Total other income, net	388	95
Net loss	$(20,754)	$(39,341)

Revenue

Revenue of $10.2 million and $7.7 million for the years ended December 31, 2019 and 2020, respectively, primarily consisted of collaboration revenue earned under the Takeda Agreement. Our collaboration revenue decreased by $1.7 million in 2020 due to increases in the budgeted reimbursable costs expected to be incurred and reimbursed over the life of the Takeda Agreement. Due to the increase in the budgeted costs, we adjusted our transaction price in 2020, causing a decrease in the overall percentage-of-completion. The decrease in revenue was also related to the decrease in contract manufacturing revenue, which had been earned during 2019 for material we manufactured and sold to OpenBiome pursuant to the QSS Agreement, and services revenue. This change during the year ended December 31, 2020 was related to partial termination of the QSS Agreement upon execution of the APL Agreement in 2019 and full termination upon the signing of the OpenBiome Agreement in November 2020.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2019 and 2020 (in thousands):

	YEAR ENDED DECEMBER 31,		
	2019	2020	INCREASE/ (DECREASE)
CDI (CP101)	$13,478	$19,841	$ 6,363
IBD (FIN-524 and FIN-525)	7,355	7,610	255
Autism Spectrum Disorder (ASD)	1,531	3,164	1,633
Hepatitis B (HBV)	—	737	737
Unallocated	1,179	1,792	613
	$23,543	$33,144	$ 9,601

Research and development expenses for the year ended December 31, 2020 were $33.1 million, compared to $23.5 million for the year ended December 31, 2019. The increase of $9.6 million included a $6.4 million increase in costs related to the continuing clinical development of our lead product candidate, CP101, including the completion of our Phase 2 trial in 2020. There was also a $1.6 million increase in expenses related to the expansion and development of the ASD program. Additionally, during the year ended December 31, 2020, we incurred costs of $0.7 million related to our Hepatitis B program as we move towards a Phase 1b clinical trial.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2019 and 2020 (in thousands):

	YEAR ENDED DECEMBER 31,		
	2019	2020	INCREASE/ (DECREASE)
Personnel expenses (including stock-based compensation)	$5,519	$ 9,041	$ 3,522
Facilities and supplies	192	581	389
Professional fees	939	3,479	2,540
Other expenses	789	910	121
	$7,439	$14,011	$ 6,572

General and administrative expenses were $14.0 million for the year ended December 31, 2020, compared to $7.4 million for the year ended December 31, 2019. The increase of $6.6 million was primarily due to a $2.5 million increase in legal and professional fees and a $3.5 million increase in personnel expenses. The increase in professional fees related to increased needs to support our path towards becoming a public

company. The increase in personnel expenses is related to $2.8 million of stock-based compensation expense for the sale of common stock from certain of our founders and employees to SIG Global US Fund I, LLLP at a price above fair value.

Other Income, Net

Total other income, net was $0.1 million for the year ended December 31, 2020, compared to $0.4 million for the year ended December 31, 2019. The decrease of $0.3 million was primarily related to a $0.4 million decrease in interest income, offset by the $0.1 million loss related to the sale of assets to OpenBiome pursuant to the APL Agreement in 2019. The decrease in interest income was primarily due to a decrease in the interest rate yield on our money market accounts.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not recognized any product revenue and have incurred operating losses and negative cash flows from our operations. We have not yet commercialized any product and we do not expect to generate revenue from sales of any products for several years, if at all. We have funded our operations primarily with proceeds from the sale of convertible preferred stock and from collaboration revenue, and have raised an aggregate of approximately $177.0 million from the sale of convertible preferred stock and $14.0 million in collaboration revenue from the upfront payment and milestone payments received under our collaboration agreement.

In April 2020, we received proceeds of $1.8 million from a loan, or the PPP Loan, under the Paycheck Protection Program, or the PPP, of the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, a portion of which may be forgiven, which we used to retain current employees, maintain payroll and make lease and utility payments. The PPP Loan matures on April 23, 2022 and bears annual interest at a rate of 1.0%. Payments of principal and interest on the PPP Loan were originally deferred for the first six months of the PPP Loan term. Thereafter, we are required to pay the lender equal monthly payments of principal and interest.

The CARES Act and the PPP provide a mechanism for forgiveness of up to the full amount borrowed. Under the PPP, we may apply for and be granted forgiveness for all or part of the PPP Loan. The amount of loan proceeds eligible for forgiveness was originally based on a formula that takes into account a number of factors, including the amount of loan proceeds used by us during the eight-week period after the loan origination for certain purposes, including payroll costs, interest on certain mortgage obligations, rent payments on certain leases, and certain qualified utility payments, provided that at least 75% of the loan amount was used for eligible payroll costs. Subject to the other requirements and limitations on loan forgiveness, only loan proceeds spent on payroll and other eligible costs during the covered eight-week period would have qualified for forgiveness.

We have determined that loan forgiveness of the PPP Loan would become probable of occurring upon acceptance by the Small Business Administration of our forgiveness application.

Funding Requirements

We expect that our existing cash and cash equivalents of $99.7 million as of December 31, 2020 will not be sufficient to fund our operating expenses and capital expenditure requirements for twelve months from the issuance date of the annual consolidated financial statements for the year ended December 31, 2020. Based on our recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and need to raise additional capital to finance its future operations, we have concluded that there is substantial doubt about our ability to continue as a going concern within one year after the date that our consolidated financial statements are issued. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our preclinical studies and clinical trials, research and development programs or commercialization efforts. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we may enter into additional collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated preclinical studies and clinical trials. To the extent that we raise additional capital through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2019 and 2020 (in thousands):

	YEAR ENDED DECEMBER 31,	
	2019	2020
Net cash used in operating activities	$ (17,320)	$ (31,329)
Net cash used in investing activities	(973)	(2,633)
Net cash provided by financing activities	53,300	91,475
Net increase in cash and cash equivalents, and restricted cash	$ 35,007	$ 57,513

Operating Activities

During the year ended December 31, 2019, cash used in operating activities was $17.3 million. This cash outflow was primarily related to our net loss and was offset by a $0.9 million increase in deferred revenue related to the additional milestones that were deferred to be recognized over the remaining research and development period, and a $1.2 million increase in accounts receivable for amounts billed to OpenBiome but not received as of December 31, 2019. The outflow was also offset by other changes in our operating assets and liabilities, including a $1.7 million net decrease in our inventory and a $0.7 million non-cash decrease in our net property and equipment related to our sale of manufacturing equipment back to OpenBiome. The cash outflow was also impacted by a $1.1 million decrease in accounts payable, a $1.9 million increase in accrued expenses and other current liabilities, and included $0.6 million in non-cash stock-based compensation expense and $0.5 million in non-cash depreciation and amortization expense for our fixed assets, including leasehold improvements.

During the year ended December 31, 2020, cash used in operating activities was $31.3 million. This cash outflow was primarily related to our net loss of $39.3 million and was offset by non-cash charges, including $0.8 million in depreciation and amortization expense on our fixed assets and $3.1 million in stock-based compensation expense. Of the $3.1 million in stock-based compensation expense, $2.8 million was related to a sale of our common stock by certain executives and founders to SIG Global US Fund I, LLLP. The net loss was also offset by changes in our operating assets and liabilities, including a $3.7 million increase in prepaid expenses and other current assets. The changes in operating assets and liabilities also include a $3.5 million

decrease in due from related party for the amounts received in 2020 related to the signing of the APL Agreement in 2019, and a $3.0 million increase in deferred revenue related to our adjustment to the amount we expect to receive for reimbursable costs under the Takeda Agreement.

Investing Activities

During the years ended December 31, 2019 and 2020, we used $1.0 million and $2.6 million, respectively, of cash in investing activities. The $1.0 million used during the year ended December 31, 2019 and $1.5 million of the cash used during the year ended December 31, 2020 was related to the purchases of property and equipment. The remaining $1.2 million of cash used in investing activities during the year ended December 31, 2020 was related to payments we made to OpenBiome in conjunction with the signing of the OpenBiome Agreement in November 2020.

Financing Activities

During the year ended December 31, 2019, net cash provided by financing activities stemmed primarily from the proceeds of $48.7 million received from the issuance of series C redeemable convertible preferred stock in July 2019 and $4.8 million received for the issuance of convertible promissory notes in February 2019, which were converted into series C redeemable convertible preferred stock pursuant to qualified financing criteria.

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

Funding Requirements

As of December 31, 2020, our cash and cash equivalents were $99.7 million. We believe that the net proceeds from this offering, together with our existing cash on hand, will enable us to fund our operating expenses and capital expenditure requirements into mid-2023. We have based this estimate on assumptions that may prove to be wrong, and we could expend our capital resources sooner than we expect.

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. We expect that our expenses will increase substantially if and as we:

- continue the research and development of our product candidates;
- initiate clinical trials for, or additional preclinical development of, our product candidates;
- further develop and refine the manufacturing process for our product candidates;
- change or add manufacturers or suppliers of product candidate materials;
- seek regulatory and marketing authorizations for any of our product candidates that successfully complete development;
- seek to identify and validate additional product candidates;
- acquire or license other product candidates, technologies or biological materials;
- make milestone, royalty or other payments under any current or future license agreements;

- obtain, maintain, protect and enforce our intellectual property portfolio;
- seek to attract and retain new and existing skilled personnel;
- create additional infrastructure to support our operations as a public company and incur increased legal, accounting, investor relations and other expenses; and
- experience delays or encounter issues with any of the above.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2020, and the effects of such obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

		Payments Due by Period			
	Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years
Lease commitments	$ 8,299	$ 1,387	$ 4,301	$ 1,496	$ 1,115
License agreements	370	20	105	110	135
Total	$ 8,669	$ 1,407	$ 4,406	$ 1,606	$ 1,250

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 an operating lease for rental space in Somerville, Massachusetts. The table above includes future minimum lease payments under the non-cancelable lease arrangement. The table above also includes payments due under our capital lease obligation, as related to leased equipment.

License Agreements

We have also entered into license agreements under which we are obligated to make milestone and royalty payments and incur annual maintenance fees. We owe an annual maintenance fee of $5,000 under our agreement with University of Minnesota, as well as escalating minimum royalty amounts. We also are required to pay minimum royalties under the agreement with Arizona State University of $5,000 annually until 2023, which increases to $20,000 in 2024. Future minimum payments through 2028 have been included in the table above, but our minimum payments continue in perpetuity for University of Minnesota until the agreement is otherwise 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 in sales-based milestone payments upon the achievement of certain net sales criteria, only once the OpenBiome Agreement closes. If the OpenBiome Agreement does not close by the end of the first quarter of 2021, we are not subject to any obligation for these amounts. We are 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, but if the OpenBiome Agreement does not close, we are not obligated to make these payments. 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 prospectus as well as Note 6 to our annual consolidated financial statements appearing elsewhere in this prospectus for a description of our license agreements.

Purchase and Other Obligations

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

Critical Accounting Policies and Significant Judgments and 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 at the end of this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

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

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

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

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

Goodwill and Acquired In-Process Research and Development

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

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

To conduct impairment tests of goodwill, the fair value of the reporting unit is compared to its carrying value. If the reporting unit's carrying value exceeds its fair value, we record an impairment loss to the extent that the carrying value of goodwill exceeds its implied fair value. Our annual assessments for impairment of goodwill as of December 31, 2019 and October 1, 2020 indicated that the fair value of our reporting unit exceeded the carrying value of the reporting unit.

To conduct impairment tests of IPR&D, the fair value of the IPR&D asset is compared to its carrying value. If the carrying value exceeds its fair value, we record an impairment loss to the extent that the carrying value of the IPR&D asset exceeds its fair value. We estimate the fair value for our IPR&D asset using discounted cash flow valuation models, which require the use of significant estimates and assumptions, including, but not limited to, estimating the timing of and expected costs to complete the in-process projects, projecting regulatory approvals, estimating future cash flows from product sales resulting from completed projects and in-process projects, and developing appropriate discount rates. Our annual assessments for impairment of IPR&D indicated that the fair value of our other IPR&D asset as of December 31, 2019 and October 1, 2020 exceeded their respective carrying values.

Through December 31, 2020, there have not been any events or changes in circumstances that indicate that the carrying value of goodwill or acquired intangible assets may not be recoverable. We continue to monitor and evaluate the financial performance of our business, including the impact of general economic conditions, to assess the potential for the fair value of the reporting unit to decline below its book value. There can be no assurance that, at the time future impairment tests are completed, a material impairment charge will not be recorded.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. We make estimates of our accrued expenses as of each balance

sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We account for all stock-based compensation awards granted as stock-based compensation expense at fair value. Our stock-based payments include stock options and grants of common stock, restricted for vesting conditions. The measurement date for awards is the date of grant, and stock-based compensation costs are recognized as expense over the requisite service period, which is generally the vesting period, on a straight-line basis. Stock-based compensation expense is classified in the accompanying statements of operations based on the function to which the related services are provided. We recognize 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.

Determination of the Fair Value of Common Stock

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors utilizing the valuation of our company's enterprise value determined by a third party valuation expert, and in accordance with the guidance outlined in the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Practice Aid.

Our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status and results of preclinical studies for our product candidates;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biopharmaceutical industry and trends within the biopharmaceutical industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of our company in light of prevailing market conditions; and

- the analysis of initial public offerings and the market performance of similar companies in the biopharmaceutical industry.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different.

Options Granted

The following table sets forth, by grant date, the number of shares underlying options granted from January 1, 2020 through the date of this prospectus, the per share exercise price of options, the fair value per share of common stock on each grant date, and the estimated per share fair value of the options granted during the period:

Grant Date	Number of Common Shares Subject to Options Granted	Exercise Price per Common Share(1)	Fair Value per Common Share at Grant Date(1)	Estimated Per-Share Fair Value of Options(2)
April 3, 2020	33,362	$ 1.45	$ 1.45	$ 0.87
February 8, 2021	247,692	$ 13.00	$ 10.12	$ 6.79
February 24, 2021	4,118	$ 13.00	$ 10.12	$ 6.94

(1) The exercise price per share of common stock and fair value of our common stock represents the fair value of our common stock on the date of grant, as determined by our board of directors, after taking into account our most recently available contemporaneous valuation of our common stock as well as additional factors that may have changed since the date of such contemporaneous valuation through the date of grant.

(2) The estimated per share fair value of options reflects the weighted average fair value of options granted on each grant date, determined using the Black-Scholes option-pricing model.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

Recently Issued Accounting Pronouncements

See Note 2 to our annual consolidated financial statements appearing elsewhere in this prospectus for a description of recent accounting pronouncements applicable to our financial statements.

Qualitative and Quantitative Disclosures about Market Risks

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, 2020, we had cash and cash equivalents of $99.7 million. Our exposure to interest rate sensitivity is impacted by changes in the underlying U.S. bank interest rates. Our surplus cash has been invested in money market fund accounts as well as interest-bearing savings accounts from time to time. We have not entered into investments for trading or speculative purposes. Due to the conservative nature of our investment portfolio, which is predicated on capital preservation of investments with short-term maturities, we do not believe an immediate one percentage point change in interest rates would have a material effect on the fair market value of our portfolio, and therefore, we do not expect our operating results or cash flows to be significantly affected by changes in market interest rates.

As of December 31, 2020, we had no debt outstanding that is subject to interest rate variability, as our only debt is related to our PPP Loan, which bears interest at a fixed rate of 1%. Therefore, we are not subject to interest rate risk related to debt.

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 EGC until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the completion of this offering, (ii) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more, (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the previous rolling three-year period, or (iv) the date on which we are deemed to be a large accelerated filer under the Securities Exchange Act of 1934, as amended.

We are also a ''smaller reporting company,'' meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 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.

BUSINESS

Overview

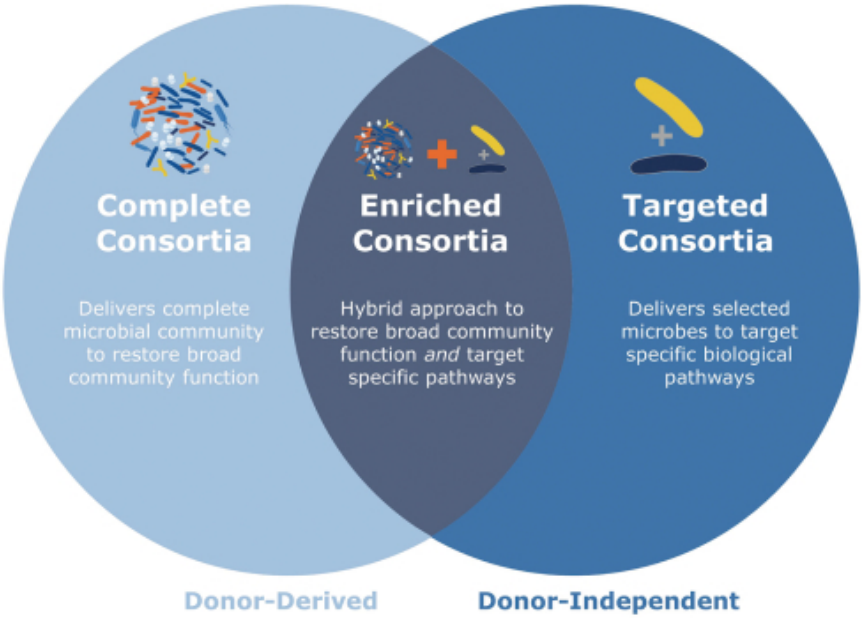
We are a clinical-stage microbiome therapeutics company leveraging our Human-First Discovery platform to develop a novel class of orally administered biological drugs. The microbiome consists of trillions of microbes that live symbiotically in and on every human and are essential to our health. When key microbes are lost, the resulting dysbiosis can increase susceptibility to immune disorders, infections, neurological conditions, cancer and other serious diseases. We are developing novel therapeutics designed to deliver missing microbes and their clinically relevant biochemical functions to correct dysbiosis and the diseases that emerge from it. Our Human-First Discovery platform uses reverse translation to identify diseases of dysbiosis and to design microbiome therapeutics that address them. Our lead product candidate, CP101, delivers a complete microbiome and is being developed initially for the treatment of patients with recurrent *Clostridioides difficile* infection, or CDI. In June 2020, we reported positive topline data from our first of two pivotal trials in recurrent CDI, and we plan to initiate a Phase 3 clinical trial, which we refer to as PRISM4, as our second pivotal trial of CP101 for recurrent CDI in mid-2021. Although we need to generate additional data confirming safety and efficacy to support regulatory approval of CP101 for the treatment of recurrent CDI, we believe data from our pivotal, Phase 2 clinical trial with CP101 validates our platform, positioning us to initiate new clinical trials in at least three new indications over the next 18 months, including chronic hepatitis B virus, or HBV, autism spectrum disorder, or ASD, and ulcerative colitis. We believe that our differentiated platform, rich pipeline and the broad therapeutic potential of this new field of medicine position us to transform care for a wide range of unmet medical needs.

Our lead candidate, CP101, consists of a lyophilized, intact microbial community harvested from rigorously screened healthy donors and formulated in orally administered capsules designed to release at the appropriate location in the gastrointestinal tract. CP101 is designed to deliver a complete microbiome, addressing the community-level dysbiosis that characterizes CDI. Patients with CDI suffer from severe diarrhea, which can progress to toxic megacolon and death, with more than 44,000 CDI-attributable deaths annually in the United States. In addition to the human cost, the economic impact of CDI is significant, with 2.4 million in-patient days and more than $5 billion in direct treatment costs each year in the United States alone. CDI often returns after cessation of antibiotic treatment because antibiotics do not address the dysbiosis that underlies this disease. We estimate there are approximately 200,000 cases of recurrent CDI annually in the United States.

In June 2020, we announced that CP101 met its primary efficacy endpoint in PRISM3, a randomized, placebo-controlled, multi-center, pivotal, Phase 2 clinical trial in recurrent CDI. Overall, 74.5% of participants who received a single administration of CP101 achieved a sustained clinical cure, defined as the absence of CDI through week 8, achieving statistical significance for the primary efficacy endpoint, with a clinically meaningful 33.8% relative risk reduction for CDI recurrence compared to placebo. In PRISM3, the prevalence of adverse events was similar across CP101 and placebo arms, with no treatment-related serious adverse events, or SAEs, in the CP101 arm. We plan to initiate a Phase 3 clinical trial as our second pivotal trial of CP101 for recurrent CDI in mid-2021 to build on the results of PRISM3. Further, based on the clinical validation of CP101 for recurrent CDI, we plan to develop CP101 in other diseases of dysbiosis, including the treatment of chronic HBV. We plan to initiate our first clinical trial of CP101 in chronic HBV in mid-2021, with an initial safety review in the second half of 2021 and topline data in the second half of 2022.

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

pursue a third product strategy, Enriched Consortia, which addresses dysbiosis at both the community and pathway level. These product strategies are summarized in the schema below:



Our Human-First Discovery platform informs each of these product strategies using clinical interventional data, through a process of reverse translation. Core to this strategy is our ability to deploy our proprietary machine learning algorithms to mine clinical data generated internally and by third parties, including experience with fecal microbiota transplantation, or FMT, a procedure that has been used to restore the gut microbiome and address community-level dysbiosis. FMT is a procedure, not a product. It is not approved by the U.S. Food and Drug Administration, or the FDA, and there are no standards for testing, processing and delivery of FMT, though it typically requires a colonoscopy. Despite these limitations, FMT has been used to treat more than 50,000 patients, with hundreds of clinical studies ongoing across a range of disease areas. We believe that this data can be used to (1) identify diseases where addressing dysbiosis provides therapeutic benefit, (2) reveal the mechanisms that underlie these results and (3) uncover key microbes and functional pathways that drive these clinical outcomes. We believe this reverse translation strategy is the optimal approach to developing microbiome therapeutics, providing causal insights that cannot be gleaned from preclinical *in vitro* or *in vivo* experiments alone. We further believe that we are uniquely positioned to execute on this strategy because of our proprietary FMT database and biorepository, our broad network of collaborators that supports the rapid growth of our data assets and our proprietary machine learning algorithms that enable the efficient translation of clinical data into therapeutic insights.

We have used our Human-First Discovery platform to develop FIN-211, an Enriched Consortia product candidate that we are advancing for the treatment of the gastrointestinal and behavioral symptoms of ASD. Scientific research in human and animal models have highlighted the “gut-brain axis” linking dysbiosis to neurological and neurobehavioral conditions, as the microbiome impacts the enteric nervous system and the production of neurotransmitters. This basic research is supported by a growing body of third-party clinical research. In an open-label, proof-of-concept FMT trial conducted by one of our collaborators, it was observed that, two years after treatment, 33% of the study participants who had previously been diagnosed with ASD were below the ASD diagnostic cutoff score for the Childhood Autism Rating Scale (CARS), a commonly used ASD diagnostic tool. Additionally, in a third-party, open-label randomized, controlled trial, children with ASD receiving FMT and behavioral therapy showed a statistically significant improvement in their behavioral

symptoms compared to those receiving behavioral therapy alone. Both studies also observed marked improvements in the gastrointestinal symptoms that many autistic children suffer from. There are no FDA-approved therapies for the core symptoms of ASD and the total financial burden of care for this condition is estimated to exceed $100 billion in the United States annually. We have received feedback from the FDA that demonstrating a benefit for either gastrointestinal or behavioral symptoms of ASD could support a biologics license application. Building on our discussions with the FDA, we aim to continue to validate behavioral instruments as part of our clinical development plans. We have designed FIN-211 to address both aspects of ASD and plan to initiate a Phase 1 clinical trial of FIN-211 in ASD in the second half of 2021, with topline data in the second half of 2022. We believe FIN-211 has the potential to transform care for patients with ASD.

We are also advancing FIN-524 and FIN-525 as Targeted Consortia product candidates for the treatment of ulcerative colitis and Crohn's disease, the most common types of inflammatory bowel diseases, or IBD. We are partnering with Millennium Pharmaceuticals, Inc., or Takeda, a wholly-owned subsidiary of Takeda Pharmaceutical Limited, to develop these assets. FIN-524 was discovered through the computational and molecular analysis of data from 147 patients treated with FMT and 19 observational studies of an additional 2,210 patients. We plan to initiate our first clinical trial of FIN-524 in ulcerative colitis in the first half of 2022. In addition, we are conducting initial discovery efforts on FIN-525, and pending Takeda's review, we could initiate IND-enabling studies for FIN-525 in Crohn's disease in the second half of 2021.

Key Advantages of Our Platform

- ***Our Human-First Discovery platform leverages clinical data to significantly reduce drug development time and translational risk.*** Given the distinct biology of the human microbiome, developing products by relying on laboratory and animal models alone is challenging. However, with our Human-First Discovery Platform, we have deployed powerful machine learning capabilities to integrate our proprietary FMT data with information from our human strain library. We believe this strategy reduces translational risk, because we only commence programs where clinical data already exists, thereby limiting the risk that effects seen in the laboratory will not translate to the clinic. Further, in the many indications like chronic HBV where we believe a Complete Consortia product strategy is attractive, we are able to enter the clinic directly with CP101, avoiding the time, costs and translational risks associated with traditional preclinical development. We believe that this approach is enabled by the favorable tolerability profile we have observed to date with CP101.

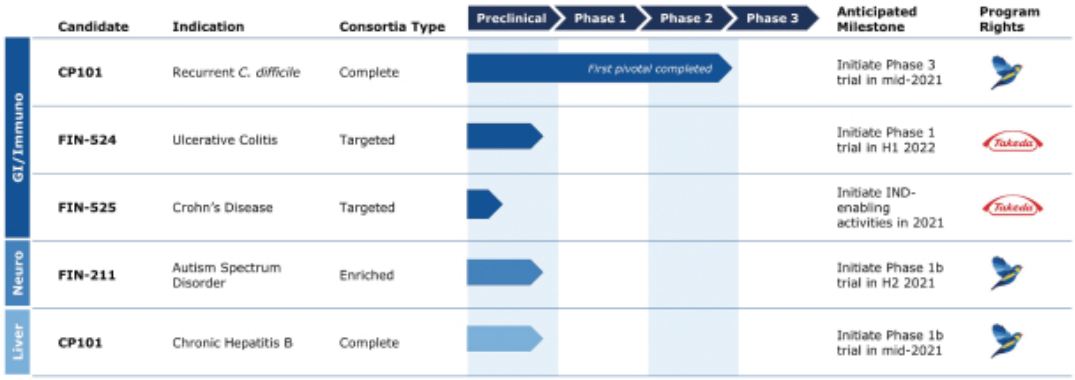
- ***We have differentiated capabilities to develop both complete and targeted microbiome therapeutics***. We have product candidates that address the distinct types of dysbiosis that lead to microbiome-mediated diseases. We have an orally administered Complete Consortia product candidate, which we believe enables both a potential near-term commercial opportunity in recurrent CDI, if approved, and the ability to expand into new therapeutic areas linked to community-level dysbiosis. We are also developing Targeted Consortia and Enriched Consortia product candidates that engage selected biological pathways to address more specific functional defects. This combination of capabilities enables us to develop product candidates that address each of the distinct types of dysbiosis that lead to microbiome-mediated diseases.

- ***We have exclusive access to certain data and thousands of samples from the largest providers of FMT in the world.*** We have developed strategic partnerships with groups that we believe are the largest providers of FMT in the United States, China and Australia, feeding our proprietary database of clinical data. One of these groups, OpenBiome, has delivered treatments to more than 50,000 patients across a network of more than 1,000 clinics. We have obtained exclusive access to a library of more than 10,000 microbiome samples from certain donors that have been administered to patients. We have demonstrated the ability to cryo-revive strains from these samples, enabling isolation of specific strains demonstrating promising results in FMT directly from the relevant source material,

rather than generic bacteria captured from samples without clinical history or murine isolates that may not exhibit clinical activity in humans. We have developed a large and growing database and biorepository which we are continually mining to develop new product candidates.

- ***We have built multi-layered patent protection with significant longevity***. We have a large and diverse patent portfolio that embodies pioneering work in the microbiome field. Our patent portfolio consists of over 50 issued U.S. and foreign patents, as well as over 130 patent applications, that have broad relevance for the industry and provide multi-layered protection for our product candidates, including key product composition claims that extend through 2031 and other relevant patents that extend through 2036.

Our Pipeline



Our Team

We are led by an energetic team of experienced biotechnology executives and recognized leaders in the microbiome therapeutics space. Our co-founder and Chief Executive Officer, Mark Smith, Ph.D. has been a pioneer in microbiome research, authoring over 50 peer-reviewed publications in the field. Dr. Smith founded OpenBiome, establishing the universal donor model for microbiota transplantation as a new standard of care for CDI. Gregory D. Perry, our Chief Financial Officer, has more than 20 years of experience managing teams at leading biotechs such as Transkaryotic Therapies, Inc., Eleven Biotherapeutics, Inc. and ImmunoGen, Inc. Our co-founder and Chief Medical Officer, Zain Kassam, M.D., M.P.H., is a world-class clinical researcher in the microbiome field and has authored over 150 peer-reviewed abstracts and papers. Dr. Kassam has collaborated on dozens of clinical studies investigating applications of the microbiome to treat disease. Our senior management team combines decades of experience in microbiology, data science, clinical research and the manufacture and commercialization of complex biologics, collectively developing more than 40 approved therapies across a wide range of modalities and therapeutic areas. We have assembled an exceptional team, including 34 individuals who hold a Ph.D. or M.D. degree.

Our Strategy

We believe that the human microbiome represents an untapped opportunity for therapeutic intervention. We have developed our Human-First Discovery platform to create orally administered microbiome therapeutics that can correct dysbiosis and the many diseases that we believe emerge from it. Our goal is to transform patient care by becoming the leading biopharmaceutical platform company developing and commercializing microbiome therapeutics. The key elements of our strategy to achieve this goal are to:

- ***Drive CP101 for recurrent CDI toward regulatory approval and commercialization.*** We achieved our primary efficacy endpoint, demonstrating superiority over standard of care alone in our first

pivotal trial, while also observing no treatment-related SAEs. We plan to initiate a Phase 3 clinical trial of CP101 for recurrent CDI in mid-2021, with data expected in the first half of 2023.

- ***Advance CP101 into additional indications where FMT demonstrates compelling clinical outcomes.*** With dozens of completed and hundreds of ongoing clinical studies by third parties with FMT, we have already identified several therapeutic areas where we believe addressing community-level dysbiosis through microbiome modulation has demonstrated compelling proof-of-concept clinical signals. We believe CP101 is uniquely well-positioned to translate these therapeutic insights into label expansion opportunities, without the translational risk associated with products that deliver only subsets of the full microbiome. We plan to initiate our first clinical trial of CP101 in chronic HBV in mid-2021, which will be the first example of this strategy in action.

- ***Leverage our Enriched Consortia product strategy to drive clinical development of FIN-211 for the treatment of ASD and other high value indications.*** We intend to advance FIN-211, an Enriched Consortia product candidate for the treatment of ASD, into a Phase 1 clinical trial in the second half of 2021. We are initially focusing on pediatric ASD patients with gastrointestinal symptoms and see this patient segment as a natural bridge into the broader opportunities to engage the gut-brain axis, given the role of the microbiome in metabolizing and modulating important neurotransmitters.

- ***Continue to use our Human-First Discovery platform to translate clinical data into a pipeline of differentiated product candidates, including Targeted Consortia.*** We plan to continue growing and evaluating our proprietary database and analytical tools to discover and develop new product candidates directly informed by clinical data. Importantly, because our machine learning algorithms become increasingly powerful as available data scales, we expect our efficiency to increase over time as we continue to expand our databases.

- ***Selectively enter into strategic collaborations to maximize the value of our platform and pipeline.*** As the potential impact of this emerging modality becomes clear, we believe the breadth of our collaboration opportunities will expand, particularly since large pharmaceutical companies may focus on accessing technology from early leaders like us. While, if approved, we plan to independently commercialize our products in indications and geographies where we can maximize their value, given the breadth of our portfolio and the significant potential for this new modality, we intend to selectively enter into partnerships with biopharmaceutical companies whose capabilities and resources may accelerate the development of our pipeline. Our partnership with Takeda is an example of such a collaboration.

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 a 1,000-fold more microbial genes than host genes and that microbiome signaling is fundamentally intertwined with many aspects of human physiology ranging from immune and metabolic functions to neurological function and reproductive health. The deep inter-relationship between microbes and their human hosts is a co-evolution that has resulted in a learned dependency, leaving humans now reliant on inputs from this previously unrecognized organ system.

Disruption of the gut microbiome is associated with a large number of diseases that have dramatically increased in prevalence among populations in developed countries over the past century. We believe these epidemiological trends are linked to changes in the microbiome, which if reversed could potentially address an underlying cause of these diseases and change the epidemiology as a result. The rise of these chronic illnesses coincides with our adoption of a number of practices that disrupt the microbiome: more than 42 billion doses of

antibiotics are administered annually, many killing 40-60% of microbial species in the gut; a third of babies in the United States today are born by caesarean sections, and are consequently unable to inherit this organ from their mother; and a highly sanitized and artificial environment, absent the environmental inputs expected by our microbiome, applies further pressure on this ecosystem within us. The effects of these environmental inputs coalesce around the gut microbiome resulting in dysbiosis and these changes are linked to a wide variety of chronic diseases. For example, antibiotic exposure doubles the risk of developing IBD, as well as significantly increases the risk of developing over 10 types of cancer. Early microbiome disruption is also associated with ASD, autoimmune indications such as celiac diseases, and allergies and asthma, and microbiome disruption later in life has been linked to neurodegenerative diseases, including Alzheimer's disease and Parkinson's disease. Importantly, in multiple animal models, these diseases can be induced by microbiome disruption and corrected by restoration, providing evidence of causality. For several of these therapeutic areas, this has been further bolstered by clinical data with FMT.

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

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

The human microbiome, a new organ system

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

The microbiome drives key elements of human physiology

Immune modulation	Metabolic function
Pathogen resistance	Neurological function

Our Approach

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

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

    - **Clinical Indication Selection**: We aim to de-risk development by targeting indications with known underlying dysbiosis, an understanding of relevant mechanistic pathways and, critically, data from FMT that provide proof-of-concept that a microbial intervention has the potential to positively impact clinically meaningful outcomes. We have exclusive access to certain data and samples from groups that we believe are the largest providers of FMT in the world, including OpenBiome, which has delivered more than 50,000 FMTs to over 1,000 clinical sites. With more than 300 third-party clinical studies evaluating FMT around the world, we are uniquely well positioned to leverage this trove of clinical data to identify promising new drug development opportunities. We believe that by requiring a foundation of clinical data prior to indication selection and program initiation, our programs are already significantly de-risked before we begin development.

    - **Target Identification and Validation**: We use translational assays and high-throughput sequencing to generate curated datasets from FMT studies, observational clinical studies, and sometimes preclinical models, for each target indication. We then use our expertise in microbial ecology enhanced by our proprietary machine learning tools to identify microbiome compositions and functions that are deficient in our target population and whose restoration is causally linked to improved outcomes. We believe that observational clinical studies and preclinical models are valuable for generating mechanistic hypotheses which can then be validated using interventional data from FMT. Taken together, these efforts provide molecular and microbial targets, specific metabolites or bacteria, that are linked to clinical outcomes.

    - **Candidate Selection and Consortia Design**: To engage these targets, we deliver designed microbial consortia. The capability to deliver both a complete microbiome and targeted microbes gives us the flexibility to engage a diversity of mechanisms and therefore develop treatments for a wide range of indications. In diseases characterized by community-level dysbiosis like CDI, we are able to deploy Complete Consortia product candidates like CP101. In diseases where we are able to target pathway-level dysbiosis like IBD, we are able to deploy Targeted Consortia product candidates like FIN-524. Importantly, we have obtained exclusive access to a library of more than 10,000 samples from certain donors that have each been administered to patients through FMT. We are able to cryo-revive and manufacture strains from these samples, enabling precise matching of the exact strain that was associated with clinical outcomes with FMT. We believe that this direct chain of custody from a clinical sample into a Targeted Consortia significantly reduces translational risk and is uniquely enabled by our proprietary partnerships. We are also able to engage both the Targeted and Complete Consortia product strategies in a single Enriched Consortia product candidate like FIN-211 for conditions like ASD that have both community- and pathway-level dysbiosis. We believe we are uniquely positioned to align product strategy with mechanism because of our capabilities to address community- or pathway-level dysbiosis.

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

    - **Bioprocess and Formulation Development**: We have developed proprietary methods for growing, harvesting, purifying, preserving and delivering microbiome consortia. Of particular note, our advanced lyophilization technology enables the preservation of a complete microbiome in a stable formulation with more than two years of stability at 2°–8°C and more than six months of stability at room temperature to accommodate excursions during delivery and administration. Furthermore, we have developed orally administered, targeted release technologies, enabling intestinal release that facilitates robust pharmacokinetics. We believe that our deep expertise in bioprocess and formulation development have, and will continue to, enable rapid development of differentiated products.

    - **Quality Control and Product Safety**: Unlike other product candidates in development, we have developed manufacturing processes that do not rely on non-specific biocides like ethanol to exclude potential pathogens. Instead, each of our product candidates leverages molecular screening technology to exclude potential pathogens and harmful antibiotic resistance or virulence elements. This technology enables us to exclude unwanted agents without compromising potentially beneficial microbes. In addition to these purity assays, we have also developed both culture-based and culture-independent measures of viability to provide consistent potency across lots.

    - **cGMP Production**: We have developed cGMP production capabilities as a strategic asset, internalizing key activities that we believe we are uniquely positioned to execute, while externalizing activities that can be completed by third parties, in order to maximize our capital efficiency. As an example of this strategy in action, we are developing cGMP production capabilities for CP101, an orally administered Complete Consortia product candidate. With nearly a decade of operational experience and know-how enabling our Complete Consortia manufacturing platform, we believe we are the only company in the world with the cGMP capabilities required to enable this manufacturing process. By contrast, we have worked closely with third parties for the production of certain Enriched Consortia and Targeted Consortia product candidates. For these product candidates, there are rapidly maturing providers able to leverage analogous experience with large scale fermentation, including the required capital equipment and infrastructure to enable cGMP manufacture of these product candidates.

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

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

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

- **Iteration**: In addition to positioning our clinical development and translational medicine strategy to generate data that may inform expansion opportunities into new indications, we also believe that clinical data generated from the development of product candidates like FIN-211 will provide a rich pool of data that we can mine with our Human-First Discovery platform to inform follow-on product candidates in the same indication with even more favorable product attributes. In this way, our clinical development is designed to feed back into discovery, enabling iterative improvement and life cycle management as we establish franchises in new indications.

Our Clinical Programs

CP101 for the Treatment of Recurrent CDI

Overview

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

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

Our production process for CP101 is designed to be scalable. We typically collect many samples from each donor and we are able to produce many treatments from each sample collected. As a result, a small pool of donors can support a large production base. For example, we believe a pool of 200 donors could support production of approximately 100,000 treatments of CP101 annually. Furthermore, our process is designed to yield a favorable stability profile, with at least 24 months of stability at 2°–8°C and more than six months of stability at 25°C to allow for temperature excursions during delivery and administration. We believe this favorable stability profile will simplify supply chain logistics and enable more convenient care.

CP101 has received Fast Track designation and Breakthrough Therapy designation from the FDA for the prevention of recurrent *Clostridioides difficile* infection, or recurrent CDI. We are also advancing CP101 for the treatment of chronic hepatitis B virus, or HBV, and as a result of our Complete Consortia design strategy, we believe that it also has potential for additional applications in gastroenterology, hepatology, immunology and oncology.

Indication Overview

Clostridioides difficile, or *C. difficile*, is a toxin-producing, spore-forming bacterium that causes severe and persistent diarrhea in infected individuals. *C. difficile* expresses toxins that lead to inflammation of the colon, severe diarrhea and abdominal pain, as well as potentially more serious clinical outcomes including toxic megacolon, perforation of the colon, and death. The Centers for Disease Control and Prevention considers CDI to be one of the top three most urgent antibiotic resistant threats and the most common cause of healthcare associated infection in the United States. We estimate that there are over 450,000 cases of primary CDI and

approximately 200,000 cases of recurrent CDI annually in the United States, collectively resulting in more than 44,000 CDI-attributable death per year. In addition to this human toll, the economic impact is substantial, with 2.4 million inpatient days and greater than $5 billion in direct treatment costs each year in the United States.

Rationale for Microbiome Therapeutics in Recurrent CDI

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

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

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

Existing Therapeutics and Their Limitations

Antibiotics

Patients with recurrent CDI are not well served by antibiotics, the current standard of care, which are the same class of therapy believed to cause disease onset. Recurrence rates following antibiotic therapy are high as these agents exacerbate community-level dysbiosis. The leading CDI antibiotic, vancomycin, is non-specific and causes significant disruption to the microbiome. Fidaxomicin was designed as an alternative, narrow-spectrum antibiotic, with reduced activity against other microbes. While this microbiome-sparing approach can reduce further damage to the microbiome, it does not restore the missing microbes eliminated by previous antibiotic exposure. Increasingly sophisticated and precision-targeted antibiotics can mitigate further harm to the microbiome but they do not address the dysbiosis that underlies recurrent CDI.

Antibodies

Another approach is to deliver antibodies against the toxins that *C. difficile* produces, reducing the damage that these toxins cause to the host. Bezlotoxumab is an approved intravenous antibody product. However, it fails to repair dysbiosis, the underlying cause of recurrent CDI.

Probiotics

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

Fecal Microbiota Transplantation

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

Our Product Candidate: CP101

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

- **Differentiated manufacturing enables the delivery of a complete microbiome**. Our manufacturing technology enables us to exclude pathogens through molecular screening, without requiring destruction of the majority of the microbiome through non-specific biocides like ethanol. Besides enabling CP101 to address community-level dysbiosis, rather than a limited subset of the microbiome, we believe that creating a manufacturing process that moves beyond reliance on biocides enables higher yields and more efficient, less costly manufacturing. We believe these advantages will be particularly important as we evaluate CP101 in new indications where ethanol-sensitive organisms, which comprise the majority of the microbiome, are likely to play a critical role and scalable manufacturing will enable us to serve large markets.

- **Novel class of therapy that addresses the underlying cause of disease by restoring the microbiome.** While antibiotics are the current standard of care for the treatment of recurrent CDI, they fail to address the underlying community-level dysbiosis that causes recurrence of the disease. CP101 is designed to durably repair community-level dysbiosis, restoring colonization resistance and production of protective microbiome-derived secondary bile acids. Through its novel mechanism, CP101 also avoids contributing to antibiotic resistance.

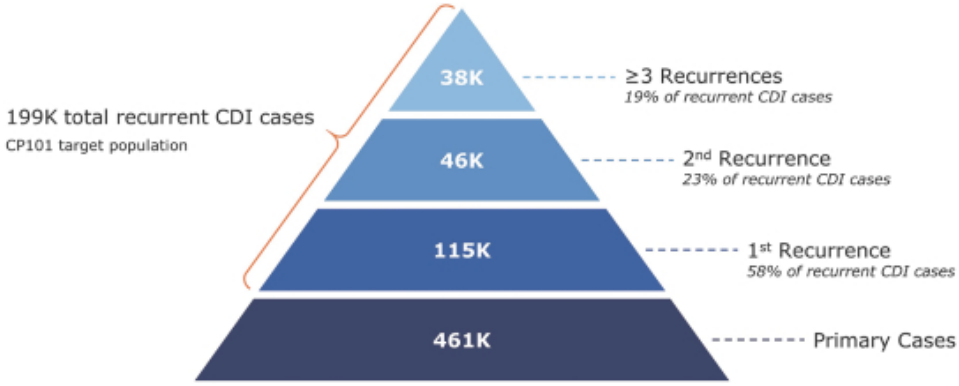
- **Achieved primary endpoint in a broad patient population.** CP101 is the only orally administered, microbiome therapeutic candidate drug in development that achieved its primary endpoint in a pivotal trial that included patients across all stages of recurrent CDI, including first recurrence, which represents more than half of all recurrent CDI episodes. Other drugs in development have focused on patients with multiple recurrences, rather than the more challenging hurdle of achieving clinical outcomes in front-line care for recurrent CDI. CP101 achieved its primary endpoint in a population that included patients diagnosed by either polymerase chain reaction, or PCR, testing or toxin enzyme immunoassay, or EIA, testing. Other drugs in development failed to demonstrate efficacy among patients diagnosed by PCR and have subsequently focused development exclusively on those diagnosed by toxin EIA. This is commercially important because PCR is the method used to diagnose more than 80% of all CDI cases each year in the United States. By incorporating patients with first recurrence and diagnosed by PCR testing into our study design, we expanded the addressable patient population more than 10-fold relative to products in development that were evaluated only in patients with multiple

recurrences and diagnosed by toxin EIA testing. We believe based on the results of our PRISM3 trial, CP101 will have broad applicability across all stages of recurrent CDI and all methods of CDI diagnosis.

- **Favorable tolerability profile with no treatment-related SAEs observed.** In our PRISM3 trial, CP101 was observed to be well-tolerated, with a similar prevalence of adverse events across the CP101 and placebo arms and no treatment-related SAEs. We believe this promising tolerability profile is enabled by our robust product and process design, including an array of purity and potency assays developed through discussions with the FDA.

Market Opportunity

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



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

Clinical Trials of CP101 for the Treatment of Recurrent CDI

PRISM3 Trial

We evaluated CP101 for the treatment of recurrent CDI in our pivotal PRISM3 trial, which represents the first positive pivotal trial with an orally administered microbiome product candidate. PRISM3 was a Phase 2 1:1 randomized, placebo-controlled, multi-national trial designed to demonstrate the superiority of CP101 following standard-of-care CDI antibiotics compared to antibiotics alone in preventing recurrence among patients with recurrent CDI. A total of 206 participants were enrolled across 51 sites, of which 198 were evaluable. Patients were recruited from across all stages of recurrent CDI, including patients experiencing their first recurrence. Qualifying episodes of recurrent CDI were diagnosed using all standard-of-care laboratory tests, including PCR- or toxin EIA-based test methods. All participants were treated with standard-of-care CDI

antibiotic therapy prior to randomization. Following antibiotic treatment, participants were randomized to receive either a one-time oral administration of CP101 or a placebo. The trial design is shown below.

PRISM3 Trial Design

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

Treatment Groups Had No Meaningful Clinical Differences at Baseline

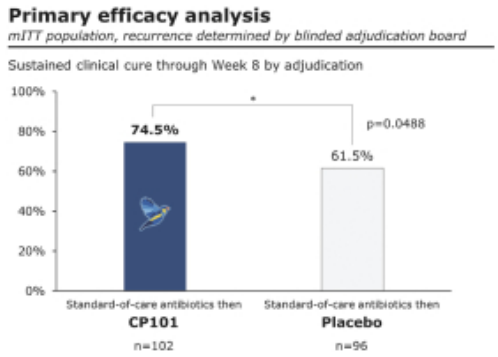
	Standard-of-care antibiotics then CP101 (n=102)	Standard-of-care antibiotics then Placebo (n=96)
Age (years) Mean ± standard deviation	65.9 ± 17.3	66.5 ± 14.3
Sex n female (% female)	69 (67.6%)	65 (67.7%)
Number of CDI recurrences at study entry		
First recurrence[1] n (%)	28 (27.5%)	29 (30.2%)
Second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

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

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

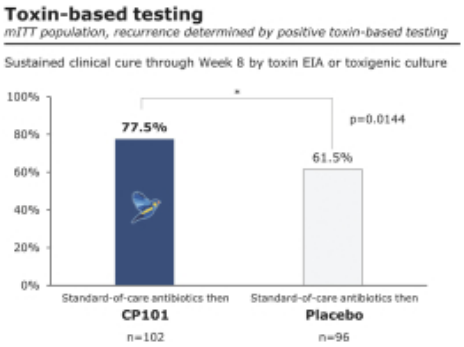
PRISM3 achieved its primary efficacy endpoint, which was sustained clinical cure defined as the absence of CDI recurrence through eight weeks following administration of study drug. Sustained clinical cure was determined by a blinded adjudication board of independent experts evaluating the totality of clinical and laboratory data including central laboratory data with PCR, toxin EIA and toxigenic culture testing. Following standard-of-care CDI antibiotics, 74.5% of participants treated with CP101 achieved sustained clinical cure, a statistically significant improvement over those receiving placebo (61.5%; p=0.0488), meeting the primary efficacy endpoint and representing a clinically meaningful 33.8% relative risk reduction for CDI recurrence.

CP101 Achieved 33.8% Relative Risk Reduction for CDI Recurrence

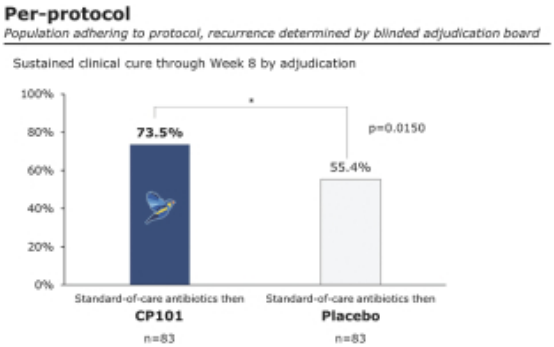


To evaluate the sensitivity of this result to the adjudication process, we also evaluated the efficacy results using the highly specific, toxin-based laboratory testing to confirm the endpoint, finding a statistically significant result (p=0.0144) and a corresponding 41.6% relative risk reduction for CDI recurrence for CP101 compared to placebo, as shown below on the left. We also evaluated the results among the per-protocol population, with participants experiencing significant protocol violations excluded prior to unblinding. In this population, we found that participants in the CP101 arm also achieved a statistically significant result (p=0.0150) with a corresponding 40.6% relative risk reduction for CDI recurrence compared to placebo, as shown below on the right.

CP101 Achieved 41.6% Relative Risk Reduction for CDI Recurrence using Toxin-Based Testing

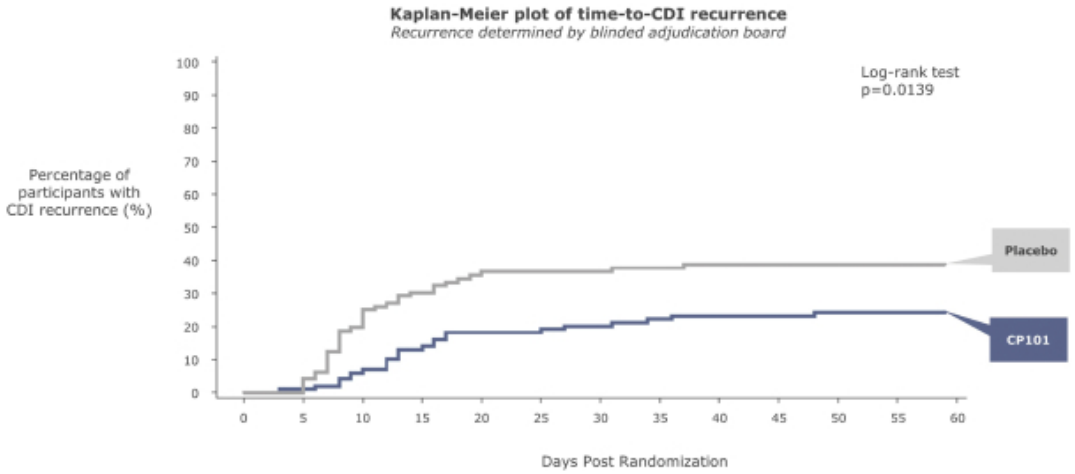


CP101 Achieved a 40.6% Relative Risk Reduction for CDI Recurrence in Per Protocol Population



In addition to achieving its primary endpoint at the eight-week timepoint, a post-hoc analysis demonstrated that CP101's effect was durable over time. We observed that CP101 was associated with a statistically significantly lower probability of CDI recurrence over time relative to placebo (p=0.0139).

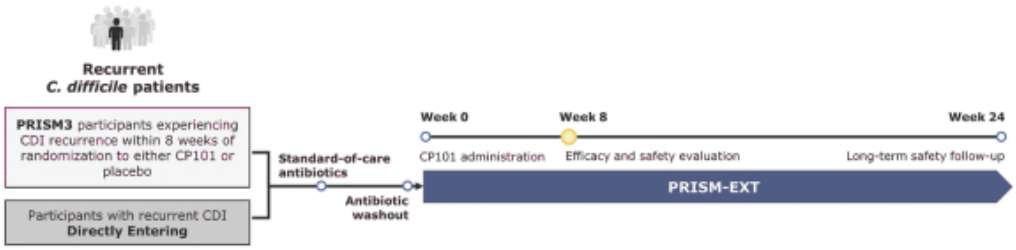
CP101 Significantly Reduced Probability of CDI Recurrence Over Time Compared to Placebo in PRISM3



PRISM3 Extension Trial

PRISM-EXT is an open-label study evaluating the safety and efficacy of CP101 for the treatment of recurrent CDI. Initially, the study only enrolled participants who had previously enrolled in the randomized, placebo-controlled PRISM3 trial and experienced a CDI recurrence. After PRISM3 enrollment was complete, a protocol amendment expanded the inclusion criteria to allow participants with recurrent CDI to enroll directly in PRISM-EXT without having previously enrolled in PRISM3. This trial is currently ongoing and, at this time, we have enrolled over 130 participants, including over 70 participants with direct entry into the study. We plan to report data from this trial in the second half of 2021.

PRISM3 Extension Trial Design



Phase 1 Clinical Trials

The first clinical trial to evaluate CP101 for the treatment of recurrent CDI was a 49 patient, single-center, open-label Phase 1 clinical trial conducted at the University of Minnesota. The trial enrolled patients who had experienced two or more recurrences of CDI. The primary endpoint was the safety and tolerability of CP101. Clinical success was defined as absence of CDI recurrence within two months post-treatment. No related SAEs occurred and 43 of the 49 patients treated achieved clinical success, resulting in an efficacy rate of 87.8% after treatment with CP101. Because the study was designed with a single arm and did not have concurrent control participants, the statistical significance of the observed efficacy rate was not assessed in this study. Approximately, a third of patients reported mild, transient gastrointestinal symptoms following the treatment. Multiple doses were evaluated in this first

cohort, including a high dose range (1.25-2.5x10^{12}) and a low dose range (2.1-2.5x10^{11}), with no meaningful dose-dependency at the dosing levels tested. An intermediate dose of 6x10^{11} was selected for further process development and tested in an additional 10-patient cohort at the University of Minnesota. In this second cohort, seven of ten patients achieved clinical success through eight weeks following CP101. These promising clinical results from Phase 1 were used to secure Fast Track designation and Breakthrough Therapy designation from the FDA.

Safety and Tolerability

CP101 has been well-tolerated throughout all stages of development to date, and there have been no treatment-related SAEs reported. In PRISM3, the topline results suggest the adverse events profile was similar across both CP101 and placebo arms. The most common treatment-emergent adverse events reported in the CP101 arm were predominantly gastrointestinal symptoms, as shown in the table below. Among the five most common adverse events in the CP101 arm, four adverse events were observed more frequently in participants treated with placebo relative to participants treated with CP101. For instance, we observed significantly fewer participants with abdominal pain among those treated with CP101 (30.8%) relative to those treated with placebo (59.6%; $p<0.0001$).

Most Frequent Adverse Events in the CP101 Arm Through Week 8

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

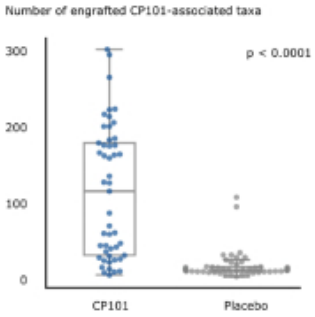
Source: PRISM3 safety population

The favorable tolerability profile to date is consistent with our belief that unlike traditional small molecule product candidates, which often represent compounds new to human physiology, the microbiome has co-evolved with humans, developing an intricate and mutually beneficial relationship.

Pharmacokinetics

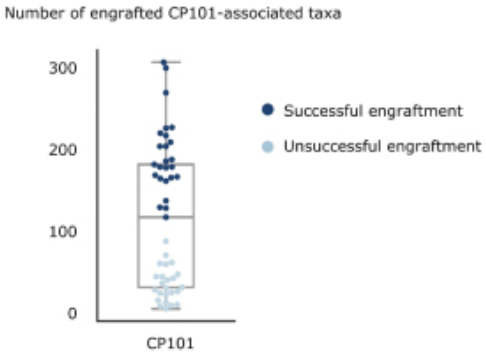
We used data from these clinical trials to confirm potential mechanisms underlying the clinical outcomes observed with CP101 for recurrent CDI. We believe the potential for CP101 transcends its initial clinical indication, prevention of recurrent CDI. CP101 is a platform product candidate that we plan to develop broadly in a range of other indications characterized by community-level microbiome dysbiosis. Given this development strategy, it is important to demonstrate that the microbiome community delivered in CP101 is able to engraft, or colonize the intestine, a key pharmacokinetic measure for this class of therapeutic. We used high-throughput sequencing to characterize the engraftment of CP101 Taxa, or groups of genetically similar bacteria, among participants treated in the PRISM3 study. As expected, participants treated with CP101 had dramatically higher engraftment of CP101 Taxa than patients treated with placebo, as shown in the graphic below, highlighting our ability to effectively deliver a viable consortia to the appropriate location in the gastrointestinal tract with our targeted oral capsule.

CP101 Shows Significant Engraftment Overall

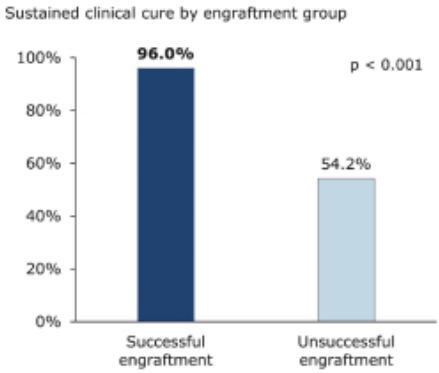


We also observed a strong relationship between engraftment of the microbes delivered in CP101 and clinical outcomes in PRISM3. Among patients with successful engraftment at week 1 following CP101 administration, 96.0% achieved a sustained clinical cure, while 54.2% of those without successful engraftment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

CP101 Engraftment Shows a Bimodal Distribution



CP101 Engraftment Correlates with Sustained Clinical Cure



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

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

In contrast to vancomycin, residual fidaxomicin, a targeted antibiotic with limited activity against CP101 microbes should not impact CP101 activity. Indeed, in a pre-specified subgroup analysis, we observed a 38.8% difference in the rate of sustained clinical cure through week 8 between CP101 (81.0%) and placebo

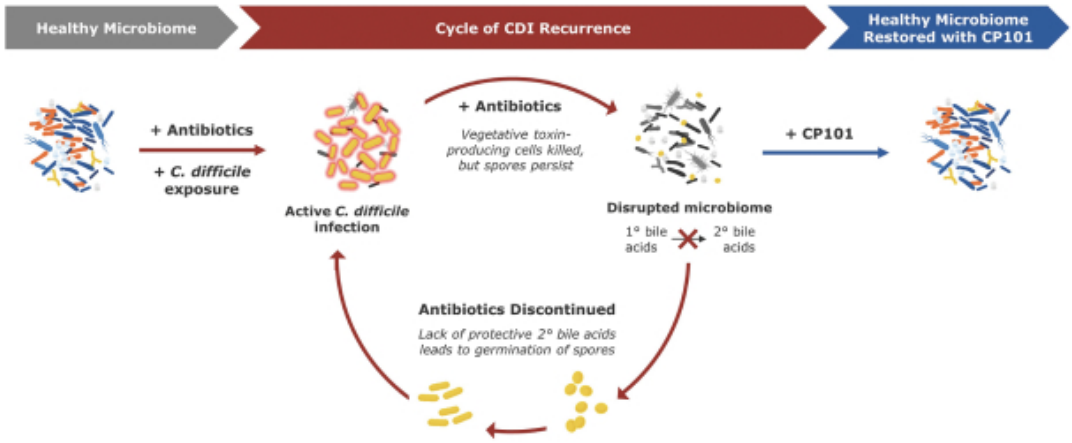
(42.1%) among those treated with fidaxomicin instead of vancomycin prior to receipt of study drug (p = 0.0211, n = 40). Taken together, these observations suggest that incomplete washout of vancomycin may have reduced CP101 engraftment and sustained clinical cure in PRISM3. To address this limitation, in PRISM4, our planned Phase 3 clinical trial of CP101 in recurrent CDI, we plan to extend the minimum antibiotic washout period prior to administration of CP101.

Pharmacodynamics

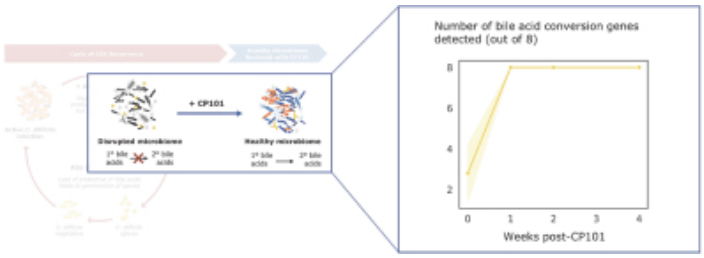
We believe bile acid metabolism plays a key role in the pathogenesis of recurrent CDI. A healthy microbiome generates microbiome-derived secondary bile acids that inhibit residual *C. difficile* spores from germinating into their vegetative toxin-producing form. Patients with recurrent CDI have depleted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

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

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



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



Clinical Development of CP101 for the Treatment of Recurrent CDI

CP101 has been granted Fast Track designation and Breakthrough Therapy designation by the FDA for the prevention of recurrent CDI. Breakthrough Therapy designation provides expedited review and access to collaborate with the FDA on rapid development of CP101. As our first pivotal trial, PRISM3 has the potential to support the approval of CP101 for the prevention of recurrent CDI. We plan to initiate a Phase 3 clinical trial, referred to as PRISM4, as our second pivotal trial of CP101 for recurrent CDI in mid-2021, with data expected in the first half of 2023. PRISM4 is expected to be a randomized, placebo-controlled, multi-national trial that will enroll approximately 300 participants with recurrent CDI and may include an interim analysis. The expected PRISM4 trial design is shown below. We plan to have further discussions with the FDA regarding the size and make-up of the safety database for CP101, which could result in the need for additional studies.

PRISM4 Trial Design

CP101 for the Treatment of Chronic HBV

Overview

Although we need to generate additional data confirming safety and efficacy to support regulatory approval of CP101 for the treatment of recurrent CDI, we believe the positive results from PRISM3 validates the potential of our Complete Consortia approach, and we intend to advance CP101 into additional indications to address community-level dysbiosis. A number of chronic liver diseases, including chronic hepatitis B virus, or HBV have been linked to microbiome dysbiosis. One potential explanation for this link is the critical role the microbiome plays in modulating our immune system. Preclinical models have demonstrated that gut microbiota disruption impairs an HBV-specific T-cell response and third-party FMT data supports our belief that CP101 has potential in the treatment of chronic HBV. Given the limitations of current standard of care, we see CP101's distinct mechanism of action as a potentially synergistic addition to the current regimen and we intend to move into a Phase 1 clinical trial of patients with chronic HBV in mid-2021, with an initial safety review in the second half of 2021 and topline data in the second half of 2022.

Indication Overview

Chronic HBV affects more than 290 million individuals worldwide, with approximately 30 million individuals becoming newly infected every year. China carries the largest burden of disease, with more than

90 million cases of chronic HBV. There is also a significant population in the United States and Europe, with more than two million and 15 million cases of chronic HBV, respectively.

Chronic infection occurs when the initial immune response fails to clear the virus, and may result in inflammation of hepatocytes, and complications including cirrhosis, liver failure requiring liver transplantation, liver cancer, and death. According to the World Health Organization, in 2015, approximately 900,000 people globally died from chronic HBV-related complications, and chronic HBV is the most common cause of liver cancer worldwide. Chronic HBV patient populations are classified as hepatitis B E-antigen (HBeAg) positive or negative. HBeAg is a biomarker associated with higher rates of viral replication and liver complications such as liver cancer. HBeAg positivity can persist despite standard-of-care antiviral therapies. HBeAg can be cleared and an antibody response generated, resulting in an HBeAg negative state associated with lower rates of viral replication, slower progression and lower rates of complications. We believe CP101 may facilitate reduction in HBeAg. Furthermore, CP101 may help achieve hepatitis B surface antigen, or HBsAg loss (a biomarker associated with a finite cure).

Existing Therapeutics and Their Limitations

There are two classes of approved therapies for the treatment of chronic HBV, and while these treatments have improved outcomes for some patients, there remains a significant unmet medical need.

Pegylated forms of interferon-alfa (PEG-IFN-a)

PEG-IFN-a is designed to boost the immune response and may augment cell-mediated immunity to promote clearance of HBV-infected hepatocytes. E-antigen loss is not common (32-36%) among HBeAg positive patients treated with PEG-IFN-alpha, and positivity for E-antigen is associated with an increase risk of developing liver complications such as liver cancer. There are further limitations with this treatment including subcutaneous administration, low rates of hepatitis B surface antigen loss, and numerous side effects. Clinical guidelines report numerous potential side effects, including autoimmune disorders, persistent flu-like symptoms and cytopenias, or abnormal blood counts, that require close laboratory monitoring.

Nucleos(t)ide analogs

Nucleos(t)ide analogs are designed to inhibit viral replication. Similar to patients who take PEG-IFN-a, E-antigen loss is not common (22-25%) among HBeAg positive patients on these treatments. Further limitations of treatment include life-long administration, low rates of HBsAg loss and potential negative side effects in some patients. Clinical guidelines report a potential risk of kidney disease (nephropathy), requiring ongoing laboratory monitoring, bone disease (osteomalacia) requiring monitoring in some patients and potentially lactic acidosis.

There is a need for safe and effective therapies that address all stages of disease and drive towards a functional cure.

Rationale for Microbiome Therapeutics in Chronic HBV

Dysbiosis: Chronic HBV results from an ineffective immune response against acute viral infection, and the epidemiology, biological mechanisms and preclinical models of HBV link this deficient immune response to the microbiome. Observational studies comparing patients with chronic HBV and healthy controls have found a distinct, community-level dysbiosis in patients with chronic HBV. The populations with the highest risk of developing chronic infection after HBV exposure are infants, whose microbiome and immune system are still developing.

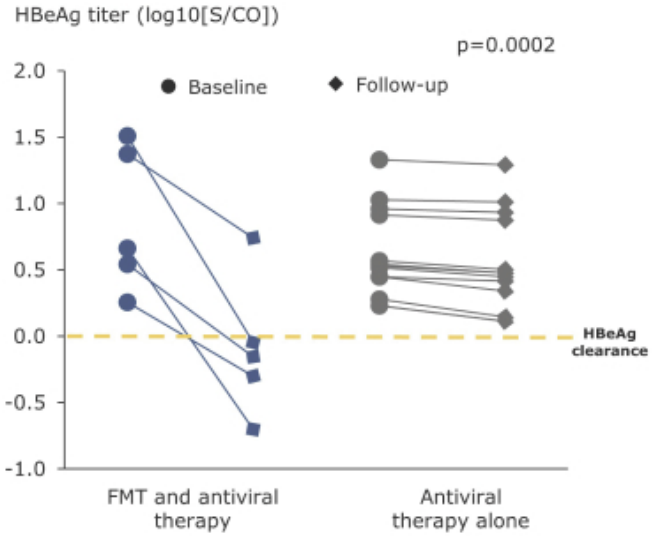
Mechanism of Action: In preclinical models, a mature and intact microbiome is necessary and sufficient to prevent chronic HBV, and juveniles and adults with antibiotic disrupted microbiota cannot clear acute infection. These microbiome deficiencies may be cured through transplantation of a complete microbiome from a

healthy adult, which rescues the ability to clear acute infection. We believe this is mediated by activation of the immune response through Toll-like receptors (TLR). Toll-like receptors form a key part of the innate immune system and have evolved specifically to interact with microbes. TLR are expressed in the gut, among circulating immune cells and in hepatocytes, but patients with chronic HBV are deficient in TLR activity. A healthy microbiome stimulates multiple toll-like receptors pathways, which may lead to HBV clearance. Preclinical models have shown that the microbiome's effect on HBV clearance requires functional TLR signaling. In murine models, gut microbiota depletion impairs the HBV-specific T-cell response, resulting in prolonged HBV infection, whereas stimulating TLR pathways enables hepatic expansion of HBV-specific cytotoxic CD8+ T cells, which eradicated HBV-infected hepatocytes during chronic infection, leading to viral clearance. A Complete Consortia product strategy is ideal to target this disease because patients have a community-level dysbiosis, which we believe CP101 has the potential to address.

Third-Party Clinical Data: As with recurrent CDI, there are several investigator-sponsored clinical studies in chronic HBV that have demonstrated encouraging proof-of-concept clinical outcomes following FMT. In these studies, patients experiencing poor disease control despite long-term antiviral therapy received FMT in addition to standard of care. In the first proof-of-concept study, HBeAg positive patients, a population with active viral replication, demonstrated a clinically meaningful 1-2 log reduction in HBeAg. Overall, there were significantly more participants in the FMT and antiviral therapy arm who had a decline in HBeAg titre (p=0.0002) and HBeAg clearance (p=0.0001) compared to participants receiving antiviral therapy alone, as shown in the below graph. Microbiome data also suggested a significant beneficial change in dysbiosis following treatment. Additional pilot studies comparing FMT and antiviral therapy compared to antiviral therapy alone have expanded upon these preliminary findings and report a meaningful reduction in HBV DNA and a decrease in HBsAg among HBeAg negative patients on long-term antiviral therapy.

These pilot studies demonstrate that delivery of a complete microbiome community may have therapeutic potential, and CP101 may help treat patients with chronic HBV by modulating the microbiome-immune interactions.

Proof-of-Concept Study Showed that FMT Induced HBeAg Clearance



Our Product Candidate: CP101

Based on the data we have generated with CP101 in recurrent CDI, where we have shown favorable clinical results as well as robust pharmacokinetic and pharmacodynamic characteristics that compare favorably to previous proof-of-concept experience with FMT, we believe that we will be able to translate the promising third-party results with FMT into a de-risked development opportunity for CP101. Building on these promising third-party FMT results, one objective is to determine if CP101 can drive HBeAg loss in HBeAg positive patients, a key sub-population who have poor clinical outcomes. An additional objective for this development program is a reduction in HBsAg. Pilot studies with FMT have demonstrated reductions in HBsAg, suggesting that CP101, when added to long-term antiviral therapy or other innovative products in development, may support a functional cure for chronic HBV.

Clinical Development of CP101 for the Treatment of Chronic HBV

Our clinical development strategy involves evaluating both HBeAg positive and HBeAg negative chronic HBV patients. Due to the favorable tolerability profile of CP101 in development to date, we plan to move directly into a Phase 1 clinical trial of patients with chronic HBV. As part of the Phase 1 clinical trial, we will assess CP101 in HBeAg positive and HBeAg negative patients without evidence of cirrhosis on standard-of-care antiviral therapy, and evaluate the safety, pharmacokinetics and pharmacodynamics including key clinically meaningful viral endpoints. We plan to initiate our clinical trial of CP101 in chronic HBV in mid-2021.

FIN-211 for the Treatment of Autism Spectrum Disorder

Overview

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

Indication Overview

ASD is a behaviorally defined condition characterized by reduced social interaction, impaired communication skills and the presence of repetitive or restrictive behaviors. Beyond the core symptoms by which it is defined, ASD is recognized as a heterogeneous medical condition by the FDA, and patients can exhibit highly varied symptoms and behaviors such as irritability, heightened sensitivities and movement disorders. A subset of patients with ASD, comprising at least 30% of the population, experience significant gastrointestinal symptoms, with the most common gastrointestinal symptom being constipation (ASD-C). There is a correlation between the severity of these gastrointestinal symptoms and the severity of behavioral symptoms. Standard treatments for constipation are often ineffective, which may be because the underlying biology of gastrointestinal symptoms is distinct in children with ASD compared to neurotypical children. Microbiome data suggests children with ASD that experience gastrointestinal symptoms have distinct community- and pathway-level dysbioses as compared to neurotypical children with gastrointestinal symptoms, and children with ASD-C have further differentiated microbiome profiles characterized by a decrease in microbiome diversity. We believe by addressing this underlying biology with a microbiome therapeutic, we will be able to improve ASD gastrointestinal symptom and neurobehavioral development.

The diagnosed prevalence of ASD is currently 1 in 54 for children in the United States, a prevalence that has increased substantially over the past few decades. Worldwide prevalence estimates vary but are thought to be similar in other developed countries. It is believed there are more than 4.6 million children and adults in the United States with ASD. By some estimates, the total financial burden of care for patients with ASD exceeds $100 billion in the United States annually.

Existing Therapeutics and Their Limitations

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

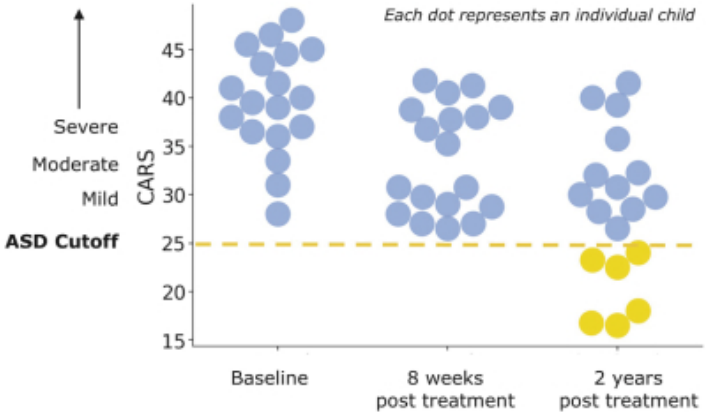
Rationale for Microbiome Therapeutics in ASD

Dysbiosis: Microbiome signals, epidemiological risk factors and gut symptoms all suggest a link between ASD and the microbiome. ASD is frequently accompanied by severe gastrointestinal manifestations, revealing symptoms more proximal to the activities of the gut microbiome. This sub-population of ASD in particular has a distinct microbiome: it is characterized by community-level dysbiosis, with lower diversity than neurotypical children who suffer from gastrointestinal symptoms. The microbiome of children with ASD and gastrointestinal symptoms is also distinct from other children with ASD that do not suffer from gastrointestinal symptoms. Moreover, the risk of developing ASD is significantly increased among children born by caesarean section or those exposed to multiple courses of antibiotics early in life. Mouse studies have demonstrated the ability to transfer ASD-like symptoms by transferring stool from humans with ASD. Conversely, certain ASD-mouse models have shown that ASD-like symptoms can be reduced by microbiome transfer from a neurotypical donor.

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

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

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



Our Product Candidate: FIN-211

FIN-211 is an orally administered, Enriched Consortia product candidate formulated into a pediatric-optimized lyophilized powder designed to deliver both a complete microbiome and targeted microbes not found in most healthy donors. Based on our understanding of the biology of ASD, we have identified species capable of inducing oxytocin production and improving gastrointestinal barrier function. We believe these strains may have important therapeutic benefits for individuals with ASD. These strains are not ubiquitous in healthy donors, so our Complete Consortia product strategy would not generally include these microbes. However, third-party studies have demonstrated that the ASD population has community-level dysbiosis that would not be corrected through a single strain or small group of strains alone. Accordingly, we have decided to pursue an Enriched Consortia product strategy that includes both strains targeting oxytocin-production and a complete microbiome to address community-level dysbiosis, which we believe best positions FIN-211 to potentially address both the gastrointestinal and behavioral symptoms of ASD.

Clinical Development of FIN-211 for the Treatment of ASD

We plan to initiate a Phase 1 clinical trial of FIN-211 in pediatric ASD patients (ages 5–17 years) with gastrointestinal symptoms in the second half of 2021, with topline data expected in the second half of 2022. Based on clinical FMT data and preclinical data with oxytocin-inducing strains, we believe FIN-211 is positioned to address both the gastrointestinal and behavioral symptoms of ASD. The FDA has indicated that either gastrointestinal or behavioral endpoints could support a biologics license application. Given the absence of FDA-approved therapies and building on our discussions with the FDA, we aim to continue to validate behavioral instruments as part of our clinical development plans. The focus of our initial development is gastrointestinal endpoints, which we believe are more objective and rapid, and therefore present a lower-risk initial clinical objective. As we advance, we plan to expand development of FIN-211 to pursue a label for behavioral endpoints. We believe FIN-211 can potentially address adults with ASD as well as both adults and children without gastrointestinal symptoms, expanding beyond our initial population of pediatrics with gastrointestinal symptoms where we expect to observe an enriched signal.

We believe this development strategy represents an attractive entry into the gut-brain axis, providing two opportunities to provide therapeutic benefit to patients with ASD, both for behavioral symptoms and lower-risk gastrointestinal endpoints. Furthermore, we believe that ASD could validate our microbiome-based approach to addressing additional gut-brain axis indications. We plan to leverage existing and emerging clinical

data from our academic collaborators to inform the development strategy of future product candidates to address additional neurological disorders that are associated with the gut-brain axis.

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

Overview

FIN-524 and FIN-525 are each orally administered Targeted Consortia product candidates designed for the treatment of ulcerative colitis (FIN-524) and Crohn's disease (FIN-525). We initially partnered with Takeda, a global leader in inflammatory bowel disease, or IBD, to develop FIN-524. FIN-524 comprises targeted strains, which do not require donors, identified by our Human-First Discovery platform. Following the achievement of certain preclinical milestones in the development of FIN-524 for ulcerative colitis, we recently expanded our development partnership with Takeda to include FIN-525, a differentiated product candidate for Crohn's disease that also comprises targeted strains identified by our Human-First Discovery platform. We are conducting initial discovery efforts on FIN-525, and Takeda may initiate a full development plan under our collaboration following its review of these data.

Indication Overview

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

Existing Therapeutics and Their Limitations

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

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

Rationale for Microbiome Therapeutics in IBD

Dysbiosis*:* Over the last decade, a number of lines of evidence have pointed to the promise of microbiome therapeutics in treating ulcerative colitis and Crohn's disease. Inflammatory bowel disease is one of the suite of chronic inflammatory diseases that has risen dramatically in prevalence in developed nations, and microbiome disrupting practices such as antibiotics are an important risk factor. Numerous studies have found that IBD patients have distinct pathway-level dysbiosis compared to matched healthy controls.

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

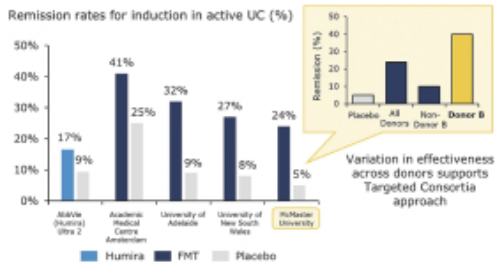
Third-Party Clinical Data: FMT studies in IBD were key in our decision to develop Targeted Consortia product candidates for ulcerative colitis and Crohn's disease. Data from over 40 FMT studies, including four randomized, placebo-controlled trials in ulcerative colitis and one randomized, placebo-controlled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

Our Product Candidates: FIN-524 and FIN-525

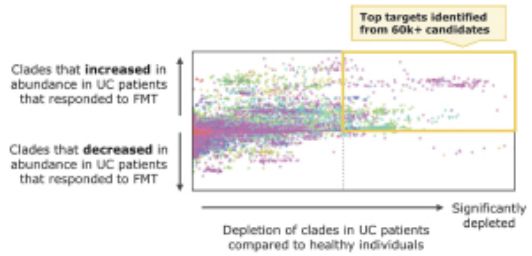
FIN-524 is a Targeted Consortia product candidate of nine bacterial strains selected for the treatment of ulcerative colitis, and is orally administered in a lyophilized formulation. This consortium was designed to target three specific modes of action: two kinds of immunoregulatory metabolites, each targeting a different set of host pathways, and donor strains linked to remission following FMT in patients with ulcerative colitis. FIN-525 is a discovery-stage program designing a Targeted Consortia product candidate for the treatment of Crohn's disease.

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

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



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



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

Clinical Development of FIN-524 for the Treatment of Ulcerative Colitis and FIN-525 for the Treatment of Crohn's Disease

In collaboration with Takeda, we expect to begin our clinical development strategy for the treatment of ulcerative colitis. We plan to initiate our first clinical trial of FIN-524 in ulcerative colitis in the first half of

2022. This trial will evaluate the safety and pharmacokinetics on FIN-524. In addition, we are conducting initial discovery efforts on FIN-525, and pending Takeda's review, we could initiate IND-enabling studies for FIN-525 in Crohn's disease in the second half of 2021.

Our Collaborations and License Agreements

Takeda Collaboration

In January 2017, we entered into an agreement, or the Takeda Agreement, with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of 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, 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 worldwide, exclusive license to a second microbiome therapeutic candidate, FIN-525.

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

Pursuant to the Takeda Agreement, we are primarily responsible for early-stage development activities pursuant to an agreed upon development plan and budget, including potentially through Phase 2 clinical trials, subject to Takeda's right to either co-develop a product with us at Phase 2 or assume responsibility for such development. After the successful completion of the first Phase 2 clinical trial for the applicable product candidate, Takeda will assume primary responsibility for the Phase 3 clinical trial for such product candidate. Initially, we are responsible for clinical supply of the relevant products; however, Takeda is required to assume responsibility for such manufacture and supply no later than six months after completion of the first Phase 2 clinical trial for the first FIN-524 product candidate or FIN-525 product candidate, as applicable. All such development and manufacturing activities will be overseen by certain joint committees. Takeda is responsible for up to 110% of our budgeted full-time equivalent costs in connection with our development activities as well as all costs related to chemistry, manufacturing and control development or other development costs incurred after the initial selection of an optimal microbial cocktail. Takeda is solely responsible for all commercial activities related to the FIN-524 and FIN-525 product candidates, at its cost.

We have agreed that prior to completion of the first Phase 2 clinical trial for the first FIN-524 product candidate being developed with the intention of seeking U.S. regulatory approval, other than as part of any development activities under the Takeda Agreement, we shall not engage in any research and development directed toward any product candidate for the treatment of IBD, or access or use certain fecal microbiota source material or any data generated from that material in IBD for any purpose. Additionally, we have agreed that prior to completion of the first Phase 2 clinical trial for the first FIN-525 product candidate being developed with the intention of seeking U.S. regulatory approval, other than as part of any development activities under the Takeda Agreement, we shall not engage in any research and development directed toward any product for the treatment of Crohn's disease, or access or use certain fecal microbiota source material or any data generated from that material in Crohn's disease for any purpose. We have also agreed for the remainder of the term of the Takeda

Agreement to certain restrictions on our access or use of certain bacterial strains having at least a threshold genetic relatedness to the strains incorporated into FIN-524 or FIN-525, our access or use of certain fecal microbiota source material, and our ability to conduct certain research and development directed toward products for the treatment of IBD and Crohn's disease that contain bacterial strains having less than a threshold genetic divergence from the bacterial strains in FIN-524 and FIN-525, respectively.

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

In connection with entering the Takeda Agreement, we received an upfront payment in the amount of $10.0 million. Additionally, we received $4.0 million in the aggregate for the achievement of certain development milestones for FIN-524 and are entitled to receive up to an additional $86.0 million in the aggregate upon achievement of certain remaining development and regulatory milestones for FIN-524 , up to $90.0 million in the aggregate upon achievement of certain commercial milestones for FIN-524, up to $87.7 million in the aggregate upon achievement of certain development and regulatory milestones for FIN-525, and up to $90.0 million in the aggregate upon achievement of certain commercial milestones for FIN-525, subject, with respect to FIN-525, to certain specified reductions based upon the nature of the FIN-525 product candidate and certain additional milestones to be negotiated by the parties. We are also entitled to receive up to $10.0 million for the first diagnostic product for each of FIN-524 and FIN-525, subject to certain reductions in the event that Takeda uses a third party to develop such diagnostic products. Pursuant to this agreement, Takeda is obligated to pay us a royalty on net sales of FIN-524 and FIN-525 products ranging from mid to high-single digits, subject to certain reductions. Such royalties are payable on a product-by-product and country-by-country basis, during the period beginning on the date of first commercial sale of such product in such country and ending on the later to occur of the expiration of the last-to-expire valid claim of any patents or patent applications controlled by us and licensed in such country that covers the composition of matter of such product, the date that regulatory exclusivity of such product expires in such country, or eight years from the date of the first commercial sale of such product in such country.

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

Exclusive License Agreement with Arizona State University

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

Pursuant to the terms of the Arizona State Agreement, we are obligated to use commercially reasonable efforts in connection with the development and commercialization of products and services, the manufacture, use, sale, offering for sale, importation or exportation of which, but for the license granted under the Arizona

State Agreement, would infringe one or more licensed patents, or licensed products. Such efforts are limited to the United States and include a specific performance milestone.

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

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

Exclusive Patent License Agreement with University of Minnesota

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

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

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

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

Competition

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

Any product candidates that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future. We are aware of a number of companies focused on developing microbiome therapeutics in various indications. For CP101, we are aware that Seres Therapeutics, Inc., Rebiotix Inc. and Vedanta Biosciences, Inc. each have a product candidate being evaluated in clinical trials for recurrent CDI. Any advances in microbiome therapies made by a competitor may be used to develop therapies that could compete against any of our product candidates.

We are aware of a number of large pharmaceutical and biotechnology companies, as well as smaller, early-stage companies, that are pursuing the development of products and disease indications we are targeting. These companies include AbbVie Inc., Arena Pharmaceuticals Inc., Bristol-Myers Squibb Company, Gilead Sciences, Inc., GlaxoSmithKline plc, Johnson & Johnson, Merck & Co., Inc., UCB S.A. and Vir Biotechnology, Inc. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others may be based on entirely different approaches.

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

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

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

Intellectual Property

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

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

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

Our patent portfolio leverages both offensive and defensive strategies to protect our business. We have a large and diverse patent portfolio consisting of more than 50 issued U.S. and foreign patents and more than 130 pending patent applications that we own or exclusively license from others. Our patent portfolio has broad applicability across the microbiome field, and provides protection for our lead product candidates CP101, FIN-211, FIN-524, FIN-525, as well as additional Complete, Enriched and Targeted Consortia product candidates that we may develop. For CP101 specifically, our patent portfolio includes more than ten U.S. patents that cover CP101 and methods of use and manufacture. These patents have expiration dates between 2031 and 2037.

Foundational Protection for Multiple Product Candidates

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

- We own a patent family that includes over ten issued U.S. patents, over five pending U.S. patent applications, granted foreign patents in Australia, Brazil, Canada, China, Israel, Mexico, New Zealand and Japan, and over five pending foreign patent applications. Representative issued U.S. patents in this family include U.S. 10,022,406, U.S. 9,962,413, U.S. 10,328,107, U.S. 10,278,997, and U.S. 10,617,724, that have claims directed to pharmaceutical compositions comprising stool

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

- We exclusively in-license a patent family from the Regents of the University of Minnesota that includes over five issued U.S. patents, one pending U.S. patent application, granted foreign patents in Australia, Europe and China, and two pending foreign patent applications. Representative issued U.S. patents within this family include U.S. 10,028,980, U.S. 10,286,011, U.S. 10,286,012, and U.S. 10,251,914, that have claims directed to formulations comprising fecal bacteria, methods of increasing fecal microbiota diversity, and methods of decreasing relative abundance of a bacteria. Patent applications, if issued, and patents in this family are expected to expire in 2032, assuming all required maintenance fees are paid and absent any applicable patent term extension or patent term adjustment.

- We own a patent family that includes over 15 issued U.S. patents, one pending U.S. patent application, and one granted foreign patent. Representative issued U.S. patents within this family include U.S. 8,460,648, U.S. 9,040,036, U.S. 9,050,358, U.S. 9,962,414, U.S. 9,468,658, U.S. 9,408,872, U.S. 9,320,763, U.S. 9,737,574, U.S. 9,572,841, U.S. 9,901,604, U.S. 9,867,858, U.S. 9,572,842, U.S. 9,610,308, U.S. 9,623,056, U.S. 9,682,108, U.S. 9,789,140, U.S. 10,369,175, and U.S. 10,772,919 that have claims directed to pharmaceutical compositions containing bacterial strains of the genus *Clostridium*, including specific bacterial strains within *Clostridium* clusters IV and XIVa, and related methods of use. Patent applications, if issued, and patents issuing from this family are expected to expire in 2021.

- We own a patent family that includes two issued U.S. patents U.S. 9,901,603 and U.S. 10,821,138, one pending U.S. patent application, a granted patent in Japan, and 11 pending foreign patent applications. These issued U.S. patents have claims directed to room temperature stable products containing human-derived bacteria. Patent applications, if issued, and patents in this family are expected to expire in 2036, assuming all required maintenance fees are paid and absent any applicable patent term extension or patent term adjustment.

Complete Consortia Product Candidates, including CP101

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

- One owned issued U.S. patent (U.S. 10,617,724) covering capsules containing lyophilized fecal microbiota from healthy donors, expected to expire in 2031.

- Three owned issued U.S. patents (U.S. 9,962,413, U.S. 10,328,107, and 10,849,937) covering the collection and processing of stool from healthy donors, expected to expire in 2031.

- One owned issued U.S. patent (U.S. 10,022,406) covering compositions comprising fecal microbiota derived from healthy donors, expected to expire in 2031.

- Four in-licensed issued U.S. patents (U.S. 10,028,980, U.S. 10,286,011, U.S. 10,286,012, and U.S. 10,251,914) covering formulations of fecal microbiota derived from healthy donors and their use, expected to expire in 2032.

- Two owned issued U.S. patents (U.S. 9,901,603 and U.S. 10,821,138) covering room-temperature stable products containing human-derived bacteria.

- One in-licensed issued U.S. patent (U.S. 10,849,936) covering a method of treating *C. difficile* infection using lyophilized fecal microbiota, expected to expire in 2037.

Targeted Consortia Product Candidates

For our Targeted Consortia product candidates and their manufacture, our portfolio consists of several issued U.S. patents from our foundational patent families that provide patent coverage. We are also pursuing product-specific patent protection for each of our Targeted Consortia product candidates including 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 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 are also pursuing patent protection for these Enriched Consortia product candidates specifically and have various pending applications directed to these product candidates. Representative patents and patent applications that have claims that cover our Enriched Consortia product candidates include:

- One owned issued U.S. patent (U.S. 10,022,406) covering compositions comprising fecal microbiota derived from healthy donors, expected to expire in 2031.

- Three owned issued U.S. patents (U.S. 9,962,413, U.S. 10,328,107, and 10,849,937) covering the collection and processing of stool from healthy donors, expected to expire in 2031.

- Two owned issued U.S. patents (U.S. 9,901,603 and U.S. 10,821,138) covering room temperature stable formulations containing human-derived bacteria, expected to expire in 2036.

- One in-licensed issued U.S. patent (U.S. 10,286,012) covering the use of formulations of fecal microbiota derived from healthy donors, expected to expire in 2032.

Patent Term

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

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

Trade Secrets

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

Agreements with OpenBiome

Asset Purchase Agreement

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

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

Pursuant to the OpenBiome Agreement, for the period prior to the closing of the transaction we granted OpenBiome a worldwide, non-exclusive license under certain of our intellectual property rights to make, use, sell, offer for sale, import and export certain Natural Products solely for the treatment of recurrent CDI in the United States under an FDA policy of enforcement discretion and to conduct clinical research in all fields other than the diagnosis, treatment, palliation or prevention in humans of CDI not subject to an FDA policy of enforcement discretion, IBD, ASD or HBV. Additionally, for the period beginning on the closing of the transaction, we granted OpenBiome a worldwide, non-exclusive license under certain of our intellectual property rights to sell certain Natural Products manufactured prior to the closing of the transaction solely for the treatment of recurrent CDI in the United States under enforcement discretion, and to make, use, sell, offer for sale, import and export certain Natural Products for purposes of conducting clinical research in all fields other than the diagnosis, treatment, palliation or prevention in humans of CDI not subject to an FDA policy of enforcement discretion, IBD, ASD or HBV. Notwithstanding the foregoing license, OpenBiome has agreed to certain

restrictions related to the use, sale and supply of such products in connection with clinical research of our competitors. Additionally, the license grant excludes any license to exploit a Natural Product wherein processed stool is lyophilized (such as in the case of CP101).

In connection with the signing of the OpenBiome Agreement, we paid OpenBiome $1.0 million in the form of an upfront payment and $150,000 as reimbursement for OpenBiome's attorneys' fees and expenses in connection the negotiation of the OpenBiome Agreement. On the closing of the transaction, we paid OpenBiome $2.25 million, plus an additional $1.6 million if no regulatory restrictions were in place preventing the sale and distribution of OpenBiome's products under enforcement discretion as of the date of closing. In addition to the foregoing payments, we are obligated to pay to OpenBiome a low single digit royalty on net sales of Natural Products by us and our affiliates and a high single digit royalty of certain sublicensing revenue (including royalties) received in connection with Natural Products, as well as a low single digit royalty on net sales of 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 and any future product candidates. We, along with third-party contractors, will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable regulatory requirements at any time during the product development process or post-approval may subject an applicant to delays in development or approval or licensure, as well as administrative or judicial sanctions.

Regulatory Approval of Biological Products in the United States

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

- completion of extensive preclinical laboratory and animal studies in accordance with applicable regulations, including studies conducted in accordance with the FDA's Good Laboratory Practice, or GLP, requirements;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin and must be updated annually and when certain changes are made;
- approval by an institutional review board, or IRB, or independent ethics committee at each clinical trial site before each clinical trial may be commenced;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, Good Clinical Practice, or GCP, requirements and other clinical trial-related regulations to establish the safety, purity and potency of the product candidate for each proposed indication;
- preparation and submission to the FDA of a biologics license application, or BLA, after completion of all clinical trials;
- payment of any user fees for FDA review of the BLA;

- a determination by the FDA within 60 days of its receipt of a BLA to accept the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the biological product, or components thereof, will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- satisfactory completion of any potential FDA audits of the clinical trial sites that generated the data in support of the BLA to assure compliance with GCPs and integrity of the clinical data; and
- FDA review and approval of the BLA, to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical Studies

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

Clinical Trials

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

There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about certain clinical trials, including clinical trial results, must be

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

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

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

- Phase 1 clinical trials generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the biological product candidate. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. The primary purpose of these clinical trials is to assess the safety, dosage tolerance, absorption, metabolism and distribution of the biological product candidate in humans, the side effects associated with increasing doses, and, if possible, early evidence of effectiveness.

- Phase 2 clinical trials generally involve studies conducted in a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide statistically significant evidence of clinical efficacy of the biological product candidate for its intended use, further evaluate its safety and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval and labeling. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the biological product candidate.

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

The FDA may, at any time while clinical trials are ongoing under the IND, impose a partial or complete clinical hold based on concerns for patient safety and/or noncompliance with regulatory requirements. This order issued by the FDA would delay a proposed clinical study or cause suspension of an ongoing study until all outstanding concerns have been adequately addressed, and the FDA has notified the company that investigations may proceed. Additionally, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including non-compliance with regulatory requirements or a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product candidate has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at

designated checkpoints based on access to certain data from the trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

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

Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the biological product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, companies must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over their shelf life.

FDA Review Processes of Biological Products

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

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

The FDA reviews a submitted BLA to determine if it is substantially complete before the FDA accepts it for filing and may request additional information from the sponsor. The FDA must make a decision on accepting a BLA for filing within 60 days of receipt, and may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission. In this event, the BLA must be resubmitted with any additional information requested. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. The FDA reviews a BLA to determine, among other things, whether the biological product candidate is safe, pure and potent and the facility in

which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. Under the goals agreed to by the FDA under PDUFA, the FDA has ten months, from the filing date, in which to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process can be extended by FDA requests for additional information or clarification. This review typically takes twelve months from the date the BLA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision. The review process and the PDUFA goal date for both standard and priority review BLAs may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission within the last three months before the PDUFA goal date.

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

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

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product is produced, it will issue either an approval letter or a Complete Response Letter, or CRL. If, because of travel restrictions during the COVID-19 pandemic, the FDA cannot complete any required pre-approval inspections, the FDA may issue a CRL or defer action on an application. An approval letter authorizes commercial marketing of the biological product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the BLA and may require additional clinical data, additional pivotal clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing in order for the FDA to reconsider the application for approval. If a CRL is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing. The FDA has committed to reviewing such resubmissions in two or six months from receipt, depending on the type of information included. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval.

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

one or more post-market clinical trials, sometimes referred to as Phase 4 clinical trials, and testing and surveillance programs to further assess and monitor the product's safety and effectiveness after approval, and may limit further marketing of the product based on the results of these post-marketing studies.

Orphan Drug Designation

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

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

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

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

Expedited Development and Review Programs

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

of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. Any product submitted to the FDA for approval, including under the Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval.

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

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

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

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

Pediatric Information and Exclusivity

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

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

Post-Approval Requirements for Biological Products

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

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

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market or product recalls;
- fines, warning or other enforcement-related letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product license approvals;

- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

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

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

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

U.S. Patent Term Restoration, Biosimilars and Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our biological product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However,

patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. In addition, a patent can only be extended once and only for a single product. The United State Patent and Trademark Office, or USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our patents, if and as applicable, to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

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

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

International Regulation

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

Coverage and Reimbursement

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

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

Outside of the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Further, the commercial success of any approved products will also depend in large part on the availability of insurance coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, and managed care organizations, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Moreover, coverage

policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. If government and other healthcare payors were not to provide adequate insurance coverage and reimbursement levels for one any of our products once approved, market acceptance and commercial success would be limited.

Other Healthcare Laws and Regulations and Legislative Reform

Healthcare Laws and Regulations

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

- the federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for, or to induce or reward either the referral of an individual for, or the purchase, lease, order or arrangement for, or recommendation of the purchase, lease, order, or arrangement for, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term “remuneration” has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Additionally, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, signed into law in 2010, provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- federal civil and criminal false claims laws, such as the False Claims Act, which can be enforced by private citizens through civil qui tam actions, and civil monetary penalty laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of or approval from the federal government, including Medicare, Medicaid and other government payors, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for

money or property presented to the U.S. government. Drug manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. For example, pharmaceutical companies have been prosecuted under the False Claims Act in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, among other things, imposes civil and criminal liability for knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense. HIPAA also creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which impose privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates and their covered subcontractors that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- the federal transparency requirements under the Physician Payments Sunshine Act, created under the ACA, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to (i) payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), and teaching hospitals and (ii) physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members. Effective January 1, 2022, these reporting obligations will extend to include information related to payments and other transfers of value provided in the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse midwives;

- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;

- state and foreign laws that are analogous to each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by non-governmental third-party payors, including private insurers, and state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and

- state and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other healthcare providers; state laws that require the reporting of marketing expenditures or drug pricing, including information pertaining to and justifying price increases; state and local laws that require the registration of pharmaceutical sales representatives; state laws that prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals; state laws that require the posting of information relating to clinical trials and their outcomes; and other federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

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

Legislative Reform

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

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

- increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program;

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

There remain judicial and congressional challenges to certain aspects of the ACA as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. For example, in 2017, the U.S. Congress enacted the Tax Cuts and Jobs Act of 2017, or Tax Act, which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, the U.S. District Court for the Northern District of Texas held that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed by the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the Supreme Court of the United States granted the petitions for writ of certiorari to review this case. On November 10, 2020, the Supreme Court then held oral arguments. It is unclear how this ruling, other litigation and the healthcare reform efforts of the Biden administration will impact the ACA. It is difficult to predict the future legislative landscape in healthcare and the effect on our business, results of operations, financial condition and prospects.

In addition, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. In 2011, the U.S. Congress enacted the Budget Control Act, which included provisions intended to reduce the federal deficit. The Budget Control Act resulted in the imposition of 2% reductions in Medicare payments to providers beginning in 2013 and, due to subsequent

legislative amendments to the statute, will remain in effect through 2030, absent additional congressional action. The Coronavirus Aid, Relief and Economic Security Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, and subsequent legislation, suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021, and extended the sequester by one year, through 2030. Proposed legislation, if passed, would extend this suspension until the end of the COVID-19 pandemic. In addition, in 2012, the U.S. Congress enacted the American Taxpayer Relief Act, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If government spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA, to continue to function at current levels, which may impact the ability of relevant agencies to timely review and approve research and development, manufacturing and marketing activities, which may delay our ability to develop, market and sell any product candidates we may develop. Moreover, any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented, or any significant taxes or fees that may be imposed on us, as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, could have an adverse impact on our anticipated product revenues.

Furthermore, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several congressional inquiries and proposed legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. At the federal level, the former Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the former Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses and place limits on pharmaceutical price increases. Further, the former Trump administration previously released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. However, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions after January 20, 2021.

Additionally, on July 24, 2020 and September 13, 2020, former President Trump announced several executive orders related to prescription drug pricing that seek to implement several of the former administration's proposals. As a result, the FDA released a final rule, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. However, in response to a lawsuit filed by several industry groups, on December 28, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction enjoining government defendants from implementing the MFN Rule pending completion of notice-and-comment procedures under the Administrative Procedure Act. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming

from the MFN Interim Final Rule shall not commence earlier than 60 days after publication of that regulation in the Federal Register. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our product candidates. The Interim Final Rule has not been finalized and is subject to revision and challenge. Moreover, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to an order entered by the U.S. District Court for the District of Columbia, the portion of the rule eliminating safe harbor protection for certain rebates related to the sale or purchase of a pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D has been delayed to January 1, 2023. Further, implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed.

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

Employees and Human Capital Resources

As of December 31, 2020, we had 131 employees, 34 of whom hold Ph.D. or M.D. degrees. Of these 131 employees, 103 are engaged in research and development activities and 28 are engaged in business development, finance, information systems, facilities, human resources or administrative support. None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our 2017 Equity Incentive Plan, as amended, is to attract, retain and motivate selected employees, consultants and directors through the granting of equity-based compensation awards.

Facilities

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. We believe that these facilities will be adequate for our near-term needs.

Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We do not have any pending litigation that, separately or in the aggregate, would, in the opinion of management, have a material adverse effect on our results of operations, financial condition or cash flows.

MANAGEMENT

The following table sets forth information concerning our executive officers and directors as of March 15, 2021.

Name	Age	Position(s)
Executive Officers		
Mark Smith, Ph.D.	34	Chief Executive Officer and Director
Gregory D. Perry	60	Chief Financial Officer
Zain Kassam, M.D., M.P.H.	39	Chief Medical Officer
Joseph Vittiglio	49	General Counsel and Corporate Secretary
Non-Employee Directors		
Chris Shumway	55	Chairman of the Board of Directors
Domenic Ferrante	55	Director
Nicholas Haft	32	Director
Christian Lange	41	Director
Jeffery A. Smisek	66	Director
Jo Viney, Ph.D.	55	Director

Executive Officers

Mark Smith, Ph.D. co-founded our company in November 2014 and has served as our Chief Executive Officer and as a member of our board of directors since August 2016. Dr. Smith is a recognized leader in the microbiome field, with over 50 peer-reviewed publications focused on the microbiome. From January 2012 until July 2016, Dr. Smith served as President and Research Director of OpenBiome, a nonprofit organization he co-founded for the purpose of expanding safe access to microbiota transplantation and catalyzing research into the human microbiome. He currently serves on the board of directors of Freya Biosciences, a privately-held biotechnology company. Dr. Smith has a B.A. in biology from Princeton University and a Ph.D. in microbiology from the Massachusetts Institute of Technology. Our board of directors believes that Dr. Smith's experience as our founder and Chief Executive Officer and his expertise in the field of microbiome therapies qualify him to serve on our board of directors.

Gregory D. Perry has served as our Chief Financial Officer since May 2018. Prior to joining us, from November 2016 to December 2017, Mr. Perry served as Chief Financial and Administrative Officer of Novelion Therapeutics Inc., or Novelion. Mr. Perry also served as Chief Financial Officer of Aegerion Pharmaceuticals Inc. from July 2015 until its merger with Novelion in November 2016. Prior to that, he served as Chief Financial and Business Officer of Eleven Biotherapeutics, Inc. from January 2014 to June 2015. In addition to these roles, Mr. Perry has held various financial leadership positions with numerous other public and private biotech companies, including InVivo Therapeutics Holdings Corp., ImmunoGen, Inc., Elixir Pharmaceuticals, Inc. and Transkaryotic Therapies, Inc. Since May 2016, Mr. Perry has served on the board of directors and as chair of the audit committee of Merus N.V., and since February 2018, he has served on the board of directors and as chair of the audit committee of Kala Pharmaceuticals, Inc. Mr. Perry previously served on the board of directors and as chair of the audit committee of Ocata Therapeutics, Inc. from December 2011 until its acquisition by Astellas Pharma Inc. in February 2016. Mr. Perry has a B.A. in economics and political science from Amherst College.

Zain Kassam, M.D., M.P.H. co-founded our company in November 2014 and has served as our Chief Medical Officer since September 2019. Before becoming our Chief Medical Officer, Dr. Kassam served as our Executive Vice President, Clinical Development & Translational Medicine from January 2018 to August 2019. From May 2014 to January 2018, Dr. Kassam was the Chief Medical Officer of OpenBiome, where as part of the founding team, he pioneered the application of the microbiome to treat disease. Dr. Kassam served as a member of the Scientific Advisory Board of the American Gastroenterological Association Center for Gut Microbiome Research & Education from 2016 to 2018, and has authored over 150 peer-reviewed publications, abstracts and

book chapters related to the microbiome. Dr. Kassam has an M.D. from Western University in Canada. He completed clinical training in internal medicine followed by a fellowship in gastroenterology both at McMaster University in Canada. He has an M.P.H. from Harvard University in quantitative methods, and completed post-doctoral training in microbiome engineering at the Massachusetts Institute of Technology.

Joseph Vittiglio has served as our General Counsel and Corporate Secretary since December 2020. From August 2015 to November 2020, Mr. Vittiglio held several positions at AMAG Pharmaceuticals, Inc., including most recently serving as its Executive Vice President, Chief Business Officer and General Counsel & Corporate Secretary. Previously, Mr. Vittiglio served as Vice President of Legal Affairs and a member of the Management Committee at Flexion Therapeutics, Inc. from March 2015 to August 2015. He also served as General Counsel and Secretary of AVEO Pharmaceuticals, Inc. from 2007 to March 2015 and as Director of Corporate Legal Affairs at Oscient Pharmaceuticals Corporation from 2005 to 2007. Mr. Vittiglio began his career as a corporate associate at Mintz, Levin, Cohn, Ferris, Glovsky and Popeo PC. Mr. Vittiglio has a B.A. in international relations from Tufts University and a J.D. from Northeastern University School of Law.

Non-Employee Directors

Chris Shumway has served on our board of directors since September 2020 and as chairman of our board of directors since March 2021. Mr. Shumway is an entrepreneur and investor who has invested in, advised and built growth businesses for over 25 years. He currently serves as the Managing Partner of Shumway Capital, a growth-focused investment firm he founded in 2001 that grew in assets to over $9 billion before converting into a family investment office in 2011. In 2015, Shumway Capital formed a predecessor microbiome company, Crestovo Holdings LLC, which combined with Finch Therapeutics, Inc. in a merger of equals in 2017. Prior to Shumway Capital, Mr. Shumway was a Senior Managing Director at Tiger Management. Mr. Shumway serves on various non-profit boards and also serves as a Visiting Scholar teaching global investing at the University of Virginia. Mr. Shumway has a B.S. from the University of Virginia and an M.B.A. from Harvard Business School. Our board of directors believes that Mr. Shumway's significant experience in advising high-growth companies qualifies him to serve on our board of directors.

Domenic Ferrante has served as a member of our board of directors since September 2019. Mr. Ferrante currently serves as Managing Partner and Chief Investment Officer of The Ferrante Group, an investment firm he founded in 2011. Prior to this, from 1993 to 2011, Mr. Ferrante held various positions at Bain Capital, including serving as a Managing Director for 12 years and as member of the firm's governing policy board. Earlier in his career, he worked at Brentwood Associates and Morgan Stanley. Mr. Ferrante earned a B.A. in economics from the University of Michigan and an M.B.A. from Harvard Business School. Our board of directors believes that Mr. Ferrante's financial expertise and extensive investment experience qualify him to serve on our board of directors.

Nicholas Haft has served as a member of our board of directors since February 2020. Since March 2020, Mr. Haft has served as Managing Director of OMX Ventures. Mr. Haft also serves as the Chief Executive Officer of Delix Therapeutics, Inc., a position he has held since September 2019. Mr. Haft previously served as managing director of Arcos Ventures, where he worked from April 2015 until March 2020. Mr. Haft currently serves on the boards of directors of multiple private companies in the life sciences industry. Mr. Haft has a B.S. from the Wharton School of the University of Pennsylvania. Our board of directors believes that Mr. Haft's experience as an investment professional in the life sciences sector qualifies him to serve on our board of directors.

Christian Lange has served as a member of our board of directors since September 2017. He also served on the board of directors of Crestovo Holdings LLC, which combined with Finch Therapeutics, Inc., from 2015 to 2017. Since September 2005, Mr. Lange has held various roles at Shumway Capital, including his current position as a Partner of the firm. In his role as Partner at Shumway Capital, Mr. Lange oversees the firm's

investment team and leads the firm's public and private investments. Prior to joining Shumway Capital, Mr. Lange previously worked at Bain Capital and Bain & Company. Mr. Lange currently serves on the boards of directors of various private companies. Mr. Lange has an A.B. from Harvard College. Our board of directors believes that Mr. Lange's financial expertise and his experience investing in public and private companies across a range of sectors qualify him to serve on our board of directors.

Jeffery A. Smisek has served as a member of our board of directors since February 2017. Mr. Smisek currently serves as President of Flight Partners Capital, an investment firm he founded in March 2002. From October 2010 to September 2015, Mr. Smisek served as President and Chief Executive Officer of United Airlines Holdings, Inc. (then United Continental Holdings, Inc.), also serving as chairman of its board of directors from December 2012 until September 2015. Prior to this, Mr. Smisek held various roles at Continental Airlines, Inc. beginning in 1995, last serving as President and Chief Executive Officer until the company's merger with United Airlines, Inc. Earlier in his career, Mr. Smisek was a partner at Vinson & Elkins L.L.P. Mr. Smisek currently serves on the boards of directors of various private companies and as a member of the board of trustees of Rice University. Mr. Smisek has an A.B. from Princeton University and a J.D. from Harvard Law School. Our board of directors believes that Mr. Smisek's experience overseeing publicly traded companies as an executive, board member and counsel qualifies him to serve on our board of directors.

Jo Viney, Ph.D. has served as a member of our board of directors since August 2019. Dr. Viney is a Co-Founder and has served as Chief Scientific Officer of Pandion Therapeutics, Inc. since April 2017, and as its President since July 2019. From November 2015 to November 2016, Dr. Viney served as Senior Vice President, Drug Discovery at Biogen Inc., after serving as Vice President, Immunology Research from July 2011 to October 2015. From September 2003 to April 2011, Dr. Viney served as Executive Director of Inflammation Research at Amgen, Inc., after serving as Director of Inflammation Research from July 2002 to August 2003. Dr. Viney has served on the board of directors of Harpoon Therapeutics, Inc. since July 2020, and has previously served and currently serves on the boards of directors of several private companies. Dr. Viney has a Ph.D. in immunology from the University of London, St. Bartholomew's Hospital Medical School and a B.Sc. from the University of East London. Our board of directors believes that Dr. Viney's substantial leadership experience in the biotechnology industry qualifies her to serve on our board of directors.

Board Composition

Our business and affairs are managed under the direction of our board of directors, which currently consists of seven members. Certain members of our board of directors were elected pursuant to the provisions of a voting agreement among certain of our major stockholders. The voting agreement will terminate upon the closing of this offering.

Our board of directors will consist of seven members upon the closing of this offering. Our amended and restated bylaws that will become effective immediately prior to the closing of this offering will provide that the authorized number of directors may be changed only by resolution approved by a majority of our board of directors.

Director Independence

Under the listing rules of the Nasdaq Stock Market LLC, or the Nasdaq Listing Rules, independent directors must comprise a majority of our board of directors within one year of listing as a public company.

Our board of directors has undertaken a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that all of our directors except Dr. Smith, representing six of our seven directors, do not have any relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the applicable rules and regulations of the SEC

and the Nasdaq Listing Rules. In making this determination, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director and the transactions involving them described in the section of this prospectus titled "Certain Relationships and Related Party Transactions."

Family Relationships

There are no family relationships among any of our executive officers or directors.

Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which will be reconstituted prior to the closing of this offering. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors.

Audit Committee

Upon the closing of this offering, our audit committee will consist of Domenic Ferrante, Nicholas Haft and Jeffery A. Smisek. The chair of our audit committee will be Mr. Ferrante. Our board of directors has determined that all members are independent under the Nasdaq Listing Rules and Rule 10A-3(b)(1) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our board of directors has determined that each member of our audit committee meets the financial literacy requirements as set forth in the Nasdaq Listing Rules. Our board of directors has also determined that Mr. Smisek is an "audit committee financial expert" as such term is currently defined in Item 407(d)(5) of Regulations S-K. In arriving at these determinations, the board of directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

The audit committee is responsible for assisting our board of directors in its oversight of the integrity of our consolidated financial statements, the qualifications and independence of our independent auditors and our internal financial and accounting controls. The principal duties and responsibilities of our audit committee will include, among other things:

- selecting a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- helping to ensure the independence and performance of the independent registered public accounting firm;

- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing our policies on risk assessment and risk management;
- reviewing related party transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes our internal quality-control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
- approving (or, as permitted, pre-approving) all audit and all permissible non-audit services, other than de minimis non-audit services, to be performed by the independent registered public accounting firm.

Our audit committee will operate under a written charter, to be effective immediately prior to the closing of this offering, which satisfies the applicable rules and regulations of the SEC and the Nasdaq Listing Rules.

Compensation Committee

Upon the closing of this offering, our compensation committee will consist of Christian Lange, Chris Shumway, Jeffery A. Smisek and Jo Viney, Ph.D. The chair of our compensation committee will be Mr. Smisek. Our board of directors has determined that all members are independent under the Nasdaq Listing Rules and are "non-employee directors" as defined in Rule 16b-3 promulgated under the Exchange Act.

The compensation committee oversees the compensation objectives for the company and the compensation of the chief executive officer and other executives. The principal duties and responsibilities of our compensation committee will include, among other things:

- reviewing and recommending to our board of directors the compensation of our executive officers, including evaluating the performance of our chief executive officer and, with his assistance, that of our other executive officers;
- reviewing and recommending to our board of directors the compensation of our directors;
- reviewing and approving, or recommending that our board of directors approves, the terms of compensatory arrangements with our executive officers;
- administering our equity and non-equity incentive plans;
- reviewing and approving, or recommending that our board of directors approves, incentive compensation and equity plans; and
- reviewing and establishing general policies relating to compensation and benefits of our employees and reviewing our overall compensation philosophy.

Our compensation committee will operate under a written charter, to be effective immediately prior to the closing of this offering, which satisfies the applicable rules and regulations of the SEC and the Nasdaq Listing Rules.

Nominating and Corporate Governance Committee

Upon the closing of this offering, our nominating and corporate governance committee will consist of Christian Lange, Chris Shumway, Jeffery A. Smisek and Jo Viney, Ph.D. The chair of our nominating and corporate governance committee will be Mr. Lange. Each member of the nominating and corporate governance committee is a non-employee director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act, an independent director as defined by the Nasdaq Listing Rules and is free from any relationship that would interfere with the exercise of his or her independent judgment, as determined by the board of directors in accordance with the applicable Nasdaq Listing Rules.

The nominating and corporate governance committee oversees our corporate governance policies and evaluates the composition of our board of directors and candidates for director. The nominating and corporate governance committee's responsibilities will include, among other things:

- identifying, evaluating and selecting, or recommending that our board of directors approves, nominees for election to our board of directors and its committees;
- evaluating the performance of our board of directors and of individual directors;
- considering and making recommendations to our board of directors regarding the composition of our board of directors and its committees;
- reviewing developments in corporate governance practices;
- evaluating the adequacy of our corporate governance practices and reporting;
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters; and
- overseeing an annual evaluation of the board's performance.

Our nominating and governance committee will operate under a written charter, to be effective immediately prior to the closing of this offering, which satisfies the applicable rules and regulations of the SEC and the Nasdaq Listing Rules.

Code of Business Conduct and Ethics

In connection with this offering, our board of directors has adopted a Code of Business Conduct and Ethics, or the Code of Ethics, applicable to all of our employees, executive officers and directors. Following the closing of this offering, the Code of Ethics will be available on our website at www.finchtherapeutics.com. The nominating and corporate governance committee will be responsible for overseeing the Code of Ethics and must approve any waivers of the Code of Ethics for our employees, executive officers and directors. We expect that any amendments to the Code of Ethics, or any waivers of its requirements, will be disclosed on our website. Information contained in, or accessible through, our website does not constitute a part of, and is not incorporated into, this prospectus.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently, or has been at any time, one of our executive officers or employees. None of our executive officers currently serves, or has served during the last year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or on our compensation committee.

Non-Employee Director Compensation

Historically, we have not had a formal compensation policy with respect to service on our board of directors. We have reimbursed and will continue to reimburse our non-employee directors for their reasonable out-of-pocket expenses incurred in attending board and committee meetings. In connection with this offering, our board of directors has adopted a formal director compensation policy for non-employee directors to be effective following the completion of this offering.

Non-Employee Director Compensation Policy

In February 2021, following market research and advice from its compensation consultant, our board of directors adopted the non-employee director compensation policy, to be effective immediately upon the closing of this offering.

Cash Compensation

Under this policy, we will pay each of our non-employee directors a cash retainer for service on our board of directors and committees of our board of directors. Our non-executive chairperson will also receive an additional cash retainer. These retainers will be payable in arrears in four equal quarterly installments within thirty days after the end of each calendar quarter, provided that the amount of such payment will be prorated for any portion of such quarter that the director is not serving on our board. We will also reimburse our directors for their reasonable out-of-pocket expenses in connection with attending our board and committee meetings.

Directors will be eligible to receive cash compensation as follows:

	Annual Cash Retainer ($)
Annual Retainer	35,000
Additional Retainer for Non-Executive Chairperson of the Board	30,000
Annual Retainer for Audit Committee Member	7,500
Additional Retainer for Audit Committee Chairperson	15,000
Annual Retainer for Compensation Committee Member	5,000
Additional Retainer for Compensation Committee Chairperson	10,000
Annual Retainer for Nominating and Corporate Governance Committee Member	4,000
Additional Retainer for Nominating and Corporate Governance Committee Chairperson	8,000

Equity Compensation

In addition to cash compensation, each non-employee director will be eligible to receive options under the 2021 Plan. Each option granted under the policy will be a nonstatutory stock option and will have an exercise price per share equal to the fair market value of a common share on the date of grant. Any options granted under this policy will have a term of ten years from the date of grant, subject to earlier termination in connection with a termination of the eligible director's continuous service with us. Vesting schedules for equity awards will be subject to the non-employee director's continuous service on each applicable vesting date.

Upon the termination of the membership of the non-employee director on the board for any reason, his or her options granted under this policy shall remain exercisable for three months following his or her date of termination (or such longer period as the board may determine in its discretion on or after the date of grant of such options).

Notwithstanding any vesting schedule, for each non-employee director who remains in continuous service with us until immediately prior to the closing of a change in control (as such term is defined in our 2021 Plan), the shares subject to his or her then-outstanding initial or annual equity awards that were granted pursuant to this policy will become fully vested immediately prior to the closing of such change in control.

Initial Award. Each new non-employee director who first joins our board of directors after the date of the execution of the underwriting agreement related to this offering will automatically, upon the date of his or her initial election or appointment to be a non-employee director, be granted an initial, one-time equity award of options to purchase with a grant date fair value of $200,000, referred to as the initial grant. One-third of each initial grant will vest on the first anniversary of the date of grant, with the remainder vesting in equal monthly installments thereafter until the third anniversary of the date of grant.

Annual Awards. On the date of each annual meeting of our shareholders following the closing of this offering, each non-employee director that continues to serve will automatically be granted either an option to purchase common stock with a grant date fair value of $100,000, each of which will vest in equal monthly installments over the 12 months following the date of grant, subject to (i) the non-employee director's continuous service through each applicable vesting date and (ii) that no annual award will be granted to a non-employee director in the same calendar year that such director received his or her initial grant.

Director Compensation Table

The following table sets forth information regarding compensation earned by or paid to our non-employee directors for the year ended December 31, 2020. Dr. Smith, our Chief Executive Officer, who is also a member of our board of directors, did not receive any additional compensation for service as a director. Dr. Smith compensation as a named executive officer is set forth below under "Executive Compensation—Summary Compensation Table."

Name	Fees Earned or Paid in Cash	Option Awards(1)(2)	Total
Chris Shumway	$ —	$ —	$ —
Domenic Ferrante	—	—	—
Nicholas Haft	—	—	—
Christian Lange	—	—	—
Jeffery A. Smisek	—	—	—
Jo Viney, Ph.D.	25,000	—	25,000

(1) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted during fiscal year 2020 computed in accordance with ASC 718. Assumptions used in the calculation of these amounts are included in the notes to our audited consolidated financial statements included elsewhere in this prospectus. These amounts do not reflect the actual economic value that will be realized by our non-employee directors upon the vesting of the options, the exercise of the options or the sale of the common stock underlying such options.

(2) The following table provides information regarding the number of shares of common stock underlying options held by our non-employee directors that were outstanding as of December 31, 2020:

Name	Option Awards Outstanding at Year End
Chris Shumway	—
Domenic Ferrante	—
Nicholas Haft	—
Christian Lange	—
Jeffery A. Smisek	—
Jo Viney, Ph.D.	13,846

EXECUTIVE COMPENSATION

Our named executive officers for the year ended December 31, 2020, consisting of our principal executive officer and the next two most highly compensated executive officers, were:

- Mark Smith, Ph.D., our Chief Executive Officer and Director;
- Zain Kassam, M.D., M.P.H., our Chief Medical Officer; and
- Gregory D. Perry, our Chief Financial Officer.

Summary Compensation Table

The following table presents all of the compensation awarded to or earned by or paid to our named executive officers for the year ended December 31, 2020.

Name and Principal Position	Salary ($)(1)	Bonus $(2)	Non-Equity Incentive Plan Comp. ($)(3)	All Other Comp. ($)	Total ($)
Mark Smith, Ph.D.(4) *Chief Executive Officer and Director*	418,000	8,000	209,000	9,520(5)	644,520
Zain Kassam, M.D., M.P.H. *Chief Medical Officer*	403,400	10,000	195,600	9,535(6)	618,535
Gregory D. Perry *Chief Financial Officer*	387,600	19,000	116,280	58,430(7)	581,310

(1) Salary amounts represent actual amounts paid during 2020. See "—Narrative to the Summary Compensation Table—Annual Base Salary" below.
(2) Reflects retention bonuses awarded to each of our named executive officers.
(3) Reflects performance-based cash bonuses awarded to our named executive officers. See "—Non-Equity Incentive Plan Compensation" below for a description of the material terms of the program pursuant to which this compensation was awarded.
(4) Dr. Smith is also a member of our board of directors but does not receive any additional compensation in his capacity as a director.
(5) Represents (i) contributions to a retirement account in the amount of $8,550, (ii) life insurance premiums we paid for Dr. Smith in the amount of $720 and (iii) a one-time home-office stipend in the amount of $250.
(6) Represents (i) contributions to a retirement account in the amount of $8,550, (ii) life insurance premiums we paid for Dr. Kassam in the amount of $735 and (iii) a one-time home-office stipend in the amount of $250.
(7) Represents (i) an annual housing stipend in the amount of $48,000, (ii) contributions to a retirement account in the amount of $8,550, (iii) life insurance premiums we paid for Mr. Perry in the amount of $1,630 and (iv) a one-time home-office stipend in the amount of $250.

Narrative to Summary Compensation Table

Our board of directors reviews compensation annually for all employees, including our named executive officers. In setting executive base salaries and bonuses and granting equity incentive awards, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders and a long-term commitment to our company.

The board of directors has historically determined the compensation of our executives, upon recommendation of the compensation committee. The compensation committee has reviewed and recommended to the board for approval the compensation and other terms of employment of our chief executive officer, and evaluates the chief executive officer's performance in light of relevant corporate goals and objectives. Our chief executive officer has typically discussed his recommendations for all other executives (other than himself) with the compensation committee and the board. Based on those discussions and its discretion, the compensation committee has recommended the compensation of each executive officer to the board, and the board of directors has then approved.

Annual Base Salary

The annual base salaries of our named executive officers are generally reviewed, determined and approved by the board of directors periodically upon the recommendation of the compensation committee in order to compensate our named executive officers for the satisfactory performance of duties to our company. Annual base salaries are intended to provide a fixed component of compensation to our named executive officers, reflecting their skill sets, experience, roles and responsibilities. Base salaries for our named executive officers have generally been set at levels deemed necessary to attract and retain individuals with superior talent.

The following table sets forth the annual base salaries for each of our named executive officers for 2020 and 2021, as determined by the board of directors upon the recommendation of the compensation committee:

Name	2020 Base Salary ($)	2021 Base Salary ($)
Mark Smith, Ph.D.(1) *Chief Executive Officer and Director*	418,000	525,000
Zain Kassam, M.D., M.P.H.(2) *Chief Medical Officer*	416,000	436,000
Gregory Perry(3) *Chief Financial Officer*	387,600	396,000

(1) Dr. Smith's base salary was increased from $176,000 to $418,000 in July 2019, from $418,000 to $525,000 in February 2021.
(2) Dr. Kassam's base salary was increased from $363,000 to $416,000 in March 2020, and from $416,000 to $436,000 in February 2021.
(3) Mr. Perry's base salary was increased from $387,600 to $396,000 in February 2021.

Non-Equity Incentive Plan Compensation

In accordance with the terms of their respective employment agreements, our named executive officers are eligible to receive discretionary annual bonuses of up to a percentage of each executive's gross base salary based on individual performance, company performance or as otherwise determined appropriate, as determined by the compensation committee of our board of directors.

Name	2020 Bonus Target (%)	2021 Bonus Target (%)
Mark Smith, Ph.D. *Chief Executive Officer and Director*	50	50
Zain Kassam, M.D., M.P.H.(1) *Chief Medical Officer*	35	40
Gregory Perry(2) *Chief Financial Officer*	30	40

(1) Dr. Kassam's 2020 bonus target percentage was increased from 30% to 35% in March 2020. Dr. Kassam's 2021 bonus target percentage was increased from 35% to 40% in February 2021.
(2) Mr. Perry's 2021 bonus target percentage was increased from 30% to 40% in February 2021.

In addition to the percentage-based bonus discussed above, Dr. Kassam received a bonus of $50,000 in 2020 in connection with the achievement of certain clinical milestones related to our PRISM3 clinical trial.

Outstanding Equity Awards as of December 31, 2020

The following table sets forth certain information about equity awards granted to our named executive officers that remained outstanding as of December 31, 2020.

			Option Awards(1)			
Name	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price per Share ($)	Option Expiration Date
Gregory D. Perry *Chief Financial Officer*	5/7/2018	5/7/2018	170,874	133,380(2)	$ 2.46	5/6/2028

(1) All of the option awards were granted under our 2017 Equity Incentive Plan, as amended, or the 2017 Plan, the terms of which are described below under "—Employee Benefit Plans."
(2) The option award vests as follows: (i) 66,145 shares of common stock underlying this option vested and became exercisable on the one-year anniversary of the vesting commencement date, (ii) 198,434 shares of common stock underlying this option will vest in 36 equal monthly installments thereafter for a period of three years and (iii) 39,675 shares of common stock underlying this option will vest in 24 equal monthly installments thereafter for a period of two years, subject to Mr. Perry's continued service through each vesting date.

Equity Awards Relating to the Completion of this Offering

On March 12, 2021, our board of directors approved grants of an aggregate of 815,214 options under our 2021 Equity Incentive Plan, or 2021 Plan, to our named executive officers and certain of our other employees, contingent and effective upon the execution of the underwriting agreement for this offering, with an exercise price equal to the initial public offering price per share. Of these option grants, an aggregate of 720,020 options will be granted to our named executive officers, including 595,402 options to Dr. Smith, 69,232 options to Dr. Kassam and 55,386 options to Mr. Perry. The options to be awarded to our named executive officers will vest over a four-year period, with 25% of the shares subject to the option vesting on the first anniversary of the vesting commencement date (which will be the date of the underwriting agreement), with the remainder vesting monthly in equal installments over the following 36 months such that the options will vest in full on the fourth anniversary of the vesting commencement date, subject to the executive's continuous service with us as of each such vesting date.

Employment Arrangements with our Named Executive Officers

We have entered into employment agreements with each of our named executive officers that will become effective upon the execution of the underwriting agreement for this offering, copies of which are filed as exhibits to this registration statement. The agreements set forth the terms and conditions of each executive's employment with us, including base salary, bonus opportunity, eligibility for employee benefits and severance benefits upon a qualifying termination of employment, and certain non-solicitation and non-competition provisions. Any potential payments and benefits due upon a qualifying termination of employment or a change in control are further described below under "— Potential Payments and Benefits upon Termination or Change in Control."

The employment of each of our named executive officers may be terminated at any time in accordance with the terms of the respective agreements. The material terms of each agreement are described below.

Mark Smith, Ph.D. We entered into an employment agreement with Dr. Smith in September 2017, effective September 21, 2017, in connection with his appointment as our President and Chief Executive Officer. In March 2021, we entered into a new employment agreement with Dr. Smith which will become effective upon the execution of the underwriting agreement for this offering. Pursuant to his March 2021 employment

agreement, Dr. Smith will be entitled to an annual base salary of $525,000, an annual target bonus with a target amount equal to 50% of his annual base salary and certain severance benefits, as described below under "—Potential Payments and Benefits upon Termination or Change of Control." Dr. Smith must be employed by us at the time of any such bonus payment in order to be eligible for any such payment. Under the March 2021 employment agreement, we agreed to grant Dr. Smith an option to acquire 595,402 common shares pursuant to the 2021 Plan, contingent and effective upon the execution of the underwriting agreement for this offering, with an exercise price equal to the initial public offering price. The options will vest over a four-year period, with 25% of the shares vesting on the one-year anniversary of the grant date, with the remainder vesting monthly in equal installments over the following 36 months such that the options will vest in full on the four-year anniversary of the grant date, subject to Dr. Smith's continuous employment as of such vesting dates. Dr. Smith is also eligible for additional equity awards under our equity compensation plans, as may be granted from time to time. Dr. Smith has also agreed not to sell or transfer any of our common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, or the affiliate securities, for a period of 12 months after the date of this this prospectus. During the 12 months following the first anniversary of the date of this prospectus, Dr. Smith may sell no more than 10% of the affiliate securities. These restrictions apply whether or not Dr. Smith is employed by us or otherwise providing service to us. Following the second anniversary after the date of this prospectus, there will be no restrictions on Dr. Smith's ability to sell or transfer any affiliate securities.

Zain Kassam, M.D., M.P.H. We entered into an employment agreement with Dr. Kassam in September 2017, effective September 21, 2017, in connection with his appointment as our Chief Scientific Officer and Vice President of Clinical Development. In March 2021, we entered into a new employment agreement with Dr. Kassam, whereby he will continue to serve as our Chief Medical Officer and which will become effective upon the execution of the underwriting agreement for this offering. Pursuant to his March 2021 employment agreement, Dr. Kassam will be entitled to an annual base salary of $436,000, an annual target bonus with a target amount equal to 40% of his annual base salary and certain severance benefits, as described below under "—Potential Payments and Benefits upon Termination or Change of Control." Dr. Kassam is also eligible to earn a bonus of $20,000, less applicable withholdings, based on us finalizing, in calendar year 2021, our clinical study report for the pivotal clinical trial referred to as PRISM3. Dr. Kassam must be employed by us at the time of any such bonus payment in order to be eligible for any such payment. Under the March 2021 employment agreement, we agreed to grant Dr. Kassam an option to acquire 69,232 common shares pursuant to the 2021 Plan, contingent and effective upon the execution of the underwriting agreement for this offering, with an exercise price equal to the initial public offering price. The options will vest over a four-year period, with 25% of the shares vesting on the one-year anniversary of the grant date, with the remainder vesting monthly in equal installments over the following 36 months such that options will vest in full on the four-year anniversary of the grant date, subject to Dr. Kassam's continuous employment as of such vesting dates. Dr. Kassam is also eligible for additional equity awards under our equity compensation plans, as may be granted from time to time.

Gregory D. Perry We entered into an employment agreement with Mr. Perry in May 2018, effective May 1, 2018, in connection with his appointment as our Chief Financial Officer. In March 2021, we entered into a new employment agreement with Mr. Perry which will become effective upon the execution of the underwriting agreement for this offering. Pursuant to his March 2021 employment agreement, Mr. Perry will be entitled to an annual base salary of $396,000, an annual target bonus with a target amount equal to 40% of his annual base salary and certain severance benefits, as described below under "—Potential Payments and Benefits upon Termination or Change of Control." Mr. Perry must be employed by us at the time of any such bonus payment in order to be eligible for any such payment. Under the March 2021 employment agreement, we agreed to grant Mr. Perry an option to acquire 55,386 common shares pursuant to the 2021 Plan, contingent and effective upon the execution of the underwriting agreement for this offering, with an exercise price equal to the initial public offering price. The options will vest over a four-year period, with 25% of the shares vesting on the one-year anniversary of the grant date, with the remainder vesting monthly in equal installments over the following 36 months such that it will vest in full on the four-year anniversary of the grant date, subject to Mr.

Perry's continuous employment as of such vesting dates. Mr. Perry is also eligible for additional equity awards under our equity compensation plans, as may be granted from time to time.

Potential Payments and Benefits upon Termination or Change in Control

Regardless of the manner in which the executive's service with us terminates, each of Dr. Smith, Dr. Kassam and Mr. Perry is entitled to receive amounts earned during his term of service, including unpaid salary, accrued but unused vacation and any vested entitlements under any employee benefit plan. Pursuant to the employment agreements we entered into with each of Dr. Smith, Dr. Kassam and Mr. Perry in March 2021, which will become effective upon the execution of the underwriting agreement for this offering, each executive will be entitled to the following payments and benefits upon a qualifying termination of employment or a change in control. The terms of "cause," "disability" and "good reason" are each defined in the respective amended and restated employment agreements.

If the executive is terminated by us involuntarily without "cause" and not due to death or "disability" or the executive resigns for "good reason," in each case, not in connection with a "change in control" (as defined in the 2021 Plan), then:

- With respect to Dr. Smith, he shall be entitled to (1) cash severance equal to 12 months of base salary, paid in 12 equal monthly installments; (2) the same life, accident, health and dental insurance benefits, if any, that the executive was receiving immediately prior to the termination of employment for up to 12 months, provided, that if the executive's continued participation is not possible under the terms of any one or more of those insurance plans, and if the executive was participating in our group health plan immediately prior to the date of termination and timely elects COBRA health continuation, then we shall pay to the executive a monthly payment in a gross amount equal to the COBRA premium for up to 12 months; and (3) any unpaid annual bonus that is earned and payable and approved by the board of directors.

- With respect to Dr. Kassam and Mr. Perry, the executive shall be entitled to (1) cash severance equal to nine months of base salary, paid in nine equal monthly installments; (2) the same life, accident, health and dental insurance benefits, if any, that the executive was receiving immediately prior to the termination of employment for up to 12 months, provided, that if the executive's continued participation is not possible under the terms of any one or more of those insurance plans, and if the executive was participating in our group health plan immediately prior to the date of termination and timely elects COBRA health continuation, then we shall pay to the executive a monthly payment in a gross amount equal to the COBRA premium for up to 12 months; and (3) any unpaid annual bonus that is earned and payable and approved by the board of directors.

If within 12 months following a change in control, either of Dr. Smith, Dr. Kassam and Mr. Perry is terminated by us (or a successor) involuntarily without "cause" and not due to death or "disability" or the executive resigns for "good reason," then:

- With respect to Dr. Smith, he shall be entitled to (1) cash severance equal to 18 months of base salary, paid in 12 equal monthly installments; (2) the same life, accident, health and dental insurance benefits, if any, that the executive was receiving immediately prior to the termination of employment for up to 18 months, provided, that if the executive's continued participation is not possible under the terms of any one or more of those insurance plans, and if the executive was participating in our group health plan immediately prior to the date of termination and timely elects COBRA health continuation, then we shall pay to the executive a monthly payment in a gross amount equal to the COBRA premium for up to eighteen months; (3) any unpaid annual bonus that is earned and payable and approved by the board of directors; (4) a lump sum

payment equal to his target bonus pro-rated for the calendar year of termination; and (5) any equity awards with respect to our stock then held by the Dr. Smith which vest based on continued service shall become fully vested and exercisable as of the date of such termination.

- With respect to Dr. Kassam and Mr. Perry, the executive will be entitled to (1) cash severance equal to 12 months of base salary, paid in 12 equal monthly installments; (2) the same life, accident, health and dental insurance benefits, if any, that the executive was receiving immediately prior to the termination of employment for up to 12 months, provided, that if the executive's continued participation is not possible under the terms of any one or more of those insurance plans, and if the executive was participating in our group health plan immediately prior to the date of termination and timely elects COBRA health continuation, then we shall pay to the executive a monthly payment in a gross amount equal to the COBRA premium for up to 12 months; (3) any unpaid annual bonus that is earned and payable and approved by the board of directors; (4) a lump sum payment equal to his target bonus pro-rated for the calendar year of termination; and (5) any equity awards with respect to our stock then held by the executive which vest based on continued service shall become fully vested and exercisable as of the date of such termination.

Dr. Smith's, Dr. Kassam's and Mr. Perry's severance payments and benefits under the employment agreements to become effective upon the execution of the underwriting agreement for this offering are, in the case of a termination by executive for good reason, conditioned on the executive, among other things, giving notice following a cure period (as applicable), complying with post-resignation or post termination obligations under the applicable agreement, including any non-disparagement and confidentiality obligations contained therein, and signing a general release of claims against us.

Further, in the event that executive's employment terminates for "cause" or the executive terminates his employment for any reason other than "good reason" (including due to death or "disability"), then:

- With respect to Dr. Smith, Dr. Kassam and Mr. Perry, the executive shall not be entitled to any severance benefits or other considerations; provided that, if we do not waive the non-competition provisions of the executive's employment agreement in connection with such termination, we will pay executive an amount equal to the sum of six times his monthly base salary (at the monthly base salary rate in effect for the executive immediately prior to the termination of his employment), except to the extent such termination arises from executive's breach of his fiduciary duty or theft of company property (whether physical or electronic).

Employee Benefit Plans

The principal features of our equity plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus is a part.

2021 Equity Incentive Plan

In March 2021, our board of directors adopted, and our stockholders approved, our 2021 Plan. The 2021 Plan will become effective on the date of the underwriting agreement related to this offering. No grants will be made under the 2021 Plan prior to its effectiveness. Once the 2021 Plan becomes effective, no further grants will be made under the 2017 Plan.

Awards. Our 2021 Plan will provide for the grant of incentive stock options, or ISOs, within the meaning of Section 422 of the Code to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit, or RSU, awards, performance awards and other forms of awards to employees, directors and consultants, including employees and consultants of our affiliates.

Authorized Shares. Initially, the maximum number of shares of our common stock that may be issued under our 2021 Plan after it becomes effective will not exceed 5,291,446 shares of our 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 our common stock subject to outstanding stock options or other stock awards granted under our 2017 Plan that, on or after the 2021 Plan becomes 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 our common stock reserved for issuance under our 2021 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2022 through January 1, 2031, in an amount equal to (i) 5.0% of the total number of shares of our 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 our board of directors prior to the applicable January 1. The maximum number of shares of our common stock that may be issued on the exercise of ISOs under our 2021 Plan will be 14,100,000 shares.

Shares subject to stock awards granted under our 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 our 2021 Plan. Shares withheld under a stock award to satisfy the exercise, strike or purchase price of a stock award or to satisfy a tax withholding obligation will not reduce the number of shares available for issuance under our 2021 Plan. If any shares of our common stock issued pursuant to a stock award are forfeited back to or repurchased or reacquired by us (1) because of a failure to meet a contingency or condition required for the vesting of such shares, (2) to satisfy the exercise, strike or purchase price of an award or (3) to satisfy a tax withholding obligation in connection with an award, the shares that are forfeited or repurchased or reacquired will revert to and again become available for issuance under the 2021 Plan. Any shares previously issued which are reacquired in satisfaction of tax withholding obligations or as consideration for the exercise or purchase price of a stock award will again become available for issuance under the 2021 Plan.

Plan Administration. Our board of directors, or a duly authorized committee of our board of directors, will administer our 2021 Plan and is referred to as the “plan administrator” herein. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees (other than officers) to receive specified stock awards and (2) determine the number of shares subject to such stock awards. Under our 2021 Plan, our board of directors will have the authority to determine award recipients, grant dates, the numbers and types of stock awards to be granted, the applicable fair market value, and the provisions of each stock award, including the period of exercisability and the vesting schedule applicable to a stock award.

The plan administrator will have the power to modify outstanding awards under our 2021 Plan. Subject to the terms of our 2021 Plan, the plan administrator will have the authority to reprice any outstanding stock award, cancel and re-grant any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

Stock Options. ISOs and NSOs are granted under stock option agreements adopted by the plan administrator. The plan administrator will determine the exercise price for stock options, within the terms and conditions of the 2021 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2021 Plan will vest at the rate specified in the stock option agreement as determined by the plan administrator.

The plan administrator will determine the term of stock options granted under the 2021 Plan, up to a maximum of ten years. Unless the terms of an optionholder’s stock option agreement, or other written agreement between us and the recipient approved by the plan administrator, provide otherwise, if an optionholder’s service relationship with us or any of our affiliates ceases for any reason other than disability, death, or cause, the

optionholder may generally exercise any vested options for a period of three months following the cessation of service. This period may be extended in the event that either an exercise of the option or an immediate sale of shares acquired upon exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 18 months following the date of death. If an optionholder's service relationship with us or any of our affiliates ceases due to disability, the optionholder may generally exercise any vested options for a period of 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, or (5) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options or stock appreciation rights generally are not transferable except by will or the laws of descent and distribution. Subject to approval of the plan administrator or a duly authorized officer, an option may be transferred pursuant to a domestic relations order, official marital settlement agreement, or other divorce or separation instrument.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an award holder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (2) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Unit Awards. RSU awards are granted under restricted stock unit award agreements adopted by the plan administrator. RSU awards may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. An RSU award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the RSU award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by an RSU award. Except as otherwise provided in the applicable award agreement, or other written agreement between us and the recipient approved by the plan administrator, RSU awards that have not vested will be forfeited once the participant's continuous service ends for any reason.

Restricted Stock Awards. Restricted stock awards are granted under restricted stock award agreements adopted by the plan administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past or future services to us, or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The plan administrator will determine the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

Stock Appreciation Rights. Stock appreciation rights are granted under stock appreciation right agreements adopted by the plan administrator. The plan administrator will determine the purchase price or strike

price for a stock appreciation right, which generally will not be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under the 2021 Plan will vest at the rate specified in the stock appreciation right agreement as determined by the plan administrator. Stock appreciation rights may be settled in cash or shares of common stock or in any other form of payment as determined by our board of directors and specified in the stock appreciation right agreement.

The plan administrator will determine the term of stock appreciation rights granted under the 2021 Plan, up to a maximum of ten years. If a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability, or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. This period may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. The 2021 Plan will permit the grant of performance awards that may be settled in stock, cash or other property. Performance awards may be structured so that the stock or cash will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, the common stock.

The performance goals may be based on any measure of performance selected by the board of directors. The performance goals may be based on company-wide performance or performance of one or more business units, divisions, affiliates, or business segments, and may be either absolute or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the board of directors at the time the performance award is granted, the board will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (i) to exclude restructuring and/or other nonrecurring charges; (ii) to exclude exchange rate effects; (iii) to exclude the effects of changes to generally accepted accounting principles; (iv) to exclude the effects of any statutory adjustments to corporate tax rates; (v) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (vi) to exclude the dilutive effects of acquisitions or joint ventures; (vii) to assume that any portion of our business which is divested achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (viii) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (ix) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (x) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (xi) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles.

Other Stock Awards. The plan administrator will be permitted to grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award (or cash equivalent) and all other terms and conditions of such awards.

Non-Executive Director Compensation Limit. The aggregate value of all compensation granted or paid to any non-executive director with respect to any calendar year, including awards granted and cash fees paid by us to such non-executive director, will not exceed $750,000 in total value; provided that such amount will increase to $1.0 million for the first year for newly appointed or elected non-executive directors.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2021 Plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued on the exercise of ISOs, and (4) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. In the event of a corporate transaction, unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the plan administrator at the time of grant, any stock awards outstanding under the 2021 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the corporate transaction), and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction.

In the event a stock award will terminate if not exercised prior to the effective time of a corporate transaction, the plan administrator may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the per share amount payable to holders of common stock in connection with the corporate transaction, over (ii) any per share exercise price payable by such holder, if applicable. In addition, any escrow, holdback, earn out or similar provisions in the definitive agreement for the corporate transaction may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of common stock.

Under the 2021 Plan, a corporate transaction is generally defined as the consummation of: (i) a sale of all or substantially all of our assets, (ii) the sale or disposition of at least 50% of our outstanding securities, (iii) a merger or consolidation where we do not survive the transaction, or (iv) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

Change in Control. Awards granted under the 2021 Plan may be subject to acceleration of vesting and exercisability upon or after a change in control as may be provided in the applicable stock award agreement or in any other written agreement between us or any affiliate and the participant, but in the absence of such provision, no such acceleration will automatically occur.

Under the 2021 Plan, a change in control is generally defined as: (i) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock; (ii) a consummated merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity) in substantially the same proportions as their ownership immediately prior to such transaction; (iii) a consummated sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders in substantially the same proportions as their ownership of our outstanding voting securities

immediately prior to such transaction; or (iv) when a majority of our board of directors becomes comprised of individuals who were not serving on our board of directors on the date the 2021 Plan was adopted by the board of directors, or the incumbent board, or whose nomination, appointment, or election was not approved by a majority of the incumbent board still in office.

Plan Amendment or Termination. Our board of directors has the authority to amend, suspend, or terminate our 2021 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopts our 2021 Plan. No stock awards may be granted under our 2021 Plan while it is suspended or after it is terminated.

2021 Employee Stock Purchase Plan

In March 2021, our board of directors adopted, and our stockholders approved, our 2021 Employee Stock Purchase Plan, or ESPP. Our ESPP will become effective immediately prior to and contingent upon the date of the underwriting agreement related to this offering. The purpose of our ESPP will be to secure the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. Our ESPP will include two components. One component will be designed to allow eligible U.S. employees to purchase our common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code. The other component will permit the grant of purchase rights that do not qualify for such favorable tax treatment in order to allow deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the United States while complying with applicable foreign laws.

S*hare Reserve.* Following this offering, the ESPP will authorize the issuance of 500,000 shares of our common stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2022 through January 1, 2031, by the lesser of (1) 1.0% of the total number of shares of our common stock outstanding on the last day of the year before the date of the automatic increase, and (2) 1,400,000 shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (1) and (2).

Administration. Our board of directors will administer the ESPP and may delegate its authority to administer the ESPP to our compensation committee. The ESPP will be implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under the ESPP, our board of directors will be permitted to specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, will be eligible to participate in the ESPP and may contribute, normally through payroll deductions, up to a maximum percentage (which will be set forth in the offering terms at such times as offerings commence) of their earnings (as defined in the ESPP) for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for the accounts of employees participating in the ESPP at a price per share that is at least the lesser of (1) 85% of the fair market value of a share of our common stock on the first date of an offering, or (2) 85% of the fair market value of a share of our common stock on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors, including: (1) being customarily employed for

more than 20 hours per week, (2) being customarily employed for more than five months per calendar year, or (3) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee will be permitted to purchase shares under the ESPP at a rate in excess of $25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each calendar year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value under Section 424(d) of the Code.

Changes to Capital Structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock ividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or similar transaction, the board of directors will make appropriate adjustments to: (1) the class(es) and maximum number of shares reserved under the ESPP, (2) the class(es) and maximum number of shares by which the share reserve may increase automatically each year, (3) the class(es) and number of shares subject to and purchase price applicable to outstanding offerings and purchase rights, and (4) the class(es) and number of shares that are subject to purchase limits under ongoing offerings.

Corporate Transactions. In the event of certain significant corporate transactions, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued, or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within ten business days before such corporate transaction, and such purchase rights will terminate immediately after such purchase.

Under the ESPP, a corporate transaction is generally the consummation of: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of more than 50% of our outstanding securities, (3) a merger or consolidation where we do not survive the transaction, and (4) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

ESPP Amendment or Termination. Our board of directors will have the authority to amend or terminate our ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

2017 Equity Incentive Plan

We currently maintain the 2017 Plan, which became effective in September 2017. We have previously granted stock options under the 2017 Plan. The principal purpose of the 2017 Plan is to encourage stock ownership by employees, consultants, officers and directors and to provide additional incentive for them to promote the success of the Company's business. This summary is qualified in its entirety by reference to the actual text of the 2017 Plan, which is filed as an exhibit to the registration statement of which this prospectus is a part.

Share Reserve. Subject to certain capitalization adjustments, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2017 Plan will not exceed 1,617,745 shares.

Administration. Our board or a committee thereof is authorized to administer the 2017 Plan. Subject to the terms and conditions of the 2017 Plan, the plan administrator has the authority to select the persons to whom awards are to be made, to determine the number of shares to be subject to awards and the terms and conditions of awards, and to make all other determinations and to take all other actions necessary or advisable for the

administration of the 2017 Plan. The administrator is also authorized to adopt, amend or repeal rules relating to administration of the 2017 Plan.

Eligibility and Awards. Options, restricted stock and restricted stock units may be granted under the 2017 Plan may be granted to officers, employees, directors and consultants of the Company and its affiliates. Only employees of the Company or certain of its affiliates may be granted incentive stock options.

Change of Control. In the event of a "change of control" (as defined in the 2017 Plan), awards may be accelerated, assumed or terminated (in the latter case, for such consideration as the plan administrator may determine).

Transferability and Restrictions. With limited exceptions for the laws of descent and distribution, awards under the 2017 Plan are generally non-transferable prior to vesting unless otherwise determined by the plan administrator and set forth in the applicable agreement, and are exercisable only by the participant.

Amendment and Termination. The plan administrator may terminate, amend or modify the 2017 Plan at any time. However, we must generally obtain stockholder approval to the extent required by applicable law.

401(k) Plan

We maintain a 401(k) retirement savings plan for the benefit of our employees, including our executive officers who remain employed with us, and who satisfy certain eligibility requirements. Effective January 1, 2021, eligible employees may defer eligible compensation on a pre-tax or after-tax (Roth) basis, up to the statutorily prescribed annual limits on contributions under the Code. Contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. We currently make matching contributions into the 401(k) plan on behalf of participants equal to 100% on participant contributions up to 3% of their compensation, and equal to 50% on participant contributions above 3% up to 5% of their contribution. Participants are immediately and fully vested on all contributions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan (except for Roth contributions) and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from the director or officer. It is also possible that the director or officer could amend or terminate the plan when not in possession of material, nonpublic information. In addition, our directors and executive officers may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

Limitations on Liability and Indemnification Matters

Upon the closing of this offering, our amended and restated certificate of incorporation will contain provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;

- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies, such as injunctive relief or rescission.

We plan to enter into separate indemnification agreements with our directors and officers in connection with this offering and in addition to the indemnification provided for in our bylaws. These indemnification agreements provide, among other things, that we will indemnify our directors and officers for certain expenses, including damages, judgments, fines, penalties, settlements and costs and attorneys' fees and disbursements, incurred by a director or officer in any claim, action or proceeding arising in his or her capacity as a director or officer of our company or in connection with service at our request for another corporation or entity. The indemnification agreements also provide for procedures that will apply in the event that a director or officer makes a claim for indemnification.

We also maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe that these indemnification provisions and insurance are useful to attract and retain qualified directors and officers.

The limitation of liability and indemnification provisions that will be contained in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than compensation arrangements, we describe below transactions and series of similar transactions, since January 1, 2018, to which we were a party or will be a party, in which:

- the amount involved exceeded or will exceed the lesser of $120,000 and one percent of the average of our total assets at year-end for the last two completed fiscal years; and

- any of our directors, executive officers, or holders of more than 5% of any class of our capital stock at the time of such transaction, or any member of the immediate family of the foregoing persons, which we refer to as our related parties, had or will have a direct or indirect material interest.

We have entered into various employment-related agreements and compensatory arrangements with our directors and executive officers that, among other things, provide for compensatory and certain severance and change in control benefits. For a description of these agreements and arrangements, see the sections titled “Management” and “Executive Compensation.”

Financing Transactions

Series B Preferred Stock Financing

In February 2018, we sold an aggregate of 5,166,203 shares of our Series B preferred stock in multiple closings at a purchase price of $7.0458 per share for an aggregate amount of $36.4 million. The following table summarizes purchases of our Series B preferred stock by related parties:

RELATED PARTY	SHARES OF SERIES B PREFERRED STOCK	TOTAL PURCHASE PRICE
Crestovo Investor LLC(1)	1,064,466	$ 7,500,000
M3 Ventures—Finch II LLC(2)	1,064,466	$ 7,500,000
Flight Partners Management LLC(3)	141,928	$ 1,000,000
The Domenic J. Ferrante 2006 Investment Trust(4)	141,928	$ 1,000,000

(1) Represents shares purchased by Crestovo Investor LLC, or Crestovo. Chris Shumway, the chairman of our board of directors, may be deemed to share voting and investment power with respect to the shares held by Crestovo. Crestovo is a holder of more than 5% of our share capital.
(2) Represents shares purchased by M3 Ventures – Finch II LLC, or M3 Ventures II. Nicholas Haft, a member of our board of directors, may be deemed to share voting and investment power with respect to the shares held by M3 Ventures II.
(3) Represents shares purchased by Flight Partners Management LLC, or Flight Partners. Jeffery A. Smisek, a member of our board of directors, is the president of Flight Partners, and, as a result, may be deemed to share voting and investment power with respect to the shares held by Flight Partners.
(4) Represents shares purchased by The Domenic J. Ferrante 2006 Investment Trust, or the Ferrante Trust. Domenic Ferrante, a member of our board of directors, is the trustee of the Ferrante Trust, and, as a result, may be deemed to share voting and investment power with respect to the shares held by the Ferrante Trust.

Convertible Promissory Note Financing

In February 2019, we entered into a secured note purchase agreement with various investors, in connection with the issuance of convertible promissory notes up to an aggregate principal amount of $18.0 million, in fifteen equal series of notes totaling $1.2 million each upon the achievement of certain milestones. From February 2019 to May 2019, we issued four series of convertible promissory notes in the aggregate principal amount of $4.8 million.

The table below sets forth the principal amount of convertible promissory notes purchased by related parties. In connection with the sale of our Series C preferred stock in May 2019, the secured note purchase agreement and all outstanding promissory notes issued thereunder were terminated.

RELATED PARTY	PRINCIPAL AMOUNT OF NOTES
Crestovo Investor LLC(1)	$ 3,305,248
M3 Ventures—Finch LLC(2)	$ 420,060
Flight Partners Management LLC(3)	$ 351,988

(1) Represents notes purchased by Crestovo. Chris Shumway, the chairman of our board of directors, may be deemed to share voting and investment power with respect to the shares held by Crestovo. Crestovo is a holder of more than 5% of our share capital.
(2) Represents notes purchased by M3 Ventures—Finch LLC, or M3 Ventures I. Nicholas Haft, a member of our board of directors, is the president of M3 Ventures I, and, as a result, may be deemed to share voting and investment power with respect to the shares held by M3 Ventures I.
(3) Represents notes purchased by Flight Partners Capital. Jeffery A. Smisek, a member of our board of directors, is the president of Flight Partners Capital, and, as a result, may be deemed to share voting and investment power with respect to the shares held by Flight Partners Capital.

Series C Preferred Stock Financing

In May 2019 and July 2019, we sold an aggregate of 7,588,254 shares of our Series C preferred stock in multiple closings at a purchase price of $7.0458 per share for an aggregate amount of approximately $53.5 million. The following table summarizes purchases of our Series C preferred stock by related parties:

RELATED PARTY	SHARES OF SERIES C PREFERRED STOCK	TOTAL PURCHASE PRICE
Thomas Layton Walton(1)	2,270,861	$16,000,000
Crestovo Investor LLC(2)	1,172,480	$ 8,261,044(3)
M3 Ventures—Finch LLC(4)	366,093	$ 2,579,423(5)
The Domenic J. Ferrante 2006 Investment Trust (6)	300,948	$ 2,120,420
Flight Partners Management LLC(7)	297,178	$ 2,093,859(8)
Arcos Ventures SPV LLC(9)	212,893	$ 1,500,000

(1) Represents shares purchased by SymBiosis LLC, over which Mr. Walton indirectly exercises sole investment power. Mr. Walton is a holder of more than 5% of our share capital.
(2) Represents shares purchased by Crestovo. Chris Shumway, the chairman of our board of directors, may be deemed to share voting and investment power with respect to the shares held by Crestovo. Crestovo is a holder of more than 5% of our share capital.
(3) The total purchase price includes the termination of convertible secured promissory notes issued by us and held by Crestovo with an aggregate principal amount of $3,305,248.
(4) Represents shares purchased by M3 Ventures I. Nicholas Haft, a member of our board of directors, may be deemed to share voting and investment power with respect to the shares held by M3 Ventures I.
(5) The total purchase price includes the termination of convertible secured promissory notes issued by us and held by M3 Ventures I with an aggregate principal amount of $420,060.
(6) Represents shares purchased by the Ferrante Trust. Domenic Ferrante, a member of our board of directors, is the trustee of the Ferrante Trust, and, as a result, may be deemed to share voting and investment power with respect to the shares held by the Ferrante Trust.
(7) Represents shares purchased by Flight Partners Capital. Jeffery A. Smisek, a member of our board of directors, is the president of Flight Partners Capital, and, as a result, may be deemed to share voting and investment power with respect to the shares held by Flight Partners Capital.
(8) The total purchase price includes the termination of convertible secured promissory notes issued by us and held by Flight Partners with an aggregate principal amount of $351,988.
(9) Represents shares purchased by Arcos Ventures SPV LLC, or Arcos Ventures SPV. Nicholas Haft, a member of our board of directors, may be deemed to share voting and investment power with respect to the shares held by Arcos Ventures SPV.

Series D Preferred Stock Financing

In September 2020, we sold an aggregate of 6,902,872 shares of our Series D preferred stock at a purchase price of $13.0381 per share for an aggregate amount of approximately $90.0 million. The following table summarizes purchases of our Series D preferred stock by related parties:

RELATED PARTY	SHARES OF SERIES D PREFERRED STOCK	TOTAL PURCHASE PRICE
OMX Ventures SPV-Finch LLC(1)	1,150,481	$ 14,999,999
Crestovo Investor LLC(2)	997,084	$ 13,000,000
Thomas Layton Walton(3)	628,072	$ 8,188,813
Flight Partners Management LLC(4)	272,245	$ 3,549,536
The Domenic J. Ferrante 2006 Investment Trust(5)	90,378	$ 1,178,361

(1) Represents shares purchased by OMX Ventures SPV-Finch LLC, or OMX Ventures SPV. Nicholas Haft, a member of our board of directors, may be deemed to share voting and investment power with respect to the shares held by OMX Ventures SPV.
(2) Represents shares purchased by Crestovo. Chris Shumway, the chairman of our board of directors, may be deemed to share voting and investment power with respect to the shares held by Crestovo. Crestovo is a holder of more than 5% of our share capital.
(3) Represents shares purchased by SymBiosis LLC, over which Mr. Walton indirectly exercises sole investment power. Mr. Walton is a holder of more than 5% of our share capital.
(4) Represents shares purchased by Flight Partners Capital. Jeffery A. Smisek, a member of our board of directors, is the president of Flight Partners Capital, and, as a result, may be deemed to share voting and investment power with respect to the shares held by Flight Partners Capital.
(5) Represents shares purchased by the Ferrante Trust. Domenic Ferrante, a member of our board of directors, is the trustee of the Ferrante Trust, and, as a result, may be deemed to share voting and investment power with respect to the shares held by the Ferrante Trust.

Secondary Sale to SIG Global

In October 2020, certain of our stockholders, including Mark Smith, Ph.D. and Zain Kassam, M.D., M.P.H., sold shares of our common stock at a price of $13.0381 per share to SIG Global US Fund I, LLLP, or SIG Global. SIG Global purchased 105,528 shares of our common stock from Dr. Smith for an aggregate purchase price of $1.4 million and 76,698 shares of our common stock from Dr. Kassam for an aggregate purchase price of $1.0 million.

Voting and Stockholders Agreements

In connection with our convertible preferred stock financings, we entered into voting and stockholders agreements containing registration rights, information rights and voting rights, among other things, with certain holders of our convertible preferred stock and certain holders of our common stock including Crestovo Investor LLC and SymBiosis LLC. These agreements will terminate upon the closing of this offering, except for the registration rights granted under our stockholders agreement, as more fully described in the section of this prospectus titled “Description of Capital Stock—Registration Rights.”

Right of First Refusal

We are party to a right of first refusal and co-sale agreement with certain holders of our convertible preferred stock and certain holders of our common stock, pursuant to which we have a right to purchase shares of our capital stock that our stockholders propose to sell to other parties, subject to certain exceptions. We waived our right of first refusal in connection with the October 2020 secondary sales of an aggregate of 258,924 shares of our common stock by Dr. Smith and Dr. Kassam, as described above.

Transactions with OpenBiome

We have historically had a close relationship with Microbiome Health Research Institute, Inc., or OpenBiome, and are currently, and have been previously, party to several agreements with OpenBiome related

to, among other things, the license of various technology and intellectual property rights, and the supply of certain materials, as further described below. Our Chief Executive Officer and member of our board of directors, Mark Smith, Ph.D. is the spouse of Carolyn Edelstein, the Executive Director and co-founder of OpenBiome.

Quality System and Supply Agreement

In February 2017, we entered into a quality system and supply agreement, or QSS Agreement, with OpenBiome, which was subsequently amended in September 2017 and was partially terminated February 2019 and, ultimately, was fully terminated in November 2020. Under the QSS Agreement, OpenBiome granted us an exclusive license, eligible for sublicense, to certain OpenBiome technology and intellectual property. Additionally, we acquired certain assets of OpenBiome for use in manufacturing and supplying product. We were responsible for providing support to OpenBiome related to the manufactured materials, which has been included as service revenue in our consolidated statement of operations. We also earned a low single-digit royalty on net sales of OpenBiome FMT materials under the QSS Agreement. Revenue under the QSS Agreement was recorded as either contract manufacturing revenue or royalty revenue on our consolidated statement of operations. We recorded contract manufacturing revenue totaling $3.5 million and $0.4 million for the years ended December 31, 2018 and 2019, respectively. We recorded $2.6 million as due from related party on our consolidated balance sheet, related to the consideration for the property, equipment and inventory OpenBiome purchased from us but had not paid for as of December 31, 2019.

Asset Purchase and License Agreement

In February 2019, OpenBiome purchased manufacturing rights, manufacturing assets and existing inventory from us for total consideration of $3.3 million under the terms of an Asset Purchase and License Agreement, or the APL Agreement, with $2.6 million specifically recorded as accounts receivable on our consolidated balance sheet related to the purchase of property, equipment and inventory. In connection with the APL Agreement, OpenBiome acquired certain of our contracts and assumed all related obligations under these contracts effective February 1, 2019. As result of the transfer, we recorded a loss on sale of assets of $0.1 million in our consolidated statement of operations as other income, net. As of February 2019, we had no further obligation to manufacture and transfer FMT materials to OpenBiome.

We sold to OpenBiome certain equipment originally purchased from OpenBiome and inventories for $0.7 million and $1.7 million, respectively. As of December 31, 2019, we do not owe OpenBiome any additional product or amounts, and we do not have inventory related to OpenBiome on our consolidated balance sheet.

Asset Purchase Agreement

In November 2020, we entered into an asset purchase agreement, or the OpenBiome Agreement, with OpenBiome, pursuant to which we acquired certain biological samples and obtained a license to certain OpenBiome technology. Upon closing of the transaction in March 2021, we acquired certain additional assets of OpenBiome, including certain additional biological samples, capital equipment and contracts. See “Business—Agreements with OpenBiome—Asset Purchase Agreement” elsewhere in this prospectus for additional information about the OpenBiome Agreement.

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. The terms of the non-exclusive license exclude any license for OpenBiome to exploit a Lyophilized Natural Product, such as CP101, where processed stool is lyophilized using our patents, patent applications and know-how, or to otherwise use the intellectual property licensed from us to lyophilize a product. See "Business—Agreements with OpenBiome—LMIC License Agreement" elsewhere in this prospectus for additional information about the LMIC Agreement.

Office and Lab Space

We sublease office and lab space to OpenBiome. Since July 2016, OpenBiome has subleased from us certain space at our corporate headquarters in Somerville, Massachusetts. In addition, in February 2019, OpenBiome assumed our lease for a donor facility on Cherry Street in Cambridge, Massachusetts.

The base rent under the sublease was $0.1 million, $0.5 million, and $0.4 million for the years ended December 31, 2018, 2019 and 2020, respectively. The amount receivable from OpenBiome at December 31, 2019 and 2020 related to the sublease was $0.4 million and approximately $28,000, respectively. There was no amount receivable from OpenBiome at December 31, 2018 related to the sublease.

Shared Services

We also have a shared services arrangement with OpenBiome related to sharing of certain office and administrative expenses. We reimbursed OpenBiome $0.3 million, $0.2 million and approximately $33,000 for the years ended December 31, 2018 , 2019 and 2020, respectively. OpenBiome reimbursed us $0.1 million for the year ended December 31, 2018 and $1.0 million for the year ended December 31, 2019. For the year ended December 31, 2020, OpenBiome reimbursed us $0.3 million. We were owed a net amount receivable from OpenBiome of approximately $43,000, $0.6 million and approximately $21,000 as of December 31, 2018, 2019 and 2020, respectively. We owed a net amount payable to OpenBiome of $0.2 million at both December 31, 2018 and 2019. We owed OpenBiome $0 related to shared expenses as of December 31, 2020.

Indemnification Agreements

We plan to enter into indemnification agreements with each of our directors and executive officers in connection with this offering. The indemnification agreements and our amended and restated bylaws, each to be in effect upon the closing of this offering, require us to indemnify our directors and executive officers to the fullest extent permitted by Delaware law. For more information regarding these agreements, see "Executive Compensation—Limitations on Liability and Indemnification Matters."

Executive and Director Compensation

We have granted stock options to certain of our executive officers and directors. See the section titled "Executive Compensation" for a description of these stock options and our employment arrangements with our named executive officers.

Related Party Transaction Policy

Prior to this offering, we did not have a formal policy regarding approval of transactions with related parties. In connection with this offering, our board of directors has adopted a written related party transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related party transactions. The policy will become effective immediately upon the execution of the underwriting agreement for this offering. For purposes of our policy only, a related party transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related party are, were or will be participants and in which the amount involved exceeds the lesser of $120,000 and one percent of the average of our total assets at year-end for the last two completed fiscal years. Transactions involving compensation for services provided to us as an employee or director are not covered by

this policy. A related party is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related party transaction, including any transaction that was not a related party transaction when originally consummated or any transaction that was not initially identified as a related party transaction prior to consummation, our management must present information regarding the related party transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related parties, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy.

In addition, under our Code of Ethics, which we intend to adopt in connection with this offering, our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest.

In considering related party transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related party is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related party transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

All of the transactions described above were entered into prior to the adoption of the written policy, but all were approved by our board of directors considering similar factors to those described above.

PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of December 31, 2020, as adjusted to reflect the sale of common stock offered by us in this offering, for:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The percentage ownership information shown in the table prior to this offering is based on 39,645,402 shares of common stock outstanding as of December 31, 2020, after giving effect to the automatic conversion of all of our outstanding shares of preferred stock into an aggregate of 31,253,609 shares of our common stock upon the closing of this offering.

The percentage ownership information shown in the table after this offering is based on 45,895,402 shares outstanding, assuming the sale of 6,250,000 shares of our common stock by us in this offering and no exercise of the underwriters' option to purchase additional shares. The table does not reflect any potential purchases by our existing principal stockholders or their affiliated entities of shares of our common stock in this offering.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options that are exercisable on or before March 1, 2021, which is 60 days after December 31, 2020. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for persons listed in the table is c/o Finch Therapeutics Group, Inc., 200 Inner Belt Road, Suite 400, Somerville, Massachusetts, 02143.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
5% or greater stockholders:			
Crestovo Investor LLC(1)	11,906,147	30.0%	25.9%
Nicholas Haft(2)	3,110,706	7.8	6.8
Thomas Layton Walton(3)	2,898,933	7.3	6.3
Named executive officers and directors:			
Mark Smith, Ph.D.(4)	1,903,033	4.8	4.1
Zain Kassam, M.D., M.P.H.(5)	1,330,351	3.4	2.9
Gregory D. Perry(6)	181,897	*	*
Chris Shumway(1)	11,906,147	30.0	25.9
Domenic Ferrante(7)	533,254	1.3	1.2
Nicholas Haft(2)	3,110,706	7.8	6.8
Christian Lange	—	—	—
Jeffery A. Smisek(8)	1,606,306	4.1	3.5
Jo Viney, Ph.D.(9)	13,846	*	*
All current executive officers and directors as a group (10 persons)(10)	20,585,541	51.7%	44.7%

* Represents beneficial ownership of less than 1%.

(1) Consists of (i) 8,672,117 shares of common stock issuable upon the conversion of Series A preferred stock, (ii) 1,064,466 shares of common stock issuable upon the conversion of Series B preferred stock, (iii) 1,172,480 shares of common stock issuable upon the conversion of Series C preferred stock and (iv) 997,084 shares of common stock issuable upon the conversion of Series D preferred stock held by Crestovo Investor LLC, or Crestovo. Chris Shumway, the chairman of our board of directors, may be deemed to share voting and investment power with respect to the shares held by Crestovo. The address of Crestovo is 28 Havemeyer Place, Greenwich, Connecticut 06830.

(2) Consists of (a) 1,064,466 shares of common stock issuable upon the conversion of Series B preferred stock held by M3 Ventures – Finch II LLC, or M3 Ventures II, (b) (i) 172,942 shares of common stock issuable upon the conversion of Series A preferred stock and (ii) 366,093 shares of common stock issuable upon the conversion of Series C preferred stock held by M3 Ventures – Finch LLC, or M3 Ventures I, (c) 212,893 shares of common stock issuable upon the conversion of Series C preferred stock held by Arcos Ventures SPV LLC, or Arcos Ventures SPV, (d) 1,150,481 shares of common stock issuable upon the conversion of Series D preferred stock held by OMX Ventures SPV-Finch LLC, or OMX Ventures SPV, and (e) 143,831 shares of common stock issuable upon the conversion of Series A preferred stock held by NBTT 2 Investments LLC, or NBTT. M3 Ventures II, M3 Ventures I, Arcos Ventures SPV, OMX Ventures SPV and NBTT are collectively referred to as the Haft Entities. Nicholas Haft, a member of our board of directors, may be deemed to share voting and investment power with respect to the shares held by the Haft Entities. The address of the Haft Entities is One Overlook Point, Suite 100, Lincolnshire, Illinois 60069.

(3) Consists of (i) 2,270,861 shares of common stock issuable upon the conversion of Series C preferred stock and (ii) 628,072 shares of common stock issuable upon the conversion of Series D preferred stock beneficially owned by Mr. Walton. The shares are held of record by Symbiosis LLC, over which Mr. Walton exercises sole investment power. The address of Mr. Walton is PO Box 1860, Bentonville, Arkansas 72712.

(4) Consists of 1,903,033 shares of common stock held by Dr. Smith.

(5) Consists of 1,330,351 shares of common stock held by Dr. Kassam.

(6) Consists of 181,897 shares of common stock issuable upon the exercise of options granted to Mr. Perry that are exercisable within 60 days of December 31, 2020.

(7) Consists of (i) 141,928 shares of common stock issuable upon the conversion of Series B preferred stock, (ii) 300,948 shares of common stock issuable upon the conversion of Series C preferred stock and (iii) 90,378 shares of common stock issuable upon the conversion of Series D preferred stock held by The Domenic J. Ferrante 2006 Investment Trust, or the Ferrante Trust. Domenic Ferrante, a member of our board of directors, is the trustee of the Ferrante Trust, and, as a result, may be deemed to share voting and investment power with respect to the shares held by the Ferrante Trust. The address of the Ferrante Trust is 821 5th Avenue S, Suite 202, Naples, Florida 34102.

(8) Consists of (i) 894,955 shares of common stock issuable upon the conversion of Series A preferred stock, (ii) 141,928 shares of common stock issuable upon the conversion of Series B preferred stock, (iii) 297,178 shares of common stock issuable upon the conversion of Series C preferred stock and (iv) 272,245 shares of common stock issuable upon the conversion of Series D preferred stock held by Flight Partners Management LLC, or Flight Partners Capital. Jeffery A. Smisek, a member of our board of directors, is the president of Flight Partners Capital, and, as a result, may be deemed to share voting and investment power with respect to the shares held by Flight Partners Capital. The address of Flight Partners Capital is PO Box 861, Leland, Michigan 49654.

(9) Consists of 13,846 shares of common stock issuable upon the exercise of options granted to Dr. Viney that are exercisable within 60 days of December 31, 2020.
(10) Consists of (i) 3,233,384 shares of common stock, (ii) 9,883,845 shares of common stock issuable upon the conversion of Series A preferred stock, (iii) 2,412,788 shares of common stock issuable upon the conversion of Series B preferred stock, (iv) 2,349,593 shares of common stock issuable upon the conversion of Series C preferred stock, (v) 2,510,188 shares of common stock issuable upon the conversion of Series D preferred stock and (vi) 195,743 shares of common stock issuable upon the exercise of options that are exercisable within 60 days of December 31, 2020.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock, certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws, as each will be in effect upon the closing of this offering, and certain provisions of Delaware law are summaries. You should also refer to the amended and restated certificate of incorporation and the amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is part.

General

Upon the closing of this offering, our amended and restated certificate of incorporation will authorize us to issue up to 200,000,000 shares of common stock, $0.001 par value per share, and 10,000,000 shares of preferred stock, $0.001 par value per share, all of which shares of preferred stock will be undesignated. Our board of directors may establish the rights and preferences of the preferred stock from time to time.

As of December 31, 2020, after giving effect to the automatic conversion of all of our outstanding shares of preferred stock into an aggregate of 31,253,609 shares of our common stock upon the closing of this offering, there would have been 39,645,402 shares of common stock issued and outstanding, held of record by 112 stockholders.

Common Stock

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Under our amended and restated certificate of incorporation and amended and restated bylaws, our stockholders will not have cumulative voting rights.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Rights and Preferences

Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Preferred Stock

As of December 31, 2020, there were 31,253,609 shares of preferred stock outstanding, which will convert, immediately prior to the closing of this offering, into 31,253,609 shares of our common stock. All

series of our convertible preferred stock will convert at a ratio of one share of common stock for each share of convertible preferred stock. All shares of common stock (including fractions thereof) issuable upon conversion of convertible preferred stock by a holder thereof shall be aggregated for purposes of determining whether the conversion would result in the issuance of any fractional share. If, after such aggregation, the conversion results in the issuance of any fractional share, we will, in lieu of issuing any fractional share, pay cash equal to the product of such fraction multiplied by the initial public offering price.

Upon the closing of this offering, our board of directors may, without further action by our stockholders, fix the rights, preferences, privileges and restrictions of up to an aggregate of 10,000,000 shares of preferred stock in one or more series and authorize their issuance. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of our common stock. The issuance of our preferred stock could adversely affect the voting power of holders of our common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change of control or other corporate action. Upon the closing of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Options

As of December 31, 2020, options to purchase an aggregate of 1,053,874 shares of common stock were outstanding under our 2017 Plan at a weighted average exercise price of $1.51 per share. See “Executive Compensation—Employee Benefit Plans” for additional information regarding the terms of our 2017 Plan.

Registration Rights

Upon the closing of this offering, certain holders of shares of our common stock, including those shares of our common stock that will be issued upon conversion of our convertible preferred stock upon the closing of this offering, will be entitled to certain rights with respect to registration of such shares under the Securities Act pursuant to the terms of an amended and restated investor rights agreement by and among us and certain of our stockholders. These shares are collectively referred to herein as registrable securities.

The amended and restated investor rights agreement provides the holders of registrable securities with demand, piggyback and S-3 registration rights as described more fully below. As of December 31, 2020, holders of an aggregate of 31,665,929 registrable securities were entitled to these demand and S-3 registration rights and 39,330,184 registrable securities were entitled to these piggyback rights. Under the terms of the investor rights agreement, holders of registrable securities will have equivalent registration rights with respect to any additional shares of our common stock acquired by these holders.

Demand Registration Rights

At any time beginning 180 days following the effective date of the registration statement of which this prospectus forms a part, the holders of at least 20% of the registrable securities then outstanding have the right to make up to two demands that we file a registration statement under the Securities Act, subject to specified conditions and exceptions. Such request for registration must cover shares with an anticipated aggregate offering price to the public of at least $25 million.

Piggyback Registration Rights

If we register any securities for public sale, the holders of our registrable securities then outstanding will each be entitled to notice of the registration and will have the right to include their shares in the registration statement, subject to specified exceptions. The underwriters of any underwritten offering will have the right to limit the number of shares having registration rights to be included in such registration statement, but not below 25% of the total amount of securities included in such registration.

Registration on Form S-3

If we are eligible to file a registration statement on Form S-3, the holders of at least 20% of the registrable securities then outstanding have the right to demand that we file registration statements on Form S-3, provided that the aggregate amount of securities to be sold under the registration statement is at least $5.0 million, net of underwriting discounts and commissions and specified expenses. We are not obligated to effect a demand for registration on Form S-3 by holders of our registrable securities more than two times during any 12-month period. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Expenses of Registration

We will pay all expenses relating to any demand, piggyback or Form S-3 registration, other than underwriting discounts and commissions, subject to specified conditions and limitations.

Termination of Registration Rights

The demand, piggyback and Form S-3 registration rights described above will terminate on the earliest to occur of (1) the closing of a deemed liquidation event, as defined in our certificate of incorporation, (2) the five-year anniversary of the closing of this offering and (3) with respect to each stockholder, at such time as Rule 144 under the Securities Act or another similar exemption is available for the sale of all of such holder's shares without limitation during a three-month period without registration.

Anti-Takeover Provisions under Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a publicly held Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (1) by persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Choice of Forum

Our amended and restated certificate of incorporation to be effective on the completion of this offering will provide that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for the following claims or causes of action under Delaware statutory or common law: (1) any derivative claim or cause of action brought on our behalf; (2) any claim or cause of action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders; (3) any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; (4) any claim or cause of action arising under or seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (including any right, obligation, or remedy thereunder); and (5) any claim or cause of action against us or any of our current or former directors, officers, or other employees that is governed by the internal-affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court having personal jurisdiction over the indispensable parties named as defendants. This choice of forum provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction, or the Securities Act. Our amended and restated certificate of incorporation to be effective on the completion of this offering will further provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. Additionally, our amended and restated certificate of incorporation to be effective on the completion of this offering will provide that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Transfer Agent and Registrar

Upon the closing of this offering, the transfer agent and registrar for our common stock will be American Stock Transfer & Trust Company, LLC. The transfer agent's address is 6201 15th Avenue, Brooklyn, New York 11219.

Listing

We have applied to list our common stock on the Nasdaq Global Market under the trading symbol "FNCH."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of our common stock, including shares issued upon the exercise of outstanding options, in the public market after the closing of this offering, or the perception that those sales may occur, could adversely affect the prevailing market price for our common stock from time to time or impair our ability to raise equity capital in the future. As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after the closing of this offering due to contractual and legal restrictions on resale described below. Future sales of our common stock in the public market either before or after restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price of our common stock at such time and our ability to raise equity capital at a time and price we deem appropriate.

Sale of Restricted Shares

Based on the number of shares of common stock outstanding as of December 31, 2020, upon the closing of this offering and assuming (i) the automatic conversion of our outstanding preferred shares into an aggregate of 31,253,609 shares of our common stock immediately prior to the closing of this offering, (ii) no exercise of the underwriters' option to purchase additional shares of our common stock, and (iii) no exercise of outstanding options, we will have 39,645,402 shares of common stock outstanding as of such date. Of these shares, all of the shares of our common stock to be sold in this offering will be freely tradable in the public market without restriction or further registration under the Securities Act, unless the shares are held by any of our "affiliates" as such term is defined in Rule 144 of the Securities Act, or Rule 144 or subject to lock-up agreements. All remaining shares of our common stock held by existing stockholders immediately prior to the consummation of this offering will be "restricted securities," as such term is defined in Rule 144. These restricted securities were issued and sold by us in private transactions and are eligible for public sale only if the offer and sale is registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701 of the Securities Act, or Rule 701, which rules are summarized below.

As a result of the lock-up agreements referred to below and the provisions of Rules 144 and 701 under the Securities Act, based on the number of shares of our common stock outstanding as of December 31, 2020, the shares (excluding the shares sold in this offering) that will be available for sale in the public market are as follows:

APPROXIMATE NUMBER OF SHARES	FIRST DATE AVAILABLE FOR SALE INTO PUBLIC MARKET
39,645,402 shares	181 days after the date of this prospectus, upon expiration of the lock-up agreements referred to below, subject in some cases to applicable volume, manner of sale and other limitations under Rule 144 and Rule 701.

We may issue shares of our common stock from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event that any such acquisition, investment or other transaction is significant, the number of shares of our common stock that we may issue may in turn be significant. We may also grant registration rights covering those shares issued in connection with any such acquisition and investment.

In addition, the shares of common stock reserved for future issuance under our equity plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements, a registration statement under the Securities Act or an exemption from registration, including Rule 144 and Rule 701.

Rule 144

In general, persons who have beneficially owned restricted shares of our common stock for at least six months, and any affiliate of the company who owns shares of our common stock, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144.

Under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, and we are current in our Exchange Act reporting at the time of sale, a person (or persons whose shares are required to be aggregated) who is not deemed to have been one of our "affiliates" for purposes of Rule 144 at any time during the 90 days preceding a sale and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, including the holding period of any prior owner other than one of our "affiliates," is entitled to sell those shares in the public market (subject to the lock-up agreement referred to below, if applicable) without complying with the manner of sale, volume limitations or notice provisions of Rule 144, but subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than "affiliates," then such person is entitled to sell such shares in the public market without complying with any of the requirements of Rule 144 (subject to the lock-up agreement referred to above, if applicable).

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, our "affiliates," as defined in Rule 144, who have beneficially owned the shares of our common stock proposed to be sold for at least six months, are entitled to sell in the public market, upon expiration of any applicable lock-up agreements and within any three-month period, a number of those shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 458,954 shares of common stock immediately upon the closing of this offering (calculated as of December 31, 2020 on the basis of the assumptions described above and assuming no exercise of the underwriter's option to purchase additional shares and no exercise of outstanding options); or

- the average weekly trading volume of our common stock on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Such sales under Rule 144 by our "affiliates" or persons selling shares on behalf of our "affiliates" are also subject to certain manner of sale provisions, notice requirements and to the availability of current public information about us. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who acquired shares of our common stock from us in connection with a written compensatory share or option plan or other written agreement in compliance with Rule 701 before the effective date of the registration statement of which this prospectus is a part (to the extent such shares are not subject to a lock-up agreement) and who are not our "affiliates" as defined in Rule 144 during the immediately preceding 90 days, is entitled to rely on Rule 701 to resell such shares beginning 90 days after the date of this prospectus in reliance on Rule 144, but without complying with the notice, manner of sale, public information requirements or volume limitation provisions of Rule 144. Persons who are our "affiliates" may resell those shares beginning 90 days after the date of this prospectus without compliance with Rule 144's minimum holding period requirements (subject to the terms of the lock-up agreement referred to below, if applicable).

Lock-Up Agreements

In connection with this offering, we, our directors, our executive officers and holders of substantially all of our outstanding common stock or securities convertible into or exchangeable for shares of common stock, have agreed, subject to certain exceptions, with the underwriters not to directly or indirectly offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of or hedge any shares of our common stock or any options to purchase shares of our common stock, or any securities convertible into or exchangeable for shares of our common stock during the period from the date of the lock-up agreement continuing through the date 180 days after the date of this prospectus, except with the prior written consent of BofA Securities, Inc., Jefferies LLC and Evercore Group L.L.C., BofA Securities, Inc., Jefferies LLC and Evercore Group L.L.C. may waive the restrictions contained in such lock-up agreements at any time in their sole discretion. See the section entitled "Underwriting" appearing elsewhere in this prospectus for more information. These agreements are described in the section titled "Underwriting."

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain security holders, including our amended and restated unanimous stockholders' agreement and our standard form of option agreement, that contain market stand-off provisions imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period of 180 days following the date of this prospectus.

Prior to the completion of the offering, certain of our employees, including our executive officers, and/or directors, may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to the offering described above.

Following the lock-up periods set forth in the agreements described above, and assuming that the representatives of the underwriters do not release any parties from these agreements and that there is no extension of the lock-up period, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144.

Registration Rights

Upon the closing of this offering, the holders of a significant majority of the shares of our common stock will be entitled to specified rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described under "—Lock-Up Agreements" above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates, immediately upon the effectiveness of the registration statement of which this prospectus is a part. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. See the section titled "Description of Capital Stock—Registration Rights."

Equity Plans

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of our common stock reserved for issuance under our equity plans. The registration statement on Form S-8 is expected to be filed and become effective as soon as practicable after the closing of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the ownership and disposition of our common stock issued pursuant to this offering. This discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the Internal Revenue Service, or the IRS, all as in effect on the date of this prospectus. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, the requirements of Section 451 of the Code with respect to conforming the timing of income accruals to financial statements or the alternative minimum tax, and does not address any estate or gift tax consequences or any tax consequences arising under any state, local or foreign tax laws, or any other U.S. federal tax laws. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the U.S. federal income tax consequences that may be relevant to an individual holder in light of such holder's particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to holders subject to special rules under the U.S. federal income tax laws, including:

- certain former citizens or long-term residents of the United States;
- partnerships or other pass-through entities (and investors therein);
- "controlled foreign corporations";
- "passive foreign investment companies";
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, financial institutions, investment funds, insurance companies, brokers, dealers or traders in securities;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons that own or have owned, actually or constructively, more than 5% of our common stock;
- persons who have elected to mark securities to market; and
- persons holding our common stock as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of a partner in the partnership will generally depend on the status of the partner and the activities of the partnership. Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our common stock.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS.

Definition of Non-U.S. Holder

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock that is not a "U.S. person" or a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation (including any entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (1) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (2) that has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

Distributions on Our Common Stock

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we distribute cash or other property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder's tax basis in our common stock, but not below zero. Any excess amount distributed will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under "—Gain On Disposition of Our Common Stock" below.

Subject to the discussions below regarding effectively connected income, backup withholding and FATCA (as defined below), dividends paid to a non-U.S. holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish us or our withholding agent with a valid IRS Form W-8BEN or IRS Form W-8BEN-E (or applicable successor form) certifying such holder's qualification for the reduced rate. This certification must be provided to us or our withholding agent before the payment of dividends and must be updated periodically. If the non-U.S. holder holds our common stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our withholding agent, either directly or through other intermediaries.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such holder's U.S. trade or business (and are attributable to such holder's permanent establishment or fixed base in the United States if required by an applicable tax treaty), the non-U.S. holder will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must generally furnish a valid IRS Form W-8ECI (or applicable successor form) to the applicable withholding agent, certifying that the dividends are effectively connected with the non-U.S. holder's conduct of trade or business within the United States.

However, any such effectively connected dividends paid on our common stock generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Gain on Disposition of Our Common Stock

Subject to the discussion below regarding backup withholding and FATCA, a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other disposition of our common stock, unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States;

- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or

- our common stock constitutes a United States real property interest by reason of our status as a "United States real property holding corporation," or a USRPHC, for U.S. federal income tax purposes, at any time during the shorter of the five-year period ending on the date of the sale or other taxable disposition of, or such non-U.S. holder's holding period for, our common stock.

Determining whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our worldwide real property interests and our other trade or business assets. We believe that we are not currently and we do not anticipate becoming a USRPHC for U.S. federal income tax purposes, although there can be no assurance we will not in the future become a USRPHC. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a non-U.S. holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded" (within the meaning of applicable Treasury regulations) on an established securities market, and such non-U.S. holder owned, actually or constructively, five percent (5%) or less of our common stock at any time during the applicable period described above.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Gain described in the second

bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules. Gain described in the third bullet point above will generally be subject to U.S. federal income tax in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business (subject to any provisions under an applicable income tax treaty), except that the branch profits tax generally will not apply.

Information Reporting and Backup Withholding

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the amount of distributions on our common stock paid to such holder and the amount of any tax withheld with respect to those distributions. These information reporting requirements apply even if no withholding was required because the distributions were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable income tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, currently at a 24% rate, generally will not apply to payments to a non-U.S. holder of dividends on or the gross proceeds of a disposition of our common stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or certain other requirements are met. Backup withholding may apply if the payor has actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder's U.S. federal income tax liability, if any.

Withholding on Foreign Entities

Sections 1471 through 1474 of the Code, which are commonly referred to as FATCA, impose a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally will impose a U.S. federal withholding tax of 30% on certain payments made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. FATCA currently applies to dividends paid on our common stock. FATCA will also apply to gross proceeds from sales or other dispositions of our common stock after December 31, 2018. However, the Treasury Department has proposed regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to gross proceeds from a disposition of our common stock. In its preamble to such proposed regulations, the Treasury Department stated that taxpayers may generally rely on the proposed regulations until final regulations are issued.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of this legislation on their investment in our common stock.

UNDERWRITING

BofA Securities, Inc., Jefferies LLC and Evercore Group L.L.C. are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
BofA Securities, Inc.	
Jefferies LLC	
Evercore Group L.L.C.	
Total	6,250,000

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
Public offering price	$	$	$
Underwriting discount	$	$	$
Proceeds, before expenses, to us	$	$	$

The expenses of the offering, not including the underwriting discount, are estimated at $2.7 million and are payable by us. We have also agreed to reimburse the underwriters for their expenses relating to clearance of this offering with the Financial Industry Regulatory Authority in an amount up to $40,000.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 937,500 additional shares at the public offering price, less the underwriting discount. If the

underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of the representatives. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock;
- exercise any right with respect to the registration of any of the common stock, or file, cause to be filed or cause to be confidentially submitted any registration statement in connection therewith; or
- enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the common stock, whether any such swap or transaction is to be settled by delivery of shares of common stock or other securities, in cash or otherwise.

The exceptions to the restrictions in the immediately preceding paragraph permit our executive officers and directors, subject to certain restrictions, to transfer the common stock:

- as a bona fide gift or gifts, including bone fide gift or gifts to a charitable organization or educational institution;
- to any immediate family member or any trust;
- to any corporation, partnership, limited liability company, or other entity, all of the beneficial ownership interests of which are held by the person subject to the lock-up;
- to affiliates or to any investment fund or other entity controlled or managed by the person subject to the lock-up;
- by will, other testamentary document or intestate succession;
- by operation of law pursuant to orders of a court or regulatory agency, a domestic order or negotiated divorce settlement;
- pursuant to any contractual arrangement that provides for the repurchase by the company of securities of the company held by the person subject to the lock-up in connection with the termination of employment with, or service to, the company;
- by surrender or forfeiture of shares of common stock or other securities of the company to the company to satisfy tax withholding obligations upon exercise or vesting or the exercise price upon a cashless net exercise, in each case, of stock options, restricted stock, other equity awards, warrants or other rights to acquire shares of common stock; or

- pursuant to a bona fide tender offer for shares of the company's securities, merger, consolidation or other similar transaction made to all holders of the company's securities that has been approved by the company's board of directors, which results in any person or group of persons becoming the beneficial owners (as defined in Rules 13d-3 and 13d-5 of the Exchange Act) of 90% of the outstanding voting securities of the company (or the surviving entity).

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

Nasdaq Global Market Listing

We have applied to list our common stock on the Nasdaq Global Market under the symbol "FNCH."

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,
- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares described above. The underwriters may close

out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. "Naked" short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the Nasdaq Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

European Economic Area and the United Kingdom

In relation to each Member State of the European Economic Area and the United Kingdom (each a "Relevant State"), no shares have been offered or will be offered pursuant to the offering to the public in that

Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation), except that offers of Shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

a. to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of coordinator for any such offer; or

c. in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of Shares shall require the Issuer or any Manager to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Relevant State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the Company and the underwriters that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Relevant State to qualified investors, in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

The company, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an “offer to the public” in relation to any Shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase or subscribe for any Shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

References to the Prospectus Regulation includes, in relation to the UK, the Prospectus Regulation as it forms part of UK domestic law by virtue of the European Union (Withdrawal) Act 2018.

The above selling restriction is in addition to any other selling restrictions set out below.

In connection with the offering, the underwriters are not acting for anyone other than the issuer and will not be responsible to anyone other than the issuer for providing the protections afforded to their clients nor for providing advice in relation to the offering.

Notice to Prospective Investors in the United Kingdom

In relation to the United Kingdom (“UK”), no Shares have been offered or will be offered pursuant to the offering to the public in the UK prior to the publication of a prospectus in relation to the Shares which has been approved by the Financial Conduct Authority in the UK in accordance with the UK Prospectus Regulation

and the FSMA, except that offers of Shares may be made to the public in the UK at any time under the following exemptions under the UK Prospectus Regulation and the FSMA:

a. to any legal entity which is a qualified investor as defined under the UK Prospectus Regulation;

b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the UK Prospectus Regulation), subject to obtaining the prior consent of coordinator for any such offer; or

c. at any time in other circumstances falling within section 86 of the FSMA,

provided that no such offer of Shares shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or Article 3 of the UK Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

Each person in the UK who initially acquires any Shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the Company and the Managers that it is a qualified investor within the meaning of the UK Prospectus Regulation.

In the case of any Shares being offered to a financial intermediary as that term is used in Article 5(1) of the UK Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the Shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in the UK to qualified investors, in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

The Company, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an “offer to the public” in relation to any Shares in the UK means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase or subscribe for any Shares, the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018, and the expression “FSMA” means the Financial Services and Markets Act 2000.

In connection with the offering, the underwriters are not acting for anyone other than the issuer and will not be responsible to anyone other than the issuer for providing the protections afforded to their clients nor for providing advice in relation to the offering.

This document is for distribution only to persons who (i) have professional experience in matters relating to investments and who qualify as investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended, the “Financial Promotion Order”), (ii) are persons falling within Article 49(2)(a) to (d) (“high net worth companies, unincorporated associations etc.”) of the Financial Promotion Order, (iii) are outside the United Kingdom, or (iv) are persons to whom an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, as amended (“FSMA”)) in connection with the issue or sale of any securities may otherwise lawfully be communicated or caused to be communicated (all such persons together being referred to as “relevant persons”). This document is directed only at relevant persons and must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only with relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority ("DFSA"). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission ("ASIC"), in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the "Corporations Act"), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the "Exempt Investors") who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities

recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the "SFA")) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

a. a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

b. a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

a. to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

b. where no consideration is or will be given for the transfer;

c. where the transfer is by operation of law; or

d. as specified in Section 276(7) of the SFA.

Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* NI 33-105, the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Cooley LLP, Boston, Massachusetts. Certain legal matters will be passed upon for the underwriters by Goodwin Procter LLP, New York, New York.

EXPERTS

The consolidated financial statements as of December 31, 2019 and 2020 and for the years then ended included in this prospectus, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein (which report expresses an unqualified opinion on the consolidated financial statements and includes an explanatory paragraph referring to our ability to continue as a going concern). Such consolidated financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock being offered by this prospectus, which constitutes a part of the registration statement. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the internet at the SEC's website at www.sec.gov.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available over the internet at the SEC's web site referred to above. We also maintain a website at finchtherapeutics.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. **However, the information contained in or accessible through our website is not part of this prospectus or the registration statement of which this prospectus forms a part, and investors should not rely on such information in making a decision to purchase our common stock in this offering.**

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, 2019 and 2020, the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' deficit, and cash flows, for each of the two years in the period ended December 31, 2020, 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, 2019 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, 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 has suffered recurring losses from operations that 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

February 26, 2021 (March 15, 2021, as to the subsequent events described in Note 16)

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, 2019	DECEMBER 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 42,186	$ 99,710
Accounts receivable	1,178	1,034
Due from related party	3,568	61
Prepaid expenses and other current assets	1,694	5,359
Total current assets	48,626	106,164
Property and equipment, net	3,776	7,004
In-process research and development	32,900	32,900
Goodwill	18,057	18,057
Deferred initial public offering costs	—	1,013
Other assets	210	200
TOTAL ASSETS	$ 103,569	$ 165,338
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Accounts payable	$ 655	$ 2,621
Accrued expenses and other current liabilities	3,958	5,228
Due to related party	334	266
Deferred revenue, current portion	2,378	3,371
Total current liabilities	7,325	11,486
Deferred tax liability	3,461	3,461
Deferred revenue, net of current portion	8,289	10,260
Loan payable	—	1,808
Deferred rent	515	766
Other liabilities	364	221
Total liabilities	19,954	28,002
COMMITMENTS AND CONTINGENCIES (Note 8)		
Series A redeemable convertible preferred stock, $0.001 par value; 167,496,570 shares authorized as of December 31, 2019 and 2020, 11,596,280 shares issued and outstanding as of December 31, 2019 and 2020; preference in liquidation of $40,115 as of December 31, 2020	53,593	53,593
Series B redeemable convertible preferred stock, $0.001 par value; 74,620,739 shares authorized as of December 31, 2019 and 2020, 5,166,203 shares issued and outstanding as of December 31, 2019 and 2020; preference in liquidation of $36,400 as of December 31, 2020	36,336	36,336
Series C redeemable convertible preferred stock, $0.001 par value; 109,604,994 shares authorized as of December 31, 2019 and 2020, 7,588,254 shares issued and outstanding as of December 31, 2019 and 2020; preference in liquidation of $53,465 as of December 31, 2020	53,221	53,221
Series D redeemable convertible preferred stock, $0.001 par value; 0 and 99,705,359 shares authorized, 0 and 6,902,872 issued and outstanding as of December 31, 2019 and 2020, respectively; preference in liquidation of $90,000 as of December 31, 2020	—	89,904
STOCKHOLDERS' DEFICIT:		
Common stock, $0.001 par value; 796,959,241 and 598,232,153 shares authorized as of December 31, 2019 and 2020, respectively; 7,778,552 and 8,391,793 shares issued and outstanding as of December 31, 2019 and 2020, respectively	8	8
Additional paid-in capital	3,951	7,109
Accumulated deficit	(63,494)	(102,835)
Total stockholders' deficit	(59,535)	(95,718)
TOTAL LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT	$ 103,569	$ 165,338

See notes to consolidated financial statements.

FINCH THERAPEUTICS GROUP, INC.

Consolidated Statements of Operations

(In thousands, except share and per share data)

	YEAR ENDED DECEMBER 31, 2019	2020
REVENUE:		
Collaboration revenue	$ 9,083	$ 7,376
Contract manufacturing revenue from related party	435	—
Royalties revenue from related party	587	343
Services revenue from related party	49	—
Total revenue	10,154	7,719
OPERATING EXPENSES:		
Cost of contract manufacturing revenue from related party	(314)	—
Research and development	(23,543)	(33,144)
General and administrative	(7,439)	(14,011)
Total operating expenses	(31,296)	(47,155)
Net operating loss	(21,142)	(39,436)
OTHER INCOME, NET:		
Interest income, net	488	106
Loss on sale of assets to related party	(140)	—
Loss on disposal of fixed assets	—	(13)
Other income, net	40	2
Total other income, net	388	95
Loss before income taxes	(20,754)	(39,341)
Income tax provision	—	—
Net loss	$ (20,754)	$ (39,341)
Net loss attributable to common stockholders—basic and diluted (Note 15)	$ (20,754)	$ (39,341)
Net loss per share attributable to common stockholders—basic and diluted	$ (2.84)	$ (4.83)
Weighted-average common stock outstanding—basic and diluted	7,295,751	8,144,855

See notes to consolidated financial statements.

FINCH THERAPEUTICS GROUP, INC.

Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit

(In thousands, except share and per share data)

	REDEEMABLE CONVERTIBLE PREFERRED STOCK								COMMON 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		$0.001 PAR VALUE		ADDITIONAL PAID-IN	ACCUMULATED	TOTAL STOCKHOLDERS
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	CAPITAL	DEFICIT	DEFICIT
BALANCE, January 1, 2019	11,596,280	$ 53,593	5,166,203	$ 36,336	—	$ —	—	$ —	6,861,218	7	$ 3,185	$ (42,740)	$ (39,548
Issuance of series C redeemable convertible preferred stock, net of issuance costs of $245	—	—	—	—	6,906,998	48,421	—	—	—	—	—	—	—
Conversion of notes payable to series C redeemable convertible preferred stock	—	—	—	—	681,256	4,800	—	—	—	—	—	—	—
Exercise of common stock options	—	—	—	—	—	—	—	—	182,360	—	150	—	150
Vesting of restricted stock	—	—	—	—	—	—	—	—	734,974	1	10	—	11
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	606	—	606
Net loss	—	—	—	—	—	—	—	—	—	—	—	(20,754)	(20,754
BALANCE, January 1, 2020	11,596,280	$ 53,593	5,166,203	$ 36,336	7,588,254	$ 53,221	—	$ —	7,778,552	8	$ 3,951	$ (63,494)	$ (59,535
Issuance of series D redeemable convertible preferred stock, net of issuance costs of $96	—	—	—	—	—	—	6,902,872	89,904	—	—	—	—	—
Exercise of common stock options	—	—	—	—	—	—	—	—	65,881	—	59	—	59
Vesting of restricted stock	—	—	—	—	—	—	—	—	547,360	—	8	—	8
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	3,091	—	3,091
Net loss	—	—	—	—	—	—	—	—	—	—	—	(39,341)	(39,341
BALANCE, December 31, 2020	11,596,280	$ 53,593	5,166,203	$ 36,336	7,588,254	$ 53,221	6,902,872	$ 89,904	8,391,793	8	$ 7,109	$ (102,835)	$ (95,718

See notes to consolidated financial statements.

FINCH THERAPEUTICS GROUP, INC.

Consolidated Statements of Cash Flows

(In thousands)

	YEAR ENDED DECEMBER 31, 2019	2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (20,754)	$ (39,341)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	482	790
Stock-based compensation expense	606	3,099
Loss on sale of assets to related party	140	—
Loss on disposal of property and equipment	—	13
Changes in operating assets and liabilities:		
Accounts receivable	1,200	143
Inventories	43	—
Due from related party	(1,152)	3,507
Prepaid expenses and other current assets	85	(3,665)
Accounts payable	(1,057)	440
Accrued expenses and other current liabilities	1,905	481
Due to related party	298	(68)
Deferred revenue	942	2,963
Deferred rent	(58)	309
Net cash used in operating activities	(17,320)	(31,329)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment—related party	—	(1,150)
Purchases of property and equipment	(1,005)	(1,483)
Proceeds from sale of property and equipment	32	—
Net cash used in investing activities	(973)	(2,633)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of deferred initial public offering costs	—	(249)
Principal payments on capital lease obligation	(71)	(47)
Proceeds from issuance of convertible notes payable	4,800	—
Proceeds from PPP Loan	—	1,808
Proceeds from issuance of series C redeemable convertible preferred stock	48,666	—
Payment of series C redeemable convertible preferred stock issuance costs	(245)	—
Proceeds from issuance of series D redeemable convertible preferred stock	—	90,000
Payment of series D redeemable convertible preferred stock issuance costs	—	(96)
Proceeds from exercise of stock options	150	59
Net cash provided by financing activities	53,300	91,475
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	35,007	57,513
Cash, cash equivalents and restricted cash at beginning of year	7,389	42,396
Cash, cash equivalents and restricted cash at end of year	$ 42,396	$ 99,909
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for interest	$ 8	$ 11
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Property and equipment in accounts payable and accrued liabilities	$ 37	$ 1,398
Property and equipment purchases under capital lease obligation	$ 47	—
Sale of property and equipment and inventory in due from related party	$ 2,411	—
Convertible notes payable converted into series C redeemable convertible preferred stock	$ 4,800	—
Deferred initial public offering costs in AP and accruals	—	$ 764

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

	FOR THE YEAR ENDED DECEMBER 31,	
	2019	2020
Cash and cash equivalents	$ 42,186	$ 99,710
Restricted cash	210	199
Total cash, cash equivalents and restricted cash	$ 42,396	$ 99,909

See notes to consolidated financial statements.

FINCH THERAPEUTICS GROUP, INC.

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"), where the former owners of Finch and Crestovo were issued equivalent stakes in the newly formed company, FTG. Crestovo was renamed Finch Therapeutics Holdings LLC in November 2020 ("Finch Holdings"). Finch and Finch Holdings are both wholly-owned subsidiaries of FTG.

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

Risks and Uncertainties

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

In response to the ongoing global COVID-19 pandemic, the Company established a cross-functional task force and has implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on its employees and business, including its clinical trials. The Company's operations are considered an essential business and have been allowed to continue operating under current governmental restrictions during this period. The Company has taken measures to secure its research and development activities, while work in laboratories and facilities has been organized to reduce risk of COVID-19 transmission. The extent of the impact of the COVID-19 pandemic on the Company's business, operations and clinical development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on clinical trial enrollment, trial sites, contract research organizations, contract manufacturing organizations, and other third parties with whom the Company does business, as well as its impact on regulatory authorities and its key scientific and management personnel. While the Company is experiencing limited financial impacts at this time, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, the Company's business, financial condition and results of operations ultimately could be materially adversely affected. The Company continues to closely monitor the COVID-19 pandemic as it evolves its business continuity plans, clinical development plans and response strategy.

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

Going Concern

The Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued.

Since its inception in 2017, the Company has focused primarily on developing and progressing its product candidates through clinical development, organizing and staffing its company, research and development activities, establishing and protecting its intellectual property portfolio including for its Human-First Discovery platform, and raising capital. To date, the Company has not generated any revenue from sales of its product candidates, as none have been approved for commercialization. The Company has historically financed its operations primarily through the sale of redeemable convertible preferred stock and collaboration revenue.

The Company has incurred recurring losses since its inception, including net losses of $20.8 million and $39.3 million for the years ended December 31, 2019 and 2020, respectively. In addition, as of December 31, 2020, the Company had an accumulated deficit of $102.8 million. The Company expects to continue to generate operating losses and negative operating cash flows for the foreseeable future as it continues to develop its product candidates. The Company expects that its cash and cash equivalents of $99.7 million as of December 31, 2020 will not be sufficient to fund its operating expenses and capital expenditure requirements for twelve months from the date these annual consolidated financial statements are issued.

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

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

Based on its recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and need to raise additional capital to finance its future operations, the Company has concluded that there is substantial doubt about its ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 Finch

and Finch Holdings. 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 under Accounting Standards Codification ("ASC") *Topic 606, Revenue from Contracts with Customers* ("ASC 606"), the accrual of research and development costs, the annual assessment of impairment of goodwill and in-process research and development assets, and the fair values of common and preferred stock. 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.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. 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, 2019 and 2020.

An entity may choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings.

Fair Value Option

The Company elected the fair value option to account for its convertible notes that were issued and settled during 2019 (the "2019 Notes"). The Company recorded the 2019 Notes at their estimated fair value with

changes in estimated fair value recorded as a component of other income (loss) in the consolidated statement of operations. The Company would continue to do so unless the change in fair value is a result of a change in credit risk of the 2019 Notes, in which case such change in estimated fair value would be recorded within other comprehensive income (loss). As the 2019 Notes were issued and settled during the year ended December 31, 2019, any estimated fair value changes related to the credit risk of the 2019 Notes were recognized as part of other income (loss) upon settlement of the 2019 Notes. No material change to the credit risk of the 2019 Notes occurred during the period they were outstanding. As a result of applying the fair value option, direct costs and fees related to the 2019 Notes were expensed as incurred and were not deferred. The Company concluded that it was appropriate to apply the fair value option to the 2019 Notes because no component of the 2019 Notes was required to be recognized as a component of stockholders' deficit.

Cash, Cash Equivalents and Restricted Cash

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 equivalents was $42.2 million and $99.7 million as of December 31, 2019 and 2020, respectively, which approximates fair value and was determined based upon Level 1 inputs. The money market account is valued using quoted market prices with no valuation adjustments applied and is categorized as Level 1.

The Company had restricted cash of $0.2 million as of December 31, 2019 and 2020, primarily related to a security deposit on its operating lease for its offices in Somerville, Massachusetts. Restricted cash is presented as a noncurrent asset on the Company's consolidated balance sheets.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. The Company may maintain deposits in financial institutions in excess of government insured limits. The Company believes that it is not exposed to significant credit risk as its deposits are held at financial institutions that management believes to be of high credit quality and the Company has not experienced any losses on these deposits. As of December 31, 2019 and 2020, the Company's cash and cash equivalents were held with one financial institution. The Company believes that the market risk arising from its holdings of these financial instruments is mitigated based on the fact that many of these securities are either government-backed or of high credit rating.

Accounts Receivable

Accounts receivable are carried at the invoiced amount less an allowance for doubtful accounts. Doubtful accounts are provided for on the basis of anticipated collection losses. The estimated losses are determined from historical collection experience and a review of outstanding accounts receivable. A receivable is considered past due if the Company has not received payment within the stated payment terms. After all attempts to collect a receivable have failed, the receivable is written off against the allowance. Based on historical receipts and collections history, management has determined that an allowance for doubtful accounts is not necessary as of December 31, 2019 and 2020.

Property and Equipment

Property and equipment are recorded at cost. Expenditures for repairs and maintenance are expensed as incurred, while any additions or improvements are capitalized. When assets are retired or disposed of, the assets

and related accumulated depreciation are derecognized from the accounts, and any resulting gain or loss is included in the determination of net loss. Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets as follows:

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

Inventories

The Company is a pre-commercial enterprise that produced certain materials not yet approved by the Food and Drug Administration ("FDA") as part of its research and development efforts. Through January 2019, the Company manufactured certain Fecal Microbiota Transplantation ("FMT") materials. FMT is an investigational drug that is sold by OpenBiome for treating CDI in patients not responding to standard therapies. The Company manufactured materials for OpenBiome that are sold under the FDA's enforcement discretion policy granted to OpenBiome and recognized them as salable inventory to FTG. The products were offered exclusively to OpenBiome, as a customer, under specific terms of a related party contract manufacturing arrangement (see Note 13).

On February 1, 2019, the Company sold all of its remaining inventory to OpenBiome, a related party (see Note 13). As of December 31, 2019 and 2020, the Company had no inventory.

Inventories are valued at the lower of cost or net realizable value. Cost is determined using a first in, first out basis. Appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors in evaluating the value of inventory. The Company periodically reviews the value of its inventory and recognizes write-downs or write-offs of inventory based on its assessment of market conditions.

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 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.

During the fourth quarter of 2020, the Company decided to change its annual goodwill and IPR&D impairment assessment date from the last day of the fiscal year to the first day of the fourth quarter, or October 1.

The change in measurement date represents a change in method of applying an accounting principle. This change was preferable because it aligned the Company's impairment testing procedures with its annual business planning and budgeting process, which occurs in the fourth quarter of each year, and with the timing of the development of its multi-year strategic plan. This change in accounting principle related to the annual testing date did not delay, accelerate, or avoid an impairment charge. This change was not applied retrospectively as it was impracticable to do so because retrospective application would have required application of significant estimates and assumptions with the use of hindsight. Accordingly, the change was applied prospectively. In addition, this change did not have a material impact on the Company's consolidated financial statements.

To conduct impairment tests of goodwill, the fair value of the Company's single reporting unit is compared to its carrying value. If the reporting unit's carrying value exceeds its fair value, the Company records an impairment loss to the extent that the carrying value of goodwill exceeds its fair value. The Company's annual assessments for impairment of goodwill as of December 31, 2019 and October 1, 2020 indicated that the fair value of its reporting unit exceeded the carrying value of the reporting unit.

To conduct impairment tests of IPR&D, the fair value of the IPR&D asset is compared to its carrying value. If the carrying value exceeds its fair value, the Company records an impairment loss to the extent that the carrying value of the IPR&D project exceeds its fair value. The Company estimates the fair value of IPR&D using discounted cash flow valuation models, which require the use of significant estimates and assumptions, including but not limited to, estimating the timing of and expected costs to complete the in-process projects, projecting regulatory approvals, estimating future cash flows from product sales resulting from completed projects and in-process projects, and developing appropriate discount rates. The Company's annual assessment for impairment of IPR&D indicated that the fair value of its IPR&D asset as of December 31, 2019 and October 1, 2020 exceeded the respective carrying value.

Any impairments are recognized as a loss in the year the goodwill and/or IPR&D are determined to be impaired. Impairment of IPR&D is recorded as research and development expense and impairment of goodwill is recorded separately as a loss in other income (expense) on the Company's consolidated statements of operations. To date, no impairment loss has been recognized. Additionally, there has been no change to the carrying value of goodwill and IPR&D for the years ended December 31, 2019 and 2020.

Deferred Initial Public Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of proceeds generated as a result of the offering.

Should a planned equity financing be abandoned, the deferred initial public offering costs would be expensed immediately as a charge to operating expenses in the consolidated statement of operations. The Company recorded no deferred initial public offering costs as of December 31, 2019 and $1.0 million as of December 31, 2020, $0.2 million of which were paid as of December 31, 2020.

Impairment of Long-lived Assets

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

Research and Development Expenses

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

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

Segment Information

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

Common Stock Valuation

Due to the absence of an active market for the Company's common stock, the Company utilized methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its common stock. In determining the exercise prices for options granted, the Company has considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock has been determined at each grant date based upon a variety of factors, including:

- the prices at which the Company sold shares of redeemable convertible preferred stock and the superior rights and preferences of the redeemable convertible preferred stock relative to its common stock at the time of each grant;
- the progress of the Company's research and development programs, including the status and results of preclinical studies for its product candidates;
- the Company's stage of development and commercialization and its business strategy;
- external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- the Company's financial position, including cash on hand, and its historical and forecasted performance and operating results;
- the lack of an active public market for the Company's common stock and redeemable convertible preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of the Company in light of prevailing market conditions; and

- the analysis of initial public offerings and the market performance of similar companies in the biotechnology industry.

Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Redeemable Convertible Preferred Stock

The Company has classified redeemable convertible preferred stock ("preferred stock") as temporary equity in the accompanying consolidated balance sheets due to terms that allow for redemption of the shares upon certain change in control events that are outside of the Company's control, including sale or transfer of control of the Company as holders of the preferred stock could cause redemption of the shares in these situations. The Company does not accrete the carrying values of the preferred stock to the redemption values since a liquidation event was not considered probable as of December 31, 2019 and 2020. Subsequent adjustments of the carrying values to the ultimate redemption values will be made only when it becomes probable that such a liquidation event will occur.

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 include stock options and grants of restricted stock awards. 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. Prior to the adoption of Accounting Standards Update ("ASU") No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"), the measurement date for non-employee awards was generally the date the services were completed, resulting in financial reporting period adjustments to stock-based compensation during the vesting terms for changes in the fair value of the awards. Since the adoption of ASU 2018-07, the measurement date for non-employee awards is the date of grant without changes in the fair value of the award. 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 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, 2019 and 2020, the Company maintains a reserve against certain federal and state research and development credits that are recorded net in deferred taxes. The Company has no accruals for interest or penalties related to income tax matters. Tax years since inception remain open to examination by federal and state tax authorities.

Revenue Recognition

The Company has historically generated revenue from the following sources: (1) collaboration revenue from the collaboration agreement with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (see Note 6); (2) contract manufacturing revenue from the sale of FMT materials to OpenBiome under the Subject Matter Agreement for Quality System and Supply, as amended, with OpenBiome (see Note 6); (3) royalty revenue from OpenBiome's sales of a licensed product under the Asset Purchase and License Agreement with OpenBiome (see Note 6); and (4) services revenue from support provided by the Company's employees to OpenBiome (see Note 6).

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

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

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

prior to the transfer of control of FMT materials and are considered activities to fulfill the Company's promise to deliver goods to the customers.

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

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

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

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

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. For performance obligations which consist of the transfer of FMT materials, 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,	
	2019	2020
Transferred at a point in time	$ 1,071	$ 343
Transferred over time	9,083	7,376
Total	$ 10,154	$ 7,719

Net Loss Per Share

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

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

Common stock equivalent shares are excluded from the computation of diluted net loss per share if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is generally the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2019 and 2020.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (ASC 842)*, which requires a lessee to record a right-of-use asset and a corresponding lease liability on the balance sheet for all leases with terms longer than 12 months. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. As the Company has elected to use the extended transition period for complying with new or revised accounting standards as available under the Jumpstart Our Business Startups Act ("JOBS Act"), the standard is effective for the Company beginning January 1, 2022, with early adoption permitted. The Company is currently evaluating the expected impact that the standard could have on its consolidated financial statements and related disclosures.

In November 2018, the FASB issued Accounting Standards Update 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606 (*"ASU 2018-18"). ASU

2018-18 amends ASC 808 to clarify ASC 606 should apply in entirety to certain transactions between collaborative arrangement participants. The amendments for ASU 2018-18 are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. As the Company does not have any agreements considered to be collaborative arrangements, the Company determined that this standard did not have an impact on its consolidated financial statements and related disclosures.

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

3. FAIR VALUE MEASUREMENTS

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

DESCRIPTION	DECEMBER 31, 2019	QUOTED PRICES IN ACTIVE MARKETS FOR IDENTICAL ASSETS (LEVEL 1)	SIGNIFICANT OBSERVABLE INPUTS (LEVEL 2)	SIGNIFICANT OBSERVABLE INPUTS (LEVEL 3)
Asset				
Money market funds	$ 41,184	$ 41,184	$ —	$ —
Total financial assets	$ 41,184	$ 41,184	$ —	$ —

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

There have been no transfers between fair value levels during the years ended December 31, 2019 and 2020. The carrying values of other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Convertible Notes

In February 2019, the Company issued the 2019 Notes for $18.0 million (see Note 9), of which $1.2 million was drawn each month for a total of $4.8 million drawn by May 2019. In May 2019, the 2019 Notes were converted into 681,256 shares of series B-1 redeemable convertible preferred stock ("Series B-1," which was reclassified as series C redeemable convertible preferred stock ("Series C") in June 2019) at a conversion price of $7.0458 per share, which was also the original issuance price of Series C. There were no financial

instruments measured at fair value on a recurring basis outstanding as of December 31, 2019 and 2020. The fair value of the 2019 Notes was determined based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy. The Company determined the estimated fair value of the 2019 Notes was $4.8 million based on the proceeds received for the 2019 Notes, as the proceeds from the 2019 Notes were expected to equal the fair value of the equivalent number of Series C shares.

The fair value of the 2019 Notes upon settlement in May 2019 (see Note 9) was $4.8 million. Because the issuance and extinguishment occurred within three months of each other, the Company originally recorded the 2019 Notes at the amount of the proceeds received for them, which was also equal to the fair value of shares they subsequently converted into (Series B-1, later reclassified as Series C). As such, the Company did not recognize a gain or loss on changes in fair value in the consolidated statement of operations for the year ended December 31, 2019.

4. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following as of December 31, 2019 and 2020 (in thousands):

	DECEMBER 31,	
	2019	2020
Lab equipment	$ 1,608	$ 2,363
Office furniture and fixtures	537	537
Leasehold improvements	2,748	2,143
Construction work-in-progress	—	2,635
Software	—	1,150
Computer equipment	141	205
Total	5,034	$ 9,033
Less: Accumulated depreciation	(1,258)	(2,029)
Property and equipment, net	$ 3,776	$ 7,004

Depreciation expense was $0.5 million and $0.8 million for the years ended December 31, 2019 and 2020, respectively. During the year ended December 31, 2020, the Company purchased $1.2 million of software from a related party.

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following as of December 31, 2019 and 2020 (in thousands):

	YEAR ENDED DECEMBER 31,	
	2019	2020
Accrued research and development	$ 845	$ 81
Accrued legal	100	711
Accrued compensation and benefits	2,189	3,532
Accrued other	824	904
Total accrued expenses and other current liabilities	$ 3,958	$ 5,228

6. REVENUE

Takeda Pharmaceutical Company Limited

In January 2017, the Company entered into an agreement (the "Takeda Agreement") with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of 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 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.

Under the terms of the Takeda Agreement, the Company has 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 product candidate optimized for the treatment of Crohn's disease. Takeda can determine whether to initiate a full product-specific development plan for FIN-525 following its review of the data from the Company's feasibility study.

Pursuant to the Takeda Agreement, the Company is primarily responsible for early-stage development activities pursuant to an agreed upon development plan and budget through Phase 1 clinical trials. The Company is entitled to cash reimbursement from Takeda for certain R&D costs incurred as part of the Company's commercially reasonable efforts to develop a treatment for ulcerative colitis and Crohn's disease at the direction of and for the benefit of Takeda, who expects to commercialize the treatment. The Company is contractually obligated to perform these efforts under the Takeda Arrangement, and they are also considered to be the output of the Company's ordinary business activities as the benefit from these R&D activities will be transferred to Takeda as the Company's obligations are satisfied. Takeda has the option to perform Phase 2 clinical trials itself, and if this option is not exercised, the Company will assume responsibility for such development. After the successful completion of the first Phase 2 clinical trial for the applicable product candidate, Takeda will assume primary responsibility for Phase 3 clinical trials. Takeda was also granted two options to pursue development of FIN-524 for diseases other than CDI, for an option maintenance fee payable to the Company of $0.3 million per year for each option, due even if the options were not exercised and until the options were terminated. The options each had a term of twenty-four months and Takeda could elect to terminate its option at any point; Takeda elected to terminate both options prior to December 31, 2018 and paid total option maintenance fees of $0.5 million. The Takeda Agreement provides consideration to the Company in the form of an upfront payment, milestone payments related to development and commercialization efforts, reimbursement of research and development costs, sales-based royalties, and previously, any option exercise fees or maintenance fees for the two terminated options.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Takeda, is a customer. The Company identified the following material promises at the outset of the Takeda Agreement: (1) an exclusive license to use the Company's intellectual property to conduct research activities; (2) research and development ("R&D") services for activities under the development plan; (3) two options to pursue different indications of research for the Company's product candidates; (4) manufacturing and supply for the Company's clinical trials; and (5) participation on a joint steering and joint development committee ("JSC" and "JDC"). The options were considered distinct from the other promises in the arrangement and analyzed for material rights; the Company concluded these were not material rights and the consideration related to them should be excluded as a performance obligation until the option is exercised. The Company determined that the remaining promises were not capable of being distinct from one another and were not distinct in the context of the contract, as the license has no value without the performance of the R&D activities or the technology transfer related to the outputs of those activities, and the JSC/JDC participation is dependent on these activities. Takeda would not be able to use the license without the performance of R&D activities by the

Company, as the research is novel in nature and could not be performed by another company in an economically viable timeframe. Additionally, the technology transfer is inherently dependent on the outcome of the Company's R&D activities, and as such is not capable of being distinct. The Takeda Agreement did not contain a significant financing component as of the inception 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, which were analyzed as options and deemed not to represent material rights. The option consideration is excluded as a performance obligation until the underlying option is exercised. The transaction price was allocated between the combined performance obligation and the options based on their standalone selling prices. The Company determined the contract term of the Takeda Agreement to be the period over which the Company has enforceable rights and obligations to perform R&D services, through Phase 1 clinical trials. The Company determined that it met the criteria to recognize revenue over time and identified an appropriate measure of progress for the recognition of revenue and determined it would recognize the revenue using an input method based on total costs incurred to date as compared with total expected costs, as this appropriately depicts the Company's performance in satisfaction of the performance obligation. Amounts received that have not yet been recognized as revenue are recorded in deferred revenue on the Company's consolidated balance sheet.

Takeda may terminate the Takeda Agreement at-will, with 90 days' notice to the Company, and either party may terminate for a breach of contract that is not remedied within a defined period of time. The Company assessed this termination provision and determined that because of the existence of a substantive termination penalty in the form of a reversion of the rights and license to the underlying intellectual property, the provision does not result in a material right in the form of a continuous renewal option.

The Company received an upfront payment from Takeda of $10.0 million in the year ended December 31, 2017 in exchange for the exclusive license of the Company's intellectual property. The Company has included the upfront payment and the estimable reimbursable R&D costs in the transaction price and is recognizing revenue associated with it over the period it expects to perform R&D services. All of the components of the combined performance obligation are recognized using the same measure of progress. The Company recognized revenue related to the upfront payment of $1.3 million and less than $0.1 million in the years ended December 31, 2019 and 2020, respectively, which is included under collaboration revenue in the consolidated statements of operations.

Takeda reimburses the Company for certain research and development costs under the Takeda Agreement on a quarterly basis, which are agreed upon by both parties through their participation on the JSC and JDC and included in the transaction price and recognized according to the cost input method, as they are deemed to represent estimable variable consideration that is not expected to result in a significant reversal of revenue. The Company received payments from Takeda for these reimbursable research and development costs and recognized revenue of $7.1 million in the years ended December 31, 2019 and 2020, which is included under collaboration revenue in the consolidated statements of operations. The Company also recorded accounts receivable of $1.2 million and $1.0 million on its consolidated balance sheets as of December 31, 2019 and 2020, respectively. As of December 31, 2019, the Company recorded deferred revenue of $10.7 million related to the Takeda Agreement. As of December 31, 2020, the Company recorded deferred revenue of $13.6 million ($3.4 million of which is classified as current) related to the Takeda Agreement, which represents the portion of the combined performance obligation that is considered partially unsatisfied as of December 31, 2020. This amount will be recognized over the period the Company will perform research and development services, through the end of Phase 1 clinical trials.

The Takeda Agreement contains various milestone payments associated with development and commercialization efforts that provide for a maximum available amount of $180.0 million should all of the milestones be achieved. These milestones are constrained until the Company determines it is probable that the cumulative revenue related to the milestones will not be reversed, at which point the Company adds the

consideration to the transaction price and recognizes the milestone revenue over the remaining performance period, according to the measure of progress, with a catch-up in the period it becomes probable that a significant reversal of revenue will not occur. As of December 31, 2020, the Company has earned and received $4.0 million in milestone payments, $0.7 million and $0.3 million of which was recognized as collaboration revenue in the consolidated statements of operations for the years ended December 31, 2019 and 2020, respectively.

Under the Takeda Agreement, Takeda is obligated to pay the Company mid-to-high single digit royalties based on annual aggregate net sales of the licensed products, on a product-by-product basis, subject to certain restrictions. The Company did not receive any payments or record any revenues related to sales-based royalties under the Takeda Agreement in the years ended December 31, 2019 and 2020.

OpenBiome

On December 14, 2016, the Company entered into a Master Strategic Affiliation Agreement ("Strategic Agreement") with OpenBiome (see Note 13) which provided the legal infrastructure for the strategic collaboration. Under the Strategic Agreement, a series of subject matter agreements between the Company and OpenBiome were executed that provide a detailed outline of the strategic collaboration, including agreements to govern quality and safety of the data as well as facilitate the transfer of intellectual property between the parties. In addition to the subject matter agreements, the Company and OpenBiome also entered into a Material Access and License Agreement ("MAL Agreement") in December 2016 and an Asset Purchase and License Agreement ("APL Agreement") in February 2019. The MAL Agreement provided the Company with a license to certain biological material and data from stool donors which could be used in the Company's research and development activities (see Note 8). Under the APL Agreement, the Company licensed certain intellectual property and sold certain FMT materials and equipment to OpenBiome (see Note 8).

On February 22, 2017, the Company entered into the QSS Agreement with OpenBiome, who was deemed to represent a customer, which was subsequently amended on September 19, 2017. Under the QSS, OpenBiome granted the Company an exclusive license, eligible for sublicense, of certain OpenBiome technology and intellectual property. Additionally, the Company acquired certain assets of OpenBiome for use in manufacturing and supplying FMT materials in connection with the execution of the QSS Agreement. Under the QSS Agreement, OpenBiome purchased FMT materials manufactured by the Company at cost. The QSS Agreement allows for the Company to use the licensed OpenBiome technology and intellectual property for its own research and development efforts in exchange for up to $27.5 million in milestone payments associated with the Company's development and commercialization efforts.

The Company determined that the QSS consisted of one combined performance obligation, consisting of the obligation to manufacture FMT materials. The Company recognizes revenue under the QSS at a point in time, once the underlying transfer of FMT materials occurs. In 2018, the Company entered into a Subject Matter Agreement for Materials and Services in Support of Government Contracts and a Subject Matter Agreement for Services in Support of a Single Patient IND for Compassionate Use to allow for the parties to share clinical data and align on regulatory requirements and responsibilities.

The QSS Agreement was partially terminated on February 1, 2019 in connection with the APL Agreement, and fully terminated in November 2020 in connection with the Company's execution of the OpenBiome Agreement (see Note 13). As of February 2019, the Company had no further obligation to manufacture FMT material and transfer it to OpenBiome. The Company earned $0.6 million and $0.3 million in royalty revenue related to the APL Agreement in the years ended December 31, 2019 and 2020, respectively, which is recorded as royalties revenue from related party on the Company's consolidated statements of operations.

The Company recognized revenue associated with the QSS Agreement of $0.4 million and $0 in the years ended December 31, 2019 and 2020, respectively, which is included under contract manufacturing revenue

from related party in the consolidated statements of operations. As of December 31, 2019 and 2020, there were no amounts recorded as inventory in connection with the QSS Agreement on the Company's consolidated balance sheets.

On November 19, 2020, the Company entered into the 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 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 13) and the license granted under the LMIC Agreement is unrelated to those assets acquired. The only consideration provided to the Company under the LMIC Agreement is in the form of future royalties on net sales of OpenBiome Royalty Products. The Company is entitled to receive tiered royalties on net sales of certain products, ranging from mid single digit to low second decile digits on a product-by-product and country-by-country basis. In the event that OpenBiome is required to pay a royalty to a third party to obtain rights under patents owned or controlled by such third party that are necessary for the exercise of its rights under the Company's intellectual property pursuant to the LMIC Agreement, then OpenBiome shall have the right to deduct a portion of the amount of the royalty due to the third party against the royalties that are due from OpenBiome to the Company. The Company has not earned any of these royalty payments as of December 31, 2020.

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 of the LMIC Agreement.

OpenBiome also has the right to sublicense any new in-licenses entered into by the Company for a four-year period subject to certain restrictions. The new in-licenses are licenses entered into by Company or its affiliates after the execution of the LMIC Agreement concerning third-party technology that would be reasonably useful or necessary for OpenBiome in their development of OpenBiome Natural Products, OpenBiome Licensed Drug Substances, and OpenBiome Royalty Product under the LMIC Agreement.

Pursuant to ASC 606, the Company determined that OpenBiome is a customer under the LMIC Agreement as the Company is transferring the license, which is an output of the Company's primary business operations, to OpenBiome in exchange for future consideration. The LMIC Agreement is comprised of two distinct performance obligations, one consisting of the license and relevant data exchange, and one related to the rights to future new in-licenses. The Company determined that the rights to future new in-licenses is not representative of a material right, as they do not provide future goods or services at a significant discount and are contingent upon the Company entering into such licenses. There are no new in-licenses at the execution of the LMIC Agreement, as such no value is allocated to them at execution, but the performance obligation will be reassessed at each reporting period to determine allocation of future consideration once they are executed. The performance obligation consisting of the license and relevant data exchange will be satisfied over time, as OpenBiome uses the license. As the underlying contingent royalty payments are predominantly related to the license, the Company will elect the royalty scope exception to recognize royalty revenue as the underlying sales occur.

The Company did not recognize any revenue related to the LMIC Agreement for the year ended December 31, 2020, as there are currently no marketable OpenBiome Royalty Products.

7. INCOME TAXES

For the years ended December 31, 2019 and 2020, the Company did not record a current or deferred income tax expense or benefit due to current and historical losses incurred by the Company.

The effective income tax rate differed from the statutory federal income tax rate due to the following:

	YEAR ENDED DECEMBER 31,	
	2019	2020
Federal income taxes at 21%	21.00%	21.00%
State income taxes, net of federal benefit and tax credits	5.24	6.04
Permanent differences	(0.35)	(1.60)
Research and development credit	4.50	2.03
Change in valuation allowance	(28.45)	(26.96)
Other adjustments	(1.94)	(0.51)
	0.00%	0.00%

Significant components of the Company's net deferred tax assets and liabilities as of December 31, 2019 and 2020 are as follows (in thousands):

	YEAR ENDED DECEMBER 31,	
	2019	2020
Deferred Tax Assets:		
Net operating losses	$ 20,808	$ 30,192
Tax credits	2,619	2,921
Deferred revenue	2,139	3,057
Accrued expenses	714	225
Other	138	289
Total deferred tax assets	26,418	36,684
Valuation allowance	(21,728)	(31,963)
Total net deferred tax assets	4,690	4,721
Deferred Tax Liabilities:		
Intangibles assets	7,781	7,891
Fixed assets	370	253
Other	—	38
Total deferred tax liabilities	8,151	8,182
Total net deferred tax liabilities	$ 3,461	3,461

The Company regularly assesses the need for a valuation allowance against its deferred tax assets. In making that assessment, the Company considers both positive and negative evidence related to the likelihood of realization of the deferred tax assets to determine, based on the weight of available evidence, whether it is more-likely-than-not that some or all of the deferred tax assets will not be realized. In assessing the realizability of deferred tax assets, the Company considers taxable income in prior carryback years, as permitted under the tax law, forecasted taxable earnings, tax planning strategies, and the expected timing of the reversal of temporary differences. This determination requires significant judgment, including assumptions about future taxable income that are based on historical and projected information and is performed on a jurisdiction-by-jurisdiction basis.

The Company continues to maintain a partial valuation allowance against its deferred tax assets. During the years ended December 31, 2019 and 2020, management assessed the positive and negative evidence in its U.S. operations, and concluded that it is more likely than not that a portion of its deferred tax assets as of December 31, 2019 and 2020 will not be realized given the Company's history of operating losses. In determining the amount of the valuation allowance to record, the Company considered the reversal of existing taxable temporary differences as a source of taxable income against which a portion of its deferred tax assets is benefitted. The Company recorded a full valuation allowance against the remaining U.S. deferred tax assets in excess of this source of taxable income. The valuation allowance against deferred tax assets increased by approximately $10.2 million during 2020 related to a full valuation allowance recorded against additional net operating losses and tax credits generated in the year.

As of December 31, 2019, the Company had federal net operating losses of $79.7 million, which may be available to offset future federal income tax liabilities.

As of December 31, 2020, the Company had federal net operating losses of $114.4 million, which may be available to offset future federal income tax liabilities. The Company's federal net operating losses incurred prior to 2018, $37.2 million, expire through 2037, while its federal net operating losses incurred in 2018 and onwards, $77.2 million, can be carried forward indefinitely.

As of December 31, 2019, the Company had post-apportioned state net operating losses of $5.0 million that can generally be carried forward 20 years. As of December 31, 2020, the Company had post-apportioned state net operating losses of $6.1 million that can generally be carried forward 20 years.

As of December 31, 2019, the Company had $2.0 million and $0.7 million of federal and state research and development credits, respectively, which will expire at various dates through 2039. As of December 31, 2020, the Company had $2.6 million and $0.3 million of federal and state research and development credits, respectively, which will expire at various dates through 2040.

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, 2019 and 2020, the total amount of uncertain tax liabilities relates to federal and state tax credit carryforwards and are all recorded net in deferred taxes.

A reconciliation of the beginning and ending balances of the total amounts of gross unrecognized tax benefits is as follows (in thousands):

	YEAR ENDED DECEMBER 31,	
	2019	2020
Balance, beginning of year	$ 664	$ 1,004
Additions for tax positions of current year	340	314
Balance, end of year	$ 1,004	$ 1,318

The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations. As of December 31, 2019 and 2020, no accrued interest or penalties are included on the related tax liability line in the consolidated balance sheet.

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. There are currently no pending income tax examinations. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service and state tax authorities to the extent utilized in a future period.

8. COMMITMENTS AND CONTINGENCIES

Operating lease commitments

200 Inner Belt Rd

In December 2015, the Company entered into a 10-year lease agreement ("Inner Belt Road Lease") for approximately 25,785 square feet of space for its primary office and laboratory space in Somerville, Massachusetts. The Inner Belt Road Lease provided for a two-month rent holiday in the first year of the lease and rent abatements for the first two years of the lease. 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 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 amendment to the Inner Belt Road Lease provided for leasehold improvement incentives of approximately $0.4 million related to the additional office and laboratory 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. OpenBiome did not occupy any of the Company's premises between August 2018 and February 2019, and resumed occupancy and rental payments to the Company beginning in February 2019 when the APL Agreement was executed (see Note 6). 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 (see Note 13) in the first quarter 2021.

The Company recognizes rent expense, inclusive of a reduction to reflect the impact of lease incentives, under the Inner Belt Road Lease on a straight-line basis over the respective lease term and records deferred rent for rent expense incurred but not yet paid. The Company recognizes rent income under the sublease to OpenBiome on a straight-line basis over the sublease term and records prepaid rent for rent income received but not yet earned in due from related party on its consolidated balance sheets. Gross rent expense under the Inner Belt Road Lease was $1.3 million for each of the years ended December 31, 2019 and 2020. Gross rent income under the sublease to OpenBiome for the years ended December 31, 2019 and 2020 was $0.5 million and $0.4 million, respectively, and is presented as an offset to rent expense on the consolidated statements of operations.

21 Erie Street

In May 2018, the Company entered into a 25-month lease arrangement ("Erie Street Lease") for additional lab and office space of approximately 5,400 square feet in Cambridge, Massachusetts. Upon execution of the lease, the Company paid a security deposit of $0.1 million. The Erie Street Lease was terminated in March 2019. As part of the termination agreement, the Company agreed to pay 75% of one month's rent. The early termination fee of approximately $71,000 was covered by the security deposit, and the remainder of the security deposit was returned to the Company in 2019. Rent expense under the Erie Street Lease for the years ended December 31, 2019 and 2020 was $0.3 million and $0, respectively.

Donor Locations

In February 2018, the Company entered into a 5-year lease arrangement for approximately 2,600 square feet ("Cherry Street Lease") related to its primary donor space in Cambridge, Massachusetts. Upon execution of the lease, the Company paid a security deposit of approximately $8,000.

In February 2019, the Cherry Street Lease was assumed by OpenBiome and OpenBiome reimbursed the Company for the security deposit. The Company's rent expense under the Cherry Street Lease for the years ended December 31, 2019 and 2020 was $0.1 million and $0, respectively.

Legacy Crestovo Office and Lab Space

In conjunction with the Merger with Crestovo in 2017, the Company assumed three lease agreements that were formerly entered into by Crestovo. The lease of Crestovo office space in Cambridge, Massachusetts was terminated in January 2018. The Company also assumed two former lab space locations of Crestovo, one of which terminated in April 2018 and one of which was terminated in April 2019. Rent expense during the years ended December 31, 2019 and 2020 for the lab space occupied in 2019 was approximately $34,000 and $0, respectively.

A summary of the Company's future minimum lease payments required under non-cancellable lease agreements is as follows (in thousands):

FOR THE YEAR ENDED DECEMBER 31,	
2021	$1,351
2022	1,387
2023	1,424
2024	1,460
2025	1,496
Thereafter	1,115
	$8,233

Capital lease obligation

The Company acquired certain equipment with a value of approximately $47,000 under capital lease arrangements in 2019. The Company did not acquire any additional equipment under capital lease arrangements in 2020. Amortization of assets held under capital leases is included in depreciation expense.

Future minimum lease payments under the capital lease agreements as of December 31, 2020 together with the present value of the minimum lease payments are as follows (in thousands):

FOR THE YEAR ENDED DECEMBER 31,	
2021	$ 36
2022	24
2023	6
Thereafter	—
Total minimum lease payments	66
Less: amount representing interest	(14)
Present value of minimum lease payments	$ 52

Legal contingencies

Legal claims may arise from time to time in the normal course of business. There are no such claims as of December 31, 2019 and 2020 that will have a material effect on the Company's accompanying consolidated financial statements.

License Payments

The Company enters into contracts in the normal course of business with contract research organizations and other third-parties for preclinical studies, clinical studies, and testing and manufacturing services. Most contracts do not contain minimum purchase commitments and are cancelable by the Company upon prior written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including non-cancelable obligations of our service providers up to one year after the date of cancellation. Under these agreements, in exchange for access to intellectual property the Company may be obligated to provide future minimum royalty payments and milestone payments related to regulatory approvals and sales-based events. The Company entered into the OpenBiome Agreement in November 2020 (see Note 13) that is expected to close in the first quarter of 2021, under which the Company will be required to make certain milestone and royalty payments to OpenBiome in conjunction with the license and purchase of certain intellectual property related to the underlying CMC process used to manufacture materials for its clinical trials (See Note 13). The OpenBiome Agreement in effect terminated the APL Agreement and MAL Agreement obligations.

Under the APL Agreement entered into in 2019 that was effective through November 2020, the Company was obligated to make certain contingent payments for milestones and royalties to OpenBiome, subject to the occurrence of specific underlying criteria that were dependent on regulatory approvals and sales-based events. The Company was obligated to make regulatory milestone payments to OpenBiome aggregating up to $2.5 million upon the achievement of regulatory approvals, and sales-based milestone payments of up to $23.3 million in sales-based milestone payments upon the achievement of certain net sales criteria. The Company did not pay any amounts to OpenBiome associated with milestones in 2019, and paid $0.1 million in 2020. The APL Agreement was terminated in November 2020 upon the execution of the OpenBiome Agreement (see Note 13).

Under the MAL Agreement, the Company was also obligated to pay to OpenBiome, a low single digit royalty on net sales of certain cultured products and a high single digit percentage of certain sublicensing revenue (including royalties) of licensed cultured products. These royalties were calculated on a product-by-product and country-by-country basis. The Company paid $0.2 million to OpenBiome under the MAL Agreement in 2020 related to royalty payments. In 2019, the Company owed $0.2 million to OpenBiome related to the MAL Agreement, of which $0.2 million remained due to OpenBiome as of December 31, 2019. During the year ended December 31, 2020, the Company recorded an additional $0.3 million owed to OpenBiome under the MAL Agreement, of which $0.1 million remained due as of December 31, 2020. The MAL Agreement was terminated in November 2020 upon the execution of the OpenBiome Agreement (see Note 13).

Additionally, the Company is obligated to make certain minimum royalty payments under license agreements entered into with University of Minnesota ("UMN") and Arizona State University ("ASU"). The Company owes an annual maintenance fee of $5,000 under its agreement with UMN, and is subject to minimum annual royalty payments escalating over time in the low five digits to low six digits payable at the end of each applicable year. The Company paid UMN approximately $11,000 and $14,000 in the years ended December 31, 2019 and 2020 related to these royalty payments. The Company is also required to pay an annual royalty payment in the mid four digits to low five digits that is creditable against the royalties due in such year, under the ASU agreement. The Company has not made any payments to ASU for royalties in the years ended December 31, 2019 and 2020, and the Company will not be required to make any of these royalty payments until CP101 is commercially sold.

PPP Loan

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted to, amongst other provisions, provide emergency assistance for individuals, families and businesses affected by the COVID-19 pandemic. The CARES Act includes a Paycheck Protection Program ("PPP") administered through the Small Business Association ("SBA"). Under the PPP, beginning April 3, 2020, small businesses and other entities and individuals could apply for loans from existing SBA lenders and other approved regulated lenders that enroll in the program, subject to numerous limitations and eligibility criteria.

In April 2020, the Company issued a promissory note to Silicon Valley Bank, pursuant to which it received loan proceeds of $1.8 million (the "Loan") provided under the PPP established under the CARES Act and guaranteed by the U.S. Small Business Administration. The Loan is unsecured, is scheduled to mature on April 21, 2022, and has a fixed interest rate of 1.0% per annum. No payments of principal or interest are due during the year ended December 31, 2020, although interest will accrue on the unpaid principal balance. The Company accrued less than $0.1 million of interest expense related to the Loan for the year ended December 31, 2020. Forgiveness of the Loan is only available for principal that is used for the limited purposes that expressly qualify for forgiveness under U.S. Small Business Administration requirements. The Company has determined to account for the Loan as debt under ASC 470, "Debt", and has allocated and recorded the loan proceeds as non-current liabilities as no payment is due at this time. The Company further determined that loan forgiveness would become probable of occurring upon acceptance by the SBA of the Company's forgiveness application. If and when the loan forgiveness becomes probable, the Company will recognize income for debt extinguishment pursuant to ASC 470.

9. CONVERTIBLE NOTES

On February 15, 2019, the Company executed a secured convertible note agreement ("Convertible Note Purchase Agreement") with certain investors under which the Company agreed to issue the 2019 Notes as 15 series of convertible notes, for an aggregate principal amount of up to $18.0 million, each series in the amount of $1.2 million. The first series of the 2019 Notes was issued on February 22, 2019, and the total amount drawn by the Company on the 2019 Notes was $4.8 million prior to conversion in May 2019. Of the $4.8 million of 2019 Notes issued, $4.1 million were issued to affiliates of the Company, deemed to represent related parties.

The 2019 Notes bore interest at a fixed per month rate of 0.643% compounded monthly until their maturity date of December 31, 2019, at which time all outstanding principal and interest became due and payable in cash if not already converted.

In the event of a qualified financing prior to May 31, 2019, whereby the Company issued and sold its preferred stock and raised capital of at least $18.0 million of total gross proceeds in cash, the 2019 Notes would automatically convert into preferred stock at a price equal to the issue price per share of the shares issued in the qualified financing and on the same terms and conditions of such qualified financing.

In May 2019, upon the occurrence of a qualified financing (see Note 10), the 2019 Notes converted into 681,256 shares of the Company's Series B-1, which was reclassified as Series C in June 2019, at a conversion price of $7.0458 per share, which was equal to the cash issuance price of the Series C. The then outstanding principal of $4.8 million and the accrued interest amount of approximately $36,000 was converted into Series C. The accrued interest was equal to the interest expense recorded during 2019 related to the 2019 Notes. The Company elected to account for the 2019 Notes at estimated fair value pursuant to the fair value option and recorded the change in estimated fair value in the statement of operations until the 2019 Notes were converted into Series C in May 2019 (see Note 3). The estimated fair value of the 2019 Notes immediately prior to conversion was $4.8 million. The Company recorded no gain or loss on the conversion of the 2019 Notes in the consolidated statement of operations for the year ended December 31, 2019, and as the 2019 Notes were converted prior to 2020, there were no amounts recorded related to convertible notes for the year ended December 31, 2020.

10. REDEEMABLE CONVERTIBLE PREFERRED STOCK

In December 2016, the Company authorized 167,496,750 shares and sold and issued 2,252,681 shares of $0.001 par value redeemable convertible series A preferred stock ("Series A") at a purchase price of $15.6039 per share ($1.535 post-split that occurred as a result of the 2017 Merger). Of these shares, 999,744 shares of Series A were issued pursuant to the extinguishment of historical convertible notes that had been issued by Finch.

On September 21, 2017, in exchange for the net assets of Crestovo, former Crestovo shareholders were issued 9,026,826 shares of Series A. In addition, on September 21, 2017 and related to the Merger, 316,773 shares of Series A were issued pursuant to the extinguishment of $2.2 million in principal and accrued interest on convertible promissory notes issued in August and September 2017 by Finch Therapeutics Inc.

In conjunction with the Merger, the Company reorganized its capital structure, which resulted in a modification to the fair value of all Series A, such that the liquidation value was modified to be $3.4594 per share.

In February 2018, the Company authorized 74,620,739 shares and sold and issued 5,166,203 shares of $0.001 par value series B redeemable convertible preferred stock ("Series B") at a purchase price of $7.0458 per share for proceeds of $36.4 million.

In May 2019, the Company authorized 109,604,994 shares and sold and issued 3,264,355 shares of $0.001 par value Series B-1 at a purchase price of $7.0458 per share, for gross proceeds of $23.0 million. Of the $23.0 million, $4.8 million was related to the extinguishment of the 2019 Notes (see Note 9).

In June 2019, the Company amended its certificate of incorporation to reclassify the 3,264,355 outstanding Series B-1 as Series C, in conjunction with the anticipated issuance of additional Series C shares in July 2019.

In July 2019, the Company sold and issued 4,323,899 shares of $0.001 par value Series C at a purchase price of $7.0458 per share, for gross proceeds of $30.5 million. The Company incurred issuance costs of $0.2 million associated with the Series C issuance.

In September 2020, the Company sold an aggregate of 6,902,872 shares of its series D redeemable convertible preferred stock ("Series D") at a purchase price of $13.0381 per share, for gross proceeds of $90.0 million. The Company incurred issuance costs of $0.1 million associated with the Series D issuance.

As of December 31, 2019 and 2020, preferred stock consisted of the following (in thousands, except share amounts):

		DECEMBER 31, 2019			
	PREFERRED STOCK AUTHORIZED	PREFERRED STOCK ISSUED AND OUTSTANDING	CARRYING VALUE	LIQUIDATION VALUE	COMMON STOCK ISSUABLE UPON CONVERSION
Series A	167,496,750	11,596,280	$ 53,593	$ 40,115	11,596,280
Series B	74,620,739	5,166,203	36,336	36,400	5,166,203
Series C	109,604,994	7,588,254	53,221	53,465	7,588,254
	351,722,483	24,350,737	$ 143,150	$ 129,980	24,350,737

	DECEMBER 31, 2020				
	PREFERRED STOCK AUTHORIZED	PREFERRED STOCK ISSUED AND OUTSTANDING	CARRYING VALUE	LIQUIDATION VALUE	COMMON STOCK ISSUABLE UPON CONVERSION
Series A	167,496,750	11,596,280	$ 53,593	$ 40,115	11,596,280
Series B	74,620,739	5,166,203	36,336	36,400	5,166,203
Series C	109,604,994	7,588,254	53,221	53,465	7,588,254
Series D	99,705,359	6,902,872	89,904	90,000	6,902,872
	451,427,842	31,253,609	$ 233,054	$ 219,980	31,253,609

Of the preferred stock issued above, 9,740,014 of the Company's Series A shares, 2,412,788 of the Company's Series B shares, 4,620,453 of the Company's Series C shares and 3,138,260 of the Company's Series D shares are owned by affiliates of the Company, deemed to represent related parties.

Significant terms of the Series A, Series B, Series C and Series D (collectively, "Preferred Stock") are as follows:

Voting Rights

The holders of each share of Preferred Stock ("Preferred Stockholders") have the right to one vote for each share of common stock into which such Preferred Stock could then convert.

Dividends

In the event the Company declares, pays, or sets aside any dividends on shares of any class of capital stock of the Company, other than dividends on shares of common stock payable in shares of common stock, the holders of Preferred Stock shall be first entitled to receive a dividend on each outstanding share. Dividends are not cumulative.

In the case of a dividend on common stock or any class of stock that is convertible into common stock, the Preferred Stock dividend per share would equal the product of the dividend payable on each share of stock determined and the number of shares of common stock issuable upon conversion of a share of Preferred Stock. In the case of a dividend on any class that is not convertible to common stock, the Preferred Stock dividend per share would be determined by dividing the amount of the dividend payable on each share of capital stock by the original issuance price of such stock and multiplying that fraction by an amount equal to the Preferred Stock original issue price. The dividend payable to the holders of Preferred Stock shall be based on the formula which would result in the highest preferred stock dividend. No dividends have been declared or paid by the Company.

Liquidation Preference

In the event of any liquidation, dissolution or winding up of the Company, the holders of Preferred Stock shall be entitled to be paid out an amount per share equal to the greater of (i) the original issuance price of the Preferred Stock, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Preferred Stock been converted into common stock. If insufficient assets and funds are available to permit payment to the Preferred Stockholders of the full amount, then all available assets and funds shall be distributed to the Preferred Stockholders on a pro rata basis. Note that in relation to the above, the order in which holders of Preferred Stock are entitled to be paid out of the assets of the Company is as follows: the holders of Series D, Series C, Series B, Series A and then common stock.

After payment in full to the Preferred Stockholders, the holders of common stock shall be entitled to be paid out of the assets of the Company available for distribution on a pro rata basis based on the number of shares held.

Conversion Rights

Each share of Preferred Stock is convertible at any time at the option of the holder into common stock. Each share shall be converted into such number of shares of common stock as is determined by dividing the respective original issuance price by the conversion price in effect at the time of the conversion. As of December 31, 2019 and 2020, the Series A, Series B and Series C original issuance price and conversion price is 3.4594, 7.0458, and 7.0458 per share, respectively. As of December 31, 2020, the Series D original issuance price and conversion price is $13.0381. As such, the shares of Preferred Stock convert on a one-for-one basis.

Conversion is mandatory at the earlier of the closing of an initial public offering of the Company's common stock at a price of at least one and one-half times the respective conversion price of each series of Preferred Stock, with gross proceeds to the Company of at least $25.0 million, or at the election of the majority holders of the outstanding shares of Preferred Stock.

11. COMMON STOCK

The Company was authorized to issue 796,959,241 and 598,232,153 shares of $0.001 par value common stock as of December 31, 2019 and 2020, respectively. The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers and preference of the holders of the Preferred Stock set forth above.

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. As of December 31, 2020, no cash dividends have been declared or paid.

The Company has issued restricted stock to founders, employees and consultants, and expense for this restricted stock is recognized on a straight-line basis (see Note 12). The restricted stock generally vests monthly over 36 months.

Common Stock Warrants

In June 2016, the Company issued warrants to a consultant to purchase 19,346 shares of common stock, as compensation for services provided. The warrants are classified as equity and recorded as additional paid-in capital on the Company's consolidated balance sheets and remain outstanding as of December 31, 2019 and 2020. The warrants have an exercise price of $0.03 per share, expire on June 1, 2026 and were fully vested prior to December 31, 2018.

As of December 31, 2019 and 2020, the Company has reserved the following shares of common stock for potential conversion of outstanding Preferred Stock, the vesting of restricted stock and exercise of stock options and common stock warrants:

	DECEMBER 31,	
	2019	2020
Redeemable convertible preferred stock	24,350,737	31,253,609
Unvested restricted stock	547,360	—
Options to purchase common stock	1,121,521	1,053,874
Common stock warrants	19,346	19,346
	26,038,964	32,326,829

Secondary Sale

In October 2020, certain of the Company's stockholders sold shares of the Company's common stock at a price of $13.0381 per share to an investor. The investor purchased 412,323 shares of the Company's common

stock from certain shareholders for an aggregate purchase price of $5.4 million, of which 258,924 shares of the Company's common stock, or an aggregate purchase price of $3.4 million, were sold by affiliates of the Company, who are considered to be related parties. The shares were sold above fair value and the excess of the price paid over the fair value was recognized as $2.8 million of stock-based compensation expense. The Company recognized the $2.8 million as general and administrative expense in the consolidated statement of operations for the year ended December 31, 2020 (Note 12).

12. STOCK-BASED COMPENSATION

2017 Equity Incentive Plan

The Company adopted the 2017 Equity Incentive Plan (the "Plan") in February 2017 for the issuance of stock options and other stock-based awards to employees, consultants, officers and directors. The Plan, as amended, allows for a maximum of 2,067,759 shares of common stock to be issued. There were 246,770 and 698,601 shares of common stock available for future grants under the Plan as of December 31, 2019 and 2020, respectively.

The Plan is administered by the Company's board of directors (the "Board"). The exercise prices, vesting and other restrictions are determined at the discretion of the Board, except that the exercise price per share of incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant. Stock options awarded under the Plan expire ten years after the grant date, unless the Board sets a shorter term. Vesting periods for awards under the plans are determined at the discretion of the Board. Incentive stock options granted to employees and non-statutory options and shares of restricted stock awards granted to employees, officers, members of the Board, advisors, and consultants of the Company typically vest over four years.

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 year ended December 31, 2019 and 2020 were as follows:

	2019	2020
Risk-free interest rate	1.69% - 2.34%	0.46%
Expected term (in years)	5.5 - 6.4	5.5 - 6.1
Expected volatility	73.0% - 77.0%	74.6% - 76.6%
Expected dividend yield	0.0%	0.0%

The following table summarizes the activity of the Company's stock options under the Plan for the years ended December 31, 2019 and 2020:

	SHARES	WEIGHTED-AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL TERM (in years)	AGGREGATE INTRINSIC VALUE (in thousands)
Outstanding as of December 31, 2018	1,265,328	$ 1.58	8.76	$ 1,326
Granted	371,448	$ 1.10		
Exercised	(182,360)	$ 0.82		165
Cancelled or forfeited	(332,895)	$ 1.99		
Outstanding as of December 31, 2019	1,121,521	$ 1.47	8.41	$ 424
Granted	33,362	$ 1.45		
Exercised	(65,881)	$ 0.91		350
Cancelled or forfeited	(35,128)	$ 1.47		
Outstanding as of December 31, 2020	1,053,874	$ 1.51	7.49	$ 4,964
Options exercisable as of December 31, 2019	441,257	$ 1.26	7.68	$ 250
Options exercisable as of December 31, 2020	652,549	$ 1.37	7.12	$ 3,205

The options granted during the years ended December 31, 2019 and 2020 were granted to employees and consultants of the Company. As of December 31, 2020, there was approximately $0.4 million of unrecognized compensation expense related to the stock-based compensation arrangements granted under the Plan remaining to be recognized. The Company expects to recognize this cost over a weighted average period of 2.66 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 2019 and 2020 was $0.2 million and $0.4 million, respectively. The weighted-average grant date fair value of stock options granted in the years ended December 31, 2019 and 2020 under the Black-Scholes option pricing model was $0.73 per option and $0.87 per option, respectively.

Restricted Stock

The restricted stock generally vests monthly over 36 months. A summary of the Company's restricted stock activity during the years ended December 31, 2019 and 2020 is presented below:

	SHARES	WEIGHTED-AVERAGE GRANT-DATE FAIR VALUE
Non-vested shares at December 31, 2018	1,282,334	$ 0.001
Vested	(734,974)	0.001
Non-vested shares at December 31, 2019	547,360	0.001
Vested	(547,360)	0.001
Non-vested shares at December 31, 2020	—	$ —

The restricted stock was granted to the founders of the Company, as well as employees and consultants of the Company. There was $16,000 of stock-based compensation expense recognized for the 734,974 shares of restricted stock vested during the year ended December 31, 2019. There was approximately $8,000 of stock-

based compensation expense recognized for the 547,360 shares of restricted stock vested during the year ended December 31, 2020. All restricted stock is vested as of December 31, 2020 and there is no remaining stock-compensation expense related to restricted stock to be recognized.

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, 2019 and 2020 is as follows (in thousands):

	YEAR ENDED DECEMBER 31,	
	2019	2020
Research and development	$ 389	$ 179
General and administrative	217	2,920
	$ 606	$ 3,099

The stock-based compensation expense for the year ended December 31, 2020 includes the $2.8 million recorded in relation to the secondary sale of common stock (Note 11).

13. RELATED PARTY TRANSACTIONS

OpenBiome Historical Agreements

Under the Strategic Agreement, OpenBiome and the Company reimburse one another for certain administrative expenses. The Company's Chief Executive Officer and a member of its board of directors, is the spouse of the Executive Director and co-founder of OpenBiome, and certain of the OpenBiome directors are shareholders of the Company.

For the years ended December 31, 2019 and 2020, the Company reimbursed OpenBiome $0.2 million and approximately $33,000, respectively, under the Strategic Agreement. Also, under the Strategic Agreement, OpenBiome reimbursed the Company $1.0 million and $0.3 million for the years ended December 31, 2019 and 2020, respectively. As of December 31, 2019 and 2020, respectively, the Company recorded $0.6 million and approximately $21,000 due from OpenBiome and $0.2 million and $0 due to OpenBiome related to shared services.

OpenBiome subleases office and lab space from the Company (see Note 8). The Company's rent income under the sublease was $0.5 million and $0.4 million for the years ended December 31, 2019 and 2020, respectively. As of December 31, 2019 and 2020, the Company had $0.4 million and approximately $28,000, respectively, receivable from OpenBiome related to the sublease recorded as due from related party in the consolidated balance sheets.

The Company also earned a low single digit royalty on net sales of OpenBiome's FMT materials under the QSS Agreement, which was partially terminated on February 1, 2019 (see Note 6), and, ultimately, was fully terminated in November 2020 in connection with the Company's execution of the OpenBiome Agreement (see OpenBiome 2020 Agreements below), which is expected to close in the first quarter of 2021. In February 2019 under the APL Agreement (see Note 8), the Company transferred the property, equipment, and granted a license to OpenBiome for total consideration of $3.3 million, $2.6 million of which was recorded as due from related party on the Company's consolidated balance sheets at December 31, 2019 (see Note 6). As result of the transfer, the Company recorded a loss on sale of assets of $0.1 million in its consolidated statement of operations for the year ended December 31, 2019. As of February 2019, the Company had no further obligation to manufacture and transfer FMT materials to OpenBiome.

OpenBiome 2020 Agreements

Clinical Supply and Services Agreement

On February 10, 2020, the Company entered into a Clinical Supply and Services Agreement ("CSA") with OpenBiome, the term of which is one year, as the CSA is expected to be terminated upon closing of the OpenBiome Agreement (see Note 13) in the first quarter of 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 $1.1 million in prepaid fees. The $0.5 million security deposit was returned to the Company during the same period. The Company paid $3.8 million in total to OpenBiome under the CSA for the year ended December 31, 2020, including the security deposit that was returned. The Company has recorded $0.2 million due to OpenBiome under the CSA as of December 31, 2020, which is classified as due to related party in the Company's consolidated balance sheets.

OpenBiome Purchase Agreement

On November 19, 2020, the Company entered into an asset purchase agreement (the "OpenBiome Agreement") with OpenBiome in order to leverage OpenBiome's CMC manufacturing process to enhance its current manufacturing capabilities for its lead program, CP101; the OpenBiome Agreement is expected to close in the first quarter of 2021. Simultaneously with entering into the OpenBiome Agreement, the Company terminated the Strategic Agreement, the MAL Agreement, the QSS Agreement and the APL Agreement, as well as certain subject matter agreements; upon closing, the CSA will also be terminated and the Company will not incur any additional amounts. The Company also amended the Strategic Agreement as part of the OpenBiome Agreement ("A&R Master 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 will acquire certain biological samples, service contracts and future liabilities (including, but not limited to a commercial lease) and capital equipment upon closing of the transaction in the first quarter of 2021. The Company previously licensed the biological samples and OpenBiome's CMC technology under various historical agreements with OpenBiome which terminated upon signing of the OpenBiome Agreement. The OpenBiome Agreement also releases, for a one year period upon signing, a hiring restriction under the A&R Strategic Agreement (i.e. non-solicitation) such that the Company may hire, at its discretion, certain OpenBiome employees. Thus, the Company has not acquired any such employees as part of the transaction.

In connection with the OpenBiome Agreement, the Company paid $1.2 million for the acquisition of certain assets in November 2020, which is capitalized as property and equipment as software on the Company's consolidated balance sheet as of December 31, 2020.

The Company is obligated to make additional payments of $3.8 million upon closing of the transaction. The Company is 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.

The Company previously granted OpenBiome a royalty-bearing, non-exclusive license to its intellectual property under the APL Agreement, which terminated upon the signing of the OpenBiome Agreement. The Company granted that same license under the OpenBiome Agreement so that OpenBiome may continue to produce and sell FMT materials until the executed closing. The Company will continue to earn royalties under the OpenBiome Agreement based on sales of FMT materials.

14. RETIREMENT PLAN

The Company has adopted a defined contribution plan intended to qualify under Section 401(k) of the Internal Revenue Code covering all eligible employees of the Company. All employees are eligible to become participants of the plan immediately upon hire. 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 $0.3 million and $0.4 million in the years ended December 31, 2019 and 2020, respectively.

15. LOSS PER SHARE

Basic and diluted loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average common shares outstanding (in thousands, except share and per share data):

	YEAR ENDED DECEMBER 31,	
	2019	2020
Numerator:		
Net loss	$ (20,754)	$ (39,341)
Net loss attributable to common stockholders—basic and diluted	$ (20,754)	$ (39,341)
Denominator:		
Weighted-average common stock outstanding—basic and diluted	7,295,751	8,144,855
Net loss per share attributable to common stockholders—basic and diluted	(2.84)	(4.83)

The Company's potentially dilutive securities, which include Preferred Stock, restricted stock, stock options, and warrants, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following from the computation of diluted net loss per share attributable to common stockholders at December 31, 2019 and 2020 because including them would have had an anti-dilutive effect:

	DECEMBER 31,	
	2019	2020
Preferred Stock	24,350,737	31,253,609
Unvested restricted stock	547,360	—
Options to purchase common stock	1,121,521	1,053,874
Common stock warrants	19,346	19,346
	26,038,964	32,326,829

16. SUBSEQUENT EVENTS

Management has evaluated subsequent events through February 26, 2021, which is the date the financial statements were available to be issued, and March 15, 2021 for the closing of the OpenBiome Agreement and the reverse stock split referenced below. There were no subsequent events that require adjustments to or disclosure in the financial statements, except for those referenced below.

OpenBiome Agreement Closing

On March 1, 2021, the Company closed the OpenBiome Agreement with OpenBiome (see Note 13). The Company paid $3.8 million in costs associated with the closing of the transaction.

Reverse Stock Split

The Company's Board approved a one-for-14.444 reverse stock split of its issued and outstanding common stock, stock options and preferred stock effective as of March 12, 2021. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split.

Through and including , 2021, (the 25th day after the date of this prospectus), all dealers effecting transactions in the common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

6,250,000 Shares

Common Stock

PROSPECTUS

BofA Securities

Jefferies

Evercore ISI

, 2021

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of the common stock being registered. All amounts shown are estimates except for the SEC registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the Nasdaq initial listing fee.

	Amount to be Paid
SEC registration fee	$ 13,331
FINRA filing fee	17,750
Nasdaq initial listing fee	170,000
Printing and engraving	178,000
Legal fees and expenses	1,450,000
Accounting fees and expenses	700,000
Transfer agent and registrar fees	5,750
Miscellaneous fees and expenses	165,169
Total	$ 2,700,000

Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, other than an action by or in the right of the corporation, by reason of the fact that the person is or was a director, officer, employee or agent of the corporation or is or was serving at the corporation's request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with the action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful. The power to indemnify applies to actions brought by or in the right of the corporation as well, but only to the extent of expenses, including attorneys' fees but excluding judgments, fines and amounts paid in settlement, actually and reasonably incurred by the person in connection with the defense or settlement of the action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that a court of competent jurisdiction shall determine that such indemnity is proper.

Section 145(g) of the Delaware General Corporation Law provides that a corporation shall have the power to purchase and maintain insurance on behalf of its officers, directors, employees and agents, against any liability asserted against and incurred by such persons in any such capacity.

Section 102(b)(7) of the General Corporation Law of the State of Delaware provides that a corporation may eliminate or limit the personal liability of a director to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, provided that such provision shall not eliminate or limit the liability of a director (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the General Corporation Law of the State of Delaware or (iv) for any transaction from

which the director derived an improper personal benefit. No such provision shall eliminate or limit the liability of a director for any act or omission occurring prior to the date when such provision becomes effective.

Our amended and restated certificate of incorporation that we intend to adopt in connection with this offering provides that our directors shall not be liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except to the extent that the exculpation from liabilities is not permitted under the Delaware General Corporation Law as in effect at the time such liability is determined. In addition, our amended and restated certificate of incorporation that we intend to adopt in connection with this offering provides that we may indemnify our directors, officers and other agents of the company to the fullest extent permitted by the laws of the State of Delaware and our amended and restated bylaws that we intend to adopt in connection with this offering provide that we are required to indemnify our directors and executive officers to the fullest extent not prohibited by Delaware General Corporate Law. We have entered into indemnification agreements with each of our directors and officers. These indemnification agreements provide, among other things, that we will indemnify our directors and officers for certain expenses, including damages, judgments, fines, penalties, settlements and costs and attorneys' fees and disbursements, incurred by a director or officer in any claim, action or proceeding arising in his or her capacity as a director or officer of our company or in connection with service at our request for another corporation or entity. The indemnification agreements also provide for procedures that will apply in the event that a director or officer makes a claim for indemnification. We expect to enter into a similar agreement with any new directors or officers.

Our amended and restated bylaws that we intend to adopt in connection with this offering provide that we may purchase and maintain insurance policies on behalf of our directors and officers against specified liabilities for actions taken in their capacities as such, including liabilities under the Securities Act. We have obtained directors' and officers' liability insurance to cover liabilities our directors and officers may incur in connection with their services to us, and plan to expand such coverage to include matters arising under the securities laws prior to the closing of this offering.

In addition, the underwriting agreement related to this offering will provide for indemnification by the underwriters of us and our officers and directors for certain liabilities arising under the Securities Act or otherwise. Our amended and restated investors' rights agreement with certain stockholders also provides for cross-indemnification in connection with the registration of our common stock on behalf of such investors.

Item 15. Recent Sales of Unregistered Securities.

The following list sets forth information regarding all unregistered securities issued by us since January 1, 2018 through the date of this registration statement:

Issuances of Options to Purchase Common Stock

From January 1, 2018 through the date of this registration statement, we granted stock options under our 2017 Equity Incentive Plan, as amended, to purchase up to an aggregate of 1,011,762 shares (net of expirations and cancellations) of our common stock to our employees, directors, and consultants, at a weighted average exercise price of $4.92 per share. From January 1, 2018 through the date of this registration statement, 380,803 shares of our common stock were issued upon the exercise of these options and the payment of approximately $213,000.

Issuances of Preferred Stock

In February 2018, we issued and sold an aggregate of 5,166,203 shares of Series B preferred stock to 15 accredited investors at a purchase price of $7.0458 per share for aggregate consideration of approximately $36.4 million.

In May 2019 and July 2019, we issued and sold an aggregate of 7,588,254 shares of Series C preferred stock to 23 accredited investors at $7.0458 per share for aggregate consideration of approximately $53.5 million.

In September 2020, we issued and sold an aggregate of 6,902,872 shares of Series D preferred stock to 43 accredited investors at a purchase price of $13.0381 per share for aggregate consideration of approximately $90.0 million.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise specified above, we believe these transactions were exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D or Regulation S promulgated thereunder) or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or under benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Item 16. Exhibits and Financial Statement Schedules.

Exhibits

Exhibit No.	Description
1.1*	Form of Underwriting Agreement.
3.1*	Amended and Restated Certificate of Incorporation, as amended and as presently in effect.
3.2*	Bylaws, as presently in effect.
3.3*	Form of Amended and Restated Certificate of Incorporation, to be in effect upon closing of this offering.
3.4*	Form of Amended and Restated Bylaws, to be in effect upon closing of this offering.
4.1*	Third Amended and Restated Stockholders Agreement by and among the registrant and certain of its stockholders, dated as of September 2, 2020.
4.2*	Form of Common Stock Certificate.
5.1*	Opinion of Cooley LLP.
10.1+*	2017 Equity Incentive Plan, as amended, and the forms of agreements thereunder.
10.2*	Form of Indemnity Agreement between the registrant and its directors and officers.
10.3†*	Exclusive Patent License Agreement by and between CIPAC Limited and Regents of the University of Minnesota, dated as of March 26, 2012, as amended July 10, 2014, October 23, 2014, December 13, 2016 and September 15, 2017.
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.
10.5†*	Amended and Restated Agreement by and between Finch Therapeutics, Inc. and Millennium Pharmaceuticals, Inc., dated as of October 21, 2019.
10.6†*	Asset Purchase Agreement by and between Finch Therapeutics, Inc. and Microbiome Health Research Institute, Inc., dated as of November 19, 2020.
10.7†*	LMIC License Agreement by and between Finch Therapeutics, Inc. and Microbiome Health Research Institute, Inc., dated as of November 19, 2020.
10.8++*	Lease by and between NextBiome, Inc. and North River II LLC, dated as of December 21, 2015.

Exhibit No.	Description
10.9++*	First Amendment to Lease by and between Finch Therapeutics, Inc. and North River II LLC, dated as of January 20, 2017.
10.10+*	2021 Equity Incentive Plan and the forms of agreements thereunder.
10.11+*	2021 Employee Stock Purchase Plan.
10.12+*	Amended and Restated Executive Employment Agreement by and between the registrant and Mark Smith, dated as of March 12, 2021, to be effective upon the pricing of this offering.
10.13+*	Amended and Restated Executive Employment Agreement by and between the registrant and Zain Kassam, dated as of March 12, 2021, to be effective upon the pricing of this offering.
10.14+*	Amended and Restated Executive Employment Agreement by and between the registrant and Gregory D. Perry, dated as of March 12, 2021, to be effective upon the pricing of this offering.
21.1*	Subsidiaries of the registrant.
23.1	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.
23.2*	Consent of Cooley LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (see signature page to the registration statement).

* Previously filed.
\+ Indicates management contract or compensatory plan.
\# 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 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.

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant under the foregoing provisions or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance on Rule 430A and contained in a form of prospectus filed by the registrant under Rule 424(b)(1) or (4) or 497(h) under the Securities Act will be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus will be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time will be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Amendment No. 2 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Somerville, Massachusetts, on the 18th day of March, 2021.

FINCH THERAPEUTICS GROUP, INC.

By: /s/ Mark Smith
Name: Mark Smith, Ph.D.
Title: Chief Executive Officer and Director

Pursuant to the requirements of the Securities Act of 1933, as amended, this Amendment No. 2 to the Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Name	Position	Date
/s/ Mark Smith Mark Smith, Ph.D.	Chief Executive Officer and Director (*Principal Executive Officer*)	March 18, 2021
/s/ Gregory D. Perry Gregory D. Perry	Chief Financial Officer (*Principal Financial Officer and Principal Accounting Officer*)	March 18, 2021
* Chris Shumway	Chairman of the Board of Directors	March 18, 2021
* Domenic Ferrante	Director	March 18, 2021
* Nicholas Haft	Director	March 18, 2021
* Christian Lange	Director	March 18, 2021
* Jeffery A. Smisek	Director	March 18, 2021
* Jo Viney, Ph.D.	Director	March 18, 2021

* By: /s/ Mark Smith
Mark Smith, Ph.D.
Attorney-in-Fact

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use in this Amendment to Registration Statement on Form S-1 (No. 333-253622) of our report dated February 26, 2021 (March 15, 2021, as to the subsequent events described in Note 16), relating to the consolidated financial statements of Finch Therapeutics Group, Inc. and its subsidiaries. We also consent to the reference to us under the heading “Experts” in such Registration Statement.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 18, 2021