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

FORM 10-K

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

For the fiscal year ended December 31, 2019

or

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

For the transition period from _____to _____

Commission File Number: 001-38822

KALEIDO BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**47-3048279**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
65 Hayden Avenue Lexington MA	**02421**
(Address of principal executive offices)	(Zip Code)

(617) 674-9000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 Par Value	**KLDO**	**NASDAQ Global Select Market**

Securities registered pursuant to section 12(g) of the Act:

None

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of June 28, 2019, the last day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates was approximately $119.6 million based on the closing price of the registrant's common stock on June 28, 2019. The calculation excludes shares of the registrant's common stock held by current executive officers, directors and stockholders that the registrant has concluded are affiliates of the registrant. This determination of affiliate status is not a determination for other purposes.

As of February, 27, 2020, there were 30,420,549 shares of registrant's common shares outstanding.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plan, objectives of management and expected market growth are forward-looking statements that involve risks and uncertainties. You can identify these forward-looking statements by the use of words such as “outlook,” “believes,” “expects,” “potential,” “continues,” “may,” “will,” “should,” “seeks,” “approximately,” “predicts,” “intends,” “plans,” “estimates,” “anticipates” or the negative version of these words or other comparable words. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. We believe these factors include but are not limited to those described under “Risk Factors” and include, among other things:

- our ability to continue as a going concern, including without limitation our ability to continue to advance the clinical development of our MMT candidates;
- the success, cost and timing of our research and development activities, including statements regarding the timing of initiation and completion of clinical studies or clinical trials and related preparatory work, and the period during which the results of the clinical studies or clinical trials will become available;
- our ability to advance any product candidate into or successfully complete any clinical trial or identify an alternative commercial pathway for such product candidate;
- our ability or the potential to successfully manufacture our product candidates for clinical studies, clinical trials or commercial use, if approved;
- our ability to obtain funding for our operations, when needed, including funding necessary to complete further development and commercialization of our product candidates, if approved, and to further expand our propriety product platform;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the potential for our identified research priorities to advance our product candidates or allow us to identify new product candidates;
- our expectations regarding the timing for proposed submissions of regulatory filings, including but not limited to any Investigational New Drug application filing or any New Drug Applications;
- our ability to maintain regulatory approval, if obtained, of any of our current or future product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate;
- our ability to commercialize our product candidates in light of the intellectual property rights of others;
- our plans to research, develop and commercialize our product candidates;
- our ability to attract collaborators with development, regulatory, commercialization, or other relevant expertise;
- the expected results pursuant to collaboration arrangements including the receipts of future payments that may arise pursuant to collaboration arrangements;
- existing and future agreements with third parties in connection with the research and development or commercialization of our product candidates;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets either alone or in collaboration with others;
- the rate and degree of market acceptance of our product candidates;

- the success of competing therapies that are or become available;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform their obligations adequately;
- our ability to attract and retain key scientific or management personnel;
- the impact of changes in existing laws, regulations and guidance or the adoption of new laws, regulations and guidance; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and other technologies.

All of our forward-looking statements are as of the date of this Annual Report on Form 10-K only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of or any material adverse change in one or more of the risk factors or risks and uncertainties referred to in this Annual Report on Form 10-K or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the Securities and Exchange Commission, or the SEC, could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Annual Report on Form 10-K, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Annual Report on Form 10-K that modify or impact any of the forward-looking statements contained in this Annual Report on Form 10-K will be deemed to modify or supersede such statements in this Annual Report on Form 10-K.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the U.S. Securities and Exchange Commission, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

KALEIDO BIOSCIENCES, INC. AND SUBSIDIARIES
TABLE OF CONTENTS

PART I

In this Annual Report on Form 10-K, we use the following defined terms.

We utilize our human-centric discovery and development platform to study Microbiome Metabolic Therapies, or MMTs, in microbiome samples in an *ex vivo* setting, followed by advancing MMT candidates rapidly into clinical studies in healthy subjects and patients. “Clinical studies” are conducted under regulations supporting research with food, evaluating safety, tolerability and potential markers of effect. For MMT candidates that are further developed as therapeutics, we conduct “Clinical trials” under an Investigational New Drug application, or IND, or comparable foreign regulatory equivalents outside the U.S., and in Phase 2 or later development.

KALEIDO is a registered trademark and MMT is a trademark of Kaleido Biosciences, Inc. in the United States and in other selected countries. All other brand names or trademarks appearing in this report are the property of their respective holders. Unless the context requires otherwise, references in this report to “KALEIDO,” “Kaleido Biosciences,” “our Company,” “the Company,” “we,” “us,” and “our” refer to Kaleido Biosciences, Inc. and its consolidated subsidiaries.

Item 1. Business

Overview

We are a clinical-stage healthcare company with a differentiated, chemistry-driven approach focused on leveraging the microbiome organ to treat disease and improve human health. We have built a human-centric proprietary product platform for discovery and development that we believe will enable the rapid advancement of a broad portfolio of novel product candidates into human clinical studies under regulations supporting research with food. Our product candidates are Microbiome Metabolic Therapies (“MMT” or “MMTs”) which are designed to modulate the metabolic output and profile of the microbiome by driving the function and composition of the organ’s existing microbes. We have an industrialized approach to the discovery and development of MMTs, and our initial MMTs are targeted glycans. Each targeted glycan is an ensemble of complex carbohydrates that is intended to modulate microbial metabolism to drive a specific biological response. We believe our MMTs have the potential to be novel treatments across a variety of diseases and conditions.

The human microbiome is generally a community of more than 30 trillion microbes, organisms that include bacteria, viruses, archaea and fungi, which reside on and inside the human body. By evolving together over thousands of years, microbes and humans have developed an intricate and mutually beneficial relationship. Given the profound impact that microbes have on human health, this highly complex microbial ecosystem has been referred to as a “newly discovered organ.” There is a growing body of research that links a healthy microbiome with overall human health, while dysbiosis, or imbalance, in the microbiome has been correlated with numerous human conditions including those that can cause significant morbidity and mortality. Some of these conditions include irritable bowel syndrome, Parkinson’s disease, diabetes, metabolic syndrome, cancer, allergies and ulcerative colitis. The gut microbiome remains a largely untapped frontier in healthcare, and we believe that we are uniquely positioned to succeed in translating its promise into solutions for human health.

To date, therapeutic approaches to the microbiome have focused primarily on adding or subtracting bacteria, either through fecal microbiota transplant, the introduction of a consortia of bacteria, single strain approaches or antibiotics. We believe our approach is novel in that we seek to deliver MMTs that drive the function and distribution of the gut microbiome’s existing microbes, enabling an industrialized approach to treat disease and improve human health.

We have developed proprietary synthetic chemistry technologies that allow us to create MMT candidates. We believe the key characteristics of our MMT candidates include that they are orally administered, have limited systemic exposure and are selectively metabolized, structurally diverse, readily scalable, novel and proprietary. We believe that each of our MMT candidates works through one or more mechanisms of action, including decreasing production of metabolites, such as ammonia, trimethylamine and indole generated by bacteria in the microbiome; increasing production of metabolites, such as short chain fatty acids generated by bacteria in the microbiome; and advantaging or disadvantaging certain existing species in the microbiome community.

Utilizing our proprietary product platform, we have created a library of more than 1,500 MMT candidates to probe the structure-activity relationships of our MMTs. Our MMT library is continuously growing as we continue to invest in techniques and technologies for chemical synthesis. Our MMT candidates and aspects of the proprietary product platform are supported by our expanding intellectual property portfolio, that includes nine U.S. patents, two European Patent Office, or EPO, patents and more than 100 non-provisional applications pending worldwide.

We evaluate our MMT candidates using a human-centric approach to discovery and development. Our approach is human-centric because we conduct the vast majority of our research either using human biological samples or directly in humans.

Our proprietary product platform includes *ex vivo* screening of microbiome samples from healthy volunteers, *ex vivo* testing of patient microbiome samples and rapid advancement of our MMT candidates into human clinical studies. Our *ex vivo* screening process combines advances in drug discovery with microbiome science. This screening process is designed to measure the impact of MMT candidates on a variety of endpoints in microbiome samples from healthy volunteers. We use this process to screen for modulation of bacterial metabolites, bacterial growth and community composition. In some cases, we may also utilize animal models to evaluate mechanisms to facilitate clinical designs for human trials. Once we have selected a subset of MMT candidates from our library as promising leads for a particular program, we begin to conduct *ex vivo* testing of these MMTs using patient microbiome samples. This testing helps to inform our MMT candidate selection and we believe increases the likelihood of choosing a product candidate with *in vivo* effects.

We advance our initial MMT candidates rapidly into human clinical studies under regulations supporting research with food. This enables us to gain valuable insights into our MMT candidates' effects on the microbiome and human health before choosing to allocate additional time and capital to either proceed to develop a drug product candidate under an IND or regulatory equivalent outside the United States or commercialize a non-drug product. We plan to determine the best development path for each of our MMTs at an "MMT decision point" after conducting one or more human clinical studies. We plan to make our decision about which development path to pursue based on the results of our human clinical studies, in conjunction with our research into market opportunities, patient needs and our corporate strategy.

In our human clinical studies, we are able to measure safety, tolerability and potential markers of effect, which allows us to assess the potential use of our MMT candidates in humans. In less than one year, we advanced our lead program from a mechanistic hypothesis to dosing in human clinical studies. Furthermore, we initiated our first Phase 2 clinical trial under an IND approximately two years after conducting our first *ex vivo* screening. We believe that this provides support for our belief that our approach is more expeditious and cost efficient than traditional drug development.

Data generated by our industrialized *ex vivo* screening, *ex vivo* testing and human clinical studies are captured in a database to support our computational capabilities and to improve our understanding of how the microbiome and humans interact. We have built and continue to invest in strengthening our significant capabilities in computational biology and data science that we believe will enable us to learn quickly from the human data we collect. We believe this knowledge supports our current MMT candidates and future pipeline opportunities.

We, and our wholly owned subsidiaries, Cadena Bio, Inc. and Kaleido Biosciences Securities Corporation (collectively referred to as the "Company") were incorporated in Delaware on January 27, 2015 and have a principal place of business in Lexington, Massachusetts.

Our Strategy

We are driven by our mission to lead a revolution in health by leveraging the microbiome to treat a broad range of diseases and conditions. Key elements of our strategy are to:

- ***Harness the insights and data generated through our human-centric proprietary product platform to efficiently and rapidly advance a pipeline of MMTs to ultimately deliver products that address significant unmet patient needs.*** Our human-centric discovery and development enables us to rapidly advance our MMT candidates into clinical studies, which we believe gives us an advantage in both speed and cost as compared to traditional drug development. With more than 1,500 MMTs in our library, we plan to continue to build a broad range of pipeline opportunities in areas where there is a significant unmet need for products that are differentiated, meaningful, and relevant to patients.
- ***Leverage our differentiated approach, knowledge and unique expertise to lead efforts to expand the scientific understanding of the microbiome and its impact on human health.*** We believe that we are well positioned to progress our understanding of the role of the microbiome in health and disease, given our differentiated, chemistry-driven approach, our human-centric discovery and development as well as the knowledge and expertise of our leadership team, Board of Directors and Scientific Advisory Board. We will continue to collaborate with other leaders in the field to learn more about the potential of our MMTs to address various diseases and conditions as well as advance the broader understanding and applications of modulating the microbiome.
- ***Selectively enter into strategic partnerships to maximize the value of our platform and pipeline.*** Given our potential to generate novel product candidates that could address a wide variety of diseases and conditions, we may enter into strategic collaborations around certain targets, product candidates or disease areas that we believe could benefit from the resources of companies that specialize in these areas.
- ***Further strengthen and expand our intellectual property portfolio.*** We believe we have a robust intellectual property portfolio to support our programs, with nine U.S. patents, two EPO patents, and more than 100 non-provisional applications pending worldwide, including composition of matter and method of use patents and patent applications. We also rely on trademarks, trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We intend to further strengthen and expand our intellectual property portfolio to protect our proprietary product platform and product candidates.
- ***Build on our foundation of people who are committed to scientific innovation, transforming lives and fostering a strong culture.*** We will strive to continue to attract and retain top talent who bring critical expertise in areas across our business and share a commitment to our mission and values.

Our Approach

Due to the rapid nature of bacterial growth, the microbiome is inherently amenable to swift change, and it can be readily modulated using existing approaches, such as changes in diet and treatment with antibiotics. Importantly, because microbes in the gut can thrive on compounds that are generally not bioavailable to humans, effective targeted modulators of microbial metabolism should have low bioavailability and low systemic exposure. As a result, we believe that targeted modulators will likely have limited off-target activity in humans compared with traditional pharmaceutical agents.

Our MMTs

We have developed proprietary synthetic chemistry technologies that we believe allow us to create our MMT candidates. MMTs are novel synthetic glycans that serve as metabolic and growth substrates for the microbiome. We believe the key characteristics of our MMT candidates include the following:

- **Orally administered** — Our MMT candidates are highly soluble and are orally administered.
- **Limited systemic exposure** — Our MMT candidates have been observed to have limited systemic exposure after oral administration, minimizing off-target biological effects.

- **Selectively metabolized** — We design MMT candidates that are selectively metabolized by enzymes in the microbiome to stimulate responses that ultimately reshape the microbiome's function, composition and metabolic output.
- **Structurally diverse** — Our MMT candidates are not a single, structurally-defined molecule, but rather an ensemble of molecules with a variety of structures. This structural complexity and specificity of action differentiates MMTs from any individual dietary fiber, and we believe that this is the primary factor for their differentiated microbiome activity.
- **Readily scalable** — Our MMT candidates are produced using proprietary, standard small molecule unit operations. These methods have been proven scalable and cost-effective.
- **Novel and proprietary** — Our MMT candidates are protected by what we believe to be a robust intellectual property portfolio, including by composition of matter and method of use patents.

We believe that our MMT candidates work through one or more mechanisms of action, including:

- **Decreasing production of metabolites** — By decreasing the production of certain metabolites, we believe our initial MMT candidates can result in improvements in targeted conditions where excess metabolites are a key driver of dysfunction.
- **Increasing production of metabolites** — By increasing the production of certain metabolites, we believe our initial MMT candidates can result in improvements in targeted conditions where certain metabolites are missing or not sufficient.
- **Advantage or disadvantage certain species in the microbiome community** — By modulating the distribution of existing species of bacteria within the microbiome, we believe our initial MMT candidates can result in improvements in targeted conditions.

Building Our MMT Library

Utilizing our proprietary product platform, we have created a library of more than 1,500 MMT candidates to probe the structure-activity relationships of our MMTs and the microbiome organ. Our MMT library is growing as we continue to invest in techniques and technologies for chemical synthesis.

MMT Synthesis

We synthesize MMT candidates using our proprietary chemistry technologies, which take advantage of the reactivity of carbohydrates and utilize defined mixtures of monosaccharides or polysaccharides as starting materials. We have methodically explored this approach to create a library of initial MMT candidates that vary across a wide range of structural features, including molecular weight, branching, regiochemistry and stereochemistry. By changing certain conditions and parameters, we can generate MMT candidates that have both larger and smaller variances on these structural features. The resulting MMT candidate library can then be used to explore the impact that structure has on the biology of the microbiome. We continue to develop other novel approaches to synthesize MMT candidates.

We have made extensive commitments to discovering cost-effective and proprietary synthetic methods that can produce MMT candidates that drive diverse microbial responses. We believe our computational capabilities enable robust, efficient structural characterization and cross-batch comparison, reducing laborious manual processing steps typically required to determine the structure of complex carbohydrates.

Our Human-Centric Proprietary Product Platform

We believe that our human-centric proprietary product platform will allow us to effectively move optimized, data-rich product candidates to the market in the pursuit of treating disease and improving human health.

Traditional drug development requires extensive preclinical development ahead of filing an IND in the United States or regulatory equivalent outside the United States to allow human dosing in clinical trials. However, it is only once clinical trials are initiated that researchers can begin to understand the effects of the product candidate in the most relevant test system. According to one study, it takes an average of five to seven years and hundreds of millions of dollars to advance a product candidate from discovery to the initiation of a Phase 2 clinical trial under an IND.

Using our approach, we advanced one of our lead programs from a mechanistic hypothesis to human dosing in less than one year and at a fraction of the cost compared to traditional drug development. Furthermore, we initiated our first Phase 2 clinical trial under an IND approximately two years after conducting our first *ex vivo* screening. This trial is being conducted globally under multiple national clinical trial applications ("CTAs") as well as in the United States.

The graphic below depicts our human-centric proprietary product platform:

We developed an *ex vivo* assay that supports a high throughput screening and lead identification process. This unique screening process combines advances in drug discovery with microbiome science and is designed to measure the impact of MMTs on a variety of endpoints. To date, we have employed this process to screen a majority of our more than 1,500 MMT candidates for the modulation of bacterial metabolites, bacterial growth and community composition. After screening our library in microbiome samples from healthy volunteers, we test the identified lead compounds in samples from the patient population of interest. This provides the evidence needed to progress directly into clinical studies in healthy subjects, and in many cases, directly into patients.

Rapid advancement into human clinical studies

Regulatory approach: food and drug

Our regulatory approach to developing MMT candidates utilizes clinical research under both food law and drug law. Under this approach, human data is collected earlier in the process as compared to traditional drug development and data collected under both clinical studies and clinical trials may be included in regulatory filings, including filings for marketing approval. The MMT candidates we have been evaluating for use in modulating the microbiome can be classified as food or as drug ingredients depending upon their intended use. When intended for nutrient use to affect the structure or function of the body, they are conventional food or dietary supplement ingredients. For the dietary management of disease, the MMTs could be developed as medical foods. When intended for the prevention, cure, diagnosis or treatment of disease, they are drug candidates. We have initially studied our MMT candidates following food regulation and guidance. We have therefore been able to advance them rapidly into human clinical studies under regulations supporting research with food. These clinical studies are run under guidelines for Good Clinical Practice ("GCP") and collect similar data as studies run under an IND or CTA. Therefore, these data can support filing an IND at Phase 2 or later, with the ultimate decision based on discussions with the U.S. Food and Drug Administration ("FDA") or comparable foreign regulatory authorities.

Food substances for human use are regulated by the FDA to assure that intended exposures are safe in the general population. This assurance can be provided by a food additive regulation, or by determination by qualified experts that the substance is Generally Recognized as Safe ("GRAS").

Although food additives must be evaluated by the FDA's Office of Food Additive Safety through a food additive petition prior to human use, this requirement excludes "substances that are generally recognized, among experts qualified by scientific training and experience to evaluate their safety as having been adequately shown to be safe under the conditions of their intended use." This can be established through a GRAS determination.

For a substance to be determined to be GRAS, the scientific data and information about its use must be widely known, and there must be a consensus among qualified experts that data and information establish that the substance is safe under the conditions of its intended use and that it meets the standard of "reasonable certainty of no harm."

A GRAS determination by qualified experts is sufficient to support clinical studies of food in humans. We rely on qualified experts from scientific consulting organizations that are highly experienced in conducting both GRAS evaluations to conduct initial safety assessments of our MMT candidates. These third-party assessments evaluate whether our MMTs are safe for intended use in human clinical studies that are intended to evaluate safety and tolerability and the effects of our MMTs on the structure and function of the body.

Our MMT candidates have been observed to have limited systemic exposure after oral administration, minimizing off-target biological effects. The direct adverse effects that we have observed to date are limited to the symptoms associated with bacterial metabolism when orally administered, such as gas, flatulence, abdominal cramping and pain and diarrhea, and not those generally associated with systemic exposure. These symptoms are the known dose limiting side effects, and they are localized and generally found to be mild and transient. We believe that we can achieve significantly higher doses with our MMT candidates before triggering dose-limiting side effects, unlike naturally occurring complex carbohydrates, which often result in tolerability challenges at even moderate dosage levels.

Food substances do not require FDA approval prior to commercial offering if qualified experts conclude they are GRAS under the conditions of their intended use. A review process to assess a GRAS substance may be undertaken by a company by either relying on internal or external resources. The resulting conclusion that a substance is GRAS is called a self-determination of GRAS. Once a self-determination of GRAS is made, a company may begin to market the food substance immediately. The FDA does not require companies to notify the agency of a GRAS self-determination; however, GRAS notifications may optionally be sent to FDA if a notifying entity seeks FDA review and the issuance of a "no questions" letter. We will decide whether to pursue GRAS determination for conducting human clinical studies based on our corporate strategy relating to commercializing the product candidate as a food substance.

When a food substance is intended for the diagnosis, cure, treatment or prevention of disease, then it is regulated as a drug ingredient. If our human clinical studies and corporate strategy support further development of the food substance as a drug product, we will need to file an IND with FDA and obtain IND clearance from the FDA before commencing therapeutic clinical trials. An IND requires submission of additional information on the food substance to be studied as a therapeutic drug, including the information that supports the safety of the product for the intended population to be studied and planned exposure, non-clinical toxicology, details of the manufacturing and testing, and clinical protocols describing the proposed human therapeutic clinical trial(s). Equivalent requirements apply for drug clinical studies to be conducted outside the U.S.

If our human clinical studies and corporate strategy support marketing of a food, dietary supplement, or medical food, we may pursue non-drug development pathways to commercialization. We may commercialize our non-drug MMT products ourselves leveraging our in-house nutrition expertise or partner with established nutrition, medical food, or consumer health companies to commercialize these products. We plan to determine the best development path for each of our MMTs at an "MMT decision point" after conducting one or more human clinical studies. We plan to make our decision about which development path to pursue based on the results of our human clinical studies, in conjunction with our research into market opportunities and patient needs and our corporate strategy.

Our approach to human clinical studies

Through human clinical studies, we believe that we can gain valuable insights into the effects our MMTs have on the microbiome and human health. We are able to measure safety and tolerability and potential markers of effect in these studies, which allows us to assess the potential therapeutic and non-therapeutic viability of our MMT candidates in humans. We can also test multiple MMT candidates in the same clinical study, which allows us to assess which MMT candidate shows more potential based on *in vivo* testing.

For all human clinical studies not conducted under an IND, we will adhere to FDA guidance and best practice for food clinical trials. Furthermore, each of our clinical investigators attests that the protocol and study activities adhere to the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, or ICH, guidelines for Good Clinical Practice, or GCP. All studies must receive Institutional Review Board ("IRB") and Ethics Committee ("EC") approval.

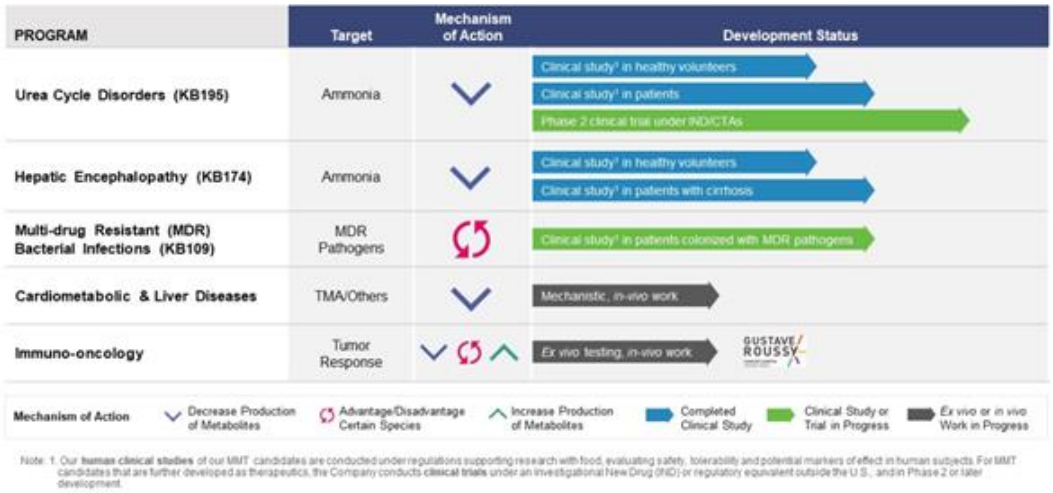
These human clinical studies also allow us to decide whether to file an IND or regulatory equivalent outside the U.S. and investigate the MMT as a drug or continue to develop a specific MMT candidate for non-drug applications. For non-drug applications, we believe we can move MMTs to market with human clinical study data developed under food regulations and guidance, allowing us to potentially pursue non-drug products with informative data. For drug applications, based on discussions with applicable regulatory authorities, we believe we can open INDs or global equivalents for our MMTs as late as Phase 3. Available data would include an abbreviated toxicology package safety review of human experience and use (similar to GRAS discussed earlier) and results of clinical studies. Our experience in our lead programs supports this approach for those of our MMTs which we decide to develop as potential therapeutics after evaluating the data from human clinical studies. For our KB195 program in UCD, we advanced into a Phase 2 trial under an IND. For future programs, we received feedback from the FDA that allows for opening an IND at Phase 3. While each program and the specific MMT candidate that we select for such program will need to be independently evaluated by the FDA, we believe that our clinical study data collected under food regulations and following GCP would be accepted by the FDA.

Data from these human clinical studies also inform our activities in discovery and development. Gathering *in vivo* human data early in the discovery process, together with chemical synthesis and high-throughput screening, allows us to rapidly iterate and improve MMT candidates based on *in vivo* effects and to continue to build a broader understanding of both our MMTs and the microbiome in general.

In 2019 alone, we initiated five human clinical studies with three of our MMT candidates in three patient populations. We have completed three of these studies, one in healthy volunteers and two in patients (UCD and cirrhosis), which demonstrated a consistent effect on a marker of ammonia metabolism and were generally well tolerated providing further validation of our platform and our confidence in our approach. In 2019, our IND for KB195 in UCD was cleared by the FDA and we initiated the Phase 2 clinical trial in patients with UCD who are uncontrolled on current standard of care.

Our pipeline

The following chart summarizes our current pipeline:



The Role of the Microbiome in Ammonia Metabolism

Urea cycle disorders ("UCD") and hepatic encephalopathy ("HE") are two diseases that are characterized by elevated plasma ammonia. Production of ammonia is a normal byproduct of protein breakdown and bacteria in the gut contribute a significant proportion of the normal load of ammonia produced during the course of the day. In healthy individuals, ammonia is processed into urea through the urea cycle, predominantly in the liver, and is subsequently excreted in the urine. When the urea cycle is disrupted or liver function is impaired, ammonia cannot be processed normally and can build up in the bloodstream to dangerous concentrations.

Ammonia is produced by the microbiome through two major pathways — deamination of amino acids and urease-mediated hydrolysis of urea. Additionally, because nitrogen is a critical component of many biomolecules, including proteins and nucleic acids, bacteria need to rapidly replenish nitrogen stores during growth. Many species of bacteria will accomplish this by assimilating ammonia.

Our MMT candidates may reduce microbiome ammonia levels by affecting these pathways and expect that a net reduction in gut ammonia production in UCD and HE patient populations should result in a net reduction of ammonia levels in their blood. In each of these diseases, addressing hyperammonemia represents a significant unmet medical need.

Urea Cycle Disorders

Disease overview

UCD is a serious and life-threatening inherited, rare genetic disease caused by a deficiency in one of the six enzymes or two amino acid transporters that constitute the urea cycle which is responsible for removing ammonia from the bloodstream. UCD can lead to hyperammonemia. Hyperammonemic crises can be fatal and may be precipitated by routine childhood illnesses or any other stress, such as surgery, that causes the body to break down protein. Although UCD encompasses eight distinct mutations, the symptoms and treatments across the subtypes are largely similar. The severity of the disease varies significantly based on the level of deficiency in the enzyme/transporter and the UCD subtype.

There are two types of onset for UCD: early and late onset. Approximately one-quarter of cases are early onset, meaning that they occur within the newborn period (within the first month of life). Even in cases of late onset, the median age of diagnosis is four years. Patient prognosis may range from relatively mild episodic altered mental state to profound developmental disability.

The estimated incidence of UCD is 1 in 35,000 live births in the United States and Europe. UCD is diagnosed either through newborn screening, or at a later point in time when symptoms of the disease present. We believe UCD remains underdiagnosed because newborn screening for the eight UCD subtypes is not universal, and some patients may have milder manifestations and a definitive diagnosis is either never made or made only when a patient presents in crisis. Mortality rates in UCD is reported at 5%, the majority of whom die in the neonatal period. We estimate that there are approximately 3,000 patients with UCD in the United States and approximately 4,500 in Europe.

Currently available therapies

The long-term management of patients with UCD includes a combination of (often severe) dietary restrictions to reduce protein intake and dietary non-drug products. If these measures are insufficient to control hyperammonemia, patients are typically prescribed nitrogen binding therapy "NBT"). In one UCD subtype — N-acetylglutamate synthase deficiency — carglumic acid, which is an activator of a key enzyme missing in that genetic defect, is an additional treatment option. In some patients, manifestations may be so severe as to necessitate a liver transplant.

Our product candidate — KB195

KB195 is our lead MMT candidate for development in the treatment of patients with UCD. We selected KB195 after assessing its performance in reducing ammonia relative to a wide range of other MMTs, as well as several controls, in *ex* vivo screening of microbiome samples from healthy volunteers, as well as microbiome samples from patients with UCD. We are currently conducting a Phase 2 clinical trial under an IND and approved CTAs in a number of countries. We have conducted a clinical study with KB195 in healthy volunteers and have completed a clinical study in UCD patients.

Clinical development in UCD

The goal of the UCD program is to develop a potential treatment for UCD that significantly improves the clinical outcomes by reducing serum ammonia levels; thereby reducing the risk of life-threatening hyperammonemic crises. The objective of the program is to stabilize a greater percentage of UCD patients that are on currently available therapies, and, if data support, move to a first-line nitrogen-binding therapy sparing regimen.

Given UCD affects fewer than 200,000 individuals in the United States, we are pursuing designation of KB195 for the potential treatment of a Rare Pediatric Disease, which would eliminate the PDUFA NDA filing fee and provide for additional exclusivity. UCD is a rare and life-threatening disease that primarily affects pediatric patients. The FDA defines a "rare pediatric disease" as a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years.

In 2019, two studies with KB195 were initiated in patients with UCD. The first was a clinical study to determine safety and tolerability. This open label, single arm study enrolled 4 patients with stable UCD who received KB195 on top of standard of care. The study evaluated safety and tolerability of KB195 as well as assessed microbiome ammonia production using the established marker ^{15}N lacto-ureide as a stable isotope tracer.

In this study, KB195 was generally well tolerated with no clinically significant safety signals based on spontaneous or elicited adverse events or the Gastrointestinal Tolerability Questionnaire ("GITQ") and Bristol Stool Scale ("BSS"). Given the UCD patients had controlled disease, plasma ammonia levels were within the normal range at baseline and remained normal during the study. ^{15}N tracer data was suggestive of KB195 activity in reducing a marker of microbiome ammonia production, showing a decrease in urinary ^{15}N in two of three evaluable patients and an increase in ^{15}N in stool in four of four patients. These data extended the results observed in the clinical study of KB195 in healthy volunteers.

A Phase 2 clinical trial of KB195 under an IND and CTAs was also initiated in 2019 and is currently ongoing. This trial will enroll up to 24 patients inadequately controlled on standard of care for an 8-week treatment period; dose will be escalated from 9 g twice daily ,or BID, to 36 g BID and will evaluate plasma ammonia levels, including proportion of patients with ≥15 percent decrease in fasting plasma ammonia as well as safety and tolerability. The data are expected in the fourth quarter of 2020.

We previously conducted a randomized double-blind, placebo-controlled clinical study to evaluate the effect of KB195 on microbiome nitrogen metabolism in health volunteers. Subjects were randomized to receive KB195 (N=12), a negative control (N=11) or a comparator glycan (N=12). Safety and tolerability were assessed using the GITQ and BSS and microbiome ammonia production was measured using the established marker ^{15}N lacto-ureide as a stable isotope tracer. In this study, KB195 was generally well tolerated, with 4 patients on KB195 reporting diarrhea based on the BSS, compared with 4 patients on the negative control and 10 patients on the comparator glycan. KB195 demonstrated a 33% median decrease in urinary ^{15}N excretion compared to baseline; the difference in urinary ^{15}N excretion for KB195 compared to negative control was 41% (p=0.0126). Patients receiving the comparator glycan experienced a 49% decrease in urinary ^{15}N excretion compared to baseline; the difference between the observed decrease in urinary ^{15}N excretion between the comparator glycan and KB195 was not statistically significant.

Hepatic Encephalopathy

Disease overview

HE describes a spectrum of potentially reversible neurologic and psychiatric abnormalities generally observed in patients with liver failure. HE is a common complication of cirrhosis, ranging from minimal hepatic encephalopathy (“MHE”) to overt hepatic encephalopathy (“OHE”). The pathogenesis of HE has long been linked to ammonia levels, and is now understood to be multifactorial and includes factors such as intestinal dysbiosis, gut hyperpermeability and neuroinflammation.

Patients with cirrhosis also have an increased risk of developing bacterial infections, and infection is a common precipitant of HE, as well as an independent predictor of mortality in these patients. In the United States, we estimate that there are approximately 700,000 patients with cirrhosis inclusive of more than 100,000 patients with OHE, and up to 400,000 with MHE, many of whom remain undiagnosed. In Europe, we estimate there are more than 1 million patients with cirrhosis, inclusive of more than 200,000 patients with OHE and up to 600,000 patients with MHE, many of whom have not yet been diagnosed.

Currently available therapies

Medical treatment of HE currently includes treatment of the underlying precipitant, if present, such as gastrointestinal bleeding or infection. There are two approved chronic drug treatments for OHE-lactulose and rifaximin. Although there have been small investigational studies into treatments for MHE, there are currently no approved therapies for MHE, which is a significant medical need.

Our MMT candidate selection

We selected KB174 as a candidate for the potential treatment of HE. KB174 was selected based on its ability to reduce ammonia and pathogens *ex vivo* as well as results from a clinical study of KB174 in patients with well-compensated liver cirrhosis. Forty adult patients with liver disease were enrolled in this double-blind, controlled clinical study. Patients were randomized to receive KB174 or maltodextrin (a negative control), orally (titrated to 36g BID) for 28 days. Safety and tolerability were assessed using the GITQ and BSS and microbiome ammonia production was measured using the ^{15} N lacto-ureide as a stable isotope tracer.

In this study, patients with cirrhosis treated with KB174 had a 26% median reduction from baseline in urinary ^{15}N excretion, a biomarker of microbiome ammonia production, compared to a 3% median reduction from baseline in urinary ^{15}N excretion for patients receiving maltodextrin. KB174 was well tolerated and no clinically significant or serious treatment-related adverse events were observed.

Results from a dosing study with KB174 in healthy subjects showed reductions in urinary ^{15}N excretion consistent with the study in patients with cirrhosis and was well tolerated with no clinically significant or serious treatment-related adverse events.

Future plans for clinical development in HE

The focus of the HE program will be to further characterize the effects of KB174 and to develop a novel therapy that addresses patients at risk for HE, including those with MHE as well as OHE.

We intend to initiate the next human clinical study with KB174 in patients in the second half of 2020. This study will enroll patients with HE and evaluate the effect of KB174 on clinically relevant outcomes and to further characterize the safety and tolerability of KB174.

We intend to engage with the FDA on design elements of future clinical studies KB174 with the goal of aligning on a program that will enable evaluation, and ultimate registration, of KB174 for reduction in risk of OHE in cirrhotic patients. Feedback from the FDA is that if we elect to file an IND, we may do so with a Phase 3 pivotal trial. The European Medicines Agency ("EMA") has provided similar feedback.

Infections caused by patheogenic bacteria including multi-drug resistant strains

Scientific rationale

Gut commensal bacteria minimize colonization of potential pathogens and maintain the intestinal barrier, thus preventing pathogen translocation to the bloodstream and other organs that ultimately causes infection. A diverse microbiome has been associated with numerous positive health outcomes. The administration of chemotherapy or antibiotics reduces diversity of the microbiome, interfering with its ability to perform these critical protective functions. We believe one potential way to restore the diversity of commensal bacteria is through administration of MMTs that can be metabolized exclusively by commensal bacteria, but not by pathogens. This strategy may therefore increase the diversity and biomass of the commensal microbiota and lead to a reduction in the abundance of pathogens. MMTs thus represent an antibiotic-sparing approach with no known mechanism of resistance for the fight against infectious disease caused by MDR bacteria.

Disease overview

Multi-drug resistant ("MDR") pathogens are a significant and growing global health threat. In the United States alone, antibiotic resistant bacteria cause infections in more than 2.8 million people per year, and this number is growing. As antibiotics become less effective for the treatment and prevention of infectious diseases, infections that were once easily managed have become progressively more difficult to treat. Patients who develop MDR infections consume more healthcare resources and have a higher mortality rate than patients infected with non-resistant strains of the same bacteria.

The risk of MDR pathogen colonization is significantly increased in patients with compromised immune systems, those on long term antibiotics, and those with protracted hospitalizations. Our initial focus is in patients scheduled to undergo hematopoietic stem cell transplantation ("HSCT"), a population at high risk of infection. HSCT is used for the treatment of cancer and certain autoimmune diseases. Bacterial infections are common after HSCT, due to pre-transplant immune system ablation. The use of prophylactic antibiotics was instituted to reduce the rate of such infections; however careful studies of mortality have shown that their use is associated with a significantly increased rate of death. Patients with low microbiome diversity had a significantly greater mortality than those maintaining a high diversity (67% vs 36% mortality at three years). This is thought to be mediated by the adverse effect the antibiotics have on the microbiome. The dysbiotic microbiome in turn facilitates colonization with pathogenic organisms, which may then lead to infection. These infections are a significant cause of patient mortality, excluding mortality due to the primary disease. In the United States, approximately 23,000 patients undergo HSCT each year.

Currently available therapies

While there are no treatments currently approved for prevention of infections in patients scheduled to receive HSCT, some clinicians treat patients prophylactically with an antibiotic from one of several classes, such as quinolones, beta-lactams or glycopeptides. If a patient develops an infection, they are treated empirically with antibiotics based on the likely organism and site of infection. While a significant number of antibiotics are commercially available, delays in treating an infection with an effective antibiotic is associated with increased morbidity and mortality, and some MDR infections have limited or no effective treatment options.

Our product candidate—KB109

KB109 is our lead MMT candidate for development as a potential prevention of infections caused by MDR bacteria. KB109 nomination resulted from its performance relative to a wide range of other MMTs in *ex vivo* screening of microbiome samples from healthy volunteers, as well as microbiome samples from intensive care unit patients.

The initial opportunity is to prevent systemic infections in patients undergoing HSCT. Prophylactic treatment with antibiotics lowers gut microbiome diversity and is associated with a higher mortality rate after HSCT. KB109 is a non-antibiotic approach that is hypothesized to selectively enhance the growth of beneficial gut bacteria at the expense of pathogens (e.g. carbapenem-resistant *enterobacteriaceae*, Vancomycin-resistant *enterococcus*, and extended spectrum beta-lactamase-producing *enterobacteriaceae*) which may then reduce the risk of subsequent infection. Prior to studying patients undergoing HSCT, we are conducting a first-in-human clinical trial in medically stable patients colonized with MDR pathogens. This study will enroll up to 50 patients to assess the safety and tolerability of KB109 and to evaluate the reduction in relative abundance of the colonizing pathogens. Data from this study are expected in the fourth quarter of 2020. The results of this proof of concept study with KB109 will also provide information on the ability to reduce species that contribute to inflammation (e.g. *Enterobacteriaceae*) colonizing the microbiome and may expand the opportunity of this program beyond pathogens into immune mediated and inflammatory diseases.

Future pipeline opportunities

We are currently pursuing a number of opportunities beyond our initial pipeline. Our proprietary product platform is designed to generate the knowledge and insights required to support discovery and development work in a wide range of areas, including where evidence of a link to the microbiome exists but the biology is not yet fully defined. We believe that these areas of more complex microbiome-human biology present an opportunity to leverage our human-centric discovery and development approach and computational expertise.

We are investing in the infrastructure necessary to support this vision. We are expanding our *ex vivo* screening to incorporate new outputs. These new outputs include cell-based assays, which allow us to assess our MMT candidates' effects on human response, targeted and untargeted metabolomics, and whole transcriptome shotgun sequencing. We have started a collaboration with BIOASTER in Paris, France, to expand the functional read-outs on our *ex vivo* platform with focus on immune modulation. We believe that this platform will further strengthen the predictive value of our *ex vivo* platform in immune-driven diseases. We aspire to expand our synthetic chemistry to chemical classes beyond complex carbohydrates and thereby discover novel MMTs across multiple chemical classes. We also continue to build our computational biology and data science capabilities, which are a critical underpinning of our approach and allows us to bring large, diverse datasets together to drive richer and more meaningful conclusions about our MMT candidates and the microbiome. We are also open to opportunities to leverage our proprietary product platform in combination with other approaches to the microbiome.

We have active programs in discovery, including work in immuno-oncology and cardiometabolic and liver diseases. Correlative data has been published for each of these areas suggesting that the microbiome plays a critical role, and our discovery efforts are largely focused on either establishing a mechanistic hypothesis or establishing and optimizing an *ex vivo* screen to address these opportunities. We will advance our lead MMT candidates once identified for future pipeline opportunities through either the drug or non-drug pathway.

Over the last 12 months, we have initiated three new collaborations that we believe will help us elucidate the potential of MMTs in the areas mentioned above. A collaboration with Institute Gustave Roussy in Paris with the teams of Professor Laurence Zitvogel and Guido Kroemer will explore the potential of MMTs to improve the outcome of immune checkpoint inhibitor ("ICI") treatment. Using our *ex vivo* platform and advanced *in vitro* and *in vivo* (mouse) models at Institute Gustave Roussy, we aim to identify candidate MMTs that improve response rate to ICI treatment that will then be tested in clinical studies. In a collaboration with Jeffrey Gordon at Washington University (St. Louis), we will employ an advanced molecular toolbox to study the mechanisms by which selected MMT candidates are metabolized by the gut microbiome and the impact on key functions in the host. We believe that this will facilitate future MMT development and design of preclinical and clinical studies. Finally, we have entered into a partnership with Janssen where we aim to employ our computational capabilities and *ex vivo* platform to identify MMT candidates that favor the establishment of a gut microbial ecosystem that decreases the risk of the development of child-onset of atopic diseases, including food allergies. This program is designed to deliver MMT candidates for subsequent clinical testing.

Manufacturing

We have developed proprietary methods for the manufacture of MMT candidates that we believe are scalable and transferable to current good manufacturing practice requirements ("cGMP"). Our MMT candidates are synthesized, purified and isolated using standard small molecule unit operations (such as batch synthesis and column chromatography). The manufacturing process produces bulk MMT candidates suitable for oral administration in a variety of forms, including liquids and spray dried powders in sachets. In addition, we have established robust analytical methods to assess the identity and purity of our MMT candidates. We believe that these controlled manufacturing processes and analytical methods will allow us to produce and release cGMP batches of material with consistent quality.

Our internal manufacturing capabilities include the production of batches of our MMTs for *ex vivo* screening and testing, toxicology and human clinical studies.

We currently rely on third-party manufacturers for the GMP production of larger quantities of MMT candidates for clinical trials. Our internal personnel have extensive cGMP manufacturing experience in order to ensure efficient technology transfer and to oversee the development and manufacturing activities conducted by third-party manufacturers.

While we do not have a current need for commercial scale manufacturing capacity, at the appropriate time we intend to evaluate options for further engaging our existing third-party manufacturers and/or building our own pharmaceutical grade cGMP internal capabilities.

Intellectual property

Overview

We strive to protect the proprietary technology that we believe is important to our business, including seeking and maintaining patent protection in the United States and internationally for our product candidates and discovery platform. We also rely on trademarks, trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

We plan to continue to expand our intellectual property estate by filing patent applications directed to pharmaceutical compositions, methods of treatment, methods of manufacture or identified from our ongoing development of our product candidates, as well as discovery based on our proprietary product platform. Our level of success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce any patents that we may obtain, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties.

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 guarantee that our pending patent applications, or any patent applications that we may in the future file or license from third parties, will result in the issuance of patents. 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. We cannot predict the scope of claims that may be allowed or enforced in our patents. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our programs and product candidates.

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, and we may have to participate in interference proceedings or derivation proceedings declared by the United States Patent and Trademark Office "USPTO", to determine priority of invention. For more information regarding the risks related to our intellectual property, see "Risk Factors—Risks Related to Our Intellectual Property."

Patent portfolio

Our patent portfolio includes patent applications in varying stages of prosecution in the United States and selected jurisdictions outside of the United States. As of December 31, 2019, our patent portfolio in total consisted of nine issued U.S. patents, two issued European patents, 13 issued patents in other jurisdictions (Argentina, Australia, Canada, China, Colombia, Hong Kong, Indonesia, Mexico, New Zealand, Singapore and South Africa), and over 100 pending non-provisional applications (U.S., EP and other jurisdictions), which include claims directed to compositions, methods of use and manufacturing processes. All patents are owned by us. Certain patents and patent applications described above are licensed exclusively to Midori USA, Inc. for use in the animal health field

The patent portfolio includes patents and applications (numbers for U.S. and Europe only) with claims directed to the following:

MMT platform

We own five issued U.S. patents (U.S.10,131,721; 9,205,418; 9,079,171; 8,476,388; and 8,466,242), two issued EP patents (EP 3071235 and EP 2681247), several pending patent families (with national, non-provisional applications) and one pending Patent Cooperation Treaty ("PCT") containing composition of matter, method of making and use claims related to our MMT platform. The issued patents in the earliest of these families are expected to expire in 2032, not including any patent term adjustments and any patent term extensions.

UCD and HE

We own one issued U.S. patent (U.S. 9,901,595), one issued EP patent (EP 3071235), and three pending PCT application containing composition of matter, method of treatment and use claims related to our UCD and HE programs. The issued patents in the earliest of these families are expected to expire in 2036, not including any patent term adjustments and any patent term extensions.

Multi-drug resistant Bacteria Infections

We own two issued U.S. patents (U.S. 10,314,853; 9,757,403), one issued EP patent (EP 3071235), and one pending PCT application containing method of treatment and use claims related to our pathogen program. The issued patents in the earliest of these families are expected to expire in 2036, not including any patent term adjustments and any patent term extensions.

Immuno-oncology

We own one family of patent applications containing composition of matter, method of treatment and use claims related to our immune-oncology program.

Patent term

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, including the U.S., the base term is 20 years from the filing date of the earliest-filed non-provisional patent application from which the patent claims priority. The term of a U.S. patent can be lengthened by patent term adjustment. In some cases, the term of a U.S. patent is shortened by terminal disclaimer that reduces its term to that of an earlier-expiring patent. The term of a U.S. patent may be eligible for patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. With regard to a drug for which FDA approval is the first permitted marketing of the active ingredient, the Hatch-Waxman Act allows for extension of the term of one U.S. patent that includes at least one claim covering the composition of matter of such an FDA-approved drug, an FDA-approved method of treatment using the drug and/or a method of manufacturing the FDA-approved drug. 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, 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 directed to those product candidates, their methods of use and/or methods of manufacture. However, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. For more information regarding the risks related to our intellectual property, see “Risk Factors—Risks Related to Our Intellectual Property.”

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.

Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. For more information regarding the risks related to our intellectual property, see “Risk Factors — Risks Related to Our Intellectual Property.”

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, strong competition and an emphasis on proprietary products. While we believe that our technology, knowledge, experience and scientific resources provide us with competitive advantages, we face substantial competition from many different sources, including larger pharmaceutical companies with more resources. Specialty biotechnology companies, academic research institutions, governmental agencies, as well as public and private institutions are also potential sources of competitive products and technologies. We believe that the key competitive factors affecting the success of any of our product candidates will include efficacy, safety profile, method of administration, cost, level of promotional activity and intellectual property protection.

The field of microbiome drug development is rapidly evolving and although there are currently many bacterial product candidates in development by companies that target the microbiome (e.g., Seres Therapeutics, Inc., Synlogic, Inc. and Evelo Biosciences, Inc.), we believe that we have a differentiated approach and do not consider ourselves to be in competition with these bacterial microbiome approaches.

Although our novel chemistry approach is unique from most other existing or investigational therapies across the disease areas where our development is focused, we will need to compete with all currently or imminently available therapies in these areas. We are aware of several marketed and investigational products in our leading disease areas, including but not limited to:

- *Urea Cycle Disorders*: The currently approved treatments for UCD are largely NBTs such as glycerol phenylbutyrate, sodium phenylbutyrate and sodium benzoate. Investigational therapies are being developed by several specialty pharmaceutical and biotechnology companies, including UltraGenyx Pharmaceuticals Inc. and Acer Therapeutics.
- *Hepatic Encephalopathy*: The two marketed therapies for HE are rifaximin and lactulose, but there are several investigational therapies being developed by large and specialty pharmaceutical and biotechnology companies, including Mallinckrodt Pharmaceuticals, Axcella Health, Inc. and Bausch Health Companies Inc.
- *Multi-drug Resistant Pathogens:* All existing marketed therapies targeting vancomycin-resistant enterococci and carbapenem-resistant enterobacteriaceae are antibiotics, such as those made by Pfizer Inc., Allergan plc, Merck & Company, Inc., and others. Investigational therapies that are in later stages of development are also antibiotic approaches. The few microbiome-based approaches in clinical development are intended as combination therapies with antibiotics.

If we decide to commercialize any of our MMTs as non-drug products, we will compete with nutrition, medical food or consumer health companies, including Abbott Nutrition, Nestle Health Science, Nutricia, a division of Danone, Reckitt Benckiser and Perrigo.

Government regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval (when required), advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs such as those we are developing as well as dietary non-drug products and foods. We, along with our contract research organizations and contract manufacturers, 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 for our product candidates. The process of obtaining regulatory approvals of drugs for therapeutic indications or commercialization of non-drug products and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, the FDA regulates drug products as well as dietary non-drug products such as foods under the Federal Food, Drug and Cosmetic Act ("FD&C Act"), its implementing regulations and other laws. At this time none of our MMTs have been approved by the FDA for marketing for therapeutic indications in the United States or been authorized for use as a food or medical food. If we fail to comply with applicable FDA or other requirements at any time during product development, clinical testing, the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, issuance of clinical holds for ongoing studies, suspension or revocation of approved applications, warning or untitled enforcement letters, product recalls, product seizures, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution. Any FDA enforcement action could have a material adverse effect on us.

We anticipate that the process required by FDA for our MMT candidates to be marketed in the United States as drugs for therapeutic indications will generally involve the following:

- completion of preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice ("GLP") requirements;
- submission to the FDA of an IND application;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, GCP requirements and other clinical trial-related regulations, including approval by an IRB or independent ethics committee at each trial site, to establish the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of a New Drug Application ("NDA"), including payment of user fees and acceptance by the FDA of the NDA;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA;
- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States; and
- compliance with ay post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy ("REMS"), and the potential requirement to conduct post-approval studies.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

FDA regulation of food uses

To date, we have not elected a product candidate to develop and market as a food and may elect never to do so. If we decide to develop one or more of our MMTs as a conventional food product, we will have to follow regulations applicable to food uses.

The FDA and other regulatory authorities, including the Federal Trade Commission ("FTC"), regulate the manufacturing, preparation, quality control, import, export, packaging, labeling, advertising, promotion, distribution, safety, and adverse event reporting of conventional foods. Among other things, manufacturers of conventional foods and medical foods must meet relevant cGMP, and certain requirements that govern the manufacturing, packaging, labeling and holding of foods.

Under sections 201(s) and 409 of the FD&C Act, any substance that is reasonably expected to become a component of food or added to food is a food additive, and is therefore subject to FDA premarket review and approval, unless the substance is generally recognized among qualified experts as having been adequately shown to be GRAS. Any food that contains an unapproved food additive is considered adulterated under section 402(a)(2)(C) of the FD&C Act. GRAS ingredients are exempt from the definition of food additive and from the mandatory premarket approval requirements for food additives. Under sections 201(s), and FDA's implementing regulations in 21 CFR § 170.3 and 21 CFR § 170.30, the use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food.

General recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information. General recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers. If an ingredient is GRAS for one use, it is not necessarily GRAS for all uses. Under section 201(s) of the FD&C Act, it is the intended use of a substance, rather than the substance itself, that is eligible for classification as GRAS.

Manufacturers of GRAS substances may voluntarily provide the FDA with a notification of GRAS determination, which includes a description of the substance, the applicable conditions of use, the dietary exposure and an explanation of how the substance was determined to be safe for the intended use. Upon review of such a notification, the FDA may respond with a "no questions" letter stating that while it has not made its own GRAS determination, it has no questions at the time regarding the applications' own GRAS determination. Alternatively, manufacturers may elect to "self-determine" a given substance as GRAS without the voluntary FDA notification but should retain all applicable safety data used for GRAS determination in the case of FDA inquiry. We currently test certain glycan substances which we have determined are safe for human clinical studies. This assessment is based on initial safety assessments conducted by qualified experts from third-party scientific consulting organizations and because these compounds are related to a class of compounds that is GRAS based on their history of safe human exposure when utilized for particular uses as food substances.

With certain exceptions, clinical investigations in which an investigational drug is administered to human subjects must be conducted under an IND, as required by FDA regulations. The FDA has published a guidance document for clinical investigators, sponsors, and IRBs, *Investigational New Drug Applications (INDs) — Determining Whether Human Research Studies Can Be Conducted Without an IND* , that provides the FDA's thinking on when an IND is required for human research studies. FDA's interpretation of its regulations, as articulated in this guidance, do not require human testing of food, dietary supplements, or GRAS substances to be conducted under an IND unless such testing is intended to evaluate the product's ability to diagnose, cure, mitigate, treat, or prevent a disease or condition. FDA specifically recognizes an IND will not be required when a study is designed to "evaluate the tolerability of a food in a specific susceptible population, including individuals with a disease in a diseased population," provided the study is not designed to assess the impact of the food or medical food on the disease. There is no assurance that FDA's thinking on this matter will not change, and if it does, FDA may decide to take enforcement action against testing of GRAS substances that it believes should be conducted under an IND, or the FDA may delay or deny an IND submitted with supporting data from human studies not conducted under an IND, or require alternate or additional data to support such a IND before authorizing an applicant to proceed.

Additionally, depending on the circumstances, the use of a substance in certain clinical investigations may restrict the marketing of such substance in food. Section 301(ll) of the FD&C Act prohibits the marketing of any food to which has been added a drug or biologic for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless the substance was marketed in food before any substantial clinical investigations involving the drug or biologic were instituted or one of the other exceptions in section 301(ll) applies. Marketing the substance of interest in food before seeking an IND or beginning any clinical investigations preserves the option to continue to market the substance in those forms after substantial clinical investigations have been instituted and their existence has been made public.

The FDA may classify some or all of our potential product candidates as containing a food additive that is not GRAS. Such classification would cause these product candidates to require pre-market approval for a food additive regulation, which could substantially delay or prevent the commercialization of these product candidates for non-drug uses. Any delay in the regulatory consultation process, or a determination that any of our drug or food product candidates do not meet regulatory requirements of FDA, including any applicable GRAS requirements, could cause a delay in the commercialization of our product candidates, which may lead to reduced acceptance by the public or others or an inability to commercialize those candidates at all.

FDA regulation of medical food uses

In parallel with our development of MMT product candidates for therapeutic indications, we are exploring the development of some of our product candidates as medical food products. To date, we have not elected a product candidate to develop and market as a medical food and may elect never to do so.

The FDA and other regulatory authorities, including the FTC also regulate the manufacturing, preparation, quality control, import, export, packaging, labeling, advertising, promotion, distribution, safety, and adverse event reporting of medical foods. Among other things, manufacturers of medical foods must meet relevant cGMP and certain requirements that govern the manufacturing, packaging, labeling and holding of foods.

As defined in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)), a medical food is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." The FDA has established a regulation at 21 C.F.R. 101.9(j)(8) that further defines medical foods as a product that is (1) is specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube; (2) is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone; (3) provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation; (4) is intended to be used under medical supervision; and (5) is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

The FDA considers the statutory definition of medical foods to narrowly constrain the types of products that fit within this category of food. Medical foods are a distinct category of food applications. The marketing of medical foods generally does not require pre-market approval. The medical food category may offer promising opportunities for our products because a medical food can be marketed without first obtaining FDA approval. There can be no assurance we will be able to develop the data that are needed to substantiate the positioning of the product as a medical food or that FDA would concur the product meets the medical food definition.

Preclinical and clinical trials for drugs

Once a product candidate is identified for development as a drug, it enters the preclinical testing stage. Preclinical studies include laboratory evaluations of drug chemistry, formulation and stability, as well as *in vitro* and animal studies to evaluate the potential for adverse events, which must be conducted in accordance with federal regulations and requirements, including GLP requirements. The results of the preclinical studies, together with manufacturing information and analytical data as well as the results of our human clinical studies, are submitted 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 IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing clinical trials to commence on the terms originally specified in the IND. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development, and the FDA must grant permission, either explicitly or implicitly by not objecting, before each clinical trial can begin.

Clinical trials involve the administration of the product candidate to human volunteers under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol for our product candidates for therapeutic indications must be submitted to the FDA as part of the IND. An IRB for each investigator site proposing to participate in a clinical trial must also review and approve the clinical trial before it can begin at that site. The FDA's regulations provide additional safeguards for pediatric subjects enrolled in clinical trials of investigational products. For example, under the FDA's regulations, a clinical investigation involving greater than minimal risk to children but that presents the prospect of direct benefit to individual subjects may involve pediatric subjects only if

the IRB finds that the risk is justified by the anticipated benefit to the subjects, the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches, and adequate provisions are made for soliciting the consent of the pediatric subjects and the permission of their parents and guardians. Further, the IRB must monitor the clinical trial until it is completed. The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Clinical testing of product candidates for therapeutic indications also must satisfy extensive GCP requirements, including requirements for informed consent.

Human clinical trials for therapeutic indications are typically conducted in three sequential phases, which may overlap or be combined. In certain circumstances, where sufficient evidence of safety and tolerability are collected from preclinical studies and other human experience with a product, such as our human clinical studies, we believe a human clinical trial may begin as late as Phase 3.

- *Phase 1* — Phase 1 clinical trials involve initial introduction of the investigational product into healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, excretion the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- *Phase 2* — Phase 2 clinical trials typically involve administration of the investigational product to 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.
- *Phase 3* — Phase 3 clinical trials typically involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval and physician labeling.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the product available in the United States for the disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA or a Biologics License Application. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan products are eligible for certain incentives, including tax credits for qualified clinical testing and waiver of application fees.

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 a seven-year period of marketing exclusivity during which the FDA may not approve any other applications to market the same therapeutic agent for the same indication, except in limited circumstances, such as a subsequent product's showing of clinical superiority over the product with orphan exclusivity or where the original applicant cannot produce sufficient quantities of product. Competitors, however, may receive approval of different therapeutic agents for the indication for which the orphan product has exclusivity or obtain approval for the same therapeutic agent for a different indication than that for which the orphan product has exclusivity. Orphan product exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for the same therapeutic agent for the same indication before we do, unless we are able to demonstrate that our product is clinically superior. Furthermore, if a designated orphan product receives marketing approval for an indication broader than the rare disease or condition for which it received orphan designation, it may not be entitled to orphan exclusivity.

Expedited development and review programs for drugs

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs and biologics to address unmet medical needs in the treatment of serious or life- threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval, and the purpose of these programs is to either expedite the development or review of important new drugs to get them to patients earlier than under standard FDA development and review procedures.

A new drug or biologic is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the agency may review portions of the marketing application before the sponsor submits the complete application, as well as Priority Review, discussed below. In addition, a new drug or biologic may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient drug development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review designation and accelerated approval. A product is eligible for Priority Review if it has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under Priority Review, FDA must review an application in six months compared to ten months for a standard review. Additionally, products are eligible for accelerated approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality which 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.

Accelerated approval is usually contingent on a sponsor’s agreement to conduct additional post-approval studies to verify and describe the product’s clinical benefit. In addition, unless otherwise informed by the FDA, the FDA currently requires, as a condition for accelerated approval, that all advertising and promotional materials that are intended for dissemination or publication within 120 days following marketing approval be submitted to the agency for review during the pre-approval review period, and that after 120 days following marketing approval, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial 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 review process.

U.S. marketing approval for drugs

Assuming successful completion of the required clinical testing of our product candidates for drug uses, the results of the preclinical and clinical studies, together with detailed information relating to the product’s chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. An NDA is a request for approval to market a new drug for one or more specified indications and must contain proof of the drug’s safety and efficacy. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of an NDA must be obtained before a drug may be marketed in the United States.

In addition, under the Pediatric Research Equity Act of 2003, as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. An Agreed Initial Pediatric Study Plan requesting a waiver from the requirement to conduct clinical studies has been submitted to the FDA.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are compliant with cGMP requirements and adequate to assure consistent production of the Sponsor product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

After evaluating the NDA and all related information, including any inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, depending on the specific risk(s) to be addressed it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

U.S. post-approval requirements for drugs

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. There is also a continuing, annual prescription drug product program user fee.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-market testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and their subcontractors involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our contract manufacturers. Failure to comply with statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution.

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, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other potential consequences up to and including revocation of product approvals.

Other regulatory matters

Manufacturing, sales, promotion and other activities following product approval or commercialization are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the FTC, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

Other healthcare laws

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations.

Current and future healthcare reform legislation

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

The Patient Protection and Affordable Care Act (“ACA”) for example, may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies’ share of sales to federal health care programs. With the current Administration and Congress, there will likely be additional administrative or legislative changes, including modification, repeal, or replacement of all, or certain provisions of, the ACA, which may impact reimbursement for drugs. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent or loosen certain requirements mandated by the ACA. While Congress has not passed repeal legislation, the Tax Reform Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Further, the Bipartisan Budget Act of 2018 (“BBA”), among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” Congress may consider other legislation to repeal and replace elements of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Packaging and distribution in the United States

If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Other U.S. environmental, health and safety laws and regulations

We may be 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. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Government regulation of drugs outside of the United States

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization or identification of an alternate regulatory pathway, manufacturing, commercial sales and distribution of our products. For instance, in the European Economic Area ("EEA") medicinal products must be authorized for marketing by using either the centralized authorization procedure or national authorization procedures.

- *Centralized procedure* — If pursuing marketing authorization of a product candidate for a therapeutic indication under the centralized procedure, following the opining of the EMA's Committee for Medicinal Products for Human Use ("CHMP"), the European Commission issues a single marketing authorization valid across the EEA. The centralized procedure is compulsory for human medicines derived from biotechnology processes or advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products), products that contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunctions, viral diseases, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned contains a new active substance not yet authorized in the EEA, is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health in the EEA. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding clock stops.

- *National authorization procedures* — There are also two other possible routes to authorize products for therapeutic indications in several countries, which are available for products that fall outside the scope of the centralized procedure:
- *Decentralized procedure* — Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure.
- *Mutual recognition procedure* — In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, additional marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned recognize the validity of the original, national marketing authorization.

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP and the related national implementing provisions of the individual EU Member States govern the system for the approval of clinical trials in the European Union. Under this system, an applicant must obtain prior approval from the competent national authority of the EU Member States in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee has issued a favorable opinion. The CTA must be accompanied by, among other documents, an investigational medicinal product dossier (the Common Technical Document) with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC, where relevant the implementing national provisions of the individual EU Member States and further detailed in applicable guidance documents.

The collection and use of personal health data in the European Union, previously governed by the provisions of the Data Protection Directive, is now governed by the General Data Protection Regulation ("GDPR"), which became effective on May 25, 2018. While the Data Protection Directive did not apply to organizations based outside the EU, the GDPR has expanded its reach to include any business, regardless of its location, that provides goods or services to residents in the EU. This expansion would incorporate any clinical trial activities in EU members states. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information" which includes health and genetic information of data subjects residing in the EU. GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the European Union to the United States or other regions that have not been deemed to offer "adequate" privacy protections. Failure to comply with the requirements of the GDPR and the related national data protection laws of the European Union Member States, which may deviate slightly from the GDPR, may result in fines of up to 4% of global revenues, or €20,000,000, whichever is greater. As a result of the implementation of the GDPR, we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules.

There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is not clear if the authorities will conduct random audits of companies doing business in the EU, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated. Enforcement uncertainty and the costs associated with ensuring GDPR compliance are onerous and may adversely affect our business, financial condition, results of operations and prospects.

Additionally, should we elect one or more product candidates to develop and market as non-therapeutic dietary non-drug products or food products in foreign countries, such products would also be subject to regulation under various national, local, and international laws that include provision governing, among other things, the formulation, manufacturing, packaging, labeling, advertising. These regulations may prevent or delay entry into the market or prevent or delay the introduction, or require the reformulation, of certain of our non-therapeutic product candidates.

The regulatory environment outside the United States varies and in general is less developed then in the United States, but some exceptions do exist. The regulatory requirements for nutritional non-drug products and food products outside of the United States varies greatly from jurisdiction to jurisdiction. Each jurisdiction may have its own regulatory framework regarding nutritional non-drug products and food products. The two leading jurisdictions, the United States and the Europe, currently have and may continue to in the future to have distinctly different regulatory regimes with different rules and requirements nutritional non-drug products and food products, with, for example, the European Union having a stronger process for claims review and preapproval for nutritional products. Regulation in Europe is exercised primarily through the European Union, which regulates the combined market of each of its member states. Other European countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to dietary products.

We cannot predict how the global regulatory landscape regarding our possible nutritional non-drug products or food products, if any, will evolve and we may incur increased regulatory costs as regulations in the jurisdictions in which we operate evolve or change. We cannot predict whether or when any jurisdiction will change its regulations with respect to any of our product candidates.

Should we utilize third part distributors, compliance with such foreign governmental regulations would generally be the responsibility of such distributors, who may be independent contractors over whom we have limited control.

Government regulation of food for special medical purpose in the European Union

The regulatory requirements for foods for special medical purposes (“FSMPs”), in the European Union cover FSMP development and commercialization.

In the European Union, FSMPs are designed to feed patients who, because of a particular disease, disorder or medical condition, have nutritional needs that cannot be met by consuming standard foodstuffs. European Union Regulation defines ‘ *food for special medical purposes* ’ as food specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolize or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone.

Businesses intending to commercialize FSMPs in the European Union are required to register their FSMPs by submitting notifications regarding FSMP use, demonstrating compliance with applicable European Union rules, prior to market commercialization. These notifications to competent authority of each European Union Member State include information appearing on the label, and any other information the competent authority may reasonably request to establish compliance with this Regulation.

The European Commission may decide, by means of implementing acts (a) whether a given food falls within the scope of this Regulation; and (b) to which specific category of food a given food belongs. European Food Safety Authority Guidance provides, among other requirements, that the dossier must include an explanation of the scientific and medical basis on which it has been concluded that the use of the specific food product is necessary or is more practical or safer than the exclusive use of non-FSMP foodstuffs.

FSMPs can also fall within the scope of the novel food legislation in the European Union. Where an ingredient used in the FSMP to be marketed in the European Union falls within the definition of a ‘novel food ingredient’ prior authorization for use of the ingredient needs to be sought. A “novel” food or food ingredients as food that has not been consumed to a significant degree by humans in the European Union before May 15, 1997 and that falls within one of the ten food categories listed. Novel foods and novel food ingredients can only be authorized if they do not pose a safety risk to human health, their intended use does not mislead the consumer and they do not differ from the food they are intended to replace in such a way that its normal consumption would be nutritionally disadvantageous for the consumer. The authorization procedure is likely to take between 12 and 18 months.

In accordance with European Union clinical trials directives, before a clinical trial site is allowed to start enrolling patients in a clinical trial, the IRB or (IEC), must provide a positive opinion concerning the study protocol and all study-related materials. The competent authorities of the relevant European Union Member State must also provide their related authorization. Clinical trials involving the investigation of the action of non-medicinal products (e.g. foods, such as many FSMPs), are not covered and are not required to register the clinical trial or to complete a CTA for approval by an European Union Member State.

Employees

As of December 31, 2019, we had 91 full-time employees, of which 31 have Ph.D. or M.D. degrees and 69 are currently engaged in research and clinical development activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be very strong.

Facilities

Our corporate headquarters are located in Lexington, Massachusetts, where we currently lease 107,000 square feet of laboratory and office space. The lease expires in 2029, subject to one option to extend the lease for 10 years.

We also lease 50,000 square feet of laboratory and office space located in Bedford, Massachusetts. This lease expires in June 2020 and currently houses our pilot production operations. We believe our facilities are sufficient for our current needs.

Legal proceedings

We are not currently a party to any material legal proceedings.

Corporate Information

We were incorporated in January 2015 as VL32, Inc. under the laws of the State of Delaware. In November 2015, we changed our name to Kaleido Biosciences, Inc. Our principal executive office is located at 65 Hayden Avenue, Lexington, Massachusetts, and our telephone number is (617) 674-9000. Our website address is *www.kaleido.com*. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K. You should not rely on any such information in making your decision whether to purchase our common stock.

On March 4, 2019, we completed the IPO of our common stock pursuant to which we issued and sold 5,000,000 shares of our common stock at a price to the public of $15.00 per share. We received aggregate gross proceeds from our IPO of $75.0 million, or aggregate net proceeds of $67.8 million after deducting underwriting discounts and commissions and other offering costs. None of the underwriting discounts and commissions or offering expenses were incurred or paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of the IPO, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Financial Information and Segments

The financial information required under this Item 1 is incorporated herein by reference to the section of this Annual Report titled “Part II—Item 8—Financial Statements and Supplementary Data. The company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The company is developing red cell therapeutics for the treatment of patients with severe diseases. All of the company’s tangible assets are held in the United States. See Note 2 to our consolidated audited financial statements included in this Annual Report on Form 10-K. For financial information regarding our business, see “Part II—Item 7—Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this Annual Report on Form 10-K and our consolidated audited financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

Available Information

Our Internet address is *www.kaleido.com*. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available through the “Investors and Media” portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. Our filings with the SEC may be accessed through the SEC’s Interactive Data Electronic Applications system at *http://www.sec.gov*. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Item 1A. Risk Factors.

Our business is subject to numerous risks. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes and "Management's discussion and analysis of financial condition and results of operations," and in our other filings with the Securities and Exchange Commission. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks related to our business, technology and industry

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

We may be forced to amend, delay, limit, reduce terminate the scope of our development programs and/or limit or cease our operations if we are unable to obtain additional funding. As of December 31, 2019, we had cash and cash equivalents totaling $71.2 million. Based on our current operating plans, we do not have sufficient cash and cash equivalents to fund our operating expenses and capital expenditures for at least the next 12 months from the filing date of this Annual Report on Form 10-K. We will require additional capital to sustain our operations, including our development programs. We expect to seek additional funds through equity or debt financings or through collaborations, licensing transactions or other sources. However, there can be no assurance that we will be able to complete any such transactions on acceptable terms or otherwise. The failure to obtain sufficient funds on commercially acceptable terms when needed would have a material adverse effect on our business, results of operations, and financial condition. We may implement cost reduction strategies, which may include amending, delaying, limiting, reducing, or terminating one or more of our ongoing or planned clinical trials of our MMT candidates. These factors raise substantial doubt about our ability to continue as a going concern.

We 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 healthcare company with a limited operating history. Investment in product development in the healthcare industry, including of biopharmaceutical products, 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, as necessary, and become commercially viable. Our lead product candidates are currently in clinical development. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and 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 in 2015. For the years ended December 31, 2019 and 2018, we reported net losses of $86.3 million and $61.7 million, respectively. As of December 31, 2019, we had an accumulated deficit of $192.6 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 product candidates.

To become and remain profitable, we or any potential future collaborator must develop and eventually commercialize products with significant market potential at an adequate profit margin after cost of goods sold and other expenses. This will require us to be successful in a range of challenging activities, including completing preclinical studies, clinical studies and clinical trials, obtaining marketing approval or identifying alternate regulatory pathways for product candidates, cGMP manufacturing, marketing and selling products for which we may obtain marketing approval or successfully identify alternate regulatory pathways 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 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.

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

We will require additional capital to fund our operations and if we fail to obtain necessary financing, we will not be able to complete the development and commercialization of our product candidates.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to conduct further research and development, preclinical studies, clinical studies and clinical trials of our current and future product candidates, to validate the manufacturing process and establish specifications for our product candidates, to seek regulatory approvals for or identify alternate regulatory pathways to market for our product candidates and to launch and commercialize any products for which we receive regulatory approval or identify an alternate regulatory pathway to market, including potentially building our own commercial organization. As of December 31, 2019, we had $71.2 million of cash and cash equivalents on hand. However, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will in any event require additional capital in order to complete clinical development of any of our current product candidates. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities.

In addition, as noted above, we have identified conditions and events that raise substantial doubt as to our ability to continue as a going concern if we are unable to obtain funding on a timely basis. Based on our current operating plans, we do not have sufficient cash and cash equivalents to fund our operating expenses and capital expenditures for at least the next 12 months from the filing date of this Annual Report.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient product or royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible into or exchangeable for common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or acquiring or licensing intellectual property rights. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

We have a limited operating history, which may make it difficult to evaluate our technology and product development capabilities and predict our future performance.

We were formed in 2015, have no products approved for commercial sale or marketed via other regulatory pathways (e.g., non-drug products) and have not generated any revenue from product sales. Our ability to generate product revenue or profits, which we do not expect will occur for many years, if ever, will depend on the successful development and eventual commercialization of our product candidates, which may never occur. We may never be able to develop or commercialize a marketable product.

Our current and future therapeutics programs and product candidates require additional discovery research, preclinical development, clinical development, regulatory approval in multiple jurisdictions or identification of alternate regulatory pathways to market, manufacturing validation, obtaining cGMP manufacturing supply, capacity and expertise, building of a commercial and distribution organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. In addition, our drug product candidates must be approved for marketing by the FDA or certain other health regulatory agencies, including the EMA, or we must secure alternate non-therapeutic regulatory pathways to market our non-therapeutic product candidates before we may commercialize any product in the respective jurisdictions.

Our limited operating history may make it difficult to evaluate our technology and industry and predict our future performance. Our short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage companies in evolving fields. If we do not address these risks successfully, our business will suffer. Similarly, we expect that our financial condition and operating results will fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. As a result, our stockholders should not rely upon the results of any quarterly or annual period as an indicator of future operating performance.

In addition, as an early-stage company, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown circumstances. As we advance our product candidates, we will need to transition from a company with a research focus to a company capable of supporting clinical development and, if successful, commercial activities. We may not be successful in such a transition.

Microbiome Metabolic Therapies ("MMT" or "MMTs") are a novel approach and negative perception of any product candidates that we develop could adversely affect our ability to conduct our business, obtain regulatory approvals or identify alternate regulatory pathways to market for such product candidates.

Microbiome therapies and therapy candidates in general, and our MMT candidates in particular, are a relatively new and novel approach. In the United States and the European Union, no products to date have been approved specifically demonstrating an impact on the microbiome as part of their therapeutic effect. MMTs and 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, if available, with which they are more familiar and for which greater clinical data may be available. Our access will also depend on consumer acceptance and adoption of our products that we commercialize. Adverse events in clinical studies and clinical trials of our product candidates or in clinical trials by others developing similar products and the resulting publicity, as well as any other adverse events in the field of the microbiome, could result in a decrease in demand for any product that we may develop. In addition, responses by the United States, 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.

All of our initial product candidates for which we make a drug development path decision, including any targeting urea cycle disorders ("UCD"), and hepatic encephalopathy (" HE"), will require significant additional preclinical and clinical development before we can seek regulatory approval for and launch a therapeutic product commercially.

For any product candidate that we choose to develop as a drug product candidate, our business and future success depends on our ability to obtain regulatory approval of and then successfully launch and commercialize our initial product candidates as a drug targeting UCD or HE. We filed an IND with the FDA, for our initial therapeutic product candidate, which has cleared and allowed us to commence a Phase 2 clinical trial for UCD. Similar clinical trial applications have been approved in countries outside the US, including in Europe and the Middle East, where we are also conducting the study. However, our clinical trials may experience preliminary complications in trial execution, such as complexities surrounding regulatory clearance of our clinical trial applications, the need for additional preclinical data to support allowance for those applications, the need for additional preclinical data to support authorization to proceed under those applications, trial design and establishing trial protocols, bioanalytical assay method development, dose level and regimen selection, patient recruitment and enrollment, quality and supply of clinical doses or safety issues.

Our Phase 2 clinical trial is intended to allow us to evaluate the efficacy of KB195 in reducing ammonia in UCD patients. In compliance with FDA regulations, the clinical trial is initially enrolling only adults. We plan to include pediatric patients as soon as possible, as UCD primarily affects pediatric patients. We expect this will also be acceptable to regulatory authorities outside of the United States where we plan to conduct the trial. However, trials involving pediatric populations can be difficult to conduct, can be quite costly and, like other clinical trials, may not yield the anticipated results. In addition, pediatric studies can be difficult to recruit for and many sites are largely ill-equipped to manage pediatric subjects for the requisite daily time period to ensure adherence to the schedule of a clinical trial, which in turn can limit site availability, therein driving cost. Moreover, it may be challenging to ensure that pediatric or adolescent patients adhere to clinical trial protocols. Our inability to enroll a sufficient number of pediatric patients for our clinical trial could result in significant delays, could require us to abandon one or more clinical trials altogether, could impact our ability to raise additional capital and could delay or prevent our ability to obtain necessary regulatory approvals for any drug product candidate. In addition, because UCD primarily affects pediatric patients, if we are unable to obtain regulatory approval for KB195 for an indication including pediatric patients, the commercial prospects or viability for our product candidate could be materially harmed, even if we obtain regulatory approval for an indication including adult patients.

All of our initial product candidates are in the early stages of development and will require significant additional preclinical and clinical development, regulatory review and approval in multiple jurisdictions or identification of alternate non-therapeutic regulatory pathways, substantial investment, access to sufficient validated and cGMP compliant commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. In addition, because KB195 is our most advanced product candidate, if KB195 encounters safety, efficacy, supply or manufacturing problems, developmental delays, regulatory or commercialization issues or other problems, our development plans, including for other product candidates, and business would be significantly harmed.

The successful development of our product candidates is highly uncertain.

Successful development of product candidates is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- preclinical or clinical study results may show our product candidates to have less activity than desired or to have harmful or problematic side effects or toxicities;
- clinical trial results may show our therapeutic product candidates to be less effective than expected or desired (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;

- failure to execute the clinical studies or clinical trials caused by slow enrollment in clinical studies and clinical trials, patients dropping out of clinical trials or volunteers dropping out of clinical studies, length of time to achieve clinical trial endpoints, additional time requirements for data analysis, inability to validate the manufacturing process or to achieve cGMP compliance for our product candidates or inability to identify a suitable bioanalytical assay method agreeable to our regulators;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals for, including but not limited to, a NDA, delays in NDA preparation, a new dietary ingredient notification, discussions with and responding to the FDA or other regulatory authorities request for additional preclinical or clinical data or unexpected safety or manufacturing issues;
- manufacturing costs, formulation issues, manufacturing deficiencies or other factors that make our product candidates uneconomical; and
- proprietary rights of others and their competing products and technologies that may prevent our product candidates from being commercialized.

The length of time necessary to complete clinical trials and to submit an application for marketing approval of a drug product candidate for a final decision by a regulatory authority may be difficult to predict for our therapeutic product candidates, in large part because of their limited regulatory history.

Even if we are successful in obtaining market approval for drug products, commercial success of any approved therapeutic products will also depend in large part on marketing acceptance, 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.

In addition, if any of our drug product candidates is approved for marketing, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration. If approved, our drug products would be subject to restrictions on our products' labels and other conditions of regulatory approval that may limit our ability to market our products for therapeutic indications. We will also need to comply (and ensure that our third-party contractors comply) with current cGMPs and Good Clinical Practices ("GCPs"), as we (and our third-party contractors) will be required to comply with cGMPs for products used in any clinical trials. In addition, we will need to comply with GCPs for any therapeutic indications we develop for approval and for any additional therapeutic indications we develop after approval of our first drug candidate.

Clinical development is a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidates.

To obtain the requisite regulatory approvals to commercialize any product candidates for therapeutic uses, we must demonstrate through extensive preclinical studies, clinical studies and clinical trials that our product candidates are safe and effective in humans for their intended use. Clinical testing is expensive, difficult to design and implement and can take many years to complete, and its outcome is inherently uncertain. We may be unable to establish clinical endpoints, dose levels and regimens or bioanalytical assay methods that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. The outcome of preclinical studies, clinical studies and early clinical trials may not be predictive of the success of later preclinical studies, clinical studies and clinical trials, and interim results of these studies or trials do not necessarily predict final results. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates.

Successful completion of clinical trials is a prerequisite to submitting an NDA to the FDA, a Marketing Authorization Application to the EMA, and similar marketing applications to comparable other regulatory authorities, for each product candidate for therapeutic indications and, consequently, the ultimate approval and commercial marketing of any product candidates for therapeutic indications. We do not know whether any of our clinical trials will begin or be completed on schedule, if at all.

We may experience delays in completing our preclinical studies and initiating or completing clinical studies and clinical trials. We also may experience numerous unforeseen events during, or as a result of, any future clinical studies or clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may be unable to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation of clinical trials for therapeutic indications or the marketing of our products as non-drug products;
- regulators or IRBs, ethics committees, or ECs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations ("CROs"), or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of any product candidates may fail to show safety, potency, or produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of patients required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be more complicated or slower than we anticipate, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- we may need to add new or additional clinical trial sites;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- the cost of preclinical studies, clinical studies and clinical trials of any product candidates may be more than we anticipate or more than our available financial resources;
- the supply or quality of our product candidates or other materials necessary to conduct clinical studies and clinical trials of our product candidates may be insufficient or inadequate and may not achieve compliance with applicable cGMPs;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ECs to suspend or terminate clinical studies and clinical trials, or reports may arise from preclinical or clinical testing of our product candidates that raise safety or efficacy concerns about our product candidates;
- preclinical studies, clinical studies or clinical trials of our product candidates may produce negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs; and
- the FDA or other regulatory authorities may disagree with the design, implementation or results of our clinical studies or clinical trials or require us to submit additional data such as long-term toxicology studies or impose other requirements before permitting us to initiate a clinical trial.

We could also encounter delays if a preclinical study, clinical study or clinical trial is suspended or terminated for any reason. 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 other 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 for therapeutic indications. Further, the FDA or other 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 preclinical studies, clinical studies or clinical trials. For example, we may utilize an "open-label" trial design for some of our future clinical trials. An open-label trial is one where both the patient and investigator know whether the patient is receiving the test article or either an existing approved drug or placebo. Open-label trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label studies are aware that they are receiving treatment. Open-label 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. Open-label 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. The opportunity for bias in clinical trials as a result of open-label design may not be adequately handled and may cause any of our trials that utilize such design to fail and additional trials may be necessary to support future marketing applications.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our preclinical studies, clinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical studies, clinical studies or 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 preclinical or future clinical development programs may harm our business, financial condition and prospects significantly.

Our ongoing and planned clinical trials or those of our future collaborators may reveal significant adverse events not seen in our preclinical studies, clinical studies or other clinical trials and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

Before obtaining regulatory approvals for the commercial sale of any products for therapeutic indications, we must demonstrate through lengthy, complex and expensive preclinical studies, clinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Preclinical and 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 preclinical or clinical trial process. The results of preclinical studies, clinical studies as well as early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such clinical trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. We believe that our product candidates for therapeutic indications will be well tolerated by participants in our clinical trials, but we are not certain that we will be able to dose trial participants at a high enough dose that will demonstrate efficacy without unacceptable safety risk. Our product candidates are expected to have limited systemic exposure after oral administration but if the product candidates we use in our clinical trials are absorbed by the body, participants may suffer adverse effects. There is also a concern that the microbiome could re-configure itself in such a way as to cause a limited time window of effectiveness and tolerability of our product candidates or unanticipated short or long-term effects.

Product candidates in later stages of clinical trials also may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the healthcare industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier clinical trials. Most product candidates that commence clinical trials are never approved as products for therapeutic indications and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development or commercialization of any of our product candidates.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our clinical trials or we may be required to significantly redesign or abandon trials or our development efforts of one or more product candidates altogether. We, the FDA or other applicable regulatory authorities or an IRB or EC may suspend clinical trials of a product candidate at any time for various reasons, including a belief that patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the healthcare industry that initially showed therapeutic promise in early-stage clinical trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

Positive results from early preclinical studies, clinical studies and clinical trials of our product candidates are not necessarily predictive of the results of later preclinical studies, clinical studies and any future clinical trials of our product candidates for therapeutic indications. If we cannot replicate the positive results from our earlier preclinical studies of our product candidates in our later preclinical studies and future clinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates

Any positive results from our preclinical studies, clinical studies and clinical trials of our product candidates may not necessarily be predictive of the results from required later preclinical studies, clinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies or any future clinical studies and clinical trials of our product candidates according to our current development timeline, the positive results from such preclinical studies, clinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies, clinical studies or clinical trial results.

Many companies in the pharmaceutical and biotechnology 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, clinical 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, clinical studies and clinical trials nonetheless failed to obtain FDA or EMA approval.

If we encounter difficulties enrolling patients in our clinical studies or clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient identification and enrollment in our clinical studies and clinical trials for a variety of reasons. The timely completion of clinical studies or clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the clinical study or clinical trial until its conclusion. The enrollment of patients depends on many factors, including, but not limited to:

- the severity of the disease or condition under investigation for product candidates developed as therapeutics;
- the patient eligibility and exclusion criteria defined in the protocol;

- the size of the study patient population required for analysis of the primary endpoint(s) of the clinical study or clinical trial;
- the proximity of patients to study sites;
- the design of the clinical study or trial;
- our ability to recruit investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- the efforts to facilitate timely enrollment in clinical studies or trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents; and the risk that patients enrolled in clinical studies or clinical trials will drop out of the clinical studies or clinical trials before completion.

In addition, our clinical studies or trials will compete with other clinical studies or 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 clinical studies or trials may instead opt to enroll in a study or trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical studies or 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. Moreover, because our product candidates represent a departure from more commonly used methods for our targeted therapeutic areas, potential patients and their doctors may be inclined to use conventional therapies, rather than enroll patients in any future clinical study or trial.

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

Interim top-line and preliminary data from our clinical studies or 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 expect to publish interim top-line or preliminary data from our clinical studies and clinical trials. Interim data from these clinical studies and clinical trials that we may complete are subject to the risk that one or more of the outcomes may materially change as patient enrollment continues, and more patient data become available. Preliminary or top-line 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, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

If we 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 biological waste or 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 or 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.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of testing our product candidates in clinical studies and clinical trials and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical studies, clinical trials, manufacturing, marketing or sale. Any such product liability claims may include, but are not limited to, allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring a product candidate to the market;
- decreased demand for our products;
- damage to our reputation;
- withdrawal of clinical study or clinical trial participants and patients and inability to enroll future participants or continue clinical studies or clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation or implement corrective actions;
- diversion of management's time and our resources;
- substantial monetary awards to participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate via any regulatory pathway; and
- decline in our share price.

We maintain clinical trial insurance. We review our clinical trial insurance policy annually and we believe that our coverage is currently adequate to cover any claims that may arise in connection with our clinical studies or clinical trials. There is no guarantee that we will be able to obtain additional clinical trial insurance at an acceptable cost in the future, which could prevent or inhibit the ongoing development of our products.

Since we have not yet commenced marketing of any products, we do not yet hold product liability insurance for commercialization of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. If and when coverage is secured, our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

The market opportunities for our product candidates may be limited and our estimates of the incidence and prevalence of our target patient populations may be inaccurate.

Our projections of the market sizes we may target and number of people who have the diseases or conditions we target, as well as the subset of people with these diseases in a position to receive our therapies, if approved, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, input from key opinion leaders, patient foundations or secondary market research databases, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases or regulatory approvals may include limitations for use or contraindications that decrease the addressable patient population for product candidates we decide to develop as drug product candidates. The number of individuals may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates that we decide to develop as drugs may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our product candidates, because certain of the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications or expanding the target market size for non-drug products.

We are early in our development efforts and may not be successful in our efforts to use our proprietary product platform to build a pipeline of product candidates and develop marketable products.

We are developing our proprietary product platform to systematically direct functional outputs of the microbiome organ. However, our proprietary product platform has not yet, and may never lead to, FDA approved or commercialized products. We are developing our initial product candidates and additional product candidates that we intend to use in a number of areas of health and disease, including UCD, HE, MDR pathogens, cardiometabolic diseases, liver disease, and cancer. We may have problems applying our technologies to these other areas, and our product candidates may not demonstrate a comparable ability in treating disease as our initial product candidates. Even if we are successful in identifying additional product candidates, they may not be suitable for clinical development as a result of our inability to manufacture the compounds, limited efficacy, unacceptable safety profiles or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance.

If we do not successfully develop and commercialize product candidates based upon our platform approach, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

We face significant competition from other healthcare companies, and our operating results will suffer if we fail to compete effectively.

The healthcare industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or products that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, nutritional foods 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, experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. 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 healthcare industry may result in even more resources being concentrated amongst 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 microbiome therapies 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 anticipate competing with the largest healthcare companies in the world, all of which have greater financial and human resources than we currently have. In addition to these fully integrated healthcare companies, we also compete with those companies whose products target the same indications as our product candidates. They include pharmaceutical companies, biotechnology companies, academic institutions and other research organizations. Any treatments developed by our competitors could be superior to our product candidates. It is possible that these competitors will succeed in developing technologies that are more effective than our products or that would render our product candidates obsolete or noncompetitive. We anticipate that we will face increased competition in the future as additional companies enter our market and scientific developments surrounding other therapies targeted at the microbiome continue to accelerate.

In addition, there are a number of other companies targeting the microbiome, e.g. Synlogic, Inc., Seres Therapeutics, Inc. and Evelo Biosciences, Inc.

Even if we obtain regulatory approval to market our product candidates or are successful in identifying alternate regulatory pathways to market for our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

Even if a product candidate we develop as a therapeutic receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, consumers and others in the medical or healthcare community necessary for commercial success.

If any product candidate we develop receives marketing approval as a therapeutic, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, consumers and others in the medical community. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy, safety and potential advantages compared to alternative treatments;
- the labeled uses or limitations for use, including age limitations or contraindications, for our product candidates compared to alternative treatments;
- convenience and ease of administration compared to alternative treatments;

- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- public perception of new therapies and non-therapeutic products, including our MMTs;
- the strength of marketing and distribution support;
- the ability to offer our products, if approved, for sale at competitive prices;
- the ability to obtain sufficient third-party insurance coverage and adequate reimbursement; and
- the prevalence and severity of any side effects.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As our research, development, manufacturing and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, compensating, integrating, maintaining and motivating additional employees;
- managing our internal research and development efforts effectively, including identification of clinical candidates, scaling our manufacturing process and navigating the clinical and FDA review process for our product candidates; 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 organizations, advisors and consultants to provide certain services, including many aspects of regulatory affairs, clinical management and manufacturing. There can be no assurance that the services of these 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 clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance 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 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.

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to identify and develop new or next generation product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.

Our ability to compete in the highly competitive healthcare industry depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including Michael Bonney, our Executive Chair, Alison Lawton, our Chief Executive Officer and President, William Duke, Jr., our Chief Financial Officer, Johan van Hylckama, our Chief Scientific Officer, and Katharine Knobil, M.D., our Chief Medical Officer and Head of Research and Development. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

We conduct our operations in Massachusetts. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided restricted stock and stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Employment of our key employees is at-will, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

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

Our operations, and those of our CROs, contract manufacturing organizations, or 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. For our clinical studies, we rely on third-party manufacturers for spray drying the MMTs substance and filling sachets with the resulting spray-dried powder. For materials to be used in our clinical trials, we plan to rely on an external contract manufacturing organization for the entire manufacturing supply chain. 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.

Our current operations are located in Massachusetts, and we or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are located in Massachusetts. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our internal computer systems, or those used by our CROs, CMOs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our future CROs, CMOs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we currently rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. 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 and the further development and commercialization of our product candidates could be delayed.

Regulators globally are also imposing greater monetary fines for privacy violations. For example, in 2016, the European Union adopted a new regulation governing data practices and privacy called the GDPR, which became effective on May 25, 2018. The GDPR applies to any company that collects and uses personal data in connection with offering goods or services to individuals in the European Union or the monitoring of their behavior. Non-compliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase the cost of providing our product candidates, if approved, or even prevent us from offering our product candidates, if approved, in certain jurisdictions.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs.

Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufactures to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The

applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, 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, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of 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. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. 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, or FCA. 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. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit 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) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements 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 can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective 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 without appropriate authorization. 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 the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payment Sunshine Act, created under the ACA, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services information related to payments or other transfers of value made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign 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 otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- GDPR and other ex-U.S. protections.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as 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. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

A variety of risks associated with testing and developing our product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates for therapeutic and other uses outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act, or FCPA, or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

Additionally, we intend to contract with third parties to conduct some of our clinical trials outside the United States, which will subject us to additional risks and regulations. These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

We currently have no marketing and sales organization and have no experience in marketing products for therapeutic or other non-drug uses. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, 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 for therapeutic or other uses. 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 healthcare companies to recruit, hire, train and retain marketing and sales personnel.

In addition to establishing internal sales, marketing and distribution capabilities, we intend to optimistically pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful.

The FDA, the EMA and other regulatory authorities may implement additional regulations or restrictions on the development and commercialization of products which act on the microbiome, which may be difficult to predict.

The FDA, the EMA and regulatory authorities in other countries have each expressed interest in further regulating biotechnology products and product candidates, such as MMTs. Agencies at both the federal and state level in the United States, as well as the U.S. Congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates. Adverse developments in clinical studies or clinical trials of MMT products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. Similarly, the EMA governs the development of MMTs as drugs in the European Union and member state regulatory bodies govern the development of MMTs under food regulations and may issue new guidelines concerning the development and marketing authorization for MMT products and require that we comply with these new guidelines. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected, delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

Changes in tax laws could affect our business and financial condition.

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 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 advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

Our ability to use net operating losses and research and development credits to offset future taxable income may be subject to certain limitations.

As of December 31, 2019, we had net operating loss, or NOL, carryforwards for U.S. federal and state tax purposes of $166.8 million and $163.6 million, respectively. Federal NOLs of $38.8 million, generated before 2018, will begin expiring in varying amounts in 2035 unless utilized and the remaining NOL of $128 million, generated after 2018 will be carried forward indefinitely and could be used up to 80% of taxable income of each future tax year. The Commonwealth of Massachusetts does not follow federal on NOL carryforwards and as such the Company’s Massachusetts NOLs of $163.6 million will expire in at various times starting in 2035. As of December 31, 2019, we also had U.S. federal and state research and development tax credit carryforwards of $4.5 million and $2.5 million respectively, both of which expire at various dates through 2039. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future taxable income or tax liabilities, respectively. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating loss carryforwards or tax credits, or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation’s stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs or credits could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our NOLs or credits may also

be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U.S. federal and state taxable income. As described above under "Risk Factors—Risks Related to Our Business, Technology and Industry," we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOLs or credits that are subject to limitation by Sections 382 and 383 of the Code.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

As of December 31, 2019, we had cash and cash equivalents of approximately $71.2 million. While we are not aware of any downgrades, material losses or other significant deterioration in the fair value of our cash equivalents since December 31, 2019, no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

Legal, political and economic uncertainty surrounding the exit of the U.K. from the EU may be a source of instability in international markets, create significant currency fluctuations, adversely affect our operations in the U.K. and pose additional risks to our business, revenue, financial condition, and results of operations.

On June 23, 2016, the U.K. held a referendum in which a majority of the eligible members of the electorate voted to leave the EU, commonly referred to as Brexit. Pursuant to Article 50 of the Treaty on EU, the U.K. ceased being a Member State of the EU on January 31, 2020. However, the terms of the withdrawal have yet to be fully negotiated. The implementation period began February 1, 2020 and will continue until December 31, 2020. During this 11-month period, the U.K. will continue to follow all of the EU's rules, the EU's pharmaceutical law remains applicable to the U,K, and the U.K.'s trading relationship will remain the same. However, regulations (including financial laws and regulations, tax and free trade agreements, intellectual property rights, data protection laws, supply chain logistics, environmental, health and safety laws and regulations medicine licensing and regulations, immigration laws and employment laws), have yet to be addressed. This lack of clarity on future U.K. laws and regulations and their interaction with the EU laws and regulations may negatively impact foreign direct investment in the U.K., increase costs, depress economic activity and restrict access to capital.

The uncertainty concerning the U.K's legal, political and economic relationship with the EU after Brexit may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise) beyond the date of Brexit.

These developments, or the perception that any of them could occur, may have a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the U.K. financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

If the U.K. and the EU are unable to negotiate acceptable agreements or if other EU member states pursue withdrawal, barrier-free access between the UK and other EU member states or among the European Economic Area overall could be diminished or eliminated. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the U.K. and the EU and, in particular, any arrangements for the U.K. to retain access to EU markets either during a transitional period or more permanently.

Such a withdrawal from the EU is unprecedented, and it is unclear how the U.K's access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our current and future operations (including business activities conducted by third parties and contract manufacturers on our behalf) and clinical activities in the U.K. In addition to the foregoing, our U.K. operations support our current and future operations and clinical activities in other countries in the EU and European Economic Area, or EEA, and these operations and clinical activities could be disrupted by Brexit.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations. Depending on the terms of the U.K's withdrawal from the EU, the U.K. could lose the benefits of global trade agreements negotiated by the EU on behalf of its members, which may result in increased trade barriers that could make our doing business in the EU and the EEA more difficult. Since the regulatory framework in the U.K. covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime with respect to the approval of our product candidates in the U.K. For instance, in November 2017, EU member states voted to move the EMA, the EU's regulatory body, from London to Amsterdam. Operations in Amsterdam commenced in March 2019, and the move itself may cause significant disruption to the regulatory approval process in Europe. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the U.K. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the U.K. and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the U.K. and/or EU for our product candidates, which could significantly and materially harm our business Even prior to any change to the U.K's relationship with the EU, the announcement of Brexit has created economic uncertainty surrounding the terms of Brexit and its consequences could adversely impact customer confidence resulting in customers reducing their spending budgets on our solutions, which could adversely affect our business, revenue, financial condition, results of operations and could adversely affect the market price of our common shares.

Risks related to government regulation

We are very early in our development efforts. All of our product candidates will require significant additional preclinical and clinical development before we seek regulatory approval of our therapeutic product candidates or identify alternate regulatory pathways to market for our non-therapeutic products and launch a product commercially. If we are unable to advance our product candidates to clinical development, obtain regulatory approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts and we have invested substantially all of our efforts and financial resources in the identification and early clinical development of MMT candidates, including the development of our initial product candidates. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a marketable product. The success of our product candidates will depend on several factors, including, but not limited to, the following:

- successful completion of preclinical studies, clinical studies and, where applicable, clinical trials;
- clearance of INDs for our planned clinical trials or future clinical trials for therapeutic indications;
- successful enrollment in, and completion of, clinical studies and clinical trials;

- receipt of regulatory approvals from applicable regulatory authorities for therapeutic product candidates;
- establishing cGMP-compliant clinical supply and commercial manufacturing operations or making arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- supplying sufficient quantities of our products at appropriate quality levels;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- launching commercial sales of our product candidates, if and when approved or allowed for marketing, whether alone or in collaboration with others;
- acceptance of our therapeutic product candidates, if and when approved, by patients, the medical community and third-party payors or any non-therapeutic product by consumers;
- effectively competing with other therapies;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- enforcing and defending intellectual property rights and claims;
- the marketing of our products; and
- maintaining a continued acceptable safety profile of the product candidates following approval or commercialization.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals or identify alternate regulatory pathways to market for our product candidates, we may not be able to continue our operations.

Regulatory requirements for development of our MMT candidates as drugs and non-drugs are uncertain and evolving. Changes in these laws, including our ability to conduct clinical studies, or the current interpretation or application of these laws would have a significant adverse impact on our ability to develop and commercialize our products.

In the United States, under sections 201(s) and 409 of the FD&C Act, any substance that is reasonably expected to become a component of food is considered to be a food additive, and therefore subject to FDA premarket review and approval, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use. We believe that our initial product candidates are safe for clinical studies, based on initial safety assessments conducted by third-party qualified experts and because they are related to a class of compounds that is GRAS based on their history of safe human exposure, when utilized for particular uses as food substances. As a result, we believe we may use our product candidates to conduct clinical studies in order to evaluate safety, tolerability and biomarkers for non-drug applications in advance of deciding whether or not to file an IND. The FDA may determine that our MMT candidates are not governed by food regulations and therefore may classify any product candidates as being ineligible for use in studies without an IND. The FDA or other regulatory authorities may also take enforcement action, or otherwise delay or prevent further development or commercialization of our product candidates.

The FDA may determine that our product candidates cannot be marketed as or do not meet the regulatory requirements for marketing or testing as conventional foods or medical foods. The FDA may not agree the products meet the medical food definition or the agency may take the position that we failed to satisfy the premarket authorization requirements for GRAS ingredients or new dietary ingredients. Moreover, if we choose to study a product under an IND before the product candidate has been marketed as a food, the first to market provisions of Section 301(ll) could prevent us from marketing the product as a food if we are unable to secure FDA approval as a new drug. Any delay in the regulatory consultation process, or a determination that any of our drug or food product candidates do not meet the regulatory requirements of the FDA, including any applicable GRAS requirements, could subject the company to regulatory enforcement action, cause a delay in the commercialization of our product candidates, which may lead to reduced acceptance by the public or others, and/or may result in some or all of our products may be deemed adulterated or misbranded in violation of the FD&C Act, any or all of which may lead to reduced acceptance by the public or others for any products we are able to commercialize and could materially adversely affect our business.

The FDA may determine that the only pathway for conducting clinical studies is under an IND. Any such determination could prevent our reliance on existing regulatory frameworks to conduct clinical studies for other product candidates and could significantly increase the cost of and delay the commercialization of our product candidates for therapeutic applications. If the FDA were to disagree with our determination that we may conduct clinical studies in advance of filing an IND, they could ask us to halt any clinical trials we have commenced. Should we choose to commercialize our food products, whether as conventional foods or medical foods, and if the FDA determines our product candidates fall outside the food regulations, we may be subject to regulatory enforcement action and the agency could ask us to stop selling, withdraw, recall, re-label or repackage any products we have commercialized as foods or non-drug products from the market. In addition, if new safety issues are raised by clinical studies in advance of deciding whether to file an IND that suggest safety concerns for all of our product candidates, then FDA could ask us to modify approved labeling for or withdraw from the market any previously approved products for therapeutic uses or products being commercialized for other non-drug uses. A decision by the FDA that we cannot conduct clinical studies in advance of filing an IND would significantly impact our current business model and we may incur significant expense and operational difficulties.

Changes in the legal and regulatory environment could limit our future business activities, increase our operating or regulatory costs, reduce demand for our product candidates or result in litigation.

The conduct of our business, including the development, testing, production, storage, distribution, sale, display, advertising, marketing, labeling, health and safety practices, and possible regulatory classification and approval (where necessary) use of many of our product candidates, are subject to various laws and regulations administered by federal, state and local governmental agencies in the United States, as well as to laws and regulations administered by government entities and agencies outside the United States in markets in which our products candidates and components thereof (such as packaging) may be manufactured or sold.

These laws and regulations and interpretations thereof may change, sometimes dramatically, as a result of a variety of factors, including political, economic or social events. Such changes may include, but are not limited to, changes in:

- food and drug laws (including FDA regulations);
- laws related to product candidate labeling;
- advertising and marketing laws and practices;
- laws and programs restricting the sale and advertising of certain of product candidates;
- laws and programs aimed at regulating, restricting or eliminating ingredients present in certain of our product candidates;
- increased regulatory scrutiny of, and increased litigation involving, product claims and concerns regarding the actual or possible effects or side effects of ingredients in, or attributes of, certain of our product candidates; and
- state and federal consumer protection and disclosure laws.

New laws, regulations or governmental policy and their related interpretations, or changes in any of the foregoing, may alter the environment in which we do business and, therefore, may impact our operating results or increase our costs or liabilities.

Inadequate funding for the FDA, the SEC and other US and non US government agencies 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 to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, 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. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may rely on academic and private non-academic institutions to conduct investigator-sponsored clinical studies or trials of our product candidates. Any failure by the investigator-sponsor to meet its obligations with respect to the clinical development of our product candidates may delay or impair our ability to obtain regulatory approval or commercialize for other product candidates.

We may rely on academic and private non-academic institutions to conduct and sponsor clinical studies or trials relating to our product candidates. We will not control the design or conduct of the investigator-sponsored trials, and it is possible that the FDA or non-U.S. regulatory authorities will not view these investigator-sponsored studies or trials as providing adequate support for future clinical trials, whether controlled by us or independent investigators, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results.

Such arrangements will likely provide us certain information rights with respect to the investigator-sponsored studies or trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator-sponsored studies or trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored studies or trials. If we are unable to confirm or replicate the results from the investigator-sponsored studies or trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored studies or trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

Additionally, the FDA or non-U.S. regulatory authorities may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these investigator-sponsored studies or trials or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored studies or trials. If so, the FDA or other non-U.S. regulatory authorities may require us to obtain and submit additional preclinical, manufacturing or clinical data before we may initiate our planned clinical trials and/or may not accept such additional data as adequate to initiate our planned clinical trials. In addition, it could limit or prevent our ability to commercialize product candidates for non-therapeutic uses.

Obtaining and maintaining regulatory approval of our product candidates for therapeutic indications or the ability to commercialize our product candidates through an alternate regulatory pathway in one jurisdiction does not mean that we will be successful in obtaining regulatory approval or identifying a similar alternate regulatory pathway for our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval for therapeutic indications or identifying an alternate regulatory pathway for our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval or identify a similar alternate regulatory pathway in any other jurisdiction, while a failure or delay in obtaining regulatory approval or an alternate regulatory in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate for therapeutic indications, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies, clinical studies and clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

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

Our product candidates are in preclinical stages, and their risk of failure is high. To proceed with our development plans and ultimately commercialization, we may be required to conduct preclinical, clinical studies or clinical trials. For therapeutic applications, the FDA or non-US regulatory authorities may require additional extensive preclinical studies. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs, including the design, dose level, and dose regimen, or if the outcome of our preclinical testing and studies will ultimately support the further development of our clinical programs for therapeutic indications. As a result, we cannot be sure that we will be able to submit INDs or similar applications in the case of product candidates for which we pursue a drug pathway or comply with any other regulatory requirements where necessary for commercialization and marketing of drugs or non-drug products 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 other regulatory authorities allowing clinical trials to begin, be completed or have their data used to support commercialization and required regulatory approvals. We also cannot be certain if our testing and studies will provide support for the further development of product candidates as non-drug products or support for any associated product claims made, and, as a result, we cannot be sure that we will be able to successfully pursue alternative regulatory pathways to commercialization as non-drug product for some or all of our product candidates.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates for therapeutic indications, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization for therapeutic indications, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before we can commercialize any of our product candidates for therapeutic indications, we must obtain marketing approval. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction and it is possible that none of our product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. We, as a company, have no experience in filing and supporting the applications necessary to gain regulatory approvals for therapeutic indications and expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the drug candidate’s safety and efficacy.

Securing regulatory approval for therapeutic indications also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining regulatory approvals for therapeutic indications, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted IND, NDA or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, including study population, dose level, dose regimen, and bioanalytical assay methods, or implementation of our clinical trials;

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a drug candidate is safe and effective for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies, clinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. As a result, our ability to develop product candidates and obtain regulatory approval for therapeutic indications may be significantly impacted.

The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval for therapeutic indications. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop based on the completed clinical trials.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited therapeutic indications than we request, may include limitations for use or contraindications that limit the suitable patient population, may not approve the price we intend to charge for our products, 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.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us to interrupt, delay or halt preclinical studies or clinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical studies or trials and could result in a more restrictive clinical label or the delay or denial of regulatory approval by the FDA or other regulatory authorities for our product candidates for therapeutic indications. Results of our clinical studies or trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our clinical studies or 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. Additionally, our regulators could require significant modifications or amendments to ongoing clinical studies or trials that limit the available study population or lead to withdrawal of participation by already enrolled subjects. Any study-related side effects could affect subject recruitment or the ability of enrolled subjects to complete the study or trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, clinical studies or trials by their nature utilize a sample of the potential study population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of subjects exposed to the product candidate. If our product candidates receive marketing approval for therapeutic indications and we or others identify undesirable side effects caused by such product candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, up to and including the withdrawal by regulatory authorities of their approval of such product candidate.

Breakthrough Therapy Designation, Fast Track Designation or Rare Pediatric Disease Designation by the FDA, and equivalents granted by other regulatory authorities, even if granted for any of our product candidates developed for therapeutic indications, may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that any of our product candidates will receive marketing approval in any jurisdiction.

We may seek a Breakthrough Therapy Designation for some of our product candidates. A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. 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 and instead determine not to make such designation. 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 therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We may seek Fast Track Designation for some of our product candidates for therapeutic indications. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address unmet medical needs for this condition, the therapy sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation; we cannot assure you 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. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track Designation alone does not guarantee qualification for the FDA’s priority review procedures.

We may seek Rare Pediatric Disease Designation and conditional designation of our marketing application as a "rare pediatric disease product application" for some of our product candidates for therapeutic indications, which, if granted, could qualify us to receive a Rare Pediatric Priority Review Voucher. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it and determination whether to issue such a voucher is made by FDA only at the time of its review and approval of a marketing application. A Rare Pediatric Priority Review Voucher can be redeemed to receive a priority review of a subsequent marketing application for a different product.

We may seek priority review designation for one or more of our product candidates for therapeutic indications, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

We may fail to obtain and maintain orphan drug designations from the FDA or the EMA for our current and future therapeutic product candidates, as applicable.

Our strategy includes filing for orphan drug designation where available for our product candidates for therapeutic indications that are eligible. In the United States, under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease 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, including an NDA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the original manufacturer is unable to assure sufficient product quantity.

In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the orphan-designated disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may receive and be approved for the same condition, and only the first applicant to receive approval will receive the benefits of marketing exclusivity. Even after an orphan-designated product is approved, the FDA can subsequently approve a later drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek orphan drug designation for our product candidates, we may never receive such designations.

In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the European Union, orphan drug designation entitles a party to financial incentives such as reductions of fees or fee waivers. In addition, ten years of market exclusivity is granted following drug product approval, meaning that another application for marketing authorization of a later similar medicinal product for the same indication will generally not be approved in the European Union. This period may be reduced to six years if the orphan designation criteria are no longer met, including where it is shown that the product is not sufficiently profitable to justify maintenance of market exclusivity. The market exclusivity period is extended by two additional years for an orphan-designated condition when the results of specific studies are reflected in the summary of product characteristics addressing the pediatric population and completed in accordance with a fully compliant pediatric investigation plan.

Even if we receive regulatory approval of any product candidates for therapeutic indications, or commercialize our product candidates as non-drug products, we will be subject to ongoing regulatory compliance obligations or continued regulatory review, which may result in significant additional expense. Additionally, any of our product candidates, if approved or commercialized, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are developed as drug product candidates and approved for therapeutic indications or are commercialized as non-drug products, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, distribution, quality, safety, sale, marketing, advertising, promotion, sampling, record-keeping, export, import, conduct of post-marketing studies and submission of safety, efficacy or other post-market information. Such requirements may be imposed as federal and state requirements in the United States and or by comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP requirements as applicable to drugs and non-drug products and GCP requirements for any clinical trials that we conduct post-approval, if applicable.

The FDA or other regulatory authorities may take regulatory enforcement or other legal action or, in the case of drugs, 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.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current administration may impact our business and industry. Namely, the current administration has 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 regulatory and 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 executive actions, including any executive orders, will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, 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, where applicable, our ability to continue to market and sell our products, and we may not achieve or sustain profitability.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance requirements, where applicable, can also result in significant financial penalties.

Healthcare insurance coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates or therapies profitably.

The success of our product candidates, if approved for therapeutic indications, depends on the availability of adequate coverage and reimbursement from third-party payors. In addition, because our product candidates represent new approaches to the treatment of the diseases they target, we cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Healthcare insurance often does not cover foods or medical foods administered outside of the hospital setting. This may impact our products if we decide to commercialize them as medical food, which is required to be administered under medical supervision.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA, was passed, which substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased 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.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the current administration to repeal or replace certain aspects of the ACA.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

European Union drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our therapeutic products in the European member states.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of pharmaceutical products is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures. In some countries, we may also be required to conduct a clinical

trial or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products.

Much like the Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of European Union Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

European data collection is governed by restrictive regulations governing the use, processing, and cross-border transfer of personal information.

The collection and use of personal health data in the European Union is governed by the provisions of the Data Protection Directive, and as of May 2018 the GDPR. These directives impose several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The Data Protection Directive and GDPR also impose strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with the requirements of the Data Protection Directive, the GDPR, and the related national data protection laws of the European Union Member States may result in fines and other administrative penalties. The GDPR introduces new data protection requirements in the European Union and substantial fines for breaches of the data protection rules. The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

On June 23, 2016, the UK held a referendum in which a majority of the eligible members of the electorate voted to leave the EU. The UK's withdrawal from the EU is commonly referred to as Brexit. Pursuant to Article 50 of the Treaty on European Union, the UK ceased being a Member State of the EU on January 31, 2020. However, the terms of the withdrawal have yet to be fully negotiated. The implementation period began February 1, 2020 and will continue until December 31, 2020. During this 11-month period, the UK will continue to follow all of the EU's rules and its trading relationship will remain the same. However, regulations (including data protection laws, health and safety laws and regulations and medicine licensing and regulations), have yet to be addressed. This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and cost to our handling of EU personal information and our privacy and data security compliance programs. It is possible that over time the UK Data Protection Act could become less aligned with the EU GDPR, which could require us to implement different compliance measures for the UK and the European Union and result in potentially enhanced compliance obligations for EU personal data. This risk would apply more immediately in the event of a "no-deal" Brexit (including no transition period).

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

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

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade 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. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Risks related to our intellectual property

If we are unable to obtain and maintain patent protection for any product candidates we develop or for our proprietary product platform, our competitors could develop and commercialize products or technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates, proprietary product platform and other technologies we may develop. We seek to protect our proprietary position by filing patent applications in the United States and abroad relating to our product candidates and proprietary product platform, as well as other technologies that are important to our business. Given that the development of our technology and product candidates is at an early stage, our intellectual property portfolio with respect to certain aspects of our technology and product candidates is also at an early stage. We have filed or intend to file patent applications on these aspects of our technology and our product candidates; however, there can be no assurance that any such patent applications will issue as granted patents. Furthermore, in some cases, we have only filed provisional patent applications on certain aspects of our technology and product candidates and each of these provisional patent applications is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non-provisional patent application within this timeline could cause us to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications.

Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain, however, that the claims in our pending patent applications covering the composition of matter of our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions of matter relating to our product candidates and proprietary product platform, as well as other technologies that are important to our business, and instead may need to rely on filing patent applications with claims covering a method of use and/or method of manufacture. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their products for our targeted indications, physicians may prescribe these products “off-label” for those uses that are covered by our method of use patents. Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute. There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to our product candidates and proprietary product platform could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If any of our owned patent applications do not issue as patents in any jurisdiction, we may not be able to compete effectively.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned patents. With respect to our patent portfolio, as of December 31, 2019, our patent portfolio in total consisted of nine issued U.S. patents, two issued European patents, 13 issued patents in other jurisdictions (Argentina, Australia, Canada, China, Colombia, Hong Kong, Indonesia, Mexico, New Zealand, Singapore and South Africa), and over 100 pending non-provisional applications (U.S., EP and other jurisdictions), which include claims directed to compositions, methods of use, and manufacturing processes. With respect to owned intellectual property, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our owned or pending patent applications, or that we were the first to file for patent protection of such inventions.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and product candidates would be adversely affected.

The patent position of healthcare companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our owned pending and future patent applications may not result in patents being issued which protect our product candidates, proprietary product platform technology, or other technologies or which effectively prevent others from commercializing competitive technologies and product candidates.

No consistent policy regarding the scope of claims allowable in patents in the biotechnology field has emerged in the United States. The patent situation outside of the United States is even more uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. With respect to company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our products and the methods used to manufacture those products. Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our products. The area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent us from commercializing our patented product candidates and practicing our proprietary technology. Our issued patent and those that may issue in the future may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related products or limit the length of the term of patent protection that we may have for our product candidates. In addition, the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether our product candidates or other technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and patents that we own may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party preissuance submission of prior art to the USPTO or to foreign patent authorities or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings or other similar proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our owned patent rights, allow third parties to commercialize our product candidates, proprietary product platform technologies or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our owned patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates, proprietary product platform and other technologies. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may in the future co-own patent rights relating to future product candidates and our proprietary product platform with third parties. We may need the cooperation of any such co-owners of our patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our rights to develop and commercialize our product candidates and proprietary product platform may be subject, in part, to the terms and conditions of future licenses granted to us by others.

We may rely upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our product candidates and proprietary product platform. Patent rights that we in-license in the future may be subject to a reservation of rights by one or more third parties. As a result, any such third parties may have certain rights to such intellectual property.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution and maintenance, and we may not have the right to control the enforcement, and defense of patents and patent applications covering the technology that we license from third parties. We cannot be certain that our in-licensed patent applications (and any patents issuing therefrom) that are controlled by our licensors will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents rights, or lose rights to those patent applications (or any patents issuing therefrom), the rights we have licensed may be reduced or eliminated, our right to develop and commercialize any of our product candidates and proprietary product platform technologies that are subject of such licensed rights could be adversely affected, and we may not be able to prevent competitors from making, using and selling competing products. Moreover, we cannot be certain that such activities by our potential future licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. In addition, even where we may have the right to control patent prosecution of patents and patent applications that we may license to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our potential future licensees, licensors and their counsel that took place prior to the date of assumption of control over patent prosecution.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting and defending patents on our product candidates, proprietary product platform technologies and other technologies in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, 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 and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. 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, and our business, financial condition, results of operations, and prospects may be adversely affected.

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 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 owned patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. In some cases, an inadvertent lapse 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 patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to file any patent application related to our product candidates, proprietary product platform or other technologies.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned patent applications and the enforcement or defense of our owned issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Issued patents covering our product candidates, and any patents that may issue covering our proprietary product platform technologies and other technologies, could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

If we or any of our third-party licensees, such as Midori Animal Health, which holds an exclusive license to certain of our patents in the field of non-human animal health, initiated legal proceedings against a third party to enforce a patent covering our product candidates, proprietary product platform technologies or other technologies, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of our owned patents 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, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our product candidates, proprietary product platform technologies, or other technologies. 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 and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates, proprietary product platform or other technologies. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and prospects.

If we do not obtain patent term extension and/or data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our owned U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during 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 and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. However, we may not be granted an extension in the United States and/or foreign countries and territories because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our owned patent rights, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates, proprietary product platform or other technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our owned patent rights, trade secrets or other intellectual property. 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, intellectual property that is important to our product candidates, proprietary product platform and other technologies. 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our product candidates, proprietary product platform and other technologies, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. We expect our trade secrets and know-how to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

We currently, and may continue in the future continue to, rely on third parties to assist us in developing and manufacturing our product candidates. Accordingly, we must, at times, share know-how and trade secrets, including those related to our proprietary product platform, with them. We may in the future also enter into research and development collaborations with third parties that may require us to share know-how and trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our know-how, trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements, and including in our vendor and service agreements terms protecting our confidential information, know-how and trade secrets, with parties who have access to such information, such as our employees, scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants as well as train our employees not to bring or use proprietary information or technology from former employers to us or in their work, and we remind former employees when they leave their employment of their confidentiality obligations. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Despite our efforts, any of the aforementioned parties may breach the agreements and disclose our proprietary information, including our trade secrets, or there may be a lapses or failures in our physical and electronic security systems which lead to our proprietary information being disclosed, and we may not be able to obtain adequate remedies in the event of any such breaches. 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 our 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 party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them 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 or other third party, our competitive position would be materially and adversely harmed.

We rely on our proprietary product platform to identify microbiome therapies. Our competitive position could be materially harmed if our competitors develop a similar platform and develop rival product candidates.

We rely on know-how, inventions and other proprietary information, to strengthen our competitive position. We consider know-how to be our primary intellectual property with respect to our proprietary product platform. Our clinical trials allow us to collect clinical data, which we use as a feedback loop to make improvements to our proprietary product platform. In particular, we anticipate that, with respect to this proprietary product platform, this data may over time be disseminated within the industry through independent development, the publication of journal articles describing the method, and the movement of skilled personnel.

We cannot rule out that our competitors may have or obtain the knowledge necessary to analyze and characterize similar data to our own data for the purpose of identifying and developing products that could compete with any of our product candidates. Our competitors may also have significantly greater financial, product development, technical, and human resources and access to date. Further, our competitors may have significantly greater experience in using translational science methods to identify and develop product candidates.

We may not be able to prohibit our competitors from using technology or methods that are the same as or similar to our proprietary product platform to develop their own product candidates. If our competitors develop associated therapies, our ability to develop and market a promising product or product candidate may diminish substantially, which could have a material adverse effect on our business, financial condition, prospects and results of operations.

We may not be successful in obtaining, through acquisitions, in-licenses or otherwise, necessary rights to our product candidates, proprietary product platform technologies or other technologies.

We currently have rights to certain intellectual property, through licenses from third parties, to develop our product candidates and proprietary product platform technologies. Some healthcare companies and academic institutions are competing with us in the field of microbiome therapies and may have patents and have filed and are likely filing patent applications potentially relevant to our business. In order to avoid infringing these third-party patents, we may find it necessary or prudent to obtain licenses to such patents from such third-party intellectual property holders. We may also require licenses from third parties for certain technologies that we may evaluate for use with our current or future product candidates. However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for our current or future product candidates and our proprietary product platform at a reasonable cost or on reasonable terms, if 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.

In the event that we try to obtain rights to required third party intellectual property rights, and are ultimately unsuccessful, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates or continue to utilize our existing proprietary product platform technology, which could harm our business, financial condition, results of operations, and prospects significantly.

We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants, and advisors are currently or were previously employed at universities or other healthcare companies, including our competitors and potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual’s current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while 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. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Third-party claims of intellectual property infringement, misappropriation or other violation against us or our collaborators may prevent or delay the development and commercialization of our product candidates, proprietary product platform and other technologies.

The field of developing therapeutics that target the microbiome is competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, there may be significant intellectual property related litigation and proceedings relating to our owned, and other third party, intellectual property and proprietary rights in the future.

Our commercial success depends in part on our and our collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, due to changes in U.S. law referred to as patent reform, additional procedures including *inter partes* review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist relating to glycan technologies and in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates, proprietary product platform technologies and other technologies may give rise to claims of infringement of the patent rights of others. We cannot be assured that our product candidates, proprietary product platform technologies and other technologies that we have developed, are developing or may develop in the future will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our product candidates, proprietary product platform and other technologies might assert are infringed by our current or future product candidates, proprietary product platform or other technologies, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates, proprietary product platform or other technologies. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates, proprietary product platform or other technologies, could be found to be infringed by our product candidates, proprietary product platform or other technologies. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates, proprietary product platform or other technologies may infringe. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our proprietary product platform technologies, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Third parties may have patents or obtain patents in the future and claim that the manufacture, use or sale of our product candidates, proprietary product platform or other technologies infringes upon these patents. In the event that any third party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our product candidates, proprietary product platform or other technologies. In this case, the holders of such patents may be able to block our ability to commercialize the applicable product candidate or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be non-exclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our product candidates, proprietary product platform, or other technologies, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing our infringing product candidates, proprietary product platform, or other technologies. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing product candidates or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidates, proprietary product platform, or other technologies, which could harm our business significantly.

Engaging in litigation to defend against third parties alleging that we have infringed, misappropriated or otherwise violated their patents or other intellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming, and unsuccessful.

Competitors may infringe our patents, or we may be required to defend against claims of infringement. In addition, our patents also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time-consuming. In an infringement proceeding, a court may decide that a patent owned by us is invalid or unenforceable, the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e), or may refuse to stop the other party from using the technology at issue on the grounds that our owned patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our owned patents at risk of being invalidated or interpreted narrowly. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

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. For example:

- others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we may own;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own now or in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned intellectual property rights;
- it is possible that our current or future pending owned patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties 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;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing 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.

Risks related to our reliance on third parties

We will rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.

We will depend upon third parties, including independent investigators, to conduct our clinical trials under agreements with universities, medicinal institutions, CROs, strategic partners and others. We expect to have to negotiate budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs.

We will rely heavily on third parties over the course of our clinical trials, and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP requirements. In addition, our clinical trials for therapeutic indications must be conducted with drug product produced under cGMP requirements and may require a large number of patients.

Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval or commercialization process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our future clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their 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 clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our 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 prospects.

We expect to rely on third parties to manufacture our clinical supply of product candidates, and we intend to rely on third parties to produce and process our products, if approved.

We currently rely on outside vendors to supply raw materials and other important components, such as the heterogeneous catalyst and chromatographic resins used to purify crude MMT candidates. We have not yet caused any product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates. We will make changes as we work to optimize the manufacturing process for our product candidates, and we cannot be sure that even minor changes in the process will result in therapies that are safe and effective.

The facilities used to manufacture our product candidates that we develop as therapeutic product candidates must be approved by the FDA or other foreign regulatory agencies pursuant to inspections that will be conducted after we submit a marketing application to the FDA or other foreign regulatory agencies. Additionally, any facilities used for the manufacture of product candidates commercialized for non-therapeutic uses will be subject to registration with and inspection by the FDA and foreign regulatory authorities. We do not currently control all aspects of the manufacturing process of, and are currently largely dependent on, our contract manufacturing partners for compliance with regulatory requirements, known as cGMP requirements, for manufacture of our product candidates. If and when our manufacturing facility becomes operational, we will be responsible for compliance with cGMP requirements. If we or our contract manufacturers cannot successfully manufacture in conformance with our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we and they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities with respect to the manufacture of our product candidates. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

For more information, see “Risk Factors—Risks Related to Manufacturing and Supply” below.

If our sole contract manufacturing organization for materials to be used in our clinical trials fails to supply us with the necessary materials, we may be unable to complete our clinical trials on a timely basis, if at all.

In 2018, we entered into a services agreement with a subsidiary of Thermo Fisher Scientific, or Thermo Fisher, to handle the manufacturing supply chain from drug substance synthesis through labeling and packaging for our planned clinical trials. If Thermo Fisher is unable or unwilling to provide us with sufficient quantities of applicable MMT candidates to meet our demands or fails to meet our standards of quality or other specification or to achieve drug cGMP compliance, we may not be able to locate any alternative suppliers or enter into commercially reasonable agreements with substitute suppliers in a timely manner or at all.

Third-party relationships are important to our business. If we are unable to maintain our collaborations, enter into new relationships or if these relationships are not successful, our business could be adversely affected.

We have limited capabilities for product development and do not yet have any capability for sales, marketing or distribution. Accordingly, we enter into relationships with other companies to provide us with important technologies, and we may receive additional technologies and funding under these and other collaborations in the future. Relationships we enter into, may pose a number of risks, including the following:

- third parties have, and future third-party collaborators may have, significant discretion in determining the efforts and resources that they will apply;
- current and future third parties may not perform their obligations as expected;
- current and future third parties 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 based on clinical trial results, changes in the third parties' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- third parties may delay clinical studies or clinical trials, provide insufficient funding for a clinical study or clinical trial program, stop a clinical study or clinical trial or abandon a product candidate, repeat or conduct clinical studies or new clinical trials or require a new formulation of a product candidate for clinical testing;
- current and future third parties could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the third parties 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 current or future third parties as competitive with their own product candidates or products, which may cause such third parties to cease to devote resources to the commercialization of our product candidates;
- current and future third parties may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- current and future third parties 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 current or future third parties, 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;
- current and future third parties 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;

- current and future third parties may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if a current or future third parties 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
- current and future relationships 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 relationships do not result in the successful discovery, development and commercialization of products or if one of our third parties terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our technology and product candidates could be delayed and we may need additional resources to develop product candidates and our technology. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K also apply to the activities of our therapeutic collaborators.

Additionally, if any of our current or future third parties terminate 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.

Relationships are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable third parties on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or 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 expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into relationships or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate revenue from sales of drugs or continue to develop our technology, and our business may be materially and adversely affected.

Risks related to manufacturing and supply

Our MMT product candidates rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

Our product candidates require certain specialty raw materials, some of which we obtain from small companies with limited resources and experience to support a commercial product. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We do not currently have contracts in place with all of the suppliers that we may need at any point in time, and if needed, may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing.

Our product candidates require specialized manufacturing capabilities. If we or any of our third-party manufacturers encounter difficulties in manufacturing our product candidates, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The manufacturing process used to produce our product candidates has not yet been validated for commercial production. Our cGMP manufacturing process development and scale-up is at an early stage. 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.

Our manufacturing process may be susceptible to manufacturing issues associated with interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, lot failures, product defects, product recalls, product liability claims and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, production at such manufacturing facilities may be interrupted for an extended period of time to investigate and remedy the contamination. Further, as product candidates are developed through preclinical to late-stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way 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 and affect the results of planned clinical trials or other future clinical trials.

Although we continue to refine our manufacturing process for our MMT product candidates, 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-up, process reproducibility, stability issues, lot consistency, and timely availability of reagents and/or raw materials. We ultimately may not be successful in transferring our production system from our contract manufacturer to any manufacturing facilities we establish ourselves, or our contract manufacturer may not have the necessary capabilities to complete the implementation and development process. If we are unable to adequately validate or scale-up the manufacturing process for our product candidates with our current manufacturer, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for our product candidates with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply, and it is not certain we will be able to come to agreement on terms acceptable to us. As a result, we may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

The manufacturing process for any products that we may develop for therapeutic indications is subject to the FDA and foreign regulatory authority approval process, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements on an ongoing basis. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need, where applicable, or be able to commercialize such products. Even if we obtain regulatory approval for any of our product candidates for therapeutic indications, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects. Our future success depends on our ability to manufacture our products on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements, and an inability to do so could have a material adverse effect on our business, financial condition, and results of operations. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change, and we could need to replace, modify, design, or build and install equipment, all of which would require additional capital expenditures. Specifically, because our product candidates may have a higher cost of goods than conventional therapies, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

We may depend on third parties for clinical and commercial supplies, including, in some instances, a single supplier.

We may depend on third-party suppliers for clinical and commercial supplies, including the active ingredients which are used in our product candidates. These supplies may not always be available to us at the standards we require or on terms acceptable to us, or at all, and we may not be able to locate alternative suppliers in a timely manner, or at all. If we are unable to obtain necessary clinical or commercial supplies, our manufacturing operations and clinical trials and the clinical trials of our collaborators may be delayed or disrupted, and our business and prospects may be materially and adversely affected as a result.

We may rely on a sole supplier for certain of our supplies. If this sole supplier is unable to supply to us in the quantities we require, or at all, or otherwise defaults on its supply obligations to us, we may not be able to obtain alternative supplies from other suppliers on acceptable terms, in a timely manner, or at all.

We have limited experience manufacturing our drug product candidates for purposes of clinical trials for therapeutic indications or for non-therapeutic clinical studies or trials or the marketing of our products as non-drug products and at commercial scale, and if we decide to establish our own manufacturing facility for our drug product candidates, we cannot assure you that we can manufacture our drug product candidates in compliance with regulations at a cost or in quantities necessary to make them commercially viable.

We may establish a manufacturing facility for our product candidates for production as investigational new drugs for purposes of clinical trials for therapeutic indications or for the production of non-drug product candidates at a commercial scale. We have limited experience in cGMP compliant manufacturing of our drug product candidates for purposes of clinical trials in therapeutic indications or at a commercial scale. We similarly have limited experience in complying with the manufacturing requirements for non-drug applications for our products at a commercial scale. In the future, we may develop our manufacturing capacity in part by expanding our current facility or building additional facilities. This activity will require substantial additional funds and we would need to hire and train a significant number of qualified employees to staff these facilities. We may not be able to develop cGMP-compliant manufacturing facilities that are adequate to produce materials for additional later-stage clinical trials or commercial use.

The equipment and facilities employed in the manufacture of pharmaceuticals and foods (including medical foods) are subject to stringent qualification requirements by regulatory agencies, including validation of facility, equipment, systems, processes and analytics. We may be subject to lengthy delays and expense in conducting validation studies, if we can meet the requirements at all.

MMTs are complex and difficult to manufacture. We could experience production problems that may impact our ability to manufacture certain MMT product candidates, if at all, and result in delays in our development or otherwise adversely affect our business.

The manufacturing process we anticipate using to produce our MMT product candidates is highly complex and may be subject to variation or production difficulties. Issues with any of our manufacturing processes could result in insufficient yield, product deficiencies or manufacturing failures that result in adverse patient reactions, lot failures and insufficient inventory.

Many factors could also cause production interruptions, including raw materials shortages, raw material failures, growth media failures, equipment malfunctions, facility contamination, labor problems, natural disasters, disruption in utility services, terrorist activities or acts of god beyond our control. We also may encounter problems in hiring and retaining the experienced specialized personnel needed to operate our manufacturing process, which could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements.

Any problems in our manufacturing processes could make us a less attractive collaborator for academic research institutions and other parties, which could limit our access to additional attractive development programs, result in delays in our clinical development and materially harm our business.

Risks related to our common stock

An active trading market for our common stock may not be sustained

Our shares of common stock began trading on The NASDAQ Global Select Market on February 28, 2019. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares.

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. Since our common stock began trading on The Nasdaq Global Select Market on February 28, 2019, our stock price has traded at prices as low as $4.61 per share and as high as $19.00 per share through February 27,2020. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, these factors include:

- the commencement, enrollment or results of our ongoing and planned clinical studies and clinical trials of our product candidates or any future clinical studies or clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings;
- adverse results from or delays in clinical studies or clinical trials of our product candidates, including as a result of clinical holds, safety events, enrollment difficulties, or study protocol amendments;
- our decision to initiate a clinical study or clinical trial, not to initiate a clinical study or clinical trial or to terminate an existing clinical study or clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates for therapeutic indications or to proceed on alternate regulatory pathways to market for our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals or marketing of dietary non-drug products or food products;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations, if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- positive data readouts or introduction of new products or services by our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial target markets;
- actual or anticipated variations in quarterly operating results;
- our cash position;

- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or microbiome therapies in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- adoption of new accounting standards;
- ineffectiveness of our internal controls;
- 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;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for healthcare companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. You may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our ability to pay cash dividends is currently restricted by the terms of our credit facility with Hercules Capital, Inc., and future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited in the foreseeable future to the appreciation of their stock.

Our principal stockholders and management own a significant percentage of our stock and may be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors and their affiliates beneficially hold, in the aggregate, over 50% of our outstanding voting stock. These stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012 as well as a smaller reporting company, as defined by the Securities and Exchange Commission (SEC). For as long as we continue to be an emerging growth company or a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies or smaller reporting companies. With respect to being an emerging growth company, these exemptions include, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this Annual Report on Form 10-K and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following 2019, the year in which we completed our IPO, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO; (b) in which we have total annual gross revenue of at least $1.07 billion; or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th; and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may 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.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we may adopt the new or revised standard at the time private companies adopt the new or revised standard and may do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company. This may make comparison of our financial statements with the financial statements of another public company that is not an emerging growth company, or an emerging growth company that has opted out of using the extended transition period, difficult or impossible because of the potential differences in accounting standards used.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, which require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The NASDAQ Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as “say on pay” and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of our IPO. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our existing equity compensation plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules. If these additional shares of common stock 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. Additionally, the number of shares of our common stock reserved for issuance under our 2019 Stock Option and Incentive Plan increased on January 1, 2020 and will increase each January 1 thereafter by 4% of the number of shares of common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by our compensation committee. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution.

We have broad discretion in the use of our existing cash, cash equivalents and marketable securities and may not use them effectively.

Our management will have broad discretion in the application of our existing cash, cash equivalents and marketable securities, and you will not have the opportunity as part of your investment decision to assess whether such proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of our existing cash, cash equivalents and marketable securities, their ultimate use may vary substantially from their currently intended use. Our management might not apply our existing cash, cash equivalents and marketable securities in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business. We may invest in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our cash, cash equivalents or marketable securities in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future license and collaboration agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees, directors and non-employee consultants based on the fair value of the award on either the grant date or service completion date, and we recognize the cost as an expense over the recipient’s service period. Because the variables that we use as a basis for valuing stock-based awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time;
- our ability to enroll patients in clinical studies or clinical trials and the timing of enrollment;
- the cost of manufacturing our current and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire or develop additional product candidates and technologies;
- the timing and outcomes of clinical trials for our current product candidates and any other future product candidates or competing product candidates;
- competition from existing and potential future products that compete with our current product candidates and any other future product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval or commercialization of our current product candidates or any other future product candidates;
- the level of demand for our current product candidates and any other future product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future products that compete with our current product candidates and any other future product candidates;
- our ability to commercialize our current product candidates and any other future product candidates inside and outside of the United States, either independently or working with third parties;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated by-laws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chair of the board of directors, the chief executive officer, or by a majority of the total number of directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any by-laws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated by-laws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2020. When we lose our status as an "emerging growth company," our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting unless another exemption applies. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to implement additional financial and management controls, reporting systems and procedures and may need to hire additional accounting and finance staff.

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

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Covenants and events of default in our debt instruments could limit our ability to undertake certain types of transactions and adversely affect our liquidity.

Our current debt financing agreements contain, and our future debt financing agreements may contain covenants and events of default that may limit our financial flexibility and ability to undertake certain types of transactions. Typically, these covenants would restrict our business activities, including restrictions on:

- creating liens;
- engaging in mergers, consolidations and sales of assets;
- incurring additional indebtedness;
- providing guarantees;
- engaging in different businesses;
- making investments;
- making certain dividend, debt and other restricted payments;
- engaging in certain transactions with affiliates; and
- entering into certain contractual obligations.

Our ability to comply with these expected covenants may depend on factors outside our control. We cannot assure you that we will be able to satisfy these covenants. If we fail to satisfy the covenants established in these facilities or an event of default occurs under the applicable debt agreement, the maturity of the debt instruments could be accelerated, or we could be prohibited from future borrowing. If our obligations under the debt instruments are accelerated and we do not have sufficient cash on hand to pay all amounts due, we could be required to sell assets, to refinance all or a portion of our indebtedness or to obtain additional financing through equity or debt financings. Refinancing may not be possible and additional financing may not be available on commercially acceptable terms, or at all. If we cannot obtain such financing, we would need to curtail our planned operations.

Our amended and restated by-laws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to our amended and restated by-laws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or by-laws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or by-laws; or (5) any action asserting a claim governed by the internal affairs doctrine. The forum selection clause in our amended and restated by-laws may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us. Alternatively, if a court were to find the choice of forum provision contained in our restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate headquarters are located in Lexington, Massachusetts, where we currently lease 107,000 square feet of laboratory and office space. The lease expires in 2029, subject to one option to extend the lease for 10 years.

We also lease 50,000 square feet of laboratory and office space located in Bedford, Massachusetts. This lease expires in June 2020 and currently houses our pilot production operations. We believe our facilities are sufficient for our current needs.

Item 3. Legal Proceedings

We are not currently a party to any material legal proceedings.

Item 4. Mine Safety Disclosures

None.

PART II

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

Certain Information Regarding the Trading of Our Common Stock

Our common stock trades under the symbol "KLDO" on the NASDAQ Global Select Market and has been publicly traded since February 28, 2019. Prior to this time, there was no public market for our common stock.

Holders of Our Common Stock

As of February 27, 2020, there were approximately 57 holders of record of shares of our common stock. This number does not include stockholders for whom shares are held in "nominee" or "street" name.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans will be included in our definitive proxy statement to be filed with the SEC with respect to our 2020 Annual Meeting of Stockholders and is incorporated herein by reference.

Unregistered Sales of Equity Securities and Use of Proceeds

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from Initial Public Offering

On March 4, 2019, we completed the IPO of our common stock pursuant to which we issued and sold 5,000,000 shares of our common stock at a price to the public of $15.00 per share.

The offer and sale of all of the shares of our common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1, as amended (File No. 333- 229204), which was declared effective by the SEC on February 27, 2019. Goldman Sachs & Co. LLC, J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC, and Canaccord Genuity LLC acted as joint book-running managers of our IPO.

We received aggregate gross proceeds from our IPO of $75.0 million, or aggregate net proceeds of $66.0 million after deducting underwriting discounts and commissions and other offering costs. None of the underwriting discounts and commissions or offering expenses were incurred or paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

As of December 31, 2019, we have used $62.2 million of the net proceeds from the IPO, consisting of $59.5 million used in operations and $2.6 million for the purchase of other property, plant, and equipment. There has been no material change in our planned use of the net proceeds from the IPO as described in the Prospectus.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

Item 6. Selected Financial Data

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information requested under this item.

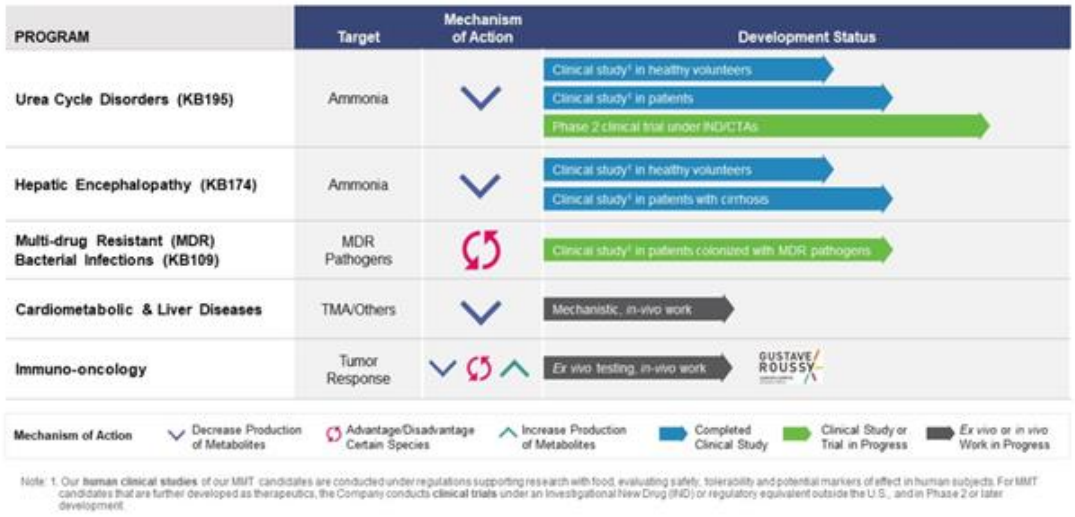
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing at the end of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage healthcare company with a differentiated, chemistry-driven approach focused on leveraging the potential of the microbiome organ to treat disease and improve human health. We have built a human-centric proprietary product platform for discovery and development that we believe will enable the rapid advancement of a broad portfolio of novel product candidates into clinical studies under regulations supporting research with food. Our product candidates are MMTs, which are designed to modulate the metabolic output and profile of the microbiome by driving the function and distribution of the organ's existing microbes. We have an industrialized approach to the discovery and development of MMTs, and our initial MMTs are targeted glycans. Each targeted glycan is an ensemble of complex carbohydrates that is intended to modulate microbial metabolism to drive a specific biological response. We believe our MMTs have the potential to be novel treatments across a variety of diseases and conditions.

The human microbiome is generally a community of more than 30 trillion microbes, organisms that include bacteria, viruses, archaea and fungi, which reside on and inside the human body. By evolving together over thousands of years, microbes and humans have developed an intricate and mutually beneficial relationship. Given the profound impact that microbes have on human health, this highly complex microbial ecosystem has been referred to as a "newly discovered organ." There is a growing body of research that links a healthy microbiome with overall human health, while dysbiosis, or imbalance, in the microbiome has been correlated with numerous human conditions, including those that can cause significant morbidity and mortality. Some of these conditions include irritable bowel syndrome, Parkinson's disease, diabetes, metabolic syndrome, cancer, allergies and ulcerative colitis. The microbiome organ remains a largely untapped frontier in healthcare, and we believe that we are uniquely positioned to succeed in translating its promise into solutions for human health.



Note: 1. Our **human clinical studies** of our MMT candidates are conducted under regulations supporting research with food, evaluating safety, tolerability and potential markers of effect in human subjects. For MMT candidates that are further developed as therapeutics, the Company conducts **clinical trials** under an Investigational New Drug (IND) or regulatory equivalent outside the U.S., and in Phase 2 or later development.

Since our inception in 2015, we have devoted substantially all of our resources to building our proprietary product platform, developing our pipeline of MMT candidates, building our intellectual property portfolio and process development and manufacturing function, business planning, raising capital and providing general and administrative support for these operations. To date, we have primarily financed our operations through public offering of our equity securities, private placement of our convertible preferred stock and borrowings of long-term debt.

We have incurred significant net losses since inception and expect to continue to incur net operating losses for the foreseeable future. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- conduct preclinical studies, clinical studies and clinical trials for our product candidates;
- advance the development of our product candidate pipeline;
- continue to discover and develop additional product candidates;
- continue to build out our proprietary product platform and to increase its throughput for the discovery and nomination of product candidates;
- develop, acquire or in-license other product candidates and technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific and commercial personnel;
- expand manufacturing capabilities, including in-house and third-party commercial manufacturing, through the purchase, renovation, customization and operation of a manufacturing facility and securing supply chain capacity sufficient to provide clinical study and clinical trial materials and commercial quantities of any product candidates which we may commercialize;
- seek regulatory approvals for any product candidates for therapeutic indications that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval or identify alternate commercial pathways for such products; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, as well as to support our transition to a public reporting company.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for or identify alternate non-drug pathways for our product candidates. If we obtain regulatory approval for or otherwise commercialize any of our product candidates, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing and distribution.

As of December 31, 2019, we had $71.2 million in cash and cash equivalents and an accumulated deficit of $192.6 million. Based on our current operating plans, we have sufficient cash and cash equivalents to fund our operating expenses and capital expenditures into the first quarter of 2021. We will require additional capital to sustain our operations, including the development of our MMT candidates. We may implement cost reduction strategies, which may include amending, delaying, limiting, reducing or terminating one or more of our ongoing or planned clinical trials of our product candidates. These factors raise substantial doubt about our ability to continue as a going concern. For more information, refer to “—Liquidity and Capital Resources” below and Note 1 to our condensed consolidated financial statements included elsewhere in this Annual Report.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through equity or debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Financial Overview

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the near future, if at all. If our development efforts for our current product candidates or additional product candidates that we may develop in the future are successful and can be commercialized, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of our product candidates. These expenses include:

- development and operation of our proprietary product platform;
- employee-related expenses, including salaries, related benefits and stock-based compensation expense, for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of our product candidates, including under agreements with third parties, such as consultants and contract research organizations, or CROs;
- the cost of laboratory supplies and acquiring, developing and manufacturing products for use in our preclinical studies, clinical studies and clinical trials, including under agreements with third parties, such as consultants and contract manufacturing organizations, or CMOs;
- facilities, depreciation and other expenses, which include direct or allocated expenses for rent and maintenance of facilities and insurance; and
- costs related to compliance with regulatory requirements.

We expense research and development costs as incurred. Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Our direct external research and development expenses are tracked on a program-by-program basis and consist of costs that include fees, reimbursed materials and other costs paid to consultants, contractors, CMOs and CROs in connection with our preclinical and clinical development and manufacturing activities. We do not allocate employee costs, costs associated with our discovery efforts, laboratory supplies and facilities expenses, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple programs and our platform technology and, as such, are not separately classified.

Product candidates in later stages of clinical development 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. We expect that our research and development expenses will increase substantially in connection with our planned preclinical and clinical development activities in the near term and in the future. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates. The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of programs we decide to pursue and their regulatory paths to market;
- raising additional funds necessary to complete preclinical and clinical development of and commercialize our product candidates;
- the progress of the development efforts of parties with whom we have entered into and may enter into collaboration arrangements;
- our ability to maintain our current research and development programs and to establish new ones;
- our ability to maintain existing and establish new licensing or collaboration arrangements;
- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities for any product candidates for therapeutic indications;
- the availability of specialty raw materials for use in production of our product candidates;
- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates is approved or commercialized on an alternate regulatory pathway;
- meeting demand in a timely fashion with sufficient supply at appropriate quality levels;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our product candidates, if and when approved if approval to market is required;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- the acceptance of our product candidates, if commercialized, by patients, consumers, the medical community and third-party payors;
- competition with other products; and
- a continued acceptable safety profile of our therapies following commercialization.

A change in the outcome of any of these variables with respect to the development of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval or commercialization for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance, corporate and business development and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and administrative consulting services; insurance costs; administrative 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 anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates.

Results of Operations

Comparison of Years Ended December 31, 2019 and 2018

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018:

	Year Ended December 31,		
	2019	2018	Change
		(in thousands)	
Operating expenses:			
Research and development	$ 64,232	$ 42,062	$ 22,170
General and administrative	22,428	18,621	3,807
Total operating expenses	$ 86,660	$ 60,683	$ 25,977
Loss from operations	$ (86,660)	$ (60,683)	$ (25,977)
Other income (expense)			
Interest income	1,693	1,118	575
Interest expense	(977)	(1,005)	28
Change in fair value of warrant liability	252	(918)	1,170
Loss on extinguishment of debt	(580)	—	(580)
Other expense	(59)	(256)	197
Total other expense, net	329	(1,061)	1,390
Net loss	$ (86,331)	$ (61,744)	$ (24,587)

Research and Development Expenses

	Year Ended December 31,		
	2019	2018	Change
		(in thousands)	
Direct research and development expense for KB195 program	$ 13,324	$ 7,739	$ 5,585
Platform development, early-stage research and unallocated expenses:			
Personnel-related	22,337	16,362	5,975
Stock-based compensation expense	3,245	1,309	1,936
External manufacturing and research	13,515	7,564	5,951
Laboratory supplies and research materials	1,468	1,547	(79)
Professional and consulting fees	3,362	1,153	2,209
Facility-related and other	6,981	6,388	593
Total research and development expenses	$ 64,232	$ 42,062	$ 22,170

The increase in direct costs related to our KB195 program of $5,585 was primarily due to continued costs incurred with external CROs and external CMOs and associated with our preclinical and clinical development activities. The increase in personnel-related costs of $5,975 and stock-based compensation expense of $1,936 was due to increased headcount in our research and development function. The increase in external manufacturing and research costs of $5,951 was primarily due to an increase in production of study material used in preclinical studies, clinical studies and clinical trials, as well as increased clinical and preclinical CRO activities. The increase in professional and consulting fees of $2,209 was primarily due to higher consulting fees within our regulatory affairs, quality, and clinical development functions as our pipeline programs have continued to advance.

General and Administrative Expenses

	Year Ended December 31,		
	2019	2018	Change
		(in thousands)	
Personnel-related	$ 7,795	$ 8,827	$ (1,032)
Stock-based compensation expense	6,823	5,655	1,168
Professional and consulting fees	3,473	3,695	(222)
Facility-related and other	4,337	444	3,893
Total general and administrative expenses	$ 22,428	$ 18,621	$ 3,807

The decrease in personnel-related costs of $1,032 was primarily due to the reduced salary and bonus expenses resulting from headcount reductions in the fourth quarter of 2019. The increase in stock-based compensation expense of $1,168 was primarily due to an increase in the number of shares outstanding and a higher fair value per share which increased the fair value of these awards. The increase in facility-related and other expenses of $3,893 was primarily due to increased facility related expenses associated with the build out of our new corporate headquarters that were attributed to general and administrative functions.

Interest Income

Interest income for the year ended December 31, 2019 was $1,693 compared to $1,118 in the year ended December 31, 2018. Interest income increased primarily as a result of higher invested balances due to cash proceeds received from our IPO in February 2019. Interest income in future periods will fluctuate based upon the amount of invested cash available.

Interest expense

Interest expense for the year ended December 31, 2019 was $977, compared to $1,005 for the year ended December 31, 2018. The interest expense is related to interest paid on our term loan. Interest expense is expected to increase in 2020 due to increased borrowings and the interest rate which increased under the new debt facility.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. To date, we have primarily financed our operations through the public offering of our equity securities, private placement of our convertible preferred stock and borrowings of long-term debt. As of December 31, 2019, $22.5 million was outstanding under the debt facility and $12.5 million was available for borrowing contingent upon successful completion of financing and operational milestones. In March 2019, we completed our IPO, pursuant to which we issued and sold 5,000,000 shares of common stock. We received aggregate net proceeds of $69.8 million, after deducting underwriting discounts and commissions, but before deducting offering costs totaling $3.8 million.

As of December 31, 2019, we had $71.2 million in cash and cash equivalents and an accumulated deficit of $192.6 million. Based on our current operating plans, we have sufficient cash and cash equivalents or borrowing capacity to fund our operating expenses and capital expenditures into the first quarter of 2021. We will require additional capital to sustain our operations, including the development of our MMT candidates. We may implement cost reduction strategies, which may include amending, delaying, limiting, reducing or terminating one or more of our ongoing or planned clinical trials of our product candidates. These factors raise substantial doubt about our ability to continue as a going concern. For more information, refer to “—Liquidity and Capital Resources” below and Note 1 to our condensed consolidated financial statements included elsewhere in this Annual Report.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Year December 31,	
	2019	2018
	(in thousands)	
Net cash used in operating activities	$ (75,796)	$ (46,316)
Net cash used in investing activities	(3,586)	(3,002)
Net cash provided by financing activities	74,642	98,907
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (4,740)	$ 49,589

Net Cash Used in Operating Activities

During the year ended December 31, 2019, operating activities used $75.8 million of cash, due to our net loss of $86.3 million, partially offset by non-cash charges of $11.8 million and net cash used by changes in our operating assets and liabilities of $1.2 million. Net cash used in our operating assets and liabilities primarily consisted of a $1.9 decrease in prepaid expenses and other assets and a $0.7 million increase in accounts payable and accrued expenses.

During the year ended December 31, 2018, operating activities used $46.3 million of cash, due to our net loss of $61.7 million, partially offset by non-cash charges of $8.9 million and net cash provided by changes in our operating assets and liabilities of $6.5 million. Net cash provided by changes in our operating assets and liabilities primarily consisted of a $4.7 million increase in accrued expenses and a $1.8 million increase in accounts payable.

Changes in prepaid expenses and other current assets, accounts payable and accrued expenses and other liabilities were generally due to growth in our business, the advancement of our research programs and the timing of vendor invoices and payments.

Net Cash Used in Investing Activities

During the years ended December 31, 2019 and 2018, net cash used in investing activities was $3.5 million and $3 million, respectively, due to purchases of property and equipment.

Net Cash Provided by Financing Activities

During the year ended December 31, 2019, net cash provided by financing activities was $74.6 million, consisting of $66.0 million in aggregate net proceeds from our IPO in March 2019, $6.6 million in net proceeds from debt refinancings, and $0.3 million in the settlement of our derivative liability.

During the year ended December 31, 2018, net cash provided by financing activities was $98.9 million, consisting primarily of $100.7 million in proceeds from the sale of our convertible preferred stock.

On December 31, 2019, we entered into a Credit Agreement (the “Credit Agreement”) with Hercules Capital, Inc. (the “Lender”). Under the Credit Agreement, the Lenders extended an initial $22.5 million to us, with the option to draw down an additional $12.5 million if certain milestones and conditions are met. The Credit Agreement replaced the existing debt. We incurred fees of $0.4 million related to a facility charge and legal fees, which was paid to the lender on the closing date. These amounts were recorded as a debt discount and are being amortized as interest expense using the effective interest method over the life of the Credit Agreement. The Credit Agreement also includes an end of term charge equal to 7.55% of the aggregate principal amount of all advances. The end of term charge is being accrued and recorded to interest expense over the life of the Loan using the effective interest method.

The Credit Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including, among others, covenants that limit or restrict the Borrower's ability to, among other things, incur additional indebtedness, merge or consolidate, make acquisitions, pay dividends or other distributions or repurchase equity, make investments, dispose of assets and enter into certain transactions with affiliates, in each case subject to certain exceptions. As security for its obligations under the Credit Agreement, the Borrowers granted the Lender a first priority security interest on substantially all of the Borrowers' assets (other than intellectual property), subject to certain exceptions.

The facility carries a 48-month term with interest only payments on the term loan for the first 15 months, which can be extended to up to 24 months, depending on the achievement of certain performance milestones. The Term Loan will mature in January 2024 and bears an interest rate of equal to the greater of (i) 8.95% plus the prime rate last quoted in The Wall Street Journal (or a comparable replacement rate if The Wall Street Journal ceases to quote such rate) minus 4.75% and (ii) 8.95%. The Term Loan is subject to mandatory prepayment provisions that require prepayment upon the occurrence of a Change in Control event (as defined in the Credit Agreement).

Funding Requirements

Over the next several quarters we are focusing our activities on key exploratory and clinical studies and clinical trials which we expect will reduce our overall expense rate. In the periods that follow, assuming the success of our clinical studies and clinical trials, we anticipate our expenses to increase as we progress towards larger and more pivotal clinical studies and clinical trials of our product candidates, with the potential for larger clinical studies, clinical trials and associated manufacturing. The timing and amount of our operating expenditures will depend largely on:

- the commencement, enrollment or results of the planned clinical studies or clinical trials of our product candidates or any future clinical studies or clinical trials we may conduct, or changes in the development status of our product candidates;
- the timing and outcome of regulatory review of our product candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;
- developments concerning our CMOs;
- our ability to obtain materials and to produce adequate cGMP compliant product supply for any approved or commercialized product or inability to do so at acceptable prices;
- our ability to establish and maintain collaborations, if needed;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we obtain marketing approval or identify an alternate regulatory pathway to market;
- the costs involved in prosecuting patent applications and enforcing patent claims and other intellectual property claims;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates; and
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses, capital expenditure requirements and debt service obligations into the first quarter of 2021. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, 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 funds through equity or debt financings or other arrangements when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Off-Balance Sheet Arrangements

As of December 31, 2019, we did not have any off-balance sheet arrangements as defined under applicable SEC rules.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are 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 judgments that affect the reported amounts of assets, 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 more detail in Note 2 to our consolidated financial statements, 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.

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. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. 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. We periodically confirm the accuracy of these estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical, human clinical studies and clinical trials; and
- CMOs in connection with the production of preclinical, human clinical studies and clinical trial materials.

We measure the expense recognized based on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CMOs and CROs that supply, conduct and manage preclinical studies, human clinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. 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. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of certain milestones. 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 changes in estimates that increase or decrease amounts recognized 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 measure stock-based awards granted to employees and directors based on fair value on the date of the grant using the Black-Scholes option-pricing model for options. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the respective award. We use the straight-line method to record the expense of awards with service-based vesting conditions. We use the graded-vesting method to record the expense of awards with both service-based and performance-based vesting conditions, commencing when achievement of the performance condition becomes probable.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield.

Prior to our IPO, there was no public market for our common stock, and consequently, the estimated fair value of our common stock was determined by our board of directors as of the date of each option grant, with input from management, considering third-party valuations of our common stock as well as our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent third-party valuation through the date of the grant. In the periods following the IPO, the fair value of our common stock is determined based on the quoted market price of our common stock.

Recent Accounting Pronouncements

Refer to Note 2, "Summary of Significant Accounting Policies," in the accompanying notes to the condensed consolidated financial statements for a discussion of recent accounting pronouncements.

Emerging Growth Company Status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until we are no longer an emerging growth company. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to use the extended transition period for complying with new or revised accounting standards and, as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. We may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of our IPO or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.07 billion in annual revenue, we have more than $700.0 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) or we issue more than $1.0 billion of non-convertible debt securities over a three-year period.

Item 7A. Qualitative and Quantitative Disclosures about Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 8. Consolidated Financial Statements and Supplementary Data

KALEIDO BIOSCIENCES, INC. AND SUBSIDIARIES
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and Board of Directors of Kaleido Biosciences, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Kaleido Biosciences, Inc. and subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' deficit, and cash flows for the years then ended 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 2018, and the results of its operations and its cash flows for each of the years then ended, 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 and recurring negative operating cash flows 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 regulation of the Securities and Exchange Commission and the PCAOB.

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

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

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 2, 2020

We have served as the Company's auditor since 2017.

PART I—FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

KALEIDO BIOSCIENCES, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
(in thousands, except share and per share data)

	As of December 31,	
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	$ 71,241	$ 76,086
Prepaid expenses and other current assets	2,038	157
Total current assets	73,279	76,243
Property and equipment, net	6,742	4,693
Restricted cash	2,285	2,180
Deferred issuance costs	—	2,209
Total assets	$ 82,306	$ 85,325
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,016	$ 3,442
Accrued expenses and other current liabilities	8,361	7,859
Total current liabilities	10,377	11,301
Long term debt, net of unamortized debt discount	20,391	14,831
Restricted shares repurchase liability	3	720
Other liabilities	2,652	278
Warrant liability	—	1,213
Total liabilities	33,423	28,343
Redeemable convertible preferred stock (Note 8)	—	153,226
Commitments and contingencies (Note 7)		
Stockholders' equity (deficit):		
Preferred shares, $0.001 par value, 10,000,000 and no shares authorized; no shares issued or outstanding at December 31, 2019 and 2018, respectively	—	—
Common shares, $0.001 par value, 150,000,000 and 66,000,000 shares authorized; 30,129,096 and 6,115,535 shares issued; 30,127,846 and 5,786,911 shares outstanding at December 31, 2019 and 2018, respectively	30	6
Additional paid-in capital	241,412	9,978
Accumulated deficit	(192,559)	(106,228)
Total stockholders' equity (deficit)	48,883	(96,244)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 82,306	$ 85,325

The accompanying notes are an integral part of these consolidated financial statements.

KALEIDO BIOSCIENCES, INC. AND SUBSIDIARIES
Consolidated Statements of Operations
(in thousands, except share and per share data)

	Years Ended December 31,	
	2019	2018
Operating expenses:		
Research and development	$ 64,232	$ 42,062
General and administrative	22,428	18,621
Total operating expenses	86,660	60,683
Loss from operations	(86,660)	(60,683)
Other (expense) income:		
Interest income	1,693	1,118
Interest expense	(977)	(1,005)
Change in fair value of warrant liability	252	(918)
Loss on extinguishment of debt	(580)	—
Other expense	(59)	(256)
Total other income (expense), net	329	(1,061)
Net loss	$ (86,331)	$ (61,744)
Net loss per share —basic and diluted	$ (3.36)	$ (12.09)
Weighted-average common shares outstanding used in net loss per share —basic and diluted	25,703,269	5,108,147

The accompanying notes are an integral part of these consolidated financial statements.

KALEIDO BIOSCIENCES, INC. AND SUBSIDIARIES
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance at January 1, 2018	26,927,398	$ 52,494	4,711,963	$ 5	$ 800	$ (44,484)	$ (43,679)
Issuance of Series C convertible preferred stock (net of issuance costs of $241)	10,107,404	100,732	—	—	—	—	—
Exercise of stock options	—	—	116,156	—	120	—	120
Stock-based compensation	—	—	—		6,964	—	6,964
Vesting of restricted shares	—	—	958,792	1	2,094	—	2,095
Conversion of redeemable convertible preferred stock into common stock	—	—	—	—	0	—	—
Net loss	—	—	—	—	—	(61,744)	(61,744)
Balance at December 31, 2018	37,034,802	153,226	5,786,911	6	9,978	(106,228)	(96,244)
Conversion of redeemable convertible preferred stock into common stock	(37,034,802)	(153,226)	18,517,386	19	153,207	—	153,226
Conversion of preferred stock warrant to common stock warrant upon closing of initial public offering	—	—	—	—	871	—	871
Issuance of common stock, net of issuance costs of $9,055	—	—	5,000,000	5	65,941	—	65,946
Exercise of common stock warrant	—	—	51,015	—	—	—	—
Exercise of stock options	—	—	445,160	—	630	—	630
Stock-based compensation	—	—	—	—	10,068	—	10,068
Vesting of restricted shares	—	—	327,374	—	717	—	717
Net loss	—	—	—	—	—	(86,331)	(86,331)
Balance at December 31, 2019	—	$ —	30,127,846	$ 30	$ 241,412	$ (192,559)	$ 48,883

The accompanying notes are an integral part of these consolidated financial statements.

KALEIDO BIOSCIENCES, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,	
	2019	**2018**
Operating activities:		
Net loss	$ (86,331)	$ (61,744)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	1,318	792
Loss on extinguishment of debt	580	—
Stock-based compensation	10,068	6,964
Amortization of debt discount	37	—
Non-cash interest expense	—	62
Loss on disposal of fixed asset	—	1
Change in fair value of warrant liability	(342)	918
Change in fair value of derivative	90	195
Changes in operating assets and liabilities:		
Due to/from related party	—	(102)
Prepaid expenses and other assets	(1,881)	40
Accounts payable	(684)	1,837
Accrued expense and other liabilities	1,349	4,721
Net cash used in operating activities	(75,796)	(46,316)
Investing activities:		
Purchase of property and equipment	(3,586)	(3,002)
Net cash and restricted cash used in investing activities	(3,586)	(3,002)
Financing activities:		
Proceeds from issuance of debt	37,500	—
Repayments on debt	(30,000)	—
Payments for deferred issuance costs related to IPO	—	(1,815)
Payments of issuance and extinguishment costs related to debt	(858)	(25)
Proceeds from preferred stock financing, net of issuance costs	—	100,732
Proceeds from exercise of stock options	630	120
Payments related to capital lease	(91)	(105)
Issuance of common stock, net of issuance costs	67,761	—
Settlement of derivative liability	(300)	—
Net cash provided by financing activities	74,642	98,907
Net (decrease) increase in cash, cash equivalents, and restricted cash	(4,740)	49,589
Cash, cash equivalents, and restricted cash, beginning of period	78,266	28,677
Cash, cash equivalents, and restricted cash, end of period	$ 73,526	$ 78,266
Supplemental cash flow information		
Interest paid	$ 881	$ 943
Supplemental disclosure of non-cash investing and financing activities		
Vesting of restricted stock	$ 717	$ 2,095
Reclassification of warrants to additional paid-in capital	$ 871	$ —
Derivative liability related to debt	$ —	$ 15
Deferred issuance costs in accounts payable and accrued expenses	$ —	$ 394
Conversion of preferred stock to common stock upon closing of the initial public offering	$ 153,226	$ —
Purchase of property and equipment in accounts payable and accrued expenses	$ 385	$ 604

The accompanying notes are an integral part of these consolidated financial statements.

1. Nature of the Business, Basis of Presentation, and Going Concern

Kaleido Biosciences, Inc. and its wholly owned subsidiaries (the “Company”) is a clinical-stage healthcare company that was incorporated in Delaware on January 27, 2015 and has a principal place of business in Lexington, Massachusetts. The Company was formed to use its differentiated, chemistry-driven approach to leverage the potential of the microbiome organ to treat disease and improve human health.

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, successful development of technology, obtaining additional funding, protection of proprietary technology, compliance with government regulations, risks of failure of preclinical studies (including *ex vivo* assays), clinical studies and clinical trials, the need to obtain marketing approval for its drug candidates and if applicable, its consumer products, fluctuations in operating results, economic pressure impacting therapeutic pricing, dependence on key personnel, risks associated with changes in technologies, development by competitors of technological innovations and the ability to supply sufficient amounts of MMTs at an acceptable quality level.

On March 4, 2019, the Company completed its initial public offering (the "IPO"), pursuant to which it issued and sold 5,000,000 shares of common stock. The aggregate net proceeds received by the Company from the IPO were $69.8 million, after deducting underwriting discounts and commissions, but before deducting offering costs payable by the Company, which totaled $3.8 million. Upon the closing of the IPO, all outstanding shares of convertible preferred stock converted into 18,517,386 shares of common stock.

Going Concern

During the years ended December 31, 2019 and 2018, the Company incurred net losses of $86.3 million and $61.7 million, respectively, and reported cash used in operations totaling $75.8 million and $46.3 million, respectively. In addition, as of December 31, 2019, the Company had an accumulated deficit of $192.6 million. The Company expects to continue to generate operating losses and use cash in operations in the foreseeable future. As of December 31, 2019, the Company had cash and cash equivalents of $71.2 million, and management expects that the cash and cash equivalents at December 31, 2019 will be sufficient to fund its operating expenses and capital expenditure requirements into the first quarter of 2021. 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 regarding the Company’s ability to continue as a going concern within one year after the data that these consolidated financial statements are issued.

The Company will require substantial additional capital to fund its research and development and ongoing operating expenses. These capital requirements are expected to be funded through debt and equity offerings as well as possible strategic collaborations with other companies. If the Company is unable to raise additional funds when needed, it may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that the Company would otherwise prefer to develop and market itself. While there can be no assurance the Company will be able to successfully reduce operating expenses or raise additional capital, management believes the historical success in managing cash flows and obtaining capital will continue in the foreseeable future.

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. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Principles of Consolidation

The accompanying consolidated financial statements reflect the operations of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results may differ from those estimates.

Cash and Cash Equivalents

Cash includes cash in readily available checking accounts. The Company's cash deposits on hand at one financial institution often exceed federally insured limits. Cash equivalents include all highly liquid investments maturing within 90 days from the date of purchase.

Restricted Cash

Restricted cash is cash that is restricted as to withdrawal or use under the terms of certain contractual agreements. The restricted cash consists of cash collateral for secured letters of credit for the security deposit on the Company's leased laboratory and office facilities.

Concentrations of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company's cash equivalents as of December 31, 2019 consisted only of money market funds. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company relies, and expects to continue to rely, on a small number of vendors to manufacture supplies and raw materials for its development programs. These programs could be adversely affected by a significant interruption in these manufacturing services or the availability of raw materials.

Property and Equipment

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets. Laboratory and office equipment, computer equipment and furniture and fixtures are depreciated over a period of five years, and leasehold improvements are amortized over the lesser of the asset's estimated useful life or the remaining lease term. Major additions and betterments are capitalized; maintenance and repairs, which do not improve or extend the life of the respective assets, are charged to operating expenses as incurred.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. When such events occur, the Company compares the carrying amounts of the assets to their undiscounted expected future cash flows. If this comparison indicates that there is an impairment, the amount of the impairment is calculated as the difference between the carrying value and the fair value. The Company has not recorded any impairment charges in the periods presented.

Deferred Issuance Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred issuance costs until such financings are consummated. After consummation of an equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering.

The Company capitalizes certain legal and other third-party fees that are directly associated with obtaining access to capital under credit facilities. Deferred financing costs related to a recognized debt liability are recorded as a reduction of the carrying amount of the debt liability and amortized to interest expense using the effective interest method over the repayment term.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the chief executive officer ("CEO"). The Company and CEO view the Company's operations and manage its business as one operating segment.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and bonuses, stock-based compensation, employee benefits, facilities costs, laboratory supplies, depreciation, manufacturing expenses and external costs of vendors engaged to conduct preclinical development activities and clinical trials, as well as the cost of licensing technology.

Upfront payments and milestone payments made for the licensing of technology are expensed as research and development in the period in which they are incurred. Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Research and Manufacturing Contract Costs and Accruals

The Company has entered into various research and development and manufacturing contracts. These agreements are generally cancelable, and related payments are recorded as the corresponding expenses are incurred. The Company records accruals for estimated ongoing costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the research studies or clinical trials and manufacturing activities, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be required in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Income Taxes

Deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided to reduce the deferred tax asset to an amount, which, more likely than not, will be realized.

The Company recognizes the tax benefit from any uncertain tax positions only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate settlement.

Fair Value Measurements

Certain assets and liabilities were carried 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** – Unadjusted quoted prices in active markets that are accessible to the reporting entity at the measurement date for identical assets and liabilities.
- **Level 2** – Inputs other than quoted prices in active markets for identical assets and liabilities that are observable either directly or indirectly for substantially the full term of the asset or liability. Level 2 inputs include the following:
    - quoted prices for similar assets and liabilities in active markets
    - quoted prices for identical or similar assets or liabilities in markets that are not active
    - observable inputs other than quoted prices that are used in the valuation of the asset or liabilities (e.g., interest rate and yield curve quotes at commonly quoted intervals)
    - inputs that are derived principally from or corroborated by observable market data by correlation or other means
- **Level 3** – Unobservable inputs for the assets or liability (i.e., supported by little or no market activity). Level 3 inputs include management's own assumptions about the assumptions that market participants would use in pricing the asset or liability (including assumptions about risk). The carrying amount of the Company's other financial assets and liabilities including cash, accounts payable and long-term debt approximate fair value because of the relatively short period of time between origination and expected realization or settlement.

Net Loss Per Share

Prior to the closing of its IPO, the Company followed the two-class method when computing net income (loss) per share as the Company had issued preferred stock shares that met the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon the respective rights to receive dividends as if all income for the period had been distributed. No losses were allocated to the preferred stock.

Subsequent to the closing of its IPO, basic net income (loss) per share is computed by dividing the net income (loss) by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) is computed by adjusting net income (loss) to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share is computed by dividing the diluted net income (loss) by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares assuming the dilutive effect of common stock equivalents.

The following table presents securities that have been excluded from the computations of diluted weighted-average shares outstanding as they would be anti-dilutive due to the net losses:

	As of December 31,	
	2019	2018
Options to purchase common stock	7,285,581	6,686,267
Unvested restricted common stock	1,250	328,624
Convertible redeemable preferred stock (as converted to common stock)	—	18,517,386
Warrant to purchase redeemable convertible preferred stock (as converted to common stock)	—	68,514
	7,286,831	25,600,791

Redeemable Convertible Preferred Stock

The Company recorded redeemable convertible preferred stock at fair value upon issuance, net of any issuance costs. The Company's redeemable convertible preferred stock was subject to a dividend when and if declared by the Company's board of directors (the "Board"). Since inception, no dividend has been declared. The Company classifies stock that is redeemable in circumstances outside of the Company's control outside of permanent equity. No accretion was recognized as the contingent events that could have given rise to redemption were not deemed probable. Upon completion of the IPO, all the Redeemable Convertible Preferred Stock was converted to shares of common stock.

Stock-Based Compensation

For stock-based awards, the Company measures the estimated fair value of the stock-based award on the date of grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. For stock-based awards with service-based vesting conditions, the Company records the expense for these awards using the straight-line method. For stock options with performance-based vesting conditions, the Company records the expense for these awards over the requisite service period using an accelerated attribution method to the extent the achievement of the performance condition is probable. The Company accounts for forfeitures as they occur.

The Company classifies stock-based compensation expense in its consolidated statements of operations in the same manner in which the award recipient's cash compensation costs are classified.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. The Company's comprehensive net loss equals the reported net loss for all periods presented.

Subsequent events

The Company evaluates events and/or transactions occurring after the balance sheet date and before the issue date of the financial statements to determine if any of those events and/or transactions require adjustment to or disclosure in the financial statements.

Accounting Pronouncements Issued and Not Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"), which applies to all leases and will require lessees to record most leases on the balance sheet but recognize expense in a manner similar to the current standard. The Company will use a modified retrospective approach of adoption for leases. As an emerging growth company, the Company expects to delay adoption until January 1, 2021 and is evaluating the impact that the adoption of ASU 2016-02 will have on its consolidated financial statements. The Company expects to recognize a significant lease obligation and right to use asset upon adoption.

3. Fair Value Measurements

The following tables set forth by level, within the fair value hierarchy, the assets and liabilities carried at fair value on a recurring basis (in thousands):

	Fair Value Measurement as of December 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds included within cash and cash equivalents	$ 25,304	—	—	$ 25,304
Total	$ 25,304	—	—	$ 25,304

	Fair Value Measurement as of December 31, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds included within cash and cash equivalents	$ 74,145	—	—	$ 74,145
Total	$ 74,145	—	—	$ 74,145
Liabilities:				
Warrant liability	$ —	—	1,213	$ 1,213
Derivative liability	—	—	210	$ 210
	$ —	—	1,423	$ 1,423

The fair value of money market funds was measured by the Company based on quoted market prices.

The convertible preferred stock warrant liability consisted of the fair value of warrants to purchase Series A and Series B convertible preferred stock and was based on significant inputs not observable in the market. The Company's valuation of the convertible preferred stock warrants utilized the Black-Scholes option-pricing model, which incorporated assumptions and estimates to value the convertible preferred stock warrants. The Company assessed these assumptions and estimates on a quarterly basis as additional information impacting the assumptions was obtained. Changes in the fair value of the convertible preferred stock warrants were recognized as other income (expense) in the consolidated statements of operations.

The quantitative elements associated with the Company's Level 3 inputs that impacted the fair value measurement of the convertible preferred stock warrant liability included the fair value per share of the underlying Series A and Series B convertible preferred stock, the remaining contractual term of the warrants, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying convertible preferred stock. The most significant assumption in the Black-Scholes option-pricing model that impacts the fair value of the convertible preferred stock warrants was the fair value of the Company's convertible preferred stock as of each re-measurement date. The Company determined the fair value per share of the underlying convertible preferred stock by taking into consideration its most recent sales of its convertible preferred stock as well as additional factors that the Company deemed relevant. The Company historically had been a private company and lacked company-specific historical and implied volatility information of its stock. Therefore, it estimated its expected stock volatility based on the historical volatility of publicly-traded peer companies for a term equal to the remaining contractual term of the warrants. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company has estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared dividends.

Upon the closing of the IPO, the warrants for the purchase of convertible preferred stock automatically became warrants for the purchase of common stock and the Company reclassified the carrying value of the warrants from a liability to additional paid-in capital in the consolidated balance sheet. The warrants were subsequently exercised and net settled.

The fair value of the derivative liability recognized in connection with the contingent success fee associated with the amended term loan agreement was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the derivative liability was determined using the probability-weighted expected return method ("PWERM"), which considered as inputs the probability of occurrence of an event (as defined), the expected timing of a liquidity event, the amount of the success fee and a risk-adjusted discount rate. As of December 31, 2018, the assumed probability of occurrence of the event that was most probable of triggering the payment was 70%, the expected timing of such an event was estimated to be less than one year, the amount of the success fee was $0.3 million and the discount rate was assessed to be 0%. As of March 4, 2019, the closing date of the IPO, the assumed probability of occurrence of the event that was most probable of triggering the payment increased to 100% and the discount rate was assessed to be 0%. Upon completion of the IPO, the success fee of $0.3 million was paid in March 2019.

The following table presents a roll-forward of the aggregate fair values of the Company's liabilities for which fair value is determined by Level 3 inputs (in thousands):

	Warrant Liability	Derivative Liability
Balance – January 1, 2018	$ 295	$ —
Initial fair value of derivative liability	—	15
Change in fair value	918	195
Balance – December 31, 2018	1,213	210
Change in fair value through the exercise /settlement date	(342)	90
Reclassification to additional paid-in capital in connection with IPO	(871)	—
Settlement of liability in connection with IPO	—	(300)
Balance – December 31, 2019	$ —	$ —

There were no transfers among Level 1, Level 2, or Level 3 categories in the periods presented.

Financial Instruments Not Recorded at Fair Value The carrying value of cash, cash equivalents, restricted cash, accounts payable and accrued expenses that are reported on the consolidated balance sheets approximate their fair value due to the short-term nature of these assets and liabilities. The carrying value of the long-term debt approximates fair value as evidenced by the recent refinancings.

4. Property and Equipment, net

Property and equipment consist of the following (in thousands):

	As of December 31,	
	2019	2018
Laboratory equipment	$ 4,526	$ 3,226
Office and computer equipment	1,418	1,337
Leasehold improvements	687	653
Construction in process	2,650	698
Property and equipment – at cost	9,281	5,914
Less accumulated depreciation and amortization	(2,539)	(1,221)
Property and equipment – net	$ 6,742	$ 4,693

Depreciation and amortization expense was $1.3 million and $0.8 million for the years ended December 31, 2019 and 2018, respectively.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	As of December 31,	
	2019	2018
Payroll and benefits	$ 2,426	$ 3,297
Consulting service	230	243
Legal service	171	90
Research and development	4,259	3,718
Capital lease payable – short term	68	91
Other	1,207	420
	$ 8,361	$ 7,859

6. Debt Financing

2015 Credit Facility

The Company was party to a loan and security agreement, as amended (the "2015 Credit Facility"), under which the Company had borrowed an aggregate of $15.0 million. Borrowings under the 2015 Credit Facility bore interest at an annual rate equal to the lender's prime rate plus 1.00%, subject to a floor of 5.75%.

In October 2019, the Company repaid all borrowings under the 2015 Credit Facility. The aggregate principal amount of the loan outstanding at the time of repayment was $15.0 million. As a result of the repayment the Company paid a prepayment fee of $0.1 million. The Company recognized a loss on the extinguishment of the time of repayment totaling $0.2 million.

2019 Credit Facility

In October 2019, the Company entered into a loan and security agreement (the "2019 Credit Facility") pursuant to which the lender made term loans in an aggregate principal amount of $15.0 million which were used to extinguish the 2015 Credit Facility. Issuance costs totaled $0.1 million.

In December 2019, the Company repaid all borrowings under the 2019 Credit Facility. The aggregate principal amount of the loan outstanding at the time of repayment was $15.0 million. The Company also paid the prepayment fee of 2% totaling $0.3 million. The Company recognized a loss on the extinguishment of the 2019 Credit Facility of $0.4 million related to the unamortized debt discount and prepayment fee at the time of repayment.

2019 Credit Agreement

On December 31, 2019, the Company entered into a Credit Agreement (the "Credit Agreement"). Under the Credit Agreement, the Company borrowed $22.5 million, and the Company has the option to draw down an additional $12.5 million if certain milestones and conditions are met. The Company incurred fees of $0.3 million, which was paid to the lender on the closing date. These amounts were recorded as a debt discount and are being amortized as interest expense using the effective interest method over the life of the Credit Agreement. The Credit Agreement also includes an end of term charge equal to 7.55% of the aggregate principal amount of all advances. The end of term charge, totaling $1.7 million at December 31, 2019, was recognized as a debt discount and is reflected as a reduction in the carrying value of the debt and recorded in other long-term liabilities. The debt discount created by the end of term charge is being accreted and will be recognized as additional interest expense over the term of the Credit Agreement using the effective interest method.

The Credit Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including, among others, covenants that limit or restrict the Company's ability to, among other things, incur additional indebtedness, merge or consolidate, make acquisitions, pay dividends or other distributions or repurchase equity, make investments, dispose of assets and enter into certain transactions with affiliates, in each case subject to certain exceptions. As security for its obligations under the Credit Agreement, the Company granted the Lender a first priority security interest on substantially all of the Company's assets (other than intellectual property), and subject to certain exceptions.

The outstanding principal under the Credit Agreement has a 48-month term with interest only payments for the first 15 months, which period can be extended to up to 24 months, depending on the achievement of certain performance milestones. The principal bears an interest rate of equal to the greater of (i) 8.95% plus the prime rate minus 4.75% and (ii) 8.95%. The Credit Agreement includes mandatory prepayment provisions that require prepayment upon the occurrence of a change in control event.

Future principal payments under the Credit Agreement as of December 31, 2019 are as follows (in thousands):

2021	5,454
2022	8,182
2023	8,182
2024	682
Total future principal payments	22,500
Less unamortized debt discount	2,109
Total balance	$ 20,391

7. Commitments and contingencies

Facilities Leases

Lexington, MA Lease

In March 2018, the Company entered into a non-cancelable ten-year lease agreement for laboratory and office space in Lexington, Massachusetts. In March 2019, the Company exercised its option to lease additional space in the building. The lease expires in 2029, subject to one option to extend the lease for 10 years.

Rent expense for the years ended December 31, 2019 and 2018 was $4.5 million and $1.8 million, respectively. Future minimum lease payments under the non-cancelable operating leases consisted of the following as of December 31, 2019 (in thousands):

Year Ending December 31,	
2020	5,843
2021	6,026
2022	6,207
2023	6,393
2024	6,584
Thereafter	32,284
	$ 63,337

8. Stockholders' Equity

As of December 31, 2018, convertible preferred stock consisted of the following:

	As of December 31, 2018				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Shares Issuable Upon Conversion
Series A Preferred Stock	14,469,180	14,383,563	$ 10,487	$ 10,500	7,191,781
Series A-1 Preferred Stock	3,057,972	3,057,972	5,168	5,168	1,528,985
Series B Preferred Stock	9,537,276	9,485,863	36,839	36,900	4,742,924
Series C Preferred Stock	10,107,404	10,107,404	100,732	100,973	5,053,696
	37,171,832	37,034,802	$ 153,226	$ 153,541	18,517,386

Upon completion of the IPO, all the outstanding shares of the Preferred Stock were converted into an aggregate of 18,517,386 shares of common stock.

Common stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are not entitled to receive dividends, unless declared by the board of directors.

In March 2019, the Company filed an amended and restated certificate of incorporation in the State of Delaware, which, among other things, restated the number of shares of all classes of stock that the Company has authority to issue to 160,000,000 shares, consisting of (i) 150,000,000 shares of common stock, $0.001 par value per share, and (ii) 10,000,000 shares of preferred stock, $0.001 par value per share. The shares of preferred stock are currently undesignated.

Stock-based compensation

2015 Stock Incentive Plan

The Company's 2015 Stock Incentive Plan (the "2015 Plan") provided for the Company to sell or issue incentive stock options or nonqualified stock options, restricted stock, and other equity awards to employees, directors and consultants of the Company.

The 2019 Stock Option and Incentive Plan (the "2019 Plan") became effective in February 27, 2019. Upon effectiveness of the 2019 Plan, the remaining shares available under the 2015 Plan ceased to be available for issuance and no future issuances will be made under the 2015 Plan.

The 2019 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards, cash-based awards and dividend equivalent rights to the Company's officers, employees, directors and consultants. The number of shares initially reserved for issuance under the 2019 Plan is 2,168,976, has increased on January 1, 2020 and will continue to increase each January 1 thereafter by 4% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by the Company's board of directors or compensation committee of the board of directors.

2019 Employee Stock Purchase Plan

The 2019 Employee Stock Purchase Plan (the "2019 ESPP") became effective on February 27, 2019. A total of 180,748 shares of common stock were reserved for issuance under this plan. In addition, the number of shares of common stock that may be issued under the ESPP automatically increased on January 1, 2020, and will continue to increase each January 1 thereafter, by the lesser of (i) 542,244 shares of common stock, (ii) 1% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or (iii) such lesser number of shares as determined by the administrator of the 2019 ESPP. No shares were issued under the 2019 ESPP in 2019.

Stock Option Valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. The Company historically has 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. For options with service-based vesting conditions, 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 expected term of stock options granted to non-employees is equal to the contractual term of the option award. 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 and does not expect to pay any cash dividends in the foreseeable future.

The Company typically grants stock options at exercise prices deemed by the Board to be equal to the fair value of the common stock at the time of grant. In the periods prior to the IPO, the fair value of the common stock has been determined by the Board at each measurement date based on a variety of different factors, including the results obtained from independent third-party appraisals, the Company's financial position and historical financial performance, the status of development of the Company's programs, the current climate in the marketplace, the illiquid nature of the common stock, the effect of the rights and preferences of the preferred stockholders, and the prospects of a liquidity event, among others. In the periods following the IPO, the fair value is determined based upon the quoted price of the Company's common stock.

The assumptions that the Company used to determine the grant-date fair value of options granted were as follows:

	Years Ended December 31,	
	2019	2018
Expected volatility	66.1% - 84%	46% - 55%
Risk-free interest rate	1.42% - 2.54%	2.66% - 3.07%
Expected term (in years)	5.50-6.25	5.81-6.25
Expected dividend yield	—%	—%

Stock Options Activity

A summary of the Company's stock option activity and related information is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Life (in Years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2019	6,686,267	$ 7.50	9.2	68,167
Granted	2,543,902	8.7		
Exercised	(445,160)	1.41		
Canceled	(1,499,428)	8.15		
Outstanding as of December 31, 2019	7,285,581	$ 8.15	8.7	5,075
Options exercisable as of December 31, 2019	1,900,395	7.3	8.1	2,158
Options vested or expected to vest as of December 31, 2019	7,285,231	8.2	8.7	5,075

The weighted-average grant date fair value of the options granted during the year ended December 31, 2019 and 2018 was $5.96 and $5.47 per share, respectively. As of December 31, 2019 there was $28.2 million of unrecognized compensation expense, which the Company expects to recognize over the weighted-average remaining term of 2.82 years.

Restricted Common Stock

During the year ended December 31, 2017, the Company signed agreements with seven employees to early exercise stock options covering 1,295,699 shares to convert such options to restricted common stock prior to the vesting of the underlying shares of common stock. The vesting conditions did not change. The consideration received due to the early exercises from the seven employees was recorded as a restricted share repurchase liability. As of December 31, 2019 and 2018, the outstanding balance of the restricted share repurchase liability was $0.0 million and $0.7 million, respectively.

The following table summarizes the Company's restricted common stock activity for the year ended December 31, 2019:

	Number of Restricted Shares	Weighted-Average Grant Date Fair Value
Issued and unvested as of January 1, 2019	328,624	$ 2.19
Vested	(327,374)	
Issued and unvested as of December 31, 2019	1,250	$ 2.22

Stock- Based Compensation Expense

The Company recorded stock-based compensation expense in the following expense categories of its consolidated statements of operations:

	Year Ended December 31,	
	2019	2018
Research and development	$ 3,245	$ 1,309
General and administrative	6,823	5,655
	$ 10,068	$ 6,964

9. Income Taxes

There is no provision for income taxes because the Company has historically incurred net operating losses and maintains a full valuation allowance against its deferred tax assets. The reported amount of income tax benefit for the years ended December 31, 2019 and 2018 differs from the amount that would result from applying domestic federal statutory rates to pretax losses primarily because of changes in the valuation allowance, state taxes, and the generation of research and development credits.

Significant components of the Company's net deferred tax assets at December 31, 2019 and 2018 are as follows:

	Years ended December 31,	
	2019	2018
Deferred tax assets		
Stock-based compensation	$ 3,754	$ 1,067
Net operating loss carryforwards	45,374	24,638
Credit carryforwards	6,519	4,252
Intangible assets	180	197
Charitable contributions	1	1
Accrued expenses	1,125	788
Total deferred tax assets	56,953	30,943
Valuation allowance	(56,817)	(30,837)
Total net deferred tax assets	136	106
Deferred tax liabilities:		
Fixed assets	(136)	(106)
Total net deferred tax liability	(136)	(106)
Total deferred tax assets (liability)	$ —	$ —

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Years ended December 31,	
	2019	2018
Federal income tax expense at statutory rate	21.0%	21.0%
Stock compensation expense	(0.5)	(1.0)
Fair value change in warrant liability	0.1	(0.4)
Permanent differences	(0.1)	(0.1)
Federal research and development credit	1.7	3.0
State research and development credit	0.9	1.1
State income tax, net of federal benefit	6.3	5.8
Other	0.7	(0.3)
Change in valuation allowance	(30.1)	(29.1)
Effective income tax rate	0%	0%

As of December 31, 2019, the Company had net operating loss (NOL) carryforwards for U.S. federal and state tax purposes of $166.8 million and $163.6 million, respectively. Federal NOLs of $38.8 million, generated before 2018, will begin expiring in varying amounts in 2035 unless utilized and the remaining NOL of $128 million, generated after 2018 will be carried forward indefinitely and could be used up to 80% of taxable income of each future tax year. The Commonwealth of Massachusetts does not follow federal on NOL carryforwards and as such the Company's Massachusetts NOLs of $163.6 million will expire in at various times starting in 2035. As of December 31, 2019, the Company also has federal research and development tax credit carryforwards of approximately $4.5 million, and state research and development tax credit carryforwards of approximately $2.5 million, which may be available to reduce future tax liabilities, and which expire at various dates through 2039.

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss carryforwards research and development tax credit carryforwards and capitalized expenditures. Under the applicable accounting standards, management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and concluded that it is more likely than not that the Company will not recognize the benefits of its federal and state deferred tax assets. Accordingly, a full valuation allowance has been established, and the valuation allowance increased $26.0 million and $18.0 million in the years ended December 31, 2019 and 2018, respectively.

Utilization of the net operating loss and research and development credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Code due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has not completed a study to assess whether a change of ownership has occurred, or whether there have been multiple ownership changes since its formation, due to the significant cost and complexity associated with a study. There could also be additional ownership changes in the future which may result in additional limitations on the utilization of net operating loss carryforwards and tax credits.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company's tax returns are open under statute from 2016 to the present.

The Company's policy is to record estimated interest and penalties related to uncertain tax positions in income tax expense. The Company has no amounts recorded for any unrecognized tax positions, accrued interest or penalties as of December 31, 2019 and 2018.

10. Related Party Transactions

The Company receives professional services from its principal investor, Flagship Pioneering, from time to time as needed. The Company reported general and administrative expense totaling $0 million and $0.2 million for the years ended December 31, 2019 and 2018, respectively.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2019. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2019, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Internal Control over Financial Reporting

Management's Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The following table sets forth information about our directors, executive officers and other key employees as of March 1, 2020.

NAME	AGE	POSITION(S)
Executive Officers		
Alison Lawton	58	President, Chief Executive Officer and Director
Katharine Knobil, M.D.	55	Chief Medical Officer and Head of Research and Development
William Duke, Jr.	47	Chief Financial Officer
Jerald Korn	41	General Counsel
Non-Employee Directors		
Michael Bonney	61	Chairman of the Board of Directors
Bonnie Bassler, Ph. D. (3)	57	Director
Grady Burnett (1)(3)	46	Director
Theo Melas-Kyriazi (1)(2)	60	Director
Jean Mixer (1)(2)	53	Director
Anthony G. Quinn, M.D., Ph.D (2)	58	Director
Geoffrey von Maltzahn, Ph.D.	39	Director

(1) Member of our audit committee
(2) Member of our compensation committee
(3) Member of our nominating and corporate governance committee

Executive Officers

Alison Lawton has served as our Chief Executive Officer and President and as a Director since August 2018. Prior to becoming Chief Executive Officer, Ms. Lawton served as our President and Chief Operating Officer from December 2017 to August 2018. Prior to joining us, Ms. Lawton was Chief Operating Officer at Aura Biosciences, Inc., an oncology therapeutics company, from January 2015 until December 2017, and, prior to joining Aura, served as a consultant to Aura from March 2014 to December 2014. Before that, Ms. Lawton served as Chief Operating Officer at OvaScience Inc., a life sciences company, from January 2013 to January 2014. In addition, from 2014 to 2017, Ms. Lawton served as a biotech consultant for various companies, including as Chief Operating Officer consultant at X4 Pharmaceuticals. Prior to that, Ms. Lawton spent more than 20 years in various positions of increasing responsibility at Genzyme Corporation, a global biopharmaceutical company, and subsequently at Sanofi S.A., also a global biopharmaceutical company, following the acquisition of Genzyme by Sanofi in 2011. Ms. Lawton currently serves as a member of the board of directors of ProQR Therapeutics N.V. and Verastem, Inc. and has served on those boards since September 2014 and November 2012, respectively. Ms. Lawton previously served as a director at CoLucid Pharmaceuticals, Inc. from 2016 until its acquisition by Eli Lilly in 2017, as a director at Cubist Pharmaceuticals, Inc. from February 2012 to December 2014 until its acquisition by Merck, and as a director at Magenta Therapeutics, Inc. from May 2017 to March 2018. She holds a B.Sc. in pharmacology from Kings College, University of London. We believe that Ms. Lawton is qualified to serve on our board of directors based on our review of her experience, qualifications, attributes and skills, including experience in operations management and executive leadership.

Katharine Knobil, M.D. has served as Chief Medical Officer and Head of Research and Development of our Company since December 2018. Prior to joining us, Dr. Knobil served in various roles at GlaxoSmithKline plc, a pharmaceutical company, from January 1997 until December 2018, including Chief Medical Officer, Senior Vice President of Value Evidence and Outcomes, Vice President of Medicines Development, Global Vice President of Respiratory Clinical Development at the Respiratory and Immunoinflammation Medicines Development Centre and Global Vice President of COPD and NCEs at the Respiratory Medicines Development Centre. Dr. Knobil was on the board of directors of the National Health Council from January 2017 to December 2018 and was a member of the National Academies of Sciences Engineering and Medicine's Drug Forum. She received a B.A. in biology from Cornell University and an M.D. from The University of Texas Southwestern Medical School.

William Duke, Jr. has served as our Chief Financial Officer since November 2019. Prior to joining us, Mr. Duke served as the chief financial officer for Pulmatrix, Inc from June 2015 to November 2019. Prior to Pulmatrix, Mr. Duke served as the Chief Financial Officer of Valeritas, a medical technology company, from January 2014 until June 2015 and from July 2011 until January 2014, he served as Valeritas' Vice President and Corporate Controller. At Valeritas, Mr. Duke led the controller relationship, financial planning and analysis, investor relations and information technology functions. Prior to joining Valeritas, Mr. Duke was Senior Director, Finance for Genzyme Corporation, a biopharmaceutical company, from January 2010 to July 2011, where he had oversight responsibility for external reporting to the Securities and Exchange Commission, internal management reporting and worldwide financial consolidation. Prior to Genzyme, he was the Director of Finance and Accounting of Haemonetics Corporation, a medical device company, from May 2008 to January 2010 and held various senior financial roles with consulting services and emerging growth organizations. Mr. Duke holds a B.S. in Accounting from Stonehill College and a M.B.A. with a concentration in Finance from Bentley University and is a Certified Public Accountant.

Jerald Korn has served as our General Counsel and Corporate Secretary since July 2019. Prior to joining us, Mr. Korn served in various roles at TESARO, Inc. from April 2015 to July 2019, including General Counsel and Chief Administrative Officer, Global Chief Compliance Officer and Deputy General Counsel, and Assistant General Counsel and Compliance Officer. Prior to TESARO, Mr. Korn served as Associate General Counsel at Cubist Pharmaceuticals from August 2013 to March 2015, as Deputy Chief Compliance Officer at Millennium Pharmaceuticals from July 2011 to August 2013 and as Associate General Counsel and Compliance Officer at AMAG Pharmaceuticals from August 2008 to July 2011. Prior to AMAG Pharmaceuticals, he was an associate in the law firm of Ropes & Gray LLP. Mr. Korn holds a bachelor's degree from Harvard University and J.D. from Boston University School of Law.

Non-Employee Directors

Michael Bonney has served as the Executive Chair of the Board of Directors since August 2018. Mr. Bonney has also served as Managing Director of Sasanoa Advisory Group Enterprises, LLC, a CEO advisory firm, since June 2019. Previously, Mr. Bonney served as our Chief Executive Officer and Chair of the Board of Directors from June 2017 until August 2018. Mr. Bonney has also served as Chairman of the board of directors of Magenta Therapeutics, Inc., a biotechnology company, since June 2018, and he previously served as Executive Chairman from November 2016 until June 2018. Prior to that, he served as Partner at Third Rock Ventures, LLC, a venture capital firm, from January 2016 to July 2016. Before joining Third Rock Ventures, LLC, Mr. Bonney served as CEO and Director at Cubist Pharmaceuticals, Inc., a biopharmaceutical company, from 2003 until 2015, when it was acquired by Merck. In addition to his role as Chairman of the board of Magenta, Mr. Bonney chairs the board of directors of Alnylam Pharmaceuticals, Inc. Mr. Bonney serves as a board member of Bristol-Myers Squibb, since the acquisition of Celgene in November 2019; Sarepta Therapeutics, Inc. since 2017 and Syros Therapeutics since June 2018. Mr. Bonney previously served on the boards of Global Blood Therapeutics from 2016 to 2017, Revolution Medicines from 2016 to 2017, and NPS Pharmaceuticals, Inc. from 2005 to 2015. He received a B.A. in economics from Bates College. We believe that Mr. Bonney is qualified to serve on our board of directors based on our review of his experience, qualifications, attributes and skills, including his extensive experience in leadership roles at other biotech ventures.

Bonnie L. Bassler, Ph.D. has served as a Director of our company since December 2018. Dr. Bassler currently serves in several roles at Princeton University, including, Chair of the Department of Molecular Biology since 2013, associated faculty member of the Department of Chemistry since 2010, Director for Recruiting and Diversity in the Sciences since 2008, investigator at the Howard Hughes Medical Institute since 2005, professor in the Department of Molecular Biology since 1994 and associate faculty member of the Princeton Environmental Institute since 1996. Previously, Dr. Bassler served as the Director of the Council on Science and Technology at Princeton University from July 2008 to June 2013. Dr. Bassler has served as a board member of Regeneron Pharmaceuticals, Inc. since 2016 and as a Trustee of the Alfred P. Sloan Foundation since 2014, and previously served as a board member of Sanofi from November 2014 to September 2016. Dr. Bassler served as a board member of the American Association for the Advancement of Science from January 2012 to December 2016. She was a member of the National Science Board from January 2010 until May 2016. She received a B.S. in biochemistry from the University of California-Davis and a Ph.D. in biochemistry from John Hopkins University. We believe that Dr. Bassler is qualified to serve on our board of directors based on our review of her experience, qualifications, attributes and skills, including her extensive experience in scientific research roles at elite universities.

Grady Burnett has served as a Director of our company since September 2018. Mr. Burnett currently serves as the General Partner at Bow Capital, an early stage venture capital firm, a position he has held since co-founding the company in July 2016. Previously, he served as the President and Chief Operating Officer of HackerRank, a technology company, from September 2015 until July 2016. Before that, from September 2013 until October 2014, Mr. Burnett served as the Chief Operating Officer of Flurry, Inc., a mobile analytics, monetization and advertising company. Mr. Burnett has also served as Vice President of Global Sales and Operations at Facebook, Inc. from 2009 to 2013 and was also previously the Director of North American Sales and Operations for Google LLC's AdWords team. Mr. Burnett is a member of the board of directors of East Palo Alto Tennis & Tutoring, Menlo School and Kenshoo, Ltd. He has an M.B.A. from the Harvard Business School and a bachelor's degree from the University of Michigan**.** We believe that Mr. Burnett is qualified to serve on our board of directors based on our review of his experience, qualifications, attributes and skills, including his experience in scaling companies and driving revenue growth.

Theo Melas-Kyriazi has served as a Director for our company since July 2019. Mr. Melas-Kyriazi has served as Chief Financial Officer of Levitronix Technologies Inc. and its predecessor companies since 2006. Levitronix Technologies Inc. manufactures and sells magnetically-levitated pumps primarily to microelectronics and life sciences customers. Mr. Melas-Kyriazi also serves as an Executive Partner at Flagship Pioneering, an innovation enterprise that conceives, creates, resources and grows first-in-category life sciences companies, which he joined in April 2019. Mr. Melas-Kyriazi served as a director at Evelo Biosciences, Inc. a role he has held since February 2017. He also served as a director at Valeant Pharmaceuticals International, Inc from 2003 to 2016. From 1986 to 2004, Mr. Melas-Kyriazi served in a variety of management roles at Thermo Fisher Scientific. Mr. Melas-Kyriazi received his M.B.A. from Harvard Business School. We believe Mr. Melas-Kyriazi's extensive financial and business experience in life sciences companies qualifies him to serve on our board of directors.

Jean Mixer has served as a Director of our company since October 2019. Ms. Mixer is the Chief Digital Transformation Officer and Vice President of Strategy at Boston Children's Hospital, which she joined in January 2014. From 2005 to January 2014, she served as Chief Executive Officer of mixerconsulting, which has helped organizations grow through strategic and organizational work. From 1992 to 2004, she was at the Boston Consulting Group, where she was partner in the Boston office. Before that, Ms. Mixer was an officer at J.P. Morgan in New York. From 2006 to February 2019, Ms. Mixer was a director on the board of NxStage Medical, Inc. where she served on the audit and commensation committees. From 2006 to January 2014, Ms. Mixer was a director on the board of the Cambridge Trust Company, a commercial bank, where she also served as a member of the board's executive committee and chair of its compensation committee. She is also an overseer at the Boys and Girls Clubs of Boston. Formerly, she served on the Business Roundtable Committee on National Health Care Reform. She has worked broadly across the restructuring healthcare market, including providers, payers, pharmaceuticals, medical devices, pharmacies and pharmacy benefit managers. She has a masters from Kellogg School of Management, Northwestern. We believe Ms. Mixer's extensive experience with respect to strategy, mergers and acquisitions, finance, leadership, and governance qualifies her to serve on our board of directors.

Anthony G. Quinn, M.D., Ph.D. has served as a Director for our company since February 2016. Currently Dr. Quinn is President and Chief Executive Officer of Aeglea BioTherapeutics, Inc., a biotechnology company where he has served as a Director since March 2016 and as CEO since July 2018. Prior to that, from October 2015 to July 2017 he worked as a private consultant for IDBioPharm Consulting LLC, a consulting firm. From August 2009 to June 2015, Dr. Quinn served as Head of Research & Development and Chief Medical Officer (initially at the Senior Vice President level and subsequently at the Executive Vice President level) for Synageva BioPharma Corp., a publicly traded biopharmaceutical company that was acquired by Alexion Pharmaceuticals, Inc. in June 2015. Following the acquisition, Dr. Quinn worked for Alexion Pharmaceuticals, Inc., a pharmaceutical company, from June 2015 to September 2015. Dr. Quinn received his BMSc. in general pathology and his MB ChB (M.D.) from the University of Dundee, UK. and his Ph.D. in cancer research from the University of Newcastle in Tyne, UK. He completed a postdoctoral fellowship at University of California, San Francisco before being appointed Professor of Dermatology at Barts & The London School of Medicine, UK. He is a fellow of the Royal College of Physicians London. He also currently serves as a member of the board of directors for Generation Bio. We believe Dr. Quinn is qualified to serve on our board of directors because of his medical and clinical experience in the biopharmaceutical industry, including the development of therapeutics for rare diseases.

Geoffrey von Maltzahn, Ph.D. has served as a Director for our company since August 2015, and also acts as an advisor on new innovation opportunities for our product platform, technology and approach to targeting the microbiome organ. He is a General Partner at Flagship Pioneering focused on company origination and has been with Flagship since 2009. Dr. von Maltzahn was founder of our company and served as our Chief Executive Officer from January 2015 to June 2017 and as Chief Innovation Officer from June 2017 to September 2018. Dr. von Maltzahn also serves as the Chief Innovation Officer of Indigo Agriculture, Inc., an agriculture biotechnology company he co-founded in 2013 as part of Flagship Pioneering's Flagship Labs innovation foundry. Dr. von Maltzahn was also a member of the Flagship Pioneering founding team for Seres Therapeutics, Inc. in 2010, and he subsequently served as Chief Technology Officer at Seres in 2012. Prior to working on Seres, Dr. von Maltzahn worked on the Flagship Pioneering founding team for Axcella Health, Inc., a biotechnology company, in 2009, and he served as Vice President of Discovery at Axcella from 2009 until 2013. Dr. von Maltzahn was awarded a Ph.D. in biomedical engineering and medical physics from MIT, a M.S. in bioengineering from the University of California, San Diego, and an S.B. in chemical engineering from MIT. We believe that Dr. von Maltzahn's significant experience co-founding and leading numerous biotechnology companies makes him qualified to serve on our board of directors.

Staggered board

In accordance with the terms of our amended and restated certificate of incorporation and amended and restated by-laws, our board of directors is divided into three staggered classes of directors and each director is assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held in the years 2020 for Class I directors, 2021 for Class II directors and 2022 for Class III directors.

- Our Class I directors are Michael Bonney, Bonnie L. Bassler and Geoffrey von Maltzahn;
- Our Class II directors are Alison Lawton, Jean Mixer and Anthony Quinn; and
- Our Class III directors are Theo Melas-Kyriazi and Grady Burnett.

Our amended and restated certificate of incorporation and amended and restated by-laws provide that the number of directors shall be fixed from time to time by a resolution of the majority of our board of directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and beneficial owners of more than 10% of our equity securities to file reports of holdings and transactions in securities of the Company with the SEC. Such reporting persons are required by the SEC regulations to furnish us with copies of all Section 16(a) reports they file.

Based solely on a review of reports furnished to us, or written representations from reporting persons, we believe all directors, executive officers, and 10% owners timely filed all reports regarding transactions in our securities required to be filed for 2019 by Section 16(a) under the Exchange Act.

Code of Business Conduct and Ethics

Our board of directors has adopted a Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics applies to all of our employees, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions), agents and representatives, including directors and consultants.

The full text of our Code of Business Conduct and Ethics is posted on our website at www.kaleido.com. We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics on our website. The inclusion of our website address in this Annual Report does not include or incorporate by reference the information on our website into this Annual Report, and you should not consider that information a part of this Annual Report.

Audit Committee

Our audit committee consists of Theo Melas-Kyriazi, Jean Mixer and Grady Burnett and is chaired by Theo Melas-Kyriazi. Our board of directors has determined that all members of our audit committee meet the requirements for independence and financial literacy for audit committee member under the applicable rules and regulations of the SEC and the Nasdaq listing rules. Our board of directors has designated each of Theo Melas-Kyriazi and Grady Burnett as an “audit committee financial expert,” as defined under the applicable rules of the SEC.

Item 11. Executive Compensation

Executive Compensation Overview

As an emerging growth company, we have opted to comply with the executive compensation disclosure rules applicable to “smaller reporting companies,” as such term is defined in the rules promulgated under the Securities Act. This section provides an overview of the compensation awarded to and earned by each individual who served as our principal executive officer at any time during our fiscal year ended December 31, 2019 our next two most highly compensated executive officers in respect of their service to our company for our fiscal year ended December 31, 2019 and a former executive officer who was one of the highest compensated individuals for 2019. We refer to these individuals as our named executive officers. Our named executive officers are:

- Alison Lawton, our President and Chief Executive Officer;
- Katharine Knobil, M.D., our Chief Medical Officer and Head of Research & Development.
- Jerald Korn, our General Counsel and Corporate Secretary; and.
- Joshua Brumm, our former Chief Operating Officer and Chief Financial Officer

Our executive compensation program has reflected our growth and development-oriented corporate culture. Compensation of our named executive officers has primarily consisted of a combination of base salary, bonuses and long-term incentive compensation. Our named executive officers, like all of our full-time employees, are eligible to participate in our health and welfare benefit plans. We currently evaluate our compensation values and philosophy and compensation plans and arrangements as circumstances require and review executive compensation annually with input from a compensation consultant. As part of this review process, our board of directors and the compensation committee apply our values and philosophy, while considering the compensation levels needed to ensure our executive compensation program remains competitive. We also review whether we are meeting our retention objectives and the potential cost of replacing key employees.

Summary Compensation Table

The following table sets forth information regarding compensation awarded to and earned by our named executive officers for services rendered to us in all capacities during our fiscal years ended December 31, 2019 and 2018 as well as for our former Chief Operating Officer and Chief Financial Officer who would have been one of our most highly compensated executive officers but for the fact that such individual was not serving as an executive officer of our company as of December 31, 2019. On February 19, 2019, we effected a reverse stock split of shares of our common stock at a ratio of one-for-two, pursuant to an amendment to our amended and restated certificate of incorporation approved by our board of directors and stockholders. All issued and outstanding common shares and per share amounts have been retroactively adjusted to reflect this reverse stock split for all periods presented.

Name and Principal Positions (9)	Year	Salary ($)	Cash Bonus ($)	Option awards ($) (1)	Non-Equity Incentive Plan Compensation $ (2)	All Other Compensation ($)	Total ($)
Alison Lawton	2019	$ 500,000	$ 250,000	2,101,475	$ 276,563	$ 11,196 (3)	$ 3,139,234
President and Chief Executive Officer (Prinicpal Executive Officer)	2018	437,500	—	5,947,117 (4)	250,000	9,512 (5)	6,644,129
Katharine Knobil, M.D.	2019	450,000	200,000	583,729	170,252	47,783 (6)	1,451,763
CMO & Head of R&D	2018	37,500 (7)		3,900,060	—	200,389 (8)	4,137,949
Jerald Korn		170,026 (9)	50,000	1,210,638	70,526	4,234 (10)	1,505,423
Joshua Brumm	2019	349,916	126,138	747,200	—	764 (11)	1,224,018
COO & CFO (former Principal Financial Officer) (12)	2018	296,891 (13)	—	2,107,576 (14)	126,138	320,586 (15)	2,851,191

(1) The amounts reported in the “Option Awards” column reflects the aggregate grant date fair value of share-based compensation awarded during the indicated year computed in accordance with the provisions of Financial Accounting Standards Board Accounting Standards Codification (ASC) Topic 718. The assumptions used in calculating the grant-date fair value are set forth in Note 8 to our audited consolidated financial statements appearing elsewhere in this Annual Report.

(2) The amounts reported represent cash incentive compensation based upon the Board’s assessment of the achievement of company and individual performance objectives for the year indicated. Cash incentive compensation for the year ended December 31, 2019, made in February 2020.

(3) The amount reported represents $8,000 for matching contributions made in February 2020 by the Company under its 401(k) plan, $320 in long-term disability insurance premiums, $2,322 in group term life insurance premiums in excess of statutory limits, and $554 Massachusetts Paid Family and Medical Leave Act.

(4) A portion of the amount reported represents a one-time non-cash compensation amount based on the September 2018 modification of certain performance-based stock option awards whereby the shares underlying this option will now be subject to time-based vesting. The amount related to the modification is equal to the modification date fair value of $1,628,349.

(5) The amount reported represents $8,000 for matching contributions made in February 2019 by the Company under its 401(k) plan, $480 in long-term disability insurance premiums and $1,032 in group term life insurance premiums in excess of statutory limits.

(6) The amount reported represents $8,000 for matching contributions made in February 2020 by the Company under its 401(k) plan, $320 in long-term disability insurance premiums, $2,322 in group term life insurance premiums in excess of statutory limits, and $499 Massachusetts Paid Family and Medical Leave Act, $6,915 in company paid relocation services, and $29,567 in commuting expense reimbursements.

(7) Dr. Knobil commenced employment with us in December 2018. Her annual base salary for 2018 was $450,000.

(8) The amount reported represents $40 in long-term disability insurance premiums and $46 in group term life insurance premiums in excess of statutory limits, $200,000 in a bonus paid to Dr. Knobil due upon the commencement of her employment with us, and $303 in commuting expense reimbursements.

(9) Mr. Korn commenced employment with us in July 2019. His annual base salary for 2019 was $380,000.

(10) The amount reported represents $3,345 for matching contributions made in February 2020 by the Company under its 401(k) plan, $220 in long-term disability insurance premiums, $247 in group term life insurance premiums in excess of statutory limits, and $419 Massachusetts Paid Family and Medical Leave Act.

(11) The amount reported represents $220 in long-term disability insurance premiums, $427 in group term life insurance premiums in excess of statutory limits, and $117 Massachusetts Paid Family and Medical Leave Act.

(12) Mr. Brumm ceased to be an officer of the Company upon his resignation in September 2019. Mr. Brumm continued to serve as a consultant until December 31, 2019 pursuant to a consulting agreement he entered into with us upon his resignation. Pursuant to such agreement Mr. Brumm's outstanding equity awards continued to vest, however he received no additional compensation.
(13) Mr. Brumm commenced employment with us in April 2018. His annual base salary for 2018 was $435,000.
(14) A portion of the amount reported represents a one-time non-cash compensation amount based on the September 2018 modification of certain performance-based stock option awards whereby the shares underlying this option will now be subject to time-based vesting. The amount related to the modification is equal to the modification date fair value of $1,006,886.
(15) The amount reported represents $8,000 for matching contributions made in February 2019 by the Company under its 401(k) plan, $150,000 in a bonus paid to Mr. Brumm upon the commencement of his employment with us, $150,000 in company paid relocation expenses, $12,900 in commuting expense reimbursements, $331 in long-term disability insurance premiums and $165 in group term life insurance premiums in excess of statutory limits.

Narrative to the Summary Compensation Table

Base Salary

Each named executive officer's base salary is a fixed component of annual compensation for performing specific duties and functions, and has been established by our board of directors taking into account each individual's role, responsibilities, skills and experience.

Annual Bonus

Our annual bonus program is intended to reward our named executive officers for meeting objective or subjective performance goals for a fiscal year.

Equity Compensation

Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, or any formal equity ownership guidelines applicable to them, we believe that equity grants provide our executive officers with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executive officers and our stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incentives our executive officers to remain in our employment during the vesting period. Accordingly, our board of directors periodically reviews the equity incentive compensation of our executives, including our named executive officers, and from time to time may grant equity incentive awards to them in the form of stock options.

We typically grant stock option awards at the start of employment to each executive officer and our other employees as well as on a twice annual basis for retention purposes. We award our stock options on a future date set by our board of directors at the time the board of directors approves the grant. We set the option exercise price equal to the fair market value of our common stock on the date of grant.

2019 Stock Option and Incentive Plan

Our 2019 Stock Option and Incentive Plan, or 2019 Plan, was adopted by our board of directors on January 23, 2019, and approved by our stockholders on February 19, 2019. The 2019 Plan replaced our 2015 Stock Incentive Plan, or 2015 Plan, as our board of directors determined not to make additional awards under that plan following the consummation of our initial public offering. The 2019 Plan allows the board of directors' compensation committee to make equity-based incentive awards to our officers, employees, directors and other key persons (including consultants).

We have initially reserved 2,168,976 shares of our common stock for the issuance of awards under the 2019 Plan, or the Initial Limit. The 2019 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2020, by 4% of the outstanding number of shares of our common stock on the immediately preceding December 31 or such lesser number of shares as determined by our compensation committee, or the Annual Increase. These limits are subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2019 Plan and 2015 Plan will be added back to the shares of common stock available for issuance under the 2019 Plan.

The maximum aggregate number of shares that may be issued in the form of incentive stock options shall not exceed the Initial Limit cumulatively increased on January 1, 2020 and on each January 1 thereafter by the lesser of the Annual Increase for such year plus shares added back as provided for above with respect to the 2015 Plan or 4,337,952 shares of common stock.

2015 Stock Incentive Plan

Our 2015 Plan, was approved and adopted by our board of directors on July 14, 2015, and approved by our stockholders on July 14, 2015. Under the 2015 Plan we initially reserved for issuance an aggregate of 1,000,000 shares of our common stock, and most recently increased the shares reserved and available for issuance to 8,395,974 shares of our common stock on December 4, 2018. The number of shares of common stock reserved for issuance under the 2015 Plan is subject to adjustment in the event of a stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off, or other similar change in our capitalization.

The shares of common stock underlying awards that are forfeited, cancelled, terminated, reacquired prior to vesting, satisfied without the issuance of shares of common stock, or withheld to cover the exercise price or tax withholding are added back to the shares of common stock available for issuance under the 2019 Plan.

The shares of common stock underlying awards that are forfeited, cancelled, terminated, reacquired prior to vesting, satisfied without the issuance of shares of common stock, or withheld to cover the exercise price or tax withholding are added back to the shares of common stock available for issuance under the 2019 Plan.

2019 Employee Stock Purchase Plan

On January 23, 2019, our board of directors adopted the 2019 Employee Stock Purchase Plan, or 2019 ESPP, and on February 19, 2019, our stockholders approved the 2019 ESPP, but the 2019 ESPP has not yet been implemented. The 2019 ESPP is intended to qualify as an “employee stock purchase plan” within the meaning of Section 423 of the Code. The 2019 ESPP initially reserves and authorizes the issuance of up to a total of 180,748 shares of common stock to participating employees. The 2019 ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2020, by the least of (i) 542,244 shares of Common Stock, (ii) 1% of the outstanding number of shares of our common stock on the immediately preceding December 31 or (iii) such lesser number of shares as determined by the 2019 ESPP administrator. The number of shares reserved under the 2019 ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

All employees whose customary employment is for more than 20 hours per week are eligible to participate in the 2019 ESPP. However, any participating employee who would own 5% or more of the total combined voting power or value of all classes of stock after an option were granted under the 2019 ESPP would not be eligible to purchase shares under the 2019 ESPP.

We will make one or more offerings each year to our employees to purchase shares under the 2019 ESPP. Offerings will usually begin on each May 1 and November 1 and will continue for six-month periods, referred to as offering periods. Each eligible employee may elect to participate in any offering by submitting an enrollment form at least 15 business days before the relevant offering date.

Each employee who is a participant in the 2019 ESPP may purchase shares by authorizing payroll deductions of up to a specified percentage of his or her base compensation during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase shares on the last business day of the offering period at a price equal to 85% of the fair market value of the shares on the first business day or the last business day of the offering period, whichever is lower. Under applicable tax rules, an employee may purchase no more than $25,000 worth of shares of common stock, valued at the start of the purchase period, under the 2019 ESPP in any calendar year.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee's rights under the 2019 ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

The 2019 ESPP may be terminated or amended by our board of directors at any time. An amendment that increases the number of shares of common stock authorized under the 2019 ESPP and certain other amendments require the approval of our stockholders.

Senior Executive Cash Incentive Bonus Plan

In October 2018, our board of directors adopted the Senior Executive Cash Incentive Bonus Plan, or the Bonus Plan, but the Bonus Plan has not yet been implemented. The Bonus Plan provides for cash bonus payments based upon the attainment of performance targets established by our compensation committee. The payment targets are related to financial and operational measures or objectives with respect to our company, or Corporate Performance Goals, as well as individual performance objectives.

Our compensation committee may select Corporate Performance Goals from among the following: cash flow (including, but not limited to, operating cash flow and free cash flow); sales or revenue; corporate revenue; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes, depreciation and/or amortization); changes in the market price of our common stock; economic value-added; development, clinical, regulatory or commercial milestones; acquisitions or strategic transactions, partnerships or joint ventures; operating income (loss); return on capital, assets, equity, or investment; stockholder returns; return on sales; gross or net profit levels; productivity; expense efficiency; margins; operating efficiency; customer satisfaction; working capital; earnings (loss) per share of our common stock; sales or market shares; number of customers; operating income and/or other strategic, financial or operational objectives, any of which may be measured in absolute terms, as compared to any incremental increase, in terms of growth, as compared to results of a peer group, against the market as a whole, compared to applicable market indices and/or measured on a pre-tax or post-tax basis.

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive. The Corporate Performance Goals will be measured at the end of each performance period after our financial reports have been published or such other appropriate time as the compensation committee determines. If the Corporate Performance Goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period. The Bonus Plan also permits the compensation committee to approve additional bonuses to executive officers in its sole discretion.

401(k) Plan

Effective as of January 1, 2017, we adopted a tax-qualified retirement plan that provides eligible employees with an opportunity to save for retirement on a tax-advantaged basis. All participants' interests in their contributions are 100% vested when contributed. During the first half of 2018, a matching contribution of 50% of employee contributions up to 6%, with a maximum of $8,000 per year was approved. Matching contributions vest 25% each year, 100% vested after 4 years of service. At the end of the year, contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The retirement plan is intended to qualify under Section 401(a) of the Code.

Limitations on Liability and Indemnification

Our amended and restated certificate of incorporation contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by the Delaware General Corporation Law, or DGCL. Consequently, our directors are not personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to us or our 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 DGCL; or
- any transaction from which the director derived an improper personal benefit.

Our amended and restated by-laws require us to indemnify our directors and officers to the maximum extent not prohibited by the DGCL and allow us to indemnify other employees and agents as set forth in the DGCL. Subject to certain limitations, our amended and restated by-laws also require us to advance expenses incurred by our directors and officers for the defense of any action for which indemnification is required or permitted.

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors, officers and certain of our key employees, in addition to the indemnification provided for in our amended and restated certificate of incorporation and amended and restated by-laws. These agreements, among other things, require us to indemnify our directors, officers and key employees for certain expenses, including attorneys' fees, judgments, penalties, fines and settlement amounts actually incurred by these individuals in any action or proceeding arising out of their service to us or any of our subsidiaries or any other company or enterprise to which these individuals provide services at our request. Subject to certain limitations, our indemnification agreements also require us to advance expenses incurred by our directors, officers and key employees for the defense of any action for which indemnification is required or permitted

We believe that provisions of our amended and restated certificate of incorporation, amended and restated by-laws and indemnification agreements are necessary to attract and retain qualified directors, officers and key employees. We also maintain directors' and officers' liability insurance.

This description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is qualified in its entirety by reference to these documents, each of which is attached as an exhibit to this Annual Report.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, executive officers or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Health and Welfare Benefits

All of our full-time employees, including our named executive officers, are eligible to participate in our health and welfare plans, including medical and dental benefits, short-term and long-term disability insurance, and life insurance. We believe these perquisites are necessary and appropriate to provide a competitive compensation package to our named executive officers.

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. The director or officer may amend or terminate the plan in some circumstances. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

Employment Arrangements and Severance Agreements with our Named Executive Officers

We have entered into employment agreements with each of our named executive officers that provide for specified payments and benefits in connection with a termination of employment in certain circumstances. Our goal in providing these severance and change in control payments and benefits is to offer sufficient cash continuity protection such that the named executive officers who are our employees will focus their full time and attention on the requirements of the business rather than the potential implications for their respective positions. We prefer to have certainty regarding the potential severance amounts payable to the named executive officers, rather than negotiating severance at the time that a named executive officer's employment terminates. We have also determined that accelerated vesting provisions with respect to outstanding equity awards in connection with a qualifying termination of employment in certain circumstances are appropriate because they encourage our named executive officers to stay focused on the business in those circumstances, rather than focusing on the potential implications for them personally. The employment agreements with our named executive officers require the named executive officers to execute a separation agreement containing a general release of claims in favor of us to receive any severance payments and benefits.

Alison Lawton

On January 24, 2019, we entered into an employment agreement with Ms. Lawton, or the Lawton Employment Agreement. Pursuant to the terms of the Lawton Employment Agreement, Ms. Lawton serves as our Chief Executive Officer and President on an at-will basis. Ms. Lawton's Employment Agreement provides her with a base salary, which is subject to periodic review and adjustment by our board of directors, and eligibility to receive cash incentive compensation as determined by our board of directors or compensation committee from time to time. Ms. Lawton's current base salary is $515,000, and Ms. Lawton is eligible for an annual performance bonus currently targeted at 50% of her base salary. Ms. Lawton is also eligible to participate in the employee benefit plans generally available to our employees, subject to the terms of those plans.

The Lawton Employment Agreement further provides that if Ms. Lawton's employment is terminated by us without Cause (as defined in the Lawton Employment Agreement) or Ms. Lawton resigns for Good Reason (as defined in the Lawton Employment Agreement), then, subject to the timely execution and effectiveness of a separation agreement, including a general release of claims in our favor, Ms. Lawton will be entitled to receive: (i) an amount equal to 12 months of base salary plus an amount equal to the incentive compensation paid to Ms. Lawton in the year prior to the year of termination, payable in substantially equal monthly installments over 12 months following termination, (ii) if Ms. Lawton was enrolled in our health care program immediately prior to the date of termination and properly elects to receive COBRA benefits, a monthly cash payment for 12 months of COBRA premiums at our normal rate of contribution for employees for coverage at the level in effect immediately prior to the date of termination and (iii) extension of the period during which Ms. Lawton can exercise any of her vested options to purchase our stock until the anniversary of Ms. Lawton's date of termination.

In lieu of the severance payments and benefits set forth in the prior paragraph, in the event that Ms. Lawton is terminated by us without Cause or she resigns for Good Reason, in each case within 15 months following a Change in Control (as defined in the Lawton Employment Agreement), subject to the timely execution and effectiveness of a separation agreement, including a general release of claims in our favor, she will be entitled to receive: (i) a lump sum cash amount equal to 1.5 times the sum of (A) her current base salary (or her base salary in effect prior to the Change in Control, if higher) plus (B) her target annual cash incentive compensation for the year of termination, (ii) if Ms. Lawton is enrolled in our health care program immediately prior to the date of termination and properly elects to receive COBRA benefits, a monthly cash payment for 18 months of COBRA premiums at our normal rate of contribution for employees for coverage at the level in effect immediately prior to the date of termination, and (iii) notwithstanding anything to the contrary in any applicable award agreement, accelerated vesting of 100% of all Equity Awards (as defined in the Lawton Agreement) held by Ms. Lawton.

Other Employment Agreements with Executive Officers

In addition to the Lawton Agreement, we have also entered into employment agreements with each of our other executive officers, Dr. Katherine Knobil and Messrs. William Duke, Jr. and Jerald Korn. We refer to these agreements collectively as the Executive Employments Agreements.

The current base salaries and discretionary cash incentive bonus amounts for the executives under the Executive Employment Agreements are as follows:

Executive	Title	Base Salary	Target Incentive Discretionary Bonus (%)
Katharine Knobil, M.D.	Chief Medical Officer and Head of Research and Development	$ 463,500	40%
William Duke, Jr.	Chief Financial Officer	420,000	40%
Jerald Korn	General Counsel	385,903	40%

Under the Executive Employment Agreements, each of the executives will continue to serve on an at-will basis. The above base salaries are subject to periodic review and adjustment by our board of directors, and eligibility to receive cash incentive compensation as determined by our board of directors or compensation committee from time to time. The executives are also eligible to participate in the employee benefit plans generally available to our employees, subject to the terms of those plans.

The Executive Employment Agreements further provides that if the executive's employment is terminated by us without Cause (as defined in the relevant Executive Employment Agreement) or the executive resigns for Good Reason (as defined in the relevant Executive Employment Agreement), then, subject to the timely execution and effectiveness of a separation agreement, including a general release of claims in our favor, the executive will be entitled to receive: (i) an amount equal to 12 months of base salary plus an amount equal to the incentive compensation paid to the executive in the year prior to the year of termination, payable in substantially equal monthly installments over 12 months following termination, (ii) if the executive was enrolled in our health care program immediately prior to the date of termination and properly elects to receive COBRA benefits, a monthly cash payment for 12 months of COBRA premiums at our normal rate of contribution for employees for coverage at the level in effect immediately prior to the date of termination and (iii) extension of the period during which the executive can exercise any of his or her vested options to purchase our stock until the anniversary of the executive's date of termination.

In lieu of the severance payments and benefits set forth in the prior paragraph, in the event that the executive is terminated by us without Cause or he or she resigns for Good Reason, in each case within 15 months following a Change in Control (as defined in the relevant Executive Employment Agreement), subject to the timely execution and effectiveness of a separation agreement, including a general release of claims in our favor, the executive will be entitled to receive: (i) a lump sum cash amount equal to 1.5 times the sum of (A) his or her current base salary (or his or her base salary in effect prior to the Change in Control, if higher) plus (B) his or her target annual cash incentive compensation for the year of termination, (ii) if the executive is enrolled in our health care program immediately prior to the date of termination and properly elects to receive COBRA benefits, a monthly cash payment for 18 months of COBRA premiums at our normal rate of contribution for employees for coverage at the level in effect immediately prior to the date of termination, and (iii) notwithstanding anything to the contrary in any applicable award agreement, accelerated vesting of 100% of all Equity Awards (as defined in the relevant Executive Employment Agreement) held by the executive.

Each of the Lawton Employment Agreement and the Executive Employment Agreements also contains a Section 280G better-off cutback provision, which provides that, in the event that the payments or benefits provided to the named executive officer pursuant to his or her employment agreement or otherwise constitute parachute payments with the meaning of Section 280G of the Code, the payments or benefits to such executive will either be delivered in full or reduced to the extent necessary to avoid an excise tax under Section 4999 of the Code, whichever would result in the executive receiving the largest amount of payments or benefits on an after-tax basis. None of the employment agreements with our named executive officers requires us to provide any tax gross-up payments.

Other agreements

We have also entered into employee confidentiality, inventions, non-solicitation and non-competition agreements with each of our named executive officers. Under such agreements, each named executive officer has agreed (1) not to compete with us during his or her employment and for a period of one year after the termination of such employment, (2) not to solicit our employees during his or her employment and for a period of one year after the termination of such employment, (3) to protect our confidential and proprietary information and (4) to assign to us related intellectual property developed during the course of his or her employment.

Outstanding Equity Awards at 2019 Fiscal Year-End

The following table sets forth information concerning outstanding equity awards held by our named executive officers as of December 31, 2019.

	OPTION AWARDS							STOCK AWARDS				
NAME	Number of Securities Underlying Unexercised Options(#) Exercisable		Number of Securities Underlying Unexercised Options (#) Unxercisable		Equity IncentivePlan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares Or Units Of Stock That Have Not Vested (#)		Market Value Of Shares Or Units Of Stock That Have Not Vested ($)(1)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not vested ($)
Alison Lawton, *President and Chief Exeutive Officer* (Prinicpal Exeutive Officer)	—		162,500	(2)	—	2.22	12/5/2027	1,250	(2)	6,275	—	—
	255,609	(3)	562,339	(3)	—	10.28	8/15/2028	—		—	—	—
	—		150,000	(4)	—	15.00	2/26/2029	—		—	—	—
	—		150,000	(5)	—	6.56	11/15/2029	—		—	—	—
Katharine Knobil, *CMO & Head of R&D*	115,250	(6)	345,750	(6)	—	17.40	12/3/2028	—		—	—	—
	—		125,000	(7)	—	6.56	11/14/2029	—		—	—	—
	—		—		—	—	—	50,000	(8)	251,000	—	—
Jerald Korn, *General Counsel*	—		180,000	(9)	—	7.67	7/31/2029	—		—	—	—
	—		75,000	(10)	—	6.56	11/14/2029	—		—	—	—
Joshua Brumm, *COO&CFO*	98,438	(11)	—		—	5.90	12/31/2020	—		—	—	—
	38,778	(11)	—		—	10.28	12/31/2020	—		—	—	—

Unless otherwise specified, all option awards vest over four years, with 25% vesting on the first anniversary of the vesting commencement date, and the remainder vesting in 12 equal quarterly installments thereafter, subject to continued employment with us.

(1) The amount represents the number of shares of restricted stock or unvested restricted stock units multiplied by the market value of a share of our common stock based on the closing price on December 31, 2019, which was $5.02. Unless otherwise specified, all stock awards listed in the table are restricted stock awards.
(2) Represents total original grant of 327,500 shares underlying a stock option. In November 2017, 165,000 shares were acquired upon the exercise of the early exercise feature. The aggregate shares from this arrangement vested 25% on November 16, 2018, then in 12 equal quarterly installments thereafter with all shares under the early-exercise stock award vesting in their entirety before any vesting will occur under the option award.
(3) The shares underlying this option vest 25% on August 16, 2019, then in 12 equal quarterly installments thereafter.
(4) The shares underlying this option vest 25% on February 26, 2020, then in 12 equal quarterly installments thereafter.
(5) The shares underlying this option vest 25% on November 15, 2020, then in 12 equal quarterly installments thereafter.
(6) The shares underlying this option vest 25% on December 3, 2019, then in 12 equal quarterly installments thereafter.
(7) The shares underlying this option vest 25% on November 15, 2020, then in 12 equal quarterly installments thereafter.
(8) Represents shares of restricted stock granted on November 15, 2019, with 50% vesting on November 15, 2020, and the remainder vesting on November 15, 2021.
(9) The shares underlying this option vest 25% on July 22, 2020, then in 12 equal quarterly installments thereafter.
(10) The shares underlying this option vest 25% on November 15, 2020, then in 12 equal quarterly installments thereafter.
(11) The shares underlying this option are fully vested and, pursuant to Mr. Brumm's consulting agreement, are available for exercise until December 31, 2020.

Compensation Risk Assessment

We believe that although a portion of the compensation provided to our executive officers and other employees is performance-based, our executive compensation program does not encourage excessive or unnecessary risk taking.

This is primarily due to the fact that our compensation programs are designed to encourage our executive officers and other employees to remain focused on both short-term and long-term strategic goals. As a result, we do not believe that our compensation programs are reasonably likely to have a material adverse effect on us.

Director Compensation

The following table presents the total compensation for each person who served as a non-employee member of our board of directors and received compensation for such service during the year ended December 31, 2019. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any additional equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2019. We reimburse non-employee members of our board of directors for reasonable travel and out-of-pocket expenses incurred in attending meetings of our board of directors and committees of our board of directors. We also do not, and do not expect to, provide separate compensation to our directors who are also our employees, such as Ms. Lawton, our Chief Executive Officer and President. Ms. Lawton's compensation as our principal executive officer in 2019 is reported above in the Summary Compensation Table.

Director Compensation Table

NAME	Fees Earned Or Paid In Cash ($)	Stock Awards ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation	All Other Compensation ($)	Total ($)
Michael Bonney	$ 397,503	$ —	$ —	$ —	$ —	**$ 397,503**
Bonnie Bassler, Ph. D	39,000	—	—	—	—	39,000
Grady Burnett	46,250	—	—	—	—	46,250
Theo Melas-Kyriazi	27,500	—	440,531	—	—	468,031
Jean Mixer	11,875	—	519,304	—	—	531,179
Anthony G. Quinn, M.D. Ph.D	48,750	—	—	—	—	48,750
Geoffrey von Maltzahn, Ph.D	35,000	—	—	—	—	35,000

(1) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted during 2019 computed in accordance with Financial Accounting Standard Board ASC Topic 718 for stock-based compensation transactions, or ASC 718.

Non-Employee Director Compensation Policy

Our board of directors has adopted a non-employee director compensation policy, that is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each director who is not an employee will be paid cash compensation, as set forth below:

	Member Annual Fee ($)	Chairman Additional Annual Fee ($)
Board of Directors	$ 35,000	$ 25,000
Audit Committee	7,500	7,500
Compensation Committee	5,000	5,000
Nominating and Corporate Governance Committee	4,000	3,500

Such base compensation is paid on a quarterly basis in arrears.

In addition, subject to the discretion of our board of directors, each non-employee director elected or appointed to our board of directors following the completion of our initial public offering received an option to purchase a number of shares, with a value equivalent to $440,000, with value determined in accordance with the reasonable assumptions and methodologies for calculating the fair value of options under ASC 718, on the date of such director's election or appointment to the board of directors, which will vest annually over three years, subject to continued service through such vesting dates.

On the date of each annual meeting of stockholders of our company, each non-employee director will also receive an option to purchase a number of shares that will be determined based on external benchmarking and with input from a compensation consultant, which will vest in full of the earlier to occur of the first anniversary of the date of grant or the next annual meeting, subject to continued service as a director through such vesting date.

Michael Bonney

On January 24, 2019, we entered into an employment agreement with Mr. Bonney, our Executive Chairman, or the Bonney Employment Agreement. Pursuant to the terms of the Bonney Agreement, Mr. Bonney serves as Executive Chair of our board of directors and he has agreed to dedicate 60% of his full working time and effort to the business and affairs of the Company. Until October 31, 2019, as compensation for Mr. Bonney's services, we paid him a base salary of $500,000 per year, which was subject to annual review and adjustment by our board of directors. Effective November 1, Mr. Bonney elected and the Board approved a reduction in compensation to $35,000 per year. Mr. Bonney is also eligible to participate in the employee benefit plans generally available to our employees, subject to the terms of those plans, provided that Mr. Bonney shall not be entitled to paid vacation.

The Bonney Employment Agreement further provides that if Mr. Bonney's employment is terminated by us without Cause (as defined in the Bonney Employment Agreement) or Mr. Bonney resigns for Good Reason (as defined in the Bonney Employment Agreement), then, subject to the timely execution and effectiveness of a separation agreement, including a general release of claims in our favor, Mr. Bonney will be entitled to receive a monthly cash payment for 12 months of COBRA premiums at our normal rate of contribution for employees for coverage at the level in effect immediately prior to his date of termination, if Mr. Bonney was enrolled in our health care program immediately prior to the date of termination and properly elects to receive COBRA benefits.

In lieu of the severance payments and benefits set forth in the prior paragraph, in the event that Mr. Bonney is terminated by us without Cause or he resigns for Good Reason, in each case within 12 months following a Change in Control (as defined in the Bonney Employment Agreement), subject to the timely execution and effectiveness of a separation agreement, including a general release of claims in our favor, he will be entitled to receive: (i) if Mr. Bonney is enrolled in our health care program immediately prior to the date of termination and properly elects to receive COBRA benefits, a monthly cash payment for 12 months of COBRA premiums at our normal rate of contribution for employees for coverage at the level in effect immediately prior to the date of termination, and (ii) notwithstanding anything to the contrary in any applicable award agreement, accelerated vesting of 100% of all Time-Based Equity Awards (as defined in the Bonney Agreement) held by Mr. Bonney.

The Bonney Employment Agreement also contains a Section 280G better-off cutback provision, which provides that, in the event that the payments or benefits provided under the agreement or otherwise constitute parachute payments with the meaning of Section 280G of the Code, the payments or benefits to such executive will either be delivered in full or reduced to the extent necessary to avoid an excise tax under Section 4999 of the Code, whichever would result in Mr. Bonney receiving the largest amount of payments or benefits on an after-tax basis. The agreement does not require us to provide any tax gross-up payments

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Securities authorized for issuance under equity compensation plans

The following table provides information relating to our equity compensation plans as of December 31, 2019. As of December 31, 2019, we had two equity compensation plans, our 2019 Plan and our 2019 ESPP, each of which was approved by our board of directors and our stockholders.

	Equity Compensation Plans		
	Number of securities to be issued upon exercise of outstanding options, warrants and right	Weighted-average exercise price of outstanding options, warrants, and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by stockholders	7,285,581	$ 8.15	1,305,250
Equity compensation plans not approved by stockholders	—	—	—
Total	7,285,581	$ 8.15	1,305,250

As described above under "Item 11. Executive Compensation," in connection with our initial public offering, our board of directors and stockholders approved two new equity compensation plans, the 2019 Plan and the 2019 ESPP. The 2019 Plan and 2019 ESPP became effective on February 27, 2019.

Security Ownership of Certain Beneficial Owners

The following table sets forth certain information known to us regarding beneficial ownership of our capital stock outstanding as of February 27, 2020 for:

- each person, or group of affiliated persons, who is known by us to be the beneficial owner of five percent or more of our outstanding common stock;
- each of our directors;
- each of our named executive officers; and
- all of our current directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Under those rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power, and includes securities that the individual or entity has the right to acquire, such as through the exercise of stock options, within 60 days of December 31, 2019. Except as noted by footnote, and subject to community property laws where applicable, we believe, based on the information provided to us, that the persons and entities named in the table below have sole voting and investment power with respect to all common stock shown as beneficially owned by them.

Each individual or entity shown on the table has furnished information with respect to beneficial ownership. Except as otherwise indicated below, the address of each officer, director and five percent stockholder listed below is c/o Kaleido Biosciences, Inc., 65 Hayden Avenue, Lexington, MA 02421.

The percentage of beneficial ownership in the table below is based on 30,420,549 shares of common stock deemed to be outstanding as of February 27, 2020.

	COMMON STOCK BENEFICIALLY OWNED	
	SHARES	PERCENTAGE
5% or Greater Shareholders		
Flagship Pioneering Funds (1)	17,360,710	57%
FMR LCC (2)	2,086,907	7%
Directors, Named Executive Officers and Other Executive Officer		
Alison Lawton (3)	509,231	2%
Katharine Knobil, M.D. (4)	115,250	*
William Duke, Jr.	—	—%
Jerald Korn	—	—%
Michael Bonney (5)	1,813,928	6%
Bonnie Bassler, Ph.D (6)	12,500	*
Grady Burnett (7)	15,625	*
Theo Melas-Kyriazi	—	—%
Jean Mixer	—	—%
Anthony G. Quinn, M.D., Ph. D (8)	62,853	*
Geoffrey von Maltzahn, Ph. D (9)	342,466	1%
All executive officers and directors as a group (11 persons)	2,871,853	9%

* Less than one percent.

(1) Consists of (a) 2,244,305 shares of common stock held by Flagship Ventures Opportunities Fund I LP, (b) 6,560,523 shares of common stock held by Nutritional Health Disruptive Innovation Fund LP, (c) 2,500,000 shares of common stock held by Flagship VentureLabs V, LLC, (d) 216,451 shares of common stock held by Flagship Ventures Fund 2007 LP, (e) 947,111 shares of common stock held by Flagship Ventures Fund IV, LP, (f) 2,560,096 shares of common stock held by Flagship Ventures Fund V, LP, (g) 639,360 shares of common stock held by Nutritional Health Side Fund, LP, (h) 42,865 shares of common stock held by VenturesLabs IV, LLC, and (i) 1,649,999 shares of common stock held by Cadena LLC.

(2) The information in the table above concerning the number of shares beneficially owned by FMR LLC was obtained from a Schedule 13G filed with the SEC by FMR LLC on February 7, 2020 reporting beneficial ownership at February 6, 2020.

(3) Consists of (i) 165,000 shares of common stock and (ii) 344,231 shares of common stock underlying options exercisable within 60 days of December 31, 2019.

(4) Consists of 115,250 shares of common stock underlying options exercisable within 60 days of December 31, 2019.

(5) Consists of (i) 1,354,676 shares of common stock held directly by Mr. Bonney, (ii) 234,252 shares of common stock underlying options exercisable within 60 days of December 31, 2019 and (iii) 225,000 shares held in the Michael and Alison Bonney 2016 Irrevocable Trust, which has an independent trustee. Michael Bonney is a holder of 5% or more of our capital stock.

(6) Consists of 12,500 shares of common stock underlying options exercisable within 60 days of December 31, 2019.

(7) Consists of 15,625 shares of common stock underlying options exercisable within 60 days of December 31, 2019.

(8) Consists of 31,603 shares of common stock held directly by Dr. Quinn and (ii) 31,250 shares of common stock underlying options exercisable within 60 days of December 31, 2019.

(9) Consists of 342,466 shares of common stock held directly by Dr. von Maltzahn.

Communications with the Board of Directors

Stockholders who want to communicate with members of the Board, including the independent directors, individually or as a group, should address their communications to the Board, the Board members or the Board committee, as the case may be, and send them by mail is c/o Kaleido Biosciences, Inc., 65 Hayden Avenue, Lexington, MA 02421. The Chair of the Audit Committee will forward all such communications directly to such Board members. Any such communications may be made on an anonymous and confidential basis.

A copy of any such written communication may also be forwarded to the Company's legal counsel and a copy of such communication may be retained for a reasonable period of time. The director may discuss the matter with the Company's legal counsel, with independent advisors, with non-management directors, or with the Company's management, or may take other action or no action as the director determines in good faith, using reasonable judgment, and applying his or her own discretion.

The Audit Committee oversees the procedures for the receipt, retention, and treatment of complaints received by the Company regarding accounting, internal accounting controls, or audit matters, and the confidential, anonymous submission by employees of concerns regarding questionable accounting, internal accounting controls or auditing matters. The Company has also established a toll-free telephone number for the reporting of such activity, which is 866-290-6353.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates pursuant to a charter adopted by our board of directors. The composition and functioning of all of our committees complies with all applicable requirements of the Sarbanes-Oxley Act of 2002, Nasdaq and SEC rules and regulations applicable to us. We intend to comply with future requirements to the extent they become applicable to us.

The full text of our audit committee charter, compensation committee charter, and nominating and corporate governance charter are posted on the investor relations portion of our website at www.kaleido.com. We do not incorporate the information contained on, or accessible through, our corporate website into this Annual Report, and you should not consider it a part of this Annual Report.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The following is a description of transactions or series of transactions since January 1, 2018 through the year ended December 31, 2019, to which we were or will be a party, in which the amount involved in the transaction exceeds, or will exceed, the lesser of $120,000 or one percent of our total assets at December 31, 2019 and December 31, 2018.

Compensation arrangements for our named executive officers and our directors are described elsewhere in this Annual Report under "Director Compensation" and "Executive Compensation."

The Company receives professional services from its principal investor, Flagship Pioneering, from time to time as needed. The Company reported general and administrative expense totaling $0 and $0.2 million related to these services for the twelve months ended December 31, 2019 and December 31, 2018, respectively.

Private Placement of Securities

Stockholder	Shares of Series C Preferred Stock	Total Purchase Price
Flagship Pioneering Funds (1)	2,502,502	$ 24,999,995

(1) Flagship Pioneering Funds consists of Flagship Ventures Fund IV, L.P., Flagship Ventures Fund V, L.P., Nutritional Health Disruptive Innovation Fund, L.P., and Flagship Ventures Opportunities Fund I, L.P.

Series C preferred stock financing

At closings held from February 21, 2018 through June 8, 2018, we sold an aggregate of 10,107,404 shares of Series C Preferred Stock at a purchase price of $9.99 per share, pursuant to a stock purchase agreement entered into with certain of our investors. The table above summarizes purchases of Series C Preferred Stock by holders of 5% or more of our capital stock.

Participation in our Initial Public Offering

Certain of our directors, executive officers and our 5% stockholders purchased shares of our common stock in our IPO at the initial public offering price. The following table sets forth the number of shares of our common stock purchased by directors, executive officers and 5% stockholders and their affiliates and the aggregate purchase price paid for such shares.

	Shares of Common Stock Purchased	Aggregate Cash Purchase Price
Flagship Pioneering Funds (1)	933,333	$ 13,999,995
Michael Bonney	71,250	1,072,800

(1) Flagship Pioneering Funds consists of Flagship Ventures Fund V, L.P., Nutritional Health Disruptive Innovation Fund, L.P., and Flagship Ventures Opportunities Fund I, L.P.

Sublease agreement with VL45, Inc.

In January 2018, we entered into a sublease with VL45, Inc., or VL45, a company affiliated with our majority stockholder, for a portion of laboratory and office space in Cambridge, Massachusetts. The term of the sublease commenced on January 18, 2018 and terminated on October 31, 2018. In September 2018, we entered into a termination agreement with the landlord to terminate the lease for a payment of $100 effective October 31, 2018.

Amended and Restated Investors' Rights Agreement

We are a party to an amended and restated investors' rights agreement, or the Investors' Rights Agreement, dated as of February 21, 2018, with certain holders of our previously-outstanding preferred stock, including certain of our 5% stockholders and their affiliates and entities affiliated with certain of our officers and directors. The Investors' Rights Agreement provides these holders the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing.

Employment Agreements

We have entered into employment agreements with certain of our executive officers. See "Item 11-Executive Compensation—Employment Arrangements and Severance Agreements with our Named Executive Officers."

Equity Grants

We have granted stock options and warrants to certain of our executive officers and members of our board of directors. See "Item 11-Executive Compensation."

Indemnification Agreements

As permitted by Delaware law, provisions in our amended and restated certificate of incorporation and amended and restated bylaws limit or eliminate the personal liability of directors for a breach of their fiduciary duty of care as a director. In addition, we have entered into indemnification agreements with each of our executive officers and the members of our board of directors which may require us to indemnify them. See "Item 11-Executive Compensation—Limitations on Liability and Indemnification."

Policies for Approval of Related Party Transactions

Our board of directors has adopted a written related party transactions policy. Pursuant to this policy, the audit committee has the primary responsibility for reviewing and approving or disapproving "related party transactions," which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed $120,000 and in which a related person has or will have a direct or indirect material interest. For purposes of this policy, a related person will be defined as a director, executive officer, nominee for director, or

greater than 5% beneficial owner of our common stock, in each case since the beginning of the most recently completed year, and their immediate family members.

Director Independence

Under the Nasdaq listing rules, independent directors must comprise a majority of a listed company's board of directors within twelve months from the date of listing. In addition, the Nasdaq listing rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent within twelve months from the date of listing. Audit committee members must also satisfy additional independence criteria, including those set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended (the Exchange Act), and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under Nasdaq listing rules, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries, other than compensation for board service; or (2) be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board of directors must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director, and whether the director is affiliated with the company or any of its subsidiaries or affiliates.

In February 2019, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that all members of our board of directors, except Michael Bonney, Allison Lawton and Geoffrey von Maltzahn, are independent directors, including for purposes of Nasdaq and SEC rules. In making that determination, our board of directors considered the relationships that each director has with us and all other facts and circumstances the board of directors deemed relevant in determining independence, including the potential deemed beneficial ownership of our capital stock by each director, including non-employee directors that are affiliated with certain of our major stockholders. There are no family relationships among any of our directors or executive officers.

Committees of our Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates pursuant to a written charter adopted by our board of directors. The composition and functioning of all of our committees comply with all applicable requirements of the Sarbanes-Oxley Act of 2002, Nasdaq and SEC rules and regulations applicable to us.

Audit Committee

As of February 28, 2020, our audit committee consists of Theo Melas-Kyriazi, Jean Mixer and Grady Burnett and is chaired by Theo Melas-Kyriazi. Our board of directors has determined that each member of the committee is "independent" for audit committee purposes as that term is defined in the rules of the SEC and the applicable Nasdaq rules, and each of the committee members has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has designated each of Theo Melas-Kyriazi and Grady Burnett as an "audit committee financial expert," as defined under the applicable rules of the SEC. The functions of the audit committee include:

- appointing, approving the compensation of and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending based upon the audit committee's review and discussions with management and our independent registered public accounting firm whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing quarterly earnings releases.

The audit committee held 3 meetings during 2019. The audit committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq. A copy of the audit committee charter is available on our website at https://investors.kaleido.com/corporate-governance/documents-charters. We do not incorporate the information contained on, or accessible through, our corporate website into this Annual Report, and you should not consider it a part of this Annual Report.

Compensation Committee

As of February 28, 2020, our compensation committee consists of Jean Mixer, Theo Melas-Kyriazi and Anthony Quinn, M.D., Ph.D., and is chaired by and Anthony Quinn, M.D., Ph.D. Our board of directors has determined that each member of the compensation committee is "independent" as defined in the applicable Nasdaq rule. The functions of the compensation committee include:

- annually reviewing and recommending to the board of directors the corporate goals and objectives relevant to the compensation of our Chief Executive Officer;

- evaluating the performance of our Chief Executive Officer in light of such corporate goals and objectives and based on such evaluation (i) recommending to the board of directors the cash compensation of our Chief Executive Officer and (ii) recommending grants and awards to our Chief Executive Officer under equity-based plans;
- reviewing and approving or recommending to the board of directors the cash compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy and policy;
- overseeing and administering our compensation and similar plans;
- evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq rules;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and recommending to the board of directors the compensation of our directors;
- preparing the compensation committee report required by SEC rules, if and when required, to be included in our annual proxy statement; and
- reviewing and approving the retention, termination or compensation of any consulting firm or outside advisor to assist in the evaluation of compensation matters.

The compensation committee held 4 meetings during 2019. The compensation committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq. A copy of the compensation committee charter is available on our website at https://investors.kaleido.com/corporate-governance/documents-charters. We do not incorporate the information contained on, or accessible through, our corporate website into this Annual Report, and you should not consider it a part of this Annual Report.

Nominating and Corporate Governance Committee

As of February 28, 2020, our nominating and corporate governance committee consists of Bonnie L. Bassler and Grady Burnett and is chaired by Bonnie L. Bassler. The functions of the nominating and corporate governance committee include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;
- developing and recommending to the board of directors a code of business conduct and ethics and a set of corporate governance guidelines; and
- overseeing the evaluation of our board of directors and management.

The nominating and corporate committee held 1 meeting during 2019. The nominating and corporate committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq. A copy of the nominating and corporate committee charter is available on our website at https://investors.kaleido.com/corporate-governance/documents-charters. We do not incorporate the information contained on, or accessible through, our corporate website into this Annual Report, and you should not consider it a part of this Annual Report.

Compensation committee interlocks and insider participation

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Director Affiliations

Some of our directors are affiliated with and serve on the board of directors as representatives of entities which beneficially own or owned 5% or more of our common stock, as indicated below:

Name	Principal Stockholder
Geoffrey von Maltzahn, Ph.D	Flagship Pioneering Funds (1)
Theo Melas-Kyriazi	Flagship Pioneering Funds (1)

(1) Flagship Pioneering Funds consists of Flagship Ventures Fund IV, L.P., Flagship Ventures Fund V, L.P., Nutritional Health Disruptive Innovation Fund, L.P., and Flagship Ventures Opportunities Fund I, L.P.

Item 14. Principal Accounting Fees and Services

The Audit Committee has selected Deloitte & Touche LLP, or Deloitte, as our independent registered public accounting firm for the fiscal year ending December 31, 2019. In addition to retaining Deloitte to audit our consolidated financial statements for fiscal 2019, we engaged the firm from time to time during the year to perform other services.

The following table sets forth the aggregate fees billed by Deloitte in connection with services rendered during the last two fiscal years.

	For the Year Ended December 31,	
	2019	2018
Audit fees	$ 357,419	$ 202,326
Audit-related fees	133,778	380,904
Tax fees	—	—
Other fees	1,895	1,895
	$ 493,092	$ 585,125

Audit Fees consist of fees for professional services rendered in connection with the audit of our annual consolidated financial statements, the review of the interim consolidated financial statements included in quarterly reports and services that are normally provided by Deloitte, such as comfort letters, in connection with statutory and regulatory filings or engagements.

Audit-Related Fees consist of fees for accounting consultations and other services that were reasonable related to the performance of audits or reviews of our financial statements and were not reported above under “Audit Fees”.

All Other Fees consist of fees billed for products and services provided by the independent registered public accounting firm other than those disclosed above.

In fiscal 2019 and 2018, no services other than those discussed above were provided by Deloitte.

The Audit Committee has adopted a policy requiring pre-approval of all audit and non-audit related services to be performed by the Company’s independent auditor regardless of amount. These services may include audit services, audit-related services, tax services and other related services. Deloitte and management are required to periodically report to the Audit Committee regarding the extent of services provided by Deloitte in accordance with this pre-approval and the fees for the services performed to date. The Audit Committee may also pre-approve particular services on a case-by-case basis.

The Audit Committee annually evaluates the qualifications, performance and independence of the Company’s independent registered public accounting firm. It selected Deloitte as the Company’s independent registered public

accounting firm for 2019. This selection was subsequently approved by the board of directors. The Audit Committee has reviewed and discussed with management and with Deloitte the Company's audited consolidated financial statements for the year ended December 31, 2019. In addition, the Audit Committee has discussed with Deloitte the matters that independent registered public accounting firms must communicate to audit committees under applicable PCAOB standards.

The Audit Committee has also discussed and confirmed with Deloitte its independence from the Company and received all written disclosures and correspondence required by the PCAOB Ethics and Independence requirements. The Audit Committee has evaluated and concluded the non-audit services provided by Deloitte to the Company do not impair Deloitte's independence.

Based on the reviews and discussions referred to above, the Audit Committee recommended to our board of directors that the audited consolidated financial statements for the year ended December 31, 2019 and the related footnotes be included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) 1. *Financial Statements*

For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page 104 of this Annual Report on Form 10-K, incorporated into this Item by reference.

2. *Financial Statement Schedules*

Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

3. *Exhibits*

The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report on Form 10-K are listed in the Exhibit Index below. The exhibits listed in the Exhibit Index are incorporated by reference herein.

(b) Exhibit Index

Exhibit No.	Exhibit Index
1.1	Form of Underwriting Agreement (incorporated by reference to Exhibit 1.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-229204) filed on January 11, 2019).
3.1	Amended and Restated Certificate of Incorporation of the Registrant, dated March 4, 2019 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38822) filed on March 4, 2019).
3.2	Amended and Restated By-laws of the Registrant, dated February 27, 2019 (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-38822) filed on March 4, 2019).
4.1	Second Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated February 21, 2018 (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-229204) filed on January 11, 2019).
4.2	Specimen Stock Certificate evidencing shares of common stock (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1/A (File No. 333-229204) filed on February 19, 2019).
4.3*	Description of Registrant's Securities.
10.1§	Umbrella Development Services Agreement, by and between Patheon UK Limited and the Registrant, dated September 6, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1/A (File No. 333-229204) filed on February 19, 2019).
10.2#	2015 Stock Incentive Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1/A (File No. 333-229204) filed on February 19, 2019).
10.3#	2019 Stock Option and Incentive Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1/A (File No. 333-229204) filed on February 19, 2019).
10.4#	Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1/A (File No. 333-229204) filed on February 19, 2019).
10.5#	2019 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1/A (File No. 333-229204) filed on February 19, 2019).
10.6#	Form of Indemnification Agreement between the Registrant and each of its directors (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1/A (File No. 333-229204) filed on February 19, 2019).
10.7#	Form of Indemnification Agreement between the Registrant and each of its executive officers (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1/A (File No. 333-229204) filed on February 19, 2019).
10.8#	Employment Agreement between the Registrant and Michael Bonney, dated January 24, 2019 (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1/A (File No. 333-229204) filed on February 19, 2019).

10.9#	Employment Agreement between the Registrant and Alison Lawton, dated January 24, 2019 (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1/A (File No. 333-229204) filed on February 19, 2019).
10.10#	Employment Agreement between the Registrant and Joshua Brumm, dated January 24, 2019 (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1/A (File No. 333-229204) filed on February 19, 2019).
10.11#	Consulting Agreement between the Registrant and Joshua Brumm, dated September 26, 2019 (incorporated by reference to Exhibit 10.1 to the Registrants Quarterly Report on Form 10-Q (File No. 001-38822) filed on October 30, 2019).
10.12#	Employment Agreement between the Registrant and Katharine Knobil, M.D., dated January 24, 2019 (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1/A (File No. 333-229204) filed on February 19, 2019).
10.13*	Employment Agreement between the Registrant and William Duke, Jr., dated December 2, 2019.
10.14	Loan and Security Agreement between the Registrant and Pacific Western Bank, dated December 21, 2015, as amended (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-229204) filed on January 11, 2019).
10.15	Lease Agreement by and between HCP/King Hayden Campus LLC and the Registrant, dated March 19, 2018 (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-229204) filed on January 11, 2019).
10.16	Lease Agreement by and between DIV Bedford, LLC and the Registrant, dated May 15, 2017 (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-229204) filed on January 11, 2019).
10.17	Credit Agreement, dated October 25, 2019, by and among Kaleido Biosciences, Inc., Cadena Bio, Inc, and JPMorgan Chase Bank, N.A. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38822) filed on October 30, 2019).
10.18	Credit Agreement, dated December 31, 2019, by and among Kaleido Biosciences, Inc., Cadena Bio, Inc., and Hercules Capital (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38822) filed on January 3, 2020).
21.1*	Subsidiaries of the Registrant
23.1 *	Consent of Deloitte and Touche LLP, Independent Registered Public Accounting Firm
31.1*	Certification of Chief Executive Officer, pursuant to Rule 13a-14(a) or 15(d)-14(1) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer, pursuant to Rule 13a-14(a) or 15(d)-14(1) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document.

101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

† This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

# Indicates a management contract or any compensatory plan, contract or arrangement.

§ Confidential treatment has been granted with respect to redacted portions of this exhibit. Redacted portions of this exhibit have been filed separately with the Securities and Exchange Commission.

Item 16. Form 10-K Summary

The Company has elected not to include summary information.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

KALEIDO BIOSCIENCES, INC.

By: /s/ Alison Lawton

Alison Lawton

Chief Executive Officer, President and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Alison Lawton Alison Lawton	Chief Executive Officer, President and Director (Principal Executive Officer)	March 2, 2020
/s/ William Duke, Jr. William Duke, Jr.	Chief Financial Officer (Principal Financial and Accounting Officer)	March 2, 2020
/s/ Michael Bonney Michael Bonney	Executive Chair	March 2, 2020
/s/ Theo Melas-Kyriazi Theo Melas-Kyriazi	Director	March 2, 2020
/s/Bonnie Bassler Bonnie Bassler, Ph.D.	Director	March 2, 2020
/s/ Grady Burnett Grady Burnett	Director	March 2, 2020
/s/ Jean Mixer Jean Mixer	Director	March 2, 2020
/s/Anthony G. Quinn Anthony G. Quinn, M.D., Ph.D.	Director	March 2, 2020
/s/ Geoffrey von Maltzahn Geoffrey von Maltzahn, Ph.D.	Director	March 2, 2020

Exhibit 4.3

Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended

The summary of the general terms and provisions of the registered securities of Kaleido Biosciences, Inc. ("Kaleido" "we," or "our") set forth below does not purport to be complete and is subject to and qualified in its entirety by reference to our Amended and Restated Certificate of Incorporation (our "certificate of incorporation") and our Amended and Restated By-laws (our "by-laws" and, together with our certificate of incorporation, our "Charter Documents"), each of which is incorporated by reference as an exhibit to our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission. We encourage you to read our Charter Documents and the applicable provisions of the General Corporation Law of the State of Delaware (the "DGCL") for additional information.

Authorized Capital Stock

Our authorized capital stock consists of One Hundred Sixty Million (160,000,000) shares of common stock, $0.001 par value per share, and Ten Million (10,000,000) shares of preferred stock, $0.001 par value per share.

Common stock

We are authorized to issue one class of common stock. Only our common stock is registered under Section 12 of the Securities Exchange Act of 1934, as amended.
Our common stock is listed on the Nasdaq Global Market under the trading symbol "KLDO".

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

Voting

Under the provisions of our certificate of incorporation, holders of our common stock are entitled to one vote for each share of common stock held of record for the election of directors and on all matters submitted to a vote of stockholders. Our certificate of incorporation does not provide cumulative voting rights to holders of our common stock.

Our by-laws provide that, except as required by law or our Charter Documents, all matters will be decided by the vote of the majority of the votes properly cast for such matter.

Dividends

Holders of our common stock are entitled to receive dividends ratably, if any, as may be declared by our board of directors out of legally available funds, subject to any preferential dividend rights of any preferred stock then outstanding.

Other Rights

Upon our dissolution, liquidation or winding up, holders of our common stock are entitled to share ratably in our net assets legally available after the payment of all our debts and other liabilities, subject to the preferential rights of any preferred stock then outstanding. Holders of our common stock have no

preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of 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 and issue in the future. Except as described under "Anti-takeover effects of Delaware Law, our certificate of incorporation and our by-laws" below, a majority vote of the holders of common stock is generally required to take action under our certificate of incorporation and by-laws.

Preferred stock

Our board of directors is authorized, without action by the stockholders, to designate and issue up to an aggregate of 10,000,000 shares of preferred stock in one or more series. Our board of directors can designate the rights, preferences and privileges of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of common stock. The issuance of preferred stock, while providing flexibility in connection with possible future financings and acquisitions and other corporate purposes could, under certain circumstances, have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying, deferring or preventing a change in control of our company, which might harm the market price of our common stock. See also "Anti-takeover effects of Delaware Law, our certificate of incorporation and our by-laws" and "Undesignated preferred stock" below.

Our board of directors will make any determination to issue such shares based on its judgment as to our Company's best interests and the best interests of our stockholders. We have no shares of preferred stock outstanding as of the date of our Annual Report on Form 10-K with which this Exhibit is filed as an exhibit and we have no current plans to issue any shares of preferred stock.

Anti-takeover effects of Delaware Law, our certificate of incorporation and our by-laws

Certain provisions of the DGCL and our Charter Documents could have the effect delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board composition and filling vacancies

Our certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No written consent of stockholders

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take

stockholder actions and would prevent the amendment of our by-laws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of stockholders

Our certificate of incorporation and by-laws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our by-laws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance notice requirements

Our by-laws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our by-laws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to certificate of incorporation and by-laws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability and the amendment of our by-laws and certificate of incorporation must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our by-laws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the by-laws, and may also be amended by the affirmative vote of at least two-thirds of the outstanding shares entitled to vote on the amendment, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated preferred stock

Our certificate of incorporation provides for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of convertible preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of convertible preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of convertible preferred stock. The issuance of shares of convertible preferred stock could decrease the amount of earnings and assets available for distribution to holders of

shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Choice of forum

Our by-laws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claim for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or by-laws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or by-laws; or (5) any action asserting a claim governed by the internal affairs doctrine.

Our by-laws also provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provisions contained in our by-laws are inapplicable or unenforceable if they are challenged in a proceeding or otherwise. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation and by-laws has been challenged in legal proceedings.

Delaware takeover statute

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which 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 commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Exhibit 10.13

KALEIDO BIOSCIENCES, INC.

EMPLOYMENT AGREEMENT

This Employment Agreement ("Agreement") is made on or before December 2, 2019, between Kaleido Biosciences, Inc., a Delaware corporation (the "Company"), and William Duke (the "Employee") and is effective as of the date executed by the parties hereto (the "Effective Date"). In consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Employment.

(a) Term. The term of this Agreement shall commence on the Effective Date and continue until terminated in accordance with the provisions hereof (the "Term"). The Employee's employment with the Company will be "at will," meaning that the Employee's employment may be terminated by the Company or the Employee at any time and for any reason subject to the terms of this Agreement.

(b) Position and Duties. During the Term, the Employee shall serve as the Company's Chief Financial Officer (CFO), reporting to the Chief Executive Officer (CEO) of the Company. The Employee shall devote his full working time and efforts to the business and affairs of the Company. Notwithstanding the foregoing, the Employee may serve on other boards of directors, with the advance written approval of the CEO, or engage in religious, charitable or other community activities as long as such services and activities do not interfere with the Executive's performance of his duties to the Company as provided in this Agreement.

2. Compensation and Related Matters.

(a) Base Salary. The Company shall pay the Employee an initial base salary of $420,000, subject to annual review by the Compensation Committee (the "Compensation Committee") of the Company's Board of Directors ("Board"). The base salary in effect at any given time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices.

(b) Performance Bonus. In addition to the foregoing, the Employee will be paid a one-time bonus of $100,000 less applicable taxes (the "Performance Bonus"), contingent upon either: (i) successfully securing a capital raise on or before June 30, 2020; or (ii) the Company successfully securing funding through means other than a capital raise (e.g., a Change of Control as defined in Section 6(c) or a significant partnership) such that the Company determines a capital raise prior to June 30, 2020 is no longer in the best interest of the Company.

The Employee will repay the Bonus to the Company if the Employee voluntarily terminates employment with the Company or is terminated for cause (as determined by the Company) during the first 12 months of your employment. That amount may be collected by the Company, either directly or indirectly, from any (i) payment of any kind due to the Employee from the Company including, without limitation, accrued wages, vacation, final wages, and expense reimbursements to the fullest extent permitted by applicable law; and/or (ii) the forfeiture or cancellation of any equity interest owned by the Employee to the Company or any subsidiary or affiliate thereof, whether now existing or hereafter formed, and regardless of the form such equity interest (e.g., common units, options to acquire common units or otherwise).

(c) Incentive Compensation. During the Term, the Employee shall be eligible to receive cash incentive compensation as determined by the Board or the Compensation Committee from time to time, in accordance with Company's bonus program. The Company will initially target the Employee's Incentive Bonus at 40% of his Base Salary with eligibility starting in the Company's 2020 plan year. The actual incentive target and any Incentive Bonus is discretionary and will be subject to the Company's assessment of the Employee' performance, as well as business conditions at the Company. The Incentive Bonus also will be subject to approval by and adjustment at the discretion of the Company and the terms of any applicable incentive plan. Any Incentive Bonus will be paid by March 15 of the year following the year in which it is earned. Except as otherwise provided in Section 4(b)(i) below or the Company's bonus program, to earn incentive compensation, the Employee must be employed by the Company on the day such incentive compensation is paid.

(d) Equity. Following the Date of Hire, the Company will recommend to the Board of Directors (the "Board"), that the Employee be eligible to participate in Kaleido's equity incentive program and be granted, at such time as the Board determines, an option to purchase 270,000 shares of common stock (such equity award is referred to as the "Equity Award"). Subject to the Board's approval of the Equity Award, the Equity Award will vest according to the following schedule: 25% of the Equity Award will vest on the first anniversary of the Date of Hire, and the remaining 75% of the Equity Award will vest in equal installments at the end of each calendar quarter over the next three years, provided that, in each case, that the Employee continues to provide continuous services to the Company as of each such vesting date. The grant of the Equity Award will be conditioned upon, among other things, the Employee's execution of all necessary documentation relating to the Equity Award as determined by the Company (all such documentation is collectively referred to as the "Equity Award Documentation"). In all respects, these options will be governed by the 2019 Stock Option and Incentive Plan and the applicable Stock Option Agreement.

(e) Expenses. The Employee shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by him during the Term in performing services hereunder, in accordance with the policies and procedures then in effect and established by the Company.

(f) Vacation. During the Term, the Employee shall be entitled to paid vacation in accordance with the Company's policies and procedures. The Employee shall also be entitled to all paid holidays given by the Company in accordance with the policies and procedures then in effect and established by the Company.

(g) Other Benefits. During the Term, the Employee shall be eligible to participate in or receive benefits under the Company's employee benefit plans in effect from time to time, subject to the terms of such plans.

3. Termination. During the Term, the Employee's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. The Employee's employment hereunder shall terminate upon his death.

(b) Disability. The Company may terminate the Employee's employment if he is disabled and unable to perform the essential functions of the Employee's then existing position or positions under this Agreement with or without reasonable accommodation for a period of 180 days (which need not be consecutive) in any 12-month period. If any question shall arise as to whether during any period the Employee is disabled so as to be unable to perform the essential functions of the Employee's then existing position or positions with or without reasonable accommodation, the Employee may, and at the request of the Company shall, submit to the Company a certification in reasonable detail by a physician selected by the Company to whom the Employee or the Employee's guardian has no reasonable objection as to whether the Employee is so disabled or how long such disability is expected to continue, and such certification shall for the purposes of this Agreement be conclusive of the issue. The Employee shall cooperate with any reasonable request of the physician in connection with such certification. If such question shall arise and the Employee shall fail to submit such certification, the Company's determination of such issue shall be binding on the Employee. Nothing in this Section 3(b) shall be construed to waive the Employee's rights, if any, under existing law including, without limitation, the Family and Medical Leave Act of 1993, 29 U.S.C. §2601 *et seq*. and the Americans with Disabilities Act, 42 U.S.C. §12101 *et seq*.

(c) Termination for Cause. The Company may terminate the Employee's employment hereunder for Cause. For purposes of this Agreement, "Cause" shall mean: (i) conduct by the Employee constituting a material act of misconduct in connection with the performance of his duties, including, without limitation, misappropriation of funds or property of the Company or any of its subsidiaries or affiliates other than the occasional, customary and de minimis use of Company property for personal purposes; (ii) the commission by the Employee of any felony or a misdemeanor involving moral turpitude, deceit, dishonesty or fraud, or any conduct by the Employee that would reasonably be expected to result in material injury or reputational harm to the Company or any of its subsidiaries or affiliates if he were retained in his position; (iii) continued non-performance by the Employee of his duties hereunder (other than by reason of the Employee's physical or mental illness, incapacity or disability) which has continued for more than 30 days following written notice of such non-performance from the CEO; (iv) a breach by the Employee of any of the provisions contained in Section 7 of this Agreement; (v) a material violation by the Employee of the Company's written employment policies; or (vi) failure to cooperate with a bona fide internal investigation or an investigation by regulatory or law enforcement authorities, after being instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation.

(d) Termination Without Cause. The Company may terminate the Employee's employment hereunder at any time without Cause. Any termination by the Company of the Employee's employment under this Agreement which does not constitute a termination for Cause under Section 3(c) and does not result from the death of the Employee under Section 3(a) or the disability of the Employee under Section 3(b) shall be deemed a termination without Cause.

(e) Termination by the Employee. The Employee may terminate his employment hereunder at any time for any reason, including but not limited to Good Reason. For purposes of this Agreement, "Good Reason" shall mean that the Employee has complied with the "Good Reason Process" (hereinafter defined) following the occurrence of any of the following events: (i) a material diminution in the Employee's responsibilities, authority or duties, provided that the hiring by the Company of any Company officers with customary responsibilities, authority or duties, will not constitute any such material diminution; (ii) a material diminution in the Employee's Base Salary except for across-the-board salary reductions based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company; (iii) a material change in the geographic location at which the Employee provides services to the Company, except for required travel for the Company's business; or (iv) the material breach of this Agreement by the Company. "Good Reason Process" shall mean that (i) the Employee reasonably determines in good faith that a "Good Reason" condition has occurred; (ii) the Employee notifies the Company in writing of the first occurrence of the Good Reason condition within 60 days of the first occurrence of such condition; (iii) the Employee cooperates in good faith with the Company's efforts, for a period not less than 30 days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) the Employee terminates his employment within 60 days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

(f) Notice of Termination. Except for termination as specified in Section 3(a), any termination of the Employee's employment by the Company or any such termination by the Employee shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon.

(g) Date of Termination. "Date of Termination" shall mean: (i) if the Employee's employment is terminated by his death, the date of his death; (ii) if the Employee's employment is terminated by the Company on account of the Employee's disability under Section 3(b) or by the Company for Cause under Section 3(c), the date on which a Notice of Termination is given; (iii) if the Employee's employment is terminated by the Employee under Section 3(e) without Good Reason, 30 days after the date on which a Notice of Termination is given, and (iv) if the Employee's employment is terminated by the Employee under Section 3(e) with Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period. Notwithstanding the foregoing, in the event that the Employee gives a Notice of Termination to the Company, the Company may unilaterally accelerate the Date of Termination and such acceleration shall not result in a termination by the Company for purposes of this Agreement.

4. Compensation Upon Termination.

(a) Termination Generally. If the Employee's employment with the Company is terminated for any reason, the Company shall pay or provide to the Employee (or to his authorized representative or estate) (i) any Base Salary earned through the Date of Termination, unpaid expense reimbursements (subject to, and in accordance with, Section 2(d) of this Agreement) and unused vacation, if applicable in accordance with the Company's policy, that accrued through the Date of Termination on or before the time required by law but in no event more than 30 days after the Employee's Date of Termination; and (ii) any vested benefits the Employee may have under any employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans (collectively, the "Accrued Benefit").

(b) Termination by the Company Without Cause or by the Employee with Good Reason. During the Term, if the Employee's employment is terminated by the Company without Cause as provided in Section 3(d), or the Employee terminates his employment for Good Reason as provided in Section 3(e), then the Company shall pay the Employee his Accrued Benefit. In addition, subject to the Employee signing a separation agreement containing, among other provisions, a general release of claims in favor of the Company and related persons and entities, confidentiality, return of property and non-disparagement, in a form and manner satisfactory to the Company (the "Separation Agreement and Release") and the Separation Agreement and Release becoming irrevocable and fully effective, all within 60 days after the Date of Termination (or such shorter time period provided in the Separation Agreement and Release):

(i) The Company shall pay the Employee an amount equal to twelve (12) months of the Employee's Base Salary plus an amount equal to the incentive compensation paid to the Employee pursuant to Section 2(c) above during the year prior to the year of termination (the "Severance Amount"). Notwithstanding the foregoing, if the Employee breaches any of the provisions contained in Section 7 of this Agreement, all payments of the Severance Amount shall immediately cease;

(ii) Notwithstanding any provision in the Equity Documents to the contrary, and subject to the Employee's compliance with the provisions contained in Section 7 of this Agreement, the Company shall extend the period during which the Employee can exercise any of his vested options to purchase stock in the Company until the anniversary of the Employee's Date of Termination;

(iii) If the Employee was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Employee a monthly cash payment for twelve (12) months or the Employee's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Employee if the Employee had remained employed by the Company; and

(iv) the amounts payable under Section 4(b)(i) and (iii) shall be paid out in substantially equal installments in accordance with the Company's payroll practice commencing within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

5. Change in Control Payment. The provisions of this Section 5 set forth certain terms of an agreement reached between the Employee and the Company regarding the Employee's rights and obligations upon the occurrence of a Change in Control of the Company. These provisions are intended to assure and encourage in advance the Employee's continued attention and dedication to his assigned duties and his objectivity during the pendency and after the occurrence of any such event. These provisions shall apply in lieu of, and expressly supersede, the provisions of Section 4(b) regarding severance pay and benefits upon a termination of employment, if such termination of employment occurs within fifteen (15) months after the occurrence of the first event constituting a Change in Control. These provisions shall terminate and be of no further force or effect beginning fifteen (15) months after the occurrence of a Change in Control.

(a) Change in Control. During the Term, if within fifteen (15) months after a Change in Control, the Employee's employment is terminated by the Company without Cause as provided in Section 3(d) or the Employee terminates his employment for Good Reason as provided in Section 3(e), then, subject to the signing of the Separation Agreement and Release by the Employee and the Separation Agreement and Release becoming irrevocable and fully effective, all within 60 days after the Date of Termination (or such shorter time period provided in the Separation Agreement and Release):

(i) the Company shall pay the Employee a lump sum in cash in an amount equal to 1.5 times the sum of (A) the Employee's current Base Salary (or the Employee's Base Salary in effect immediately prior to the Change in Control, if higher) plus (B) the target incentive compensation established for the Employee in the fiscal year of termination; and if no such target has been established, the target incentive compensation established for the Employee in the fiscal year prior to the year of termination;

(ii) notwithstanding anything to the contrary in any applicable option agreement or stock-based award agreement, all stock options and other stock-based awards held by the Employee (the "Equity Awards") shall immediately accelerate and become fully exercisable or nonforfeitable as of the later of (x) the Date of Termination or (y) the Effective Date of the Separation Agreement and Release (the "Accelerated Vesting Date"); *provided* that any termination or forfeiture of the unvested portion of such Equity Awards that would otherwise occur on the Date of Termination in the absence of this Agreement will be delayed until the Effective Date of the Separation Agreement and Release and will only occur if the vesting pursuant to this subsection does not occur due to the absence of the Separation Agreement and Release becoming fully effective within the time period set forth therein. Notwithstanding the foregoing, no additional vesting of the Equity Awards shall occur during the period between the Employee's Date of Termination and the Accelerated Vesting Date; and

(iii) if the Employee was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Employee a monthly cash payment for eighteen (18) months or the Employee's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Employee if the Employee had remained employed by the Company; and

(iv) The amounts payable under Section 5(a)(i) and (iii) shall be paid or commence to be paid within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payment shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period.

(b) Additional Limitation.

(i) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Employee, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Internal Revenue Code of 1986, as amended (the "Code") and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Employee becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in the Employee receiving a higher After Tax Amount (as defined below) than the Employee would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(ii) For purposes of this Section 5(b), the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Employee as a result of the Employee's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Employee shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 5(b)(i) shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and the Employee within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Employee. Any determination by the Accounting Firm shall be binding upon the Company and the Employee.

(c) Definitions. For purposes of this Section 5, the following terms shall have the following meanings:

"Change in Control" shall mean any of the following:

(i) any "person," as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Act") (other than the Company, any of its subsidiaries, or any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of the Company or any of its subsidiaries), together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Act) of such person, shall become the "beneficial owner" (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, of securities of the Company representing 50 percent or more of the combined voting power of the Company's then outstanding securities having the right to vote in an election of the Board ("Voting Securities") (in such case other than as a result of an acquisition of securities directly from the Company); or

(ii) the date a majority of the members of the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election; or

(iii) the consummation of (A) any consolidation or merger of the Company where the stockholders of the Company, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, shares representing in the aggregate more than 50 percent of the voting shares of the Company issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any), or (B) any sale or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of the Company and its affiliates on a consolidated basis.

Notwithstanding the foregoing, a "Change in Control" shall not be deemed to have occurred for purposes of the foregoing clause (i) solely as the result of an acquisition of securities by the Company which, by reducing the number of shares of Voting Securities outstanding, increases the proportionate number of Voting Securities beneficially owned by any person to 50 percent or more of the combined voting power of all of the then outstanding Voting Securities; provided, however, that if any person referred to in this sentence shall thereafter become the beneficial owner of any additional shares of Voting Securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from the Company) and immediately thereafter beneficially owns 50 percent or more of the combined voting power of all of the then outstanding Voting Securities, then a "Change in Control" shall be deemed to have occurred for purposes of the foregoing clause (i).

6. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of the Employee's separation from service within the meaning of Section 409A of the Code, the Company determines that the Employee is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Employee becomes entitled to under this Agreement on account of the Employee's separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after the Employee's separation from service, or (B) the Employee's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Employee during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Employee's termination of employment, then such payments or benefits shall be payable only upon the Employee's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to the Employee or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

7. Confidential Information, Noncompetition and Cooperation. The terms of the Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement (the "Restrictive Covenant Agreement"), between the Company and the Employee, attached hereto as Exhibit A, shall continue to be in full force and effect and are incorporated by reference in this Agreement. The Employee hereby reaffirms the terms of the Restrictive Covenant Agreement as material terms of this Agreement.

(a) Litigation and Regulatory Cooperation. During and after the Employee's employment, the Employee shall cooperate fully with the Company in the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while the Employee was employed by the Company. The Employee's full cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after the Employee's employment, the Employee also shall cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Employee was employed by the Company. The Company shall reimburse the Employee for any reasonable out-of-pocket expenses incurred in connection with the Employee's performance of obligations pursuant to this Section 7(a).

(b) Relief. The Employee agrees that it would be difficult to measure any damages caused to the Company which might result from any breach by the Employee of the promises set forth in this Section 7, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, subject to Section 8 of this Agreement, the Employee agrees that if the Employee breaches, or proposes to breach, any portion of this Agreement, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company. In addition, in the event the Employee breaches this Section 7 during a period when he is receiving severance benefits pursuant to Section 4 or Section 5 hereof, the Company shall have the right to suspend or terminate such severance benefits. Such suspension or termination shall not limit the Company's other options with respect to relief for such breach and shall not relieve the Employee of his duties under this Agreement.

(c) Protected Disclosures and Other Protected Action. Nothing contained in this Agreement limits the Employee's ability to communicate with any federal, state or local governmental agency or commission, including to provide documents or other information, without notice to the Company.

8. Arbitration of Disputes. Any controversy or claim arising out of or relating to this Agreement or the breach thereof or otherwise arising out of the Employee's employment or the termination of that employment (including, without limitation, any claims of unlawful employment discrimination whether based on age or otherwise) shall, to the fullest extent permitted by law, be settled by arbitration in any forum and form agreed upon by the parties or, in the absence of such an agreement, under the auspices of the American Arbitration Association ("AAA") in Boston, Massachusetts in accordance with the Employment Dispute Resolution Rules of the AAA, including, but not limited to, the rules and procedures applicable to the selection of arbitrators. In the event that any person or entity other than the Employee or the Company may be a party with regard to any such controversy or claim, such controversy or claim shall be submitted to arbitration subject to such other person or entity's agreement. Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. This Section 8 shall be specifically enforceable. Notwithstanding the foregoing, this Section 8 shall not preclude either party from pursuing a court action for the sole purpose of obtaining a temporary restraining order or a preliminary injunction in circumstances in which such relief is appropriate; provided that any other relief shall be pursued through an arbitration proceeding pursuant to this Section 8.

9. Consent to Jurisdiction. To the extent that any court action is permitted consistent with or to enforce Section 8 of this Agreement, the parties hereby consent to the jurisdiction of the Superior Court of the Commonwealth of Massachusetts and the United States District Court for the District of Massachusetts. Accordingly, with respect to any such court action, the Employee (a) submits to the personal jurisdiction of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

10. Integration. This Agreement, including the Restrictive Covenant Agreement, constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements between the parties concerning such subject matter, including the Prior Agreement.

11. Withholding. All payments made by the Company to the Employee under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law.

12. Successor to the Employee. This Agreement shall inure to the benefit of and be enforceable by the Employee's personal representatives, executors, administrators, heirs, distributees, devisees and legatees. In the event of the Employee's death after his termination of employment but prior to the completion by the Company of all payments due to him under this Agreement, the Company shall continue such payments to the Employee's beneficiary designated in writing to the Company prior to his death (or to his estate, if the Employee fails to make such designation).

13. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

14. Survival. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of the Employee's employment to the extent necessary to effectuate the terms contained herein.

15. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

16. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Employee at the last address the Employee has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

17. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Employee and by a duly authorized representative of the Company.

18. Governing Law. This is a Massachusetts contract and shall be construed under and be governed in all respects by the laws of the Commonwealth of Massachusetts without giving effect to the conflict of laws principles thereof.

19. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

20. Successor to Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company expressly to assume and agree to perform this Agreement to the same extent that the Company would be required to perform it if no succession had taken place. Failure of the Company to obtain an assumption of this Agreement at or prior to the effectiveness of any succession shall be a material breach of this Agreement.

21. Gender Neutral. Wherever used herein, a pronoun in the masculine gender shall be considered as including the feminine gender unless the context clearly indicates otherwise.

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the date and year first above written.

KALEIDO BIOSCIENCES, INC.

By: /s/ Alison Lawton
Its: CEO and President

EMPLOYEE

/s/ William Duke
William Duke

Exhibit 21.1

SUBSIDIARIES

Subsidiary	Jurisdiction of Incorporation
Cadena Bio, Inc.	Delaware
Kaleido Biosciences Securities Corporation	Massachusetts

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement No. 333-230167 on Form S-8 of our report dated March 2, 2020 relating to the financial statements of Kaleido Biosciences, Inc., appearing in this Annual Report on Form 10-K for the year ended December 31, 2019.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 2, 2020

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Alison Lawton, certify that:

1.I have reviewed this annual report on Form 10-K of Kaleido Biosciences, Inc.;

2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f)and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2020

By: /s/ Alison Lawton
Alison Lawton
Chief Executive Officer, President and Director
(Principal Executive Officer)

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, William Duke, Jr., certify that:

1.I have reviewed this annual report on Form 10-K of Kaleido Biosciences, Inc.;

2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f)and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2020

By: /s/ William Duke, Jr.
William Duke, Jr.
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Alison Lawton, Chief Executive Officer of Kaleido Biosciences, Inc. (the "Company"), do hereby certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that, to the best of my knowledge:

(1) the Annual Report on Form 10-K of the Company for the year ended December 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 2, 2020

/s/ Alison Lawton
Alison Lawton
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, William Duke, Jr., Chief Financial Officer of Kaleido Biosciences, Inc. (the "Company"), do hereby certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that, to the best of my knowledge:

(1) the Annual Report on Form 10-K of the Company for the year ended December 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 2, 2020

/s/ William Duke, Jr.
William Duke, Jr.
Chief Financial Officer
(Chief Financial Officer)