Table of Contents

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

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: 001-39634

Foghorn Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**47-5271393** **(I.R.S. Employer Identification Number)**
500 Technology Square, Ste 700 **Cambridge, Massachusetts** **(Address of principal executive offices)**	**02139** **(Zip Code)**

Registrant's telephone number, including area code: 617-586-3100

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, $0.0001 Par Value	**FHTX**	**The Nasdaq Global 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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

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

As of June 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter, there was no established public market for the registrant's Common Stock. The registrant's Common Stock began trading on the NASDAQ Global Market on October 23, 2020. The aggregate market value of Common Stock held by non-affiliates of the registrant computed by reference to the price of the registrant's Common Stock as of October 23, 2020 (based on the last reported sale price on the NASDAQ Global Market as of such date) was $291.7 million.

As of January 31, 2021 there were 36,816,714 shares of the registrant's Common Stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2021 Annual Meeting of Stockholders, which the registrant intends to file with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2020, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Foghorn Therapeutics Inc.
Index

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. All statements other than statements of historical facts contained in this Annual Report on Form 10-K are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning:

- the initiation, timing, progress and results of our research and development programs, preclinical and clinical studies;
- our ability to advance any product candidates that we may develop and successfully complete preclinical and clinical studies;
- our ability to leverage our initial programs to develop additional product candidates using our Gene Traffic Control platform;
- the impact of the COVID-19 pandemic on our and our collaborators' business operations, including our research and development programs and preclinical and clinical studies;
- developments related to our competitors and our industry;
- our ability to expand the target populations of our programs and the availability of patients for clinical testing;
- our ability to obtain regulatory approval for FHD-286, FHD-609 and any future product candidates from the U.S. Food and Drug Administration, or FDA, and other regulatory authorities;
- our ability to identify and enter into future license agreements and collaborations;
- our ability to continue to rely on our contract development and manufacturing organizations, or CDMOs, and contract research organizations, or CROs, for our manufacturing and research needs;
- regulatory developments in the United States and foreign countries;
- our ability to attract and retain key scientific and management personnel; and
- the scope of protection we are able to establish, maintain and enforce for intellectual property rights covering FHD-286, FHD-609, our future products and our Gene Traffic Control platform.

The forward-looking statements in this Annual Report on Form 10-K are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the section entitled "Item 1A. Risk Factors" in this Annual Report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. Moreover, we operate in an evolving environment. New risks and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

SUMMARY OF RISK FACTORS

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary and other risks that we face can be found below under the heading "Item 1A. Risk Factors" and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the SEC, before making an investment decision regarding our common stock.

- We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- We have incurred significant losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- We will need substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce, or eliminate our research and product development programs or future commercialization efforts.
- We are heavily dependent on the success of our product candidates, which are in preclinical and Phase 1 clinical development. We may not be successful in our efforts to identify and develop potential product candidates. If these efforts are unsuccessful, or if we experience significant delays, we may never become a commercial stage company or generate any revenues, and our business will be materially harmed.
- There is substantial competition in our field, which may result in others developing or commercializing products before we do.
- Our product candidates utilize novel mechanisms of action, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects.
- If we are unable to adequately protect our proprietary technology and platform or obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad or if we are unable to maintain the confidentiality of our trade secrets, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and products may be impaired.
- The continuing outbreak of COVID-19 in the United States and other countries may adversely affect our business and the market price of our common stock.
- If any of the product candidates we may develop or the delivery modalities we rely on cause serious adverse events, undesirable side effects or unexpected characteristics, such events, side effects or characteristics could delay or prevent regulatory approval of the product candidates, limit the commercial potential, or result in significant negative consequences following any potential marketing approval.

PART I

Unless the context otherwise requires, the terms "Foghorn," "Foghorn Therapeutics," the "Company," "we," "us" and "our" relate to Foghorn Therapeutics Inc., together with its consolidated subsidiary.

ITEM 1. BUSINESS

Overview

The chromatin regulatory system orchestrates gene expression–the turning on and off of genes–which is fundamental to how all our cells function. Breakdowns in this system lead to a wide range of diseases impacting millions of patients. Understanding the mechanism of how this system works could lead to an entirely new class of therapeutics. To our knowledge, we are the only company with the ability to study the chromatin regulatory system at scale, in context, and in an integrated way.

We are pioneering the discovery and development of a new class of medicines targeting genetically determined dependencies within the chromatin regulatory system, an untapped opportunity for therapeutic intervention. Our proprietary Gene Traffic Control platform gives us an integrated, mechanistic understanding of how the various components of the chromatin regulatory system interact, allowing us to identify, validate and potentially drug targets within the system. Breakdowns in the chromatin regulatory system are associated with over 50 percent of all cancers. Addressing these breakdowns could potentially provide therapies for over 2.5 million patients. Consequently, we are initially focused in oncology. We are developing FHD-286, a selective, allosteric ATPase inhibitor and are currently initiating separate Phase 1 studies in metastatic uveal melanoma and relapsed and/or refractory acute myeloid leukemia, or AML. The investigational new drug applications for metastatic uveal melanoma and relapsed and/or refractory AML were accepted by the FDA in late December and early January, respectively. We are developing FHD-609, a targeted protein degrader, to treat synovial sarcoma, for which we plan to submit an investigational new drug application, or IND, in the second quarter of 2021. Our vision is to use our Gene Traffic Control platform to discover and develop drugs in oncology and other therapeutic areas, including virology, autoimmune disease and neurology.

How the Chromatin Regulatory System Orchestrates Gene Expression

In order for DNA to fit in the nucleus of each human cell, DNA is densely packed into what is called chromatin, which needs to be unpacked as a necessary first step to allow for gene expression. Cells have evolved a system known as the chromatin regulatory system that can locate and unpack particular regions of chromatin, thereby enabling and orchestrating gene expression. Two of the major components of the chromatin regulatory system are chromatin remodeling complexes and transcription factors, and these components work in concert to orchestrate gene expression.

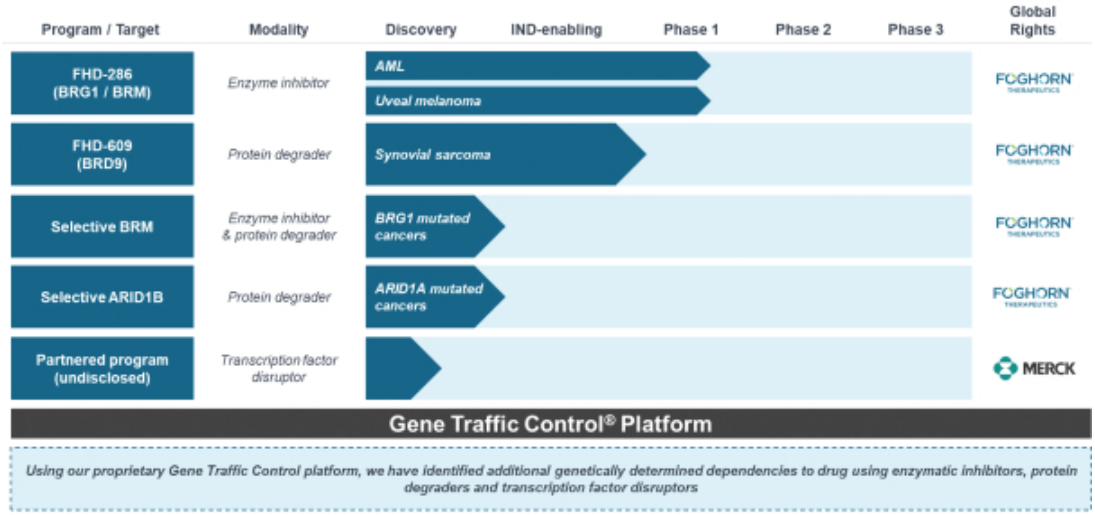
Our Gene Traffic Control Platform

We have built our proprietary Gene Traffic Control platform to give us an integrated and mechanistic understanding of how the various components of the chromatin regulatory system interact, allowing us to identify, validate and potentially drug targets within the system. We are initially using our Gene Traffic Control platform in oncology. In cancer, the mutations that are in or impinge on the chromatin regulatory system create genetically determined dependencies, on which the cancer cells rely for survival. These genetic dependencies result in diseased cell vulnerabilities, creating potential opportunities to selectively drug and kill diseased cells while minimizing impact to healthy cells. With our platform, we are able to produce components of the chromatin regulatory system at scale, thereby allowing us to identify these genetic dependencies, understand their mechanism and target their vulnerabilities. We combine our genomic and epi-genomic tools, our proprietary high throughput screening technology and our expertise in medicinal chemistry to develop enzymatic inhibitors, protein degraders and transcription factor disruptors that target the chromatin regulatory system. While initially focused in oncology, we believe our platform is broadly applicable across other disease areas.

Our Gene Traffic Control platform encompasses the following:

- **Target Identification and Validation—**We use genomic screens, and a suite of epi-genome sequencing and computational tools, including aspects of AI and machine learning, to characterize, identify, and validate targets within the chromatin regulatory system. Our epi-genome sequencing tools allow us to understand the mechanisms of how our drugs are modifying the chromatin structure. Our platform allows for the identification of genetically determined dependencies associated with the chromatin regulatory system.
- **Production of Chromatin Regulatory System Components at Scale and Proprietary Assays—**We have built unique capabilities to purify and synthesize chromatin remodeling complexes and transcription factors. These capabilities allow us to study the chromatin regulatory system at scale and in a context that, to our knowledge, is unavailable to others, and yields unique insights that are critical to systematically drugging this system.
- **Discovery and Optimization of Chemical Matter**—We perform proprietary high throughput screens that leverage our ability to produce the chromatin regulatory system components at scale. For example, we are able to screen for inhibitors of chromatin remodeling complex activity, for binders that we can turn into degraders, and for disruptors of transcription factor-chromatin remodeling complex interactions. Once we find hits from our screens, we use our unique suite of assays involving the relevant component of the chromatin regulatory system to characterize, validate, and optimize our chemical matter.
- **Targeted Protein Degradation**—In cases where our drugging efforts are directed at targets that have no enzymatic activity, we seek to degrade the protein of interest. We have built extensive protein degrader capabilities encompassing linkers and E3 ligase binders, assays to measure protein degradation and guide optimization, and ternary complex modeling. After completing screens and finding small molecule binders to the target of interest, we use our protein degradation know-how to convert binders into selective protein degraders.
- **Translation to Clinic and Identification of Biomarkers**—Early in the drug discovery process, we use various genome and epi-genome analyses to understand the mechanism of the genetic dependency of the disease on the chromatin regulatory system. Our understanding of the mechanism of the dependency enables us to identify biomarkers for patient identification and treatment. We seek to enrich our clinical studies with the genetically relevant patient populations that are most likely to benefit from treatment.

Using our proprietary Gene Traffic Control platform, we are developing a broad pipeline of product candidates that target genetically determined dependencies within the chromatin regulatory system. Our current pipeline of product candidates and discovery programs is focused on oncology and is shown below, along with anticipated milestones.



Within the chromatin regulatory system, we have initially focused our development efforts on the BAF chromatin remodeling complex, or the BAF complex, the most mutated amongst a family of chromatin remodeling complexes, and its interactions with transcription factors. Our precision approach consists of designing novel small molecules to inhibit the ATPase activity of BAF complexes, to selectively degrade mutated or dependent subunits, or to disrupt the interaction between the BAF complex and associated transcription factors. We believe our platform is broadly applicable to other chromatin remodeling complexes and transcription factors.

Our first product candidate, FHD-286, is a highly potent, selective, allosteric and orally available, small-molecule, enzymatic inhibitor of BRG1 and BRM, that we are initially developing for the potential treatment of AML and uveal melanoma. BRG1 and BRM are two highly similar proteins that are the ATPases, or the catalytic engines, across all forms of BAF. In our preclinical studies, we have observed in both AML and uveal melanoma animal xenograft models anti-tumor effects at tolerated doses. We are currently initiating Phase 1 studies for metastatic uveal melanoma and relapsed and/or refractory AML. As FHD-286 progresses through clinical testing, our intention is to expand into other indications beyond AML and uveal melanoma.

Our second product candidate, FHD-609, is a highly potent, selective and intravenous, small molecule protein degrader of BRD9, a component of a form of the BAF complex. Nearly all synovial sarcoma cancers contain a translocation, a type of mutation, between a BAF subunit gene, SS18, and another set of genes, SSX1, SSX2 and SSX4. These mutations render the cancer genetically dependent upon BRD9. FHD-609 has two domains: one that binds with high potency and selectivity to BRD9 and the other that binds to a receptor on the E3 ligase complex that directs proteins for destruction. In our preclinical studies in synovial sarcoma animal xenograft models, we have observed anti-tumor effects that we believe support submitting an IND and progressing FHD-609 into clinical studies. We have successfully completed our GLP toxicology studies for FHD-609. We plan to submit an IND for FHD-609 in the second quarter of 2021 and, if cleared, expect to initiate a clinical study in synovial sarcoma shortly thereafter. As FHD-609 progresses through clinical testing, our intention is to expand into other indications beyond synovial sarcoma.

We have used our Gene Traffic Control platform to generate additional programs targeting both large and small patient populations. Examples of programs targeting large populations include selective BRM and selective ARID1B modulators, which have potential implications in over 100,000 cancer patients and 175,000 cancer patients that harbor BRG1 and ARID1A mutations respectively. We are pursuing other programs with genetically determined dependencies on other chromatin remodeling complexes beyond the BAF complex.

In addition, we are developing compounds that disrupt the interactions between the transcription factors and BAF complexes. We believe that there are more than 100 transcription factors that could be amenable to our approach, one that disrupts the interaction of the transcription factor with the BAF complex. Preclinical activities of these early programs are underway.

Our approach to disrupting the interactions between transcription factors and the BAF complex is the basis of a collaboration signed with Merck Sharp & Dohme Corp., or Merck, in July 2020. In this collaboration, we intend to apply our Gene Traffic Control platform to identify disruptors of a single predetermined transcription factor. As part of the collaboration, we received an upfront payment of $15.0 million, and are also eligible to receive up to $245.0 million upon achievement of specified research, development and regulatory milestones by any product candidate generated by the collaboration, and up to $165.0 million upon achievement of specified sales-based milestones.

Our Team

We have assembled a team with deep scientific, clinical, manufacturing, business, and leadership expertise in biotechnology, platform research, drug discovery, and development. Our management team has extensive experience discovering, developing, and commercializing drugs to treat patients with serious diseases. Adrian Gottschalk, our President and Chief Executive Officer, has more than 15 years of experience as a biopharmaceutical executive. Prior to joining Foghorn, Mr. Gottschalk served in various roles at Biogen, Inc., where he was most recently Senior Vice President and Neurodegeneration Therapeutic Area Head. In this role, he was responsible for late-stage development and commercialization of drugs to treat Alzheimer's disease, Parkinson's disease, and amyotrophic lateral sclerosis. Our Chief Medical Officer, Samuel Agresta, M.D., M.P.H. & T.M., previously served as Chief Medical Officer at Infinity Pharmaceuticals and led the development of the marketed oncology drugs TIBSOVO® and IDHIFA® at Agios. Carl P. Decicco, Ph.D., our Chief Scientific Officer previously served as Senior Vice President, Head of Discovery at Bristol-Myers Squibb and has been involved in over 200 drug candidates transitioning into the clinic. Our research efforts are also guided by world-class scientists and physicians on our Scientific Advisory Board, including David Schenkein, M.D., formerly the chief executive officer of Agios and presently a general partner and co-leader of Google Ventures life science team, Tony Kouzarides, Ph.D., F.Med.Sci., FRS, professor of cancer biology at the University of Cambridge and deputy director of the Gurdon Institute, United Kingdom, Gerald Crabtree, M.D., founder of Ariad Pharmaceuticals, a Howard Hughes Medical Institute investigator and professor at Stanford University, and Charles Sawyers, M.D., chair of the Human Oncology and Pathogenesis Program at Memorial Sloan Kettering Cancer center, a Howard Hughes Medical Institute investigator, and past president of the American Association for Cancer Research, or AACR. We have assembled an exceptional team of 95 employees as of December 31, 2020.

Our Beginnings: Foghorn Therapeutics and Flagship Pioneering

Foghorn Therapeutics was founded in 2015 by Flagship Pioneering, working together with academic co-founders Dr. Cigall Kadoch (Dana Farber Cancer Institute, Harvard, Broad Institute) and Dr. Gerald Crabtree (Stanford, Howard Hughes Medical Institute) to develop and commercialize a new category of first-in-class therapeutics to treat patients with cancer and other serious diseases. Our platform was inspired by work in the academic co-founders' laboratories at the Dana Farber Cancer Institute and Stanford. This seminal work made it possible to understand how mutations cause disease by disrupting the machinery—the chromatin regulatory system—that orchestrates how cells turn genes on and off. Such mutations are associated with up to 50 percent of cancer and

play roles in many other diseases. A Flagship Labs innovation team at Flagship Pioneering, led by Flagship Managing Partner, Dr. Douglas Cole, and, subsequently, Foghorn's research and development team, established a fully integrated drug discovery platform based on this seminal work, which we call our Gene Traffic Control platform.

Our Strategy

Our mission is to leverage our unique insights into the chromatin regulatory system to pioneer the discovery, development and commercialization of a new class of therapies that transform the lives of patients suffering from a wide spectrum of diseases with high unmet need.

Our approach is to identify and drug genetically determined dependencies within the chromatin regulatory system. Our initial focus is in cancer with a precision oncology approach. Every program we pursue is based on a genetic dependency on the chromatin regulatory system.

To achieve our mission, we are executing a strategy with the following key elements:

- **Advance our lead precision oncology product candidates, FHD-286 and FHD-609, through clinical development in patients with select solid tumors and hematological cancers.** FHD-286 and FHD-609 are a highly selective and potent enzymatic inhibitor and protein degrader, respectively, that target two different components of a chromatin remodeling complex. We believe our lead product candidates have the potential to address significant unmet medical needs across multiple oncology indications. We are currently initiating separate Phase 1 studies for metastatic uveal melanoma and relapsed and/or refractory AML and expect preliminary clinical proof-of-concept data for FHD-286 as early as the fourth quarter of 2021. We also plan to submit an IND for FHD-609 in the second quarter of 2021 for the treatment of synovial sarcoma and, if cleared, expect to initiate a Phase 1 clinical trial shortly thereafter.
- **Expand our precision oncology pipeline by developing proprietary enzymatic inhibitors, degraders and disruptors that target genetically defined dependencies within the chromatin regulatory system.** Based on our unique insights and understanding of the chromatin regulatory system, we continue to develop proprietary selective inhibitors, protein degraders and disruptors that modulate both chromatin remodeling complexes and transcription factors, two key components of the chromatin regulatory system. For example, using our proprietary platform, we are pursuing two distinct targets BRM and ARID1B that have genetically determined dependencies within the chromatin regulatory system with combined potential impact in over 275,000 cancer patients. We plan to begin IND-enabling studies for a selective BRM modulator in the second half of 2021. We plan to continue our preclinical efforts of our selective ARID1B program. We intend to utilize our platform to consistently develop novel product candidates to further deepen our precision oncology pipeline.
- **Harness our platform to develop novel product candidates to address therapeutic areas beyond oncology.** As the orchestrator of gene expression, the chromatin regulatory system has implications in a large array of diseases. Based on academic literature and our research efforts, we believe our platform has significant potential across multiple therapeutic areas. We are committed to applying our Gene Traffic Control platform to additional therapeutic areas including virology, autoimmune diseases and neurology. We believe our platform will allow us to continue to build a long-term pipeline of novel product candidates to address areas of high unmet medical need.
- **Continue to enhance our platform to extend our leading position in developing novel therapeutics targeting the chromatin regulatory system.** Our platform and unique understanding of the chromatin regulatory system is built upon the groundbreaking work of our academic co-founders and has been further developed by our experienced team. We are committed to continuously integrating new insights, tools, technologies and capabilities to enhance our platform.

- **Selectively enter into additional strategic partnerships to maximize the potential of our pipeline and our platform.** Given the breadth of opportunities that are implicated by the chromatin regulatory system and the versatility of our platform, we may opportunistically enter into strategic collaborations intended to advance and accelerate our development programs, expand into new therapeutic areas and enhance the capabilities of our platform. In July 2020, we entered into a collaboration with Merck to discover and develop novel oncology therapeutics against a transcription factor target.

Chromatin Regulatory System: An Untapped Opportunity for Therapeutic Intervention

The chromatin regulatory system orchestrates gene expression. In order for DNA to fit in the nucleus of each human cell, it is densely packed into what is called chromatin. This packing of DNA occurs by winding it around a core of proteins called histones to form what is known as a nucleosome, having the appearance of thread (the DNA) wrapped around a spool (the histones). Multiple nucleosomes cluster further to form more densely packed chromatin. Before DNA can be transcribed to RNA and then translated into protein, chromatin needs to be "unpacked" to allow access for the cellular machinery responsible for DNA transcription. Cells have therefore evolved a system known as the chromatin regulatory system that can locate and unpack particular regions of the chromatin to orchestrate and allow for gene expression.

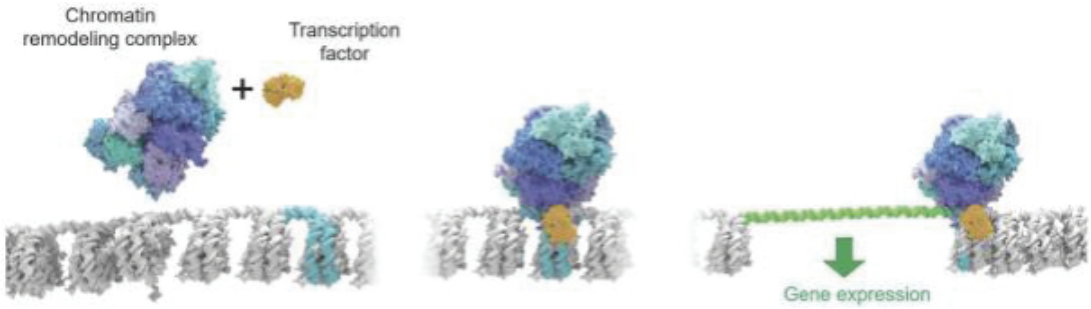


Figure 1: Chromatin Regulatory System Biology: Chromatin remodeling complexes and transcription factors work in concert to unpack chromatin to enable gene expression. The left portion of the figure shows "packed" or closed chromatin and the right portion of the figure shows "unpacked" or open chromatin with DNA highlighted in green.

Two of the major components of the chromatin regulatory system are chromatin remodeling complexes and transcription factors. Transcription factors specify the locations of genes to be transcribed by binding to specific locations on DNA. Chromatin remodeling complexes, guided by transcription factors, unpack the chromatin to expose DNA for transcription. These two components work in concert in both healthy and diseased cells. While chromatin remodeling complexes have been known in the scientific community for decades, disease relevance was not initially recognized, and consequently chromatin remodeling complexes were underappreciated as a set of relevant drug targets. Transcription factors, on the other hand, while linked decades ago to cancer and understood as relevant targets, have led to few approved oncology drugs, as companies seeking to drug these targets have lacked a systematic approach to doing so. Recently, ground-breaking work by our academic co-founders has revealed that alterations in chromatin remodeling complexes as well as their interactions with transcription factors are strongly associated with various cancers. Broad cancer sequencing initiatives have shown that mutations in the chromatin regulatory system are found in over 50 percent of all cancers, potentially impacting over 2.5 million cancer patients across the United States, Europe and Japan. Further work in the field by our founders and others has highlighted the association of this system in other therapeutic areas, including virology, autoimmune disease and neurology, implying even greater potential for therapeutic intervention.

Vulnerabilities in Cancer Created by Genetic Dependencies on the Chromatin Regulatory System

Cancer cells often contain many different mutations that lead to their abnormal growth and proliferation. Within cancer cells, these mutations give rise to genetically determined dependencies, upon which the cancer cells rely for their survival. The creation of these dependencies can be directly related to the mutation or to other cellular biology, thereby creating vulnerabilities for cancer cells and the opportunity for therapeutic intervention. In contrast, healthy cells, which lack these mutations and therefore these dependencies, are less susceptible to a therapeutic that targets these genetically determined dependencies.

There are three primary mechanisms by which genetically determined dependencies on the chromatin regulatory system arise. They are:

1. Mutations in chromatin remodeling complexes
2. Mutations or overexpression of transcription factors
3. Mutations elsewhere in the cell that impinge on chromatin remodeling complexes and/or transcription factors

Our platform enables us to identify these genetic dependencies and thereby discover the cancer cells' vulnerability within the chromatin regulatory system. We believe these vulnerabilities create opportunities to selectively drug and kill cancer cells while minimizing impact to healthy cells. These genetically determined dependencies enable us to select specific patient populations and enrich our clinical trials using a precision approach. Every program we pursue is based on a genetically determined dependency on the chromatin regulatory system.

Our Initial Focus—BAF Complexes and Associated Transcription Factors

There are 28 types of chromatin remodeling complexes. All types of chromatin remodeling complexes use ATP as an energy source for opening and closing chromatin. These remodeling complexes contain a catalytic subunit that is capable of breaking down ATP, known as the ATPase. The ATPase serves as the catalytic engine that drives the function of each chromatin remodeling complex. The breakdown or hydrolysis of each ATP molecule by the ATPase creates energy that, in turn, drives chromatin remodeling. These chromatin remodeling complexes are mutated in approximately 25 percent of cancers.

BAF, which stands for BRG1/BRM-associated factors, one type of chromatin remodeling complex, is mutated in approximately 20 percent of cancers, thus being the most mutated in the family of ATPase chromatin remodelers and among the most mutated targets in cancer. Given the breadth of mutations in cancer, the BAF complex is our initial focus among the ATPase dependent chromatin remodeling complexes.

The BAF complex is a multicomponent protein structure containing twelve to fifteen protein subunits taken from a larger set of a possible 29 subunits. Three common forms of BAF are known as canonical BAF, or cBAF; non-canonical BAF, or ncBAF; and polybromo BAF, or PBAF. While the exact compositions of these forms of BAF are different, each form contains a number of common subunits, one such being the ATPase catalytic subunit. Each BAF complex contains one of two possible ATPases, either ATPase known as BRM, also known as SMARCA2, or ATPase known as BRG1, also known as SMARCA4.

Different cell types and tissues contain different forms of BAF. This cell and tissue specificity gives rise to the possibility of additional pharmacological selectivity when drugging potential targets.

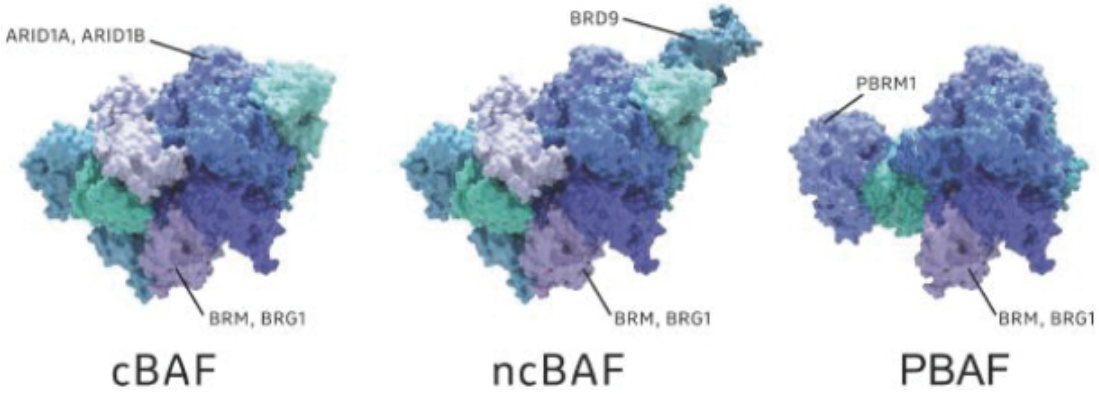


Figure 2. Schematic depicting biochemical subunit compositions of mammalian BAF, ncBAF and PBAF complexes.

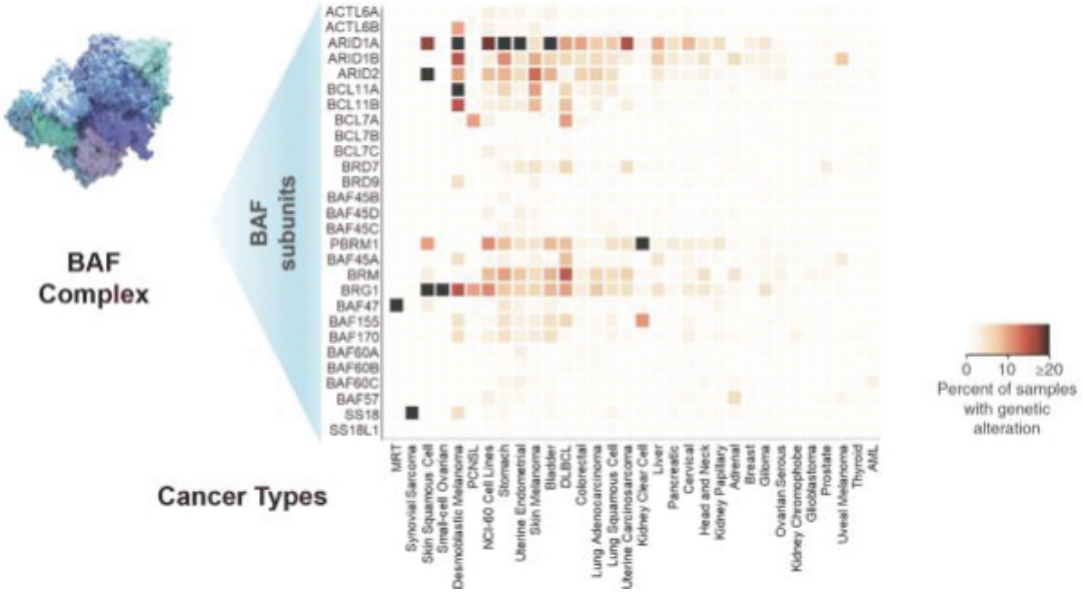


Figure 3. Genetic alterations are commonly found in subunits of the BAF complex in tumors.

The BAF complex, when aggregating mutations across all of its subunits, is the second most mutated target to the well-known cancer target TP53. Genetic alterations of various subunits of the BAF complex have been observed in a wide range of cancers. These include but are not limited to the following:

- More than 90 percent of ovarian cancer patients;
- 34 percent of uterine endometrial patients;
- 34 percent of stomach cancer patients;

- 29 percent of bladder cancer patients;
- 28 percent of non-small cell lung cancer, or NSCLC, patients; and
- 27 percent of skin cancer patients.

The following mechanistic insights provide strategies to target the BAF complex in cancer:

- Dependency exists between BAF complex subunits;

  One example is:

  - In some cancer cells, the gene encoding BRG1, a catalytic subunit of the BAF complex, is mutated causing a loss of function in BRG1
  - Often this loss of function leads to a dependency on BRM, a similar protein to BRG1 that is the other catalytic subunit of the BAF complex
  - This loss of BRG1 and subsequent dependency on BRM creates a vulnerability by rendering these cancer cells highly sensitive to targeting BRM

- Mutations elsewhere in the cell confer a dependency on the BAF complex;

  One example is:

  - Mutations in G-protein coupled receptors (GNAQ/GNA11) are found in 85 percent to 95 percent of uveal melanoma, a cancer of the eye
  - In uveal melanoma cell lines with these mutations, we have established a dependency on two transcription factors, MITF and SOX10.
  - These two transcriptions interact with the BAF complex
  - Targeting the BAF complex then inhibits MITF and SOX10 mediated transcription

Transcription factors, the proteins that guide the chromatin remodeling complexes, help determine which genes are expressed and have long been desirable but elusive targets for drug discovery efforts. Work by our academic co-founder Cigall Kadoch, as well as others in the field, revealed that transcription factors work in concert with chromatin remodeling complexes, BAF as one example, to orchestrate gene expression. A transcription factor recognizes specific guidepost-like sequences, or locations, on DNA. The transcription factor binds to the chromatin remodeling complex and in doing so directs the remodeling complex to the appropriate location on chromatin. Once recruited to the appropriate location, the chromatin remodeling complex unpacks the chromatin, exposing the DNA and allowing transcription machinery to transcribe the corresponding gene.

Some transcription factors, such as the estrogen receptor, or ER, have long been the targets of approved and efficacious drugs for the treatment of cancers such as breast cancer. However, the majority of transcription factors have not been amenable to traditional small molecule drug inhibition. While directly blocking the DNA binding site on transcription factors would be an effective way of inhibiting their activity, it is usually not possible to find small molecules that can bind to these sites with the potency and selectivity needed to advance as therapeutics.

Different healthy cell types, such as heart, brain, or muscle cells, use different types of transcription factors. In cancer cells, mutated and/or abnormal levels of specific transcription factors are found. Because many transcription factors are cell and tissue specific, there is the possibility of additional pharmacological selectivity when drugging potential transcription factor-chromatin remodeling complex interactions. We believe that there are more than 100 transcription factors that could be amenable to our approach of disrupting the interactions of transcription factors with the BAF complex.

Our Approach to Drugging the Chromatin Regulatory System

We are focused on developing small molecule product candidates that target the chromatin regulatory system through the use of enzyme inhibitors, protein degraders and transcription factor disruptors.

- **Enzyme inhibitors**. These candidates have the potential to act on targets such as the ATPases BRG1 and BRM of the BAF complex. Our screening capabilities enable us to find allosteric inhibitors which afford additional selectivity over orthosteric, or direct, inhibitors.
- **Protein degraders**. These candidates are bifunctional degraders in which one portion of the molecule specifically recognizes the target while the other portion is able to direct the destruction of the target by the cell's protein degradation system.
- **Transcription factor disruptors**. These candidates will be direct small-molecule disruptors of the protein-protein interactions between transcription factors and chromatin remodeling complexes.

We leverage the appropriate mechanism based on the target in the chromatin regulatory system. In some cases, we may take multiple approaches and remain modality agnostic in order to ensure we achieve the best approach and most appropriate molecule.

The two main approaches that we are taking to drugging chromatin remodeling complexes are inhibiting its ATPase activity and degrading mutated or dependent subunits within the chromatin remodeling complex. We are taking a different approach to modulating the activity of transcription factors than previously attempted by the field. We believe this approach can be applied across the broad set of chromatin remodeling complexes and transcription factors with which they interact, as illustrated by the BAF complex. Because transcription factors require collaboration with the BAF complex, disrupting the interaction between the two shuts down the ability of the transcription factor to drive transcription. Our approach is to find small molecule disruptors that bind to either the transcription factor or the BAF complex in order to break the interaction between the two. In order to understand whether it is possible to selectively drug these interactions, there are two important aspects that need to be understood. One is where specifically the transcription factor binds to the BAF complex and the second is how tightly it binds.

Based on our work, we have observed that individual transcription factors bind to the BAF complex at specific sites rather than all binding to a single site, implying that it should be possible to specifically interfere with the binding of one transcription factor to the BAF complex without affecting the binding of every other transcription factor. This is a critical success factor for the specificity of drug candidates binding to the BAF complex. We have also observed that the potencies of these interactions are roughly equivalent to those observed in other protein-protein interactions that have been successfully disrupted by small molecule drugs. Because many transcription factors are cell and tissue specific, there is the possibility of additional pharmacological selectivity when drugging potential transcription factor-chromatin remodeling complex interactions. We believe these findings provide the opportunity to systematically discover and develop a novel class of product candidates that are specific, selective and that will be designed to disrupt the interaction between transcription factors and the BAF complex.

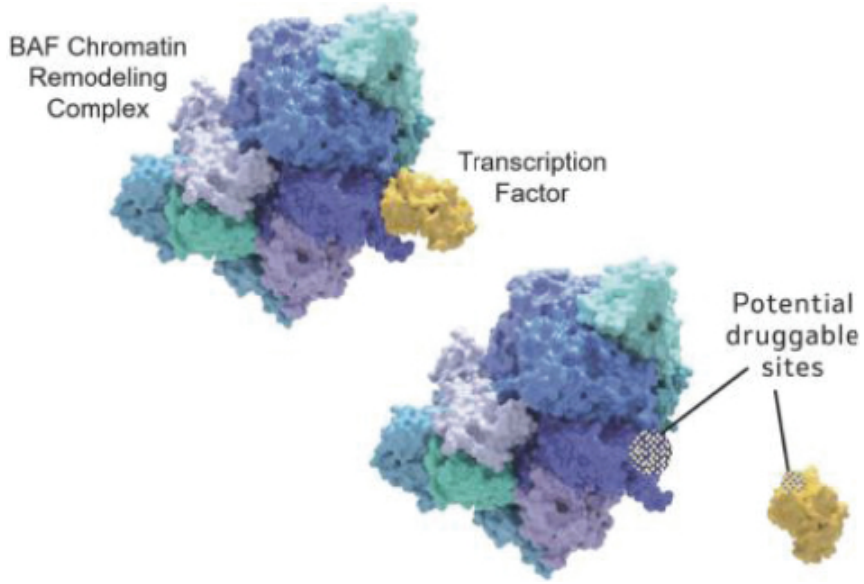


Figure 4. We are disrupting transcription factor activity by blocking interactions with the BAF complex.

Our Gene Traffic Control Platform

The chromatin regulatory system has remained an untapped opportunity for therapeutic intervention due to the inability to systematically characterize and study the chromatin remodeling complexes and associated transcription factors. Building upon the groundbreaking discoveries of our academic co-founders, we have developed our proprietary Gene Traffic Control platform which allows us to identify and validate targets within the chromatin regulatory system. We have unique capabilities to isolate, synthesize, characterize, and interrogate the BAF complex at a level of scale, precision, and efficiency, that to our knowledge, no others have achieved. We have unique capabilities to understand how transcription factors interact with the BAF complex and have generated unique insights into where and how transcription factors bind. We believe our platform is broadly applicable to other chromatin remodeling complexes and transcription factors.

Our capabilities and insights have allowed for the development of a suite of unique biochemical, biophysical, structural, and functional assays. We use these assays to discover and optimize novel small molecule chemical matter which include enzymatic inhibitors, protein degraders, and transcription factor disruptors to various targets within the chromatin regulatory system. To our knowledge, we are the only company that has the ability to study the chromatin regulatory system at scale, in context, and in an integrated way.

Our Gene Traffic Control platform encompasses the following:

- Target Identification and Validation
- Production of Chromatin Regulatory System Components at Scale and Proprietary Assays
- Discovery and Optimization of Chemical Matter
- Targeted Protein Degradation
- Translation to Clinic and Identification of Biomarkers

The key features and capabilities of our platform are described below:

Target Identification and Validation

We use genomic screens and a suite of epi-genome sequencing and computational tools to characterize, identify and validate targets within the chromatin regulatory system. Our epi-genome sequencing tools allow us to understand the mechanisms of how our drugs are modifying the chromatin structure. Our platform allows for the identification of genetically determined dependencies associated with the chromatin regulatory system. Specifically, we:

- **Conduct and leverage genomic screens to identify dependencies and relationships.** We utilize both broad and specific genomic screens to identify dependencies and relationships associated with the chromatin regulatory system. We use a mix of internal and external data sets that apply CRISPR and shRNA technology to understand relationships across and within a range of cancer cell lines.
- **Perform broad epi-genome sequencing to validate dependencies *in vitro*.** We apply cutting edge epi-genome sequencing tools in combination with proprietary tool compounds to further validate targets and enhance our understanding of the impact of drugging the chromatin regulatory system. These tools allow us to rapidly understand the gene expression profiles of specific cancer cell lines, the open / closed state of chromatin, and give us mechanistic understanding of how components of the system work together.
- **Apply machine learning and artificial intelligence to enhance discovery efforts.** We have built tools that allow us to mine and interpret external and internal datasets that aid in our discovery efforts yielding unbiased and unsupervised computer analyses to identify targets and genetic dependencies on the chromatin regulatory system and to further understand mechanism of action. Examples of external data sets include data from The Cancer Genome Atlas (TCGA) and the Broad Institute. Internal data sets include data from cell lines, data from xenograft models and epi-genomic information (RNA-seq, ATAC-seq, CHiP-seq, SNAP-seq). We also use these tools in the preclinical stage to evaluate cancer cell lines & patient samples to identify biomarkers for patient stratification and patient population identification.
- **Validate dependencies *in vivo*.** Where possible, we endeavor to validate targets in various animal models with implanted cancer cells relevant to the disease we are aiming to treat. Specifically, we use mouse xenograft models with inducible CRISPR / shRNA to validate that knockdown of our target of interest results in tumor growth inhibition. We also apply epi-genome sequencing tools in the animal model setting to identify potential biomarkers.

Production of Chromatin Regulatory System Components at Scale and Proprietary Assays

We have built unique capabilities to purify and synthesize the BAF complex and transcription factors. These capabilities allow us to study the chromatin regulatory system at scale and in context that, to our knowledge, is unavailable to others, and yields insights that are critical to systematically drugging this system. Specifically, we:

- **Purify and synthesize chromatin remodeling complexes and transcription factors at scale.** Our platform has the unique ability to purify and synthesize the BAF complex with potential applications to other chromatin remodeling complexes. Importantly, we are able to purify disease relevant and mutated forms of BAF directly from the cancer cell lines of interest. To our knowledge, we are the only company that has developed the ability to purify and manipulate BAF, sub-complexes of BAF, as well as its host of subunits, in quantities that enable us both to generate structural data to identify potential binding sites for drug candidates and to conduct high throughput screens of small molecule drug candidates against these sites.
- **Study chromatin remodeling complexes in context leading to relevant insights into the impact of drug intervention.** We have found that the properties of subunits of BAF, such as BRG1 or BRM, are

different when they are incorporated into the BAF complex than when we test them in isolation. For example, the catalytic activity of these subunits using nucleosomes was increased by over 15-fold when they were incorporated into the BAF complex compared to their activities in isolation (see Figure 5 below). This is the biologically relevant activity of the complex. Additionally, the ability to screen the full complex greatly improves the potential of finding allosteric modulators which may afford additional pharmacological selectivity. These examples underscore the importance of assaying and screening the full complex.

- **Utilize advanced analytical methods to develop and understand critical insights into how transcription factors interact with chromatin remodeling complexes.** We integrate multiple technologies and methodologies, including high-throughput-screening, biophysics, affinity screening, and surface mapping to gain unparalleled insights into the chromatin regulatory system and how its primary two components, transcription factors and chromatin remodeling complexes, interact. Based on our protein-protein interaction mapping technology, we have determined precisely the binding sites of multiple transcription factors to the BAF complex, providing us with critical insights into how these factors bind to the BAF complex, and details on how these binding interactions can be disrupted using small, drug-like molecules.

We believe that our unique capabilities as applied to the BAF complex and associated transcription factors can be applied to other chromatin remodeling complexes and transcription factors. It is our intention to further leverage our capabilities on other chromatin remodeling complex targets.

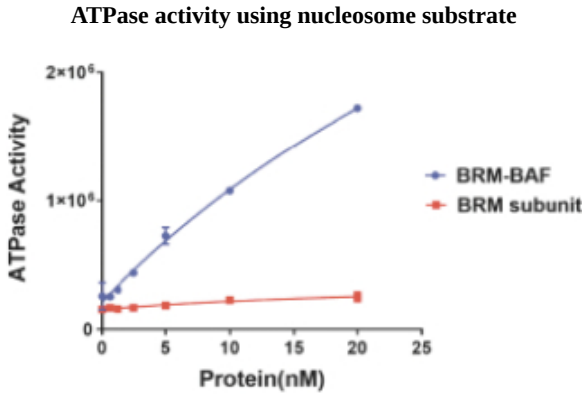


Figure 5. ATPase activity of full BAF complex underscores the importance of assaying in the appropriate biological context.

Discovery and Optimization of Chemical Matter

We perform proprietary high throughput screens that leverage our ability to produce the chromatin regulatory system components at scale. An example screen is the use of the fully assembled BAF complex which is specific to its mutated or disease relevant form (e.g., screening the BRM form of BAF which corresponds to BRG1 mutated cancer). Furthermore, we are able to screen the BAF complex when bound to a relevant transcription factor. We utilize both proprietary and publicly available chemical libraries in our screens.

Once we find hits from our screens, we use our unique suite of assays involving the relevant component of the chromatin regulatory system to characterize, validate, and optimize our chemical matter. These assays provide us with biologically relevant insights that guide our medicinal chemistry efforts.

Targeted Protein Degradation

In cases where our drugging efforts are directed at targets that have no enzymatic activity, we seek to degrade the protein of interest through targeted protein degraders. Protein degraders are bifunctional small molecules in which one portion of the molecule specifically recognizes the target while the other portion directs the destruction of the target by harnessing the cell's proteasome-based degradation system. The two chemical functionalities of the molecule are connected by a variable linker. This approach affords a general method of degrading protein targets of interest.

After completing screens, as described above, and finding small molecule binders to the target of interest, we use our protein degradation know-how to convert binders into selective protein degraders. This know-how and capabilities include:

- Proprietary library of linkers and E3 ligase binders
- Biochemical, biophysical, and cellular assays that measure protein degradation and guide optimization, including protein synthesis and degradation kinetics
- Ternary complex modeling and characterization
- Genome wide proteomic analysis of degradation to measure selectivity

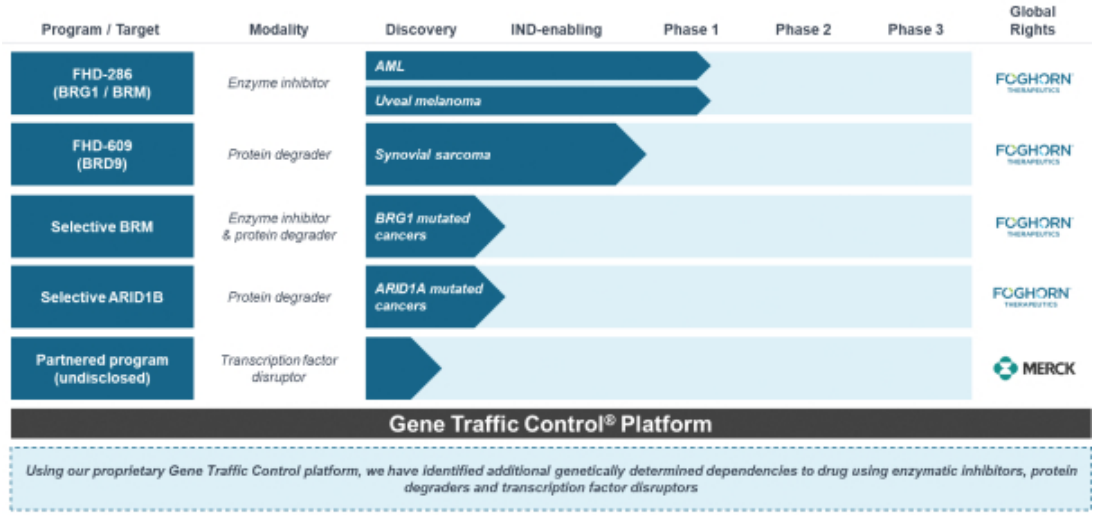
Translation to Clinic and Identification of Biomarkers

We seek to enrich our clinical studies with the genetically relevant patient populations that are most likely to benefit from treatment. Early in the drug discovery process, we use various genome and epi-genome analyses to understand the genetic dependency of the cancer on the chromatin regulatory system. Our intent is to have clear genetic markers for patients whom we seek to potentially treat.

As we progress a drug candidate, we analyze tumor models and where available direct patient samples to understand biomarkers of response (e.g., change in expression level of a particular gene or set of genes, change in protein level of a component of the chromatin regulatory system). We intend to use these biomarkers in our clinical studies to understand tumor response to our drug candidates. Additionally, we will retrospectively analyze our clinical studies for any other biomarkers that will further enhance patient stratification and response.

Our Product Candidates

We are developing a broad pipeline of product candidates that target genetically determined dependencies within the chromatin regulatory system. Our programs consist of enzyme inhibitors, protein degraders and transcription factor disruptors. For FHD-286, we are currently initiating separate Phase 1 studies for metastatic uveal melanoma and relapsed and/or refractory AML. For our second product candidate, FHD-609, we intend to submit an IND in the second quarter of 2021. Our pipeline is as follows:



FHD-286

Overview

We are currently advancing our lead product candidate, FHD-286, a highly potent, selective, allosteric and orally available, small-molecule, enzymatic inhibitor of BRG1 and BRM, for the potential treatment of AML and uveal melanoma. BRG1 and BRM are two highly similar proteins that each serves as the ATPases, or the catalytic engines, across all forms of BAF. We are currently initiating Phase 1 studies for metastatic uveal melanoma and relapsed and/or refractory AML. The IND's for metastatic uveal melanoma and relapsed and/or refractory AML were accepted by the FDA in late December and early January, respectively. Our preclinical data in both AML and uveal melanoma animal xenograft models have demonstrated anti-tumor effects that we believe support progressing FHD-286 into clinical studies. These multi-center Phase 1 studies will primarily assess the safety and tolerability of FHD-286 in adults with AML and uveal melanoma. Secondary endpoints are expected to include the pharmacokinetic and pharmacodynamic properties of FHD-286 as well as clinical activity. Proof of mechanism will be based on indicators of target engagement in association with FHD-286 treatment. As we further understand the therapeutic potential of FHD-286 in the course of these initial clinical studies, we may pursue additional clinical studies in these and other indications as a single agent and/or in combination with novel or standard of care agents.

AML Disease Overview

Acute myeloid leukemia, or AML, is a heterogeneous group of hematologic cancers characterized by a proliferation of myeloid precursors, commonly known as blasts, with limited ability to differentiate into more mature myeloid cells. These blasts replace normal hematopoietic tissue in the bone marrow, resulting in decreased hematologic cell numbers, or pancytopenia, and the morbidities associated with the cancer.

AML is the second most common subtype of leukemia in adults. In major markets (United States, EU4, UK and Japan) AML has an incidence of approximately 35,000 cases annually and is generally a disease of elderly people, with more than 60 percent of diagnosed patients being older than 60 years. The average five-year survival rate for patients with AML is 20 percent, and there are significant differences in prognosis depending on several factors, including the age of the patient and co-morbidities at diagnosis. For patients under the age of 60, the five-year survival rate is approximately 33 percent, while for those over the age of 60 it is less than 15 percent. There are likely multiple reasons for this discrepancy, including the ability of younger patients to tolerate more aggressive therapies.

Current first-line treatments for patients with AML typically involve aggressive combination chemotherapy regimens with or without hematopoietic stem cell transplantation (HSCT). Older patients or patients who cannot tolerate HSCT, typically those with comorbidities, are often treated with cytarabine and daunorubicin induction followed by high-dose cytarabine consolidation. Patients who cannot tolerate combination chemotherapy receive low dose cytarabine, azacitidine, Venclexta ® , and/or enroll in clinical trials. There is a single biologic, gemtuzumab ozogamicin or Mylotarg™, approved by the FDA for newly diagnosed and relapsed-refractory AML. Other, more recently approved therapeutics for AML target subsets of patients with tumors containing specific mutations such as midostaurin marketed as Rydapt® by Novartis for those with FLT3 mutations, enasidenib marketed as Idhifa® by Celgene for those with mutations in IDH2, and ivosidenib, marketed as Tibsovo® by Agios for those with mutations in IDH1.

Despite these advances, patients who do achieve remission, five-year disease-free survival is only 30-40 percent because the majority of patients relapse. Patients in the elderly population have a relapse rate of 80-90 percent. Younger patients have a relapse rate of between 60-80 percent. There remains a significant need for safe, durable and broadly effective AML treatments.

Uveal Melanoma Overview

Uveal melanoma is the most frequent type of ocular cancer with approximately 5,000 cases each year in the major markets (United States, EU4, UK and Japan), typically presenting upon a routine eye exam in patients without specific symptoms. Local treatment, primarily with radiation therapy, is effective in preventing local recurrence in over 95 percent of cases. Due to the asymptomatic nature of uveal melanoma, at the time of the diagnosis, a considerable portion of these patients already have metastatic disease, typically in the liver. Roughly half of all patients will eventually develop metastases. For those diagnosed with metastatic disease, the one-year survival is only 15 percent. The poor prognosis associated with metastatic disease and the lack of any effective therapy highlights the need for novel therapeutic approaches that specifically target metastatic uveal melanoma.

Between 85 percent and 95 percent of uveal melanoma tumors contain mutations in one of two G-protein-coupled receptor subunits: GNAQ or GNA11. We have established through uveal melanoma cell lines with the GNAQ/GNA11 mutations that there is a dependency of these cell lines on two over expressed transcription factors, MITF and SOX10. In uveal melanoma, these two transcription factors abnormally interact with the BAF complex.

Our Solution: FHD-286

FHD-286 is a highly potent, selective, allosteric and orally available, small molecule inhibitor of the enzymatic activity of both BRG1 and BRM. In established AML cell line-derived xenograft, or CDX, models MV4-11 and OCI-AML2, we observed robust tumor growth inhibition. In established uveal melanoma CDX models, specifically MP-46 and 92-1, we observed significant tumor growth inhibition and tumor regression, respectively. We are currently initiating separate Phase 1 studies for metastatic uveal melanoma and relapsed and/or refractory AML. The IND’s for metastatic uveal melanoma and relapsed and/or refractory AML were accepted by the FDA in late December and early January, respectively.

Either BRG1 or BRM can serve as the primary ATPase, or catalytic engine, of the BAF complex. BAF complexes will contain only BRG1 or BRM, as they are mutually exclusive subunits, as shown in the figure below. BRG1 or BRM are two proteins which are 76 percent identical at the amino acid level over their entire length and over 90 percent identical in the catalytic region.

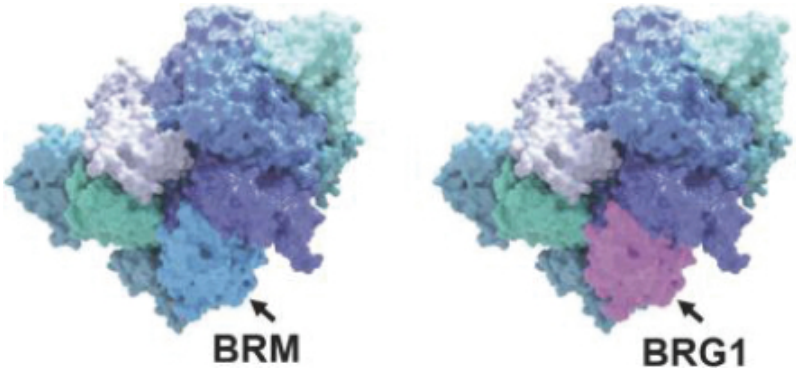


Figure 6. The enzymatic activity of the BAF complex is provided by the BRM or BRG1 subunits.

When we conducted compound screening against a panel of tumor cell lines, a number of these tumor cell lines were shown to be highly sensitive to BRG1 or BRM inhibition over a three-day period. These cell lines include nineteen of twenty-one of the hematopoietic malignancy cell lines tested, all four of the uveal melanoma cell lines, three out of four prostate tumor cell lines, and three out of seven breast tumor cell lines. We observed additional sensitivity in other tumor cell lines tested over a seven-day period.

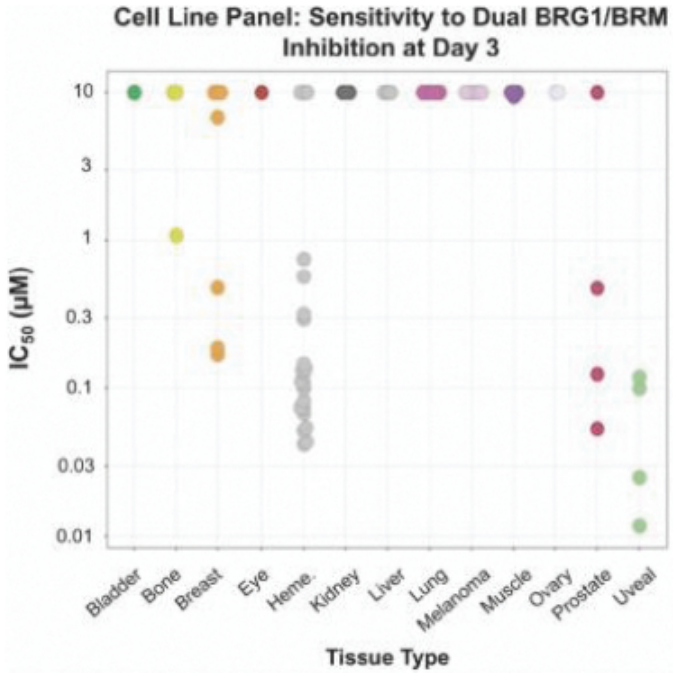


Figure 7. Certain cell lines, including those derived from uveal melanoma, hematological cancers, prostate cancer, and breast cancer were highly sensitive to BRG1/BRM inhibition.

Our Preclinical Data for AML

Genetic studies have identified a critical role of BRG1 in the maintenance of the undifferentiated state of AML cells. Knockdown of the expression of BRG1 was found both to inhibit the expression of genes associated with high proliferation and to induce the expression of genes associated with mature myeloid cells. In a mouse model of AML, partial genetic inactivation of BRG1 led to a greater than two-fold increase in overall survival. These data suggest that pharmacological inhibition of BRG1 may provide a therapeutic benefit.

We have generated *in vivo* proof of concept data that demonstrated antitumor activity of FHD-286 in AML patient samples as well as multiple AML CDX models. Using tumor cells isolated from AML patients, we demonstrated that treatment with FHD-286 allowed for appropriate differentiation of AML cells. We treated these tumor cells with a single dose of FHD-286 at increasing exposures and assessed the effects on both myeloid cellular differentiation and cell death. We observed myeloid cellular differentiation at a lower nanomolar exposure relative to where we observed cell death. The data support that pharmacologic inhibition of BRG1 can release the differentiation block associated with BRG1 overexpression in AML. Ongoing research has revealed that transcription factors interacting with over-expressed BRG1 containing BAF complexes are implicated in AML. Targeted treatment that releases a differentiation block has been observed to be clinically meaningful with ATRA treatment in acute promyelocytic leukemia as well as IDH1 and IDH2 inhibition in IDH-mutated AML. The cell killing observed was comparable to the effect of standard of care combinations: cytarabine plus daunorubicin and azacytidine plus venetoclax.

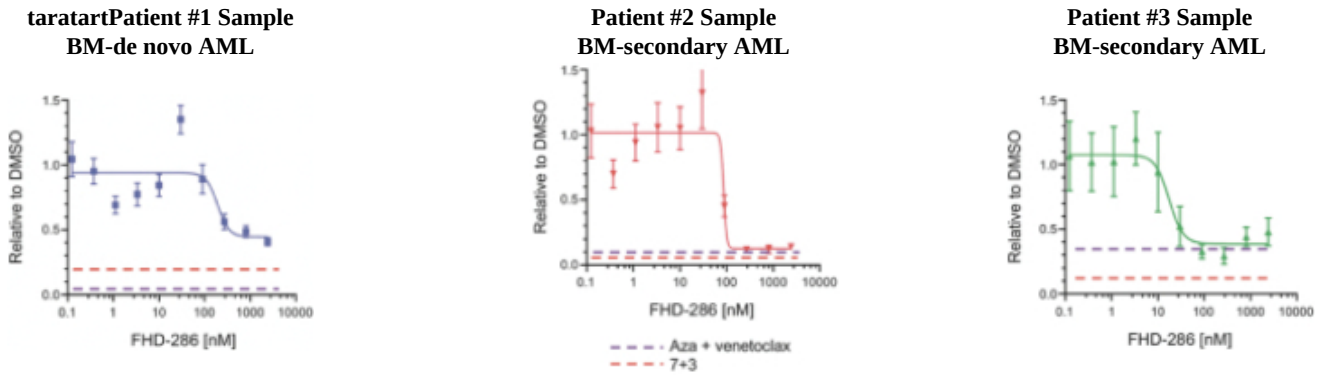


Figure 8. Treatment of patient-derived AML tumor samples with FHD-286 stimulated differentiation and cell death. Dose-dependent reduction of blast counts in samples from three patients. The blast count was normalized and plotted as relative to the level in vehicle DMSO-treated samples. The level of blast count reduction achieved by standards of care (Aza + venetoclax and "7+3") are indicated by the dashed lines. BM = Bone Marrow.

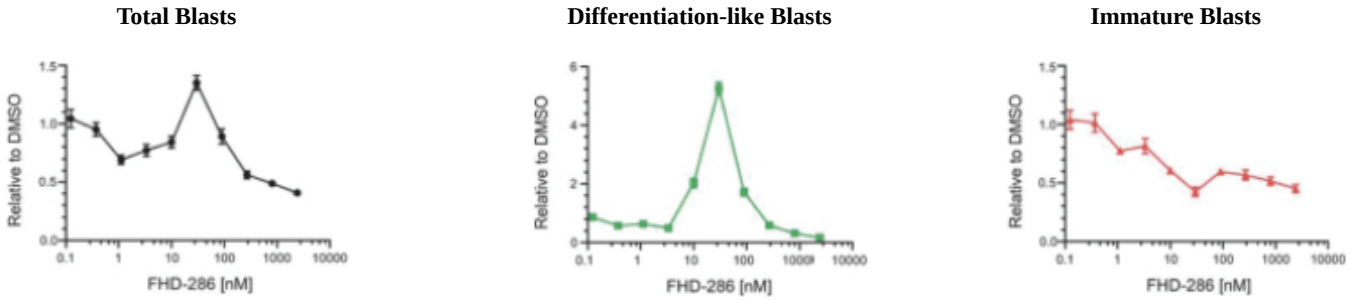
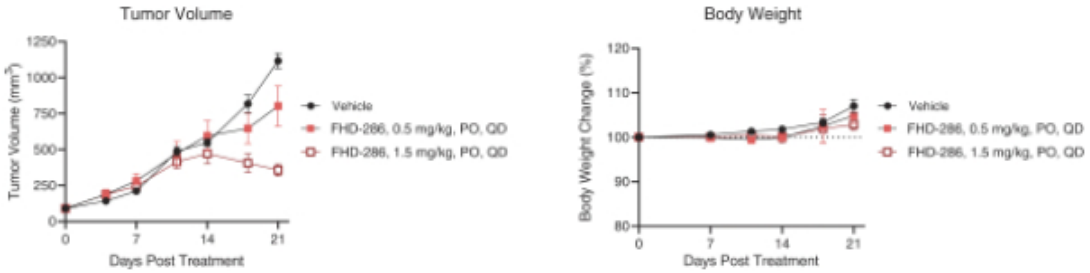


Figure 9: Evidence of a dose-dependent differentiation effect in patient #1 sample.

We have confirmed the sensitivity observed in our three-day cell line panel in CDX models created using OCI-AML2 and MV4-11, two AML cell lines with different underlying genetic mutations. In addition, we have observed robust dose response in further evaluation of FHD-286 in MV4-11 CDX models. We have also observed synergy of FHD-286 in combination with cytarabine.

MV4-11 AML CDX Model
FLT3 ITD, MLL-AF4



OCI-AML-2 AML CDX Model
MII-AF6, DNMTa3 mut.

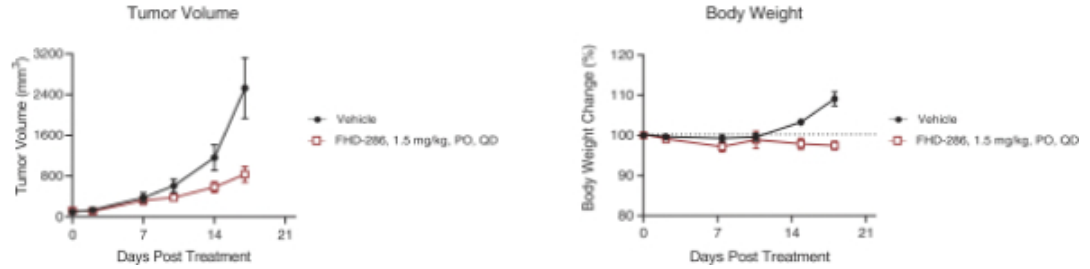


Figure 10. FHD-286, dosed as monotherapy, led to tumor growth inhibition in two AML xenograft models MV4-11 and OCI-AML-2.

Our Preclinical Data for Uveal Melanoma

In uveal melanoma cell lines that contain GNAQ/GNA11 mutations, genetic studies have revealed that these cells overexpressed two transcription factors, MITF and SOX10. Our data showed that the MITF and SOX10 transcription factors abnormally over-interacted with the BAF complex in uveal melanoma cell lines. By inhibiting the ATPase activity, both BRG1 and BRM, of the BAF complex, we observed anti-tumor effects in several CDX and patient-derived xenograft, or PDX, uveal melanoma models.

We established the genetic dependency of uveal melanoma cell lines on MITF and SOX10 by analyzing data from the Project Achilles, a functional genomics screen conducted by the Broad Institute. We found that established uveal melanoma cell lines such as 92-1 and OMM1 were highly dependent on MITF or SOX10.

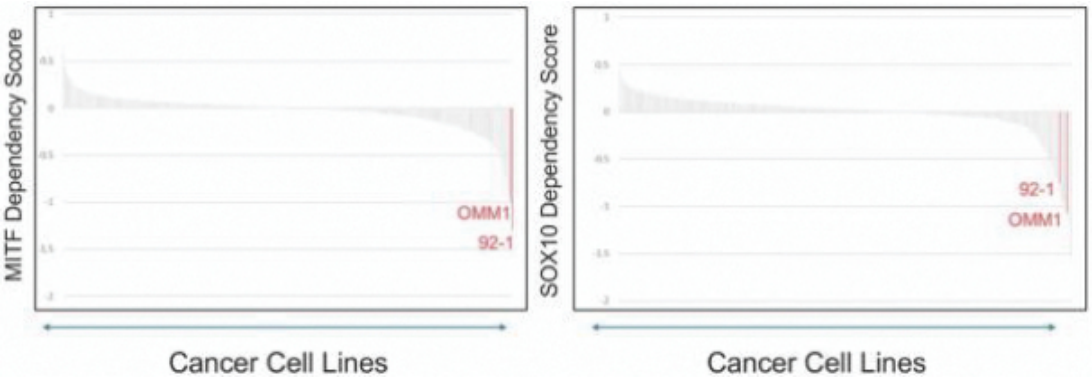


Figure 11. Uveal melanoma cell lines, such as 92-1 and OMM1, were highly dependent on MITF or SOX10.

We found that inhibition of BRG1 and BRM led to suppression of gene expression from several MITF and SOX10-dependent genes. A broader measure of the effect of dual inhibition of BRG1 and BRM on transcription of MITF and SOX10-dependent genes was obtained using a technique known as chromatin immunoprecipitation sequencing, or ChIP-seq. ChIP-seq allows us to find where particular proteins, in this case transcription factors, are binding to chromatin. Treatment of uveal melanoma cells with a research compound with similar properties to that of FHD-286 resulted in decreased binding of both MITF and SOX10 transcription factors to their respective chromatin binding sites. These results validate the mechanism of action of FHD-286 in uveal melanoma cells.

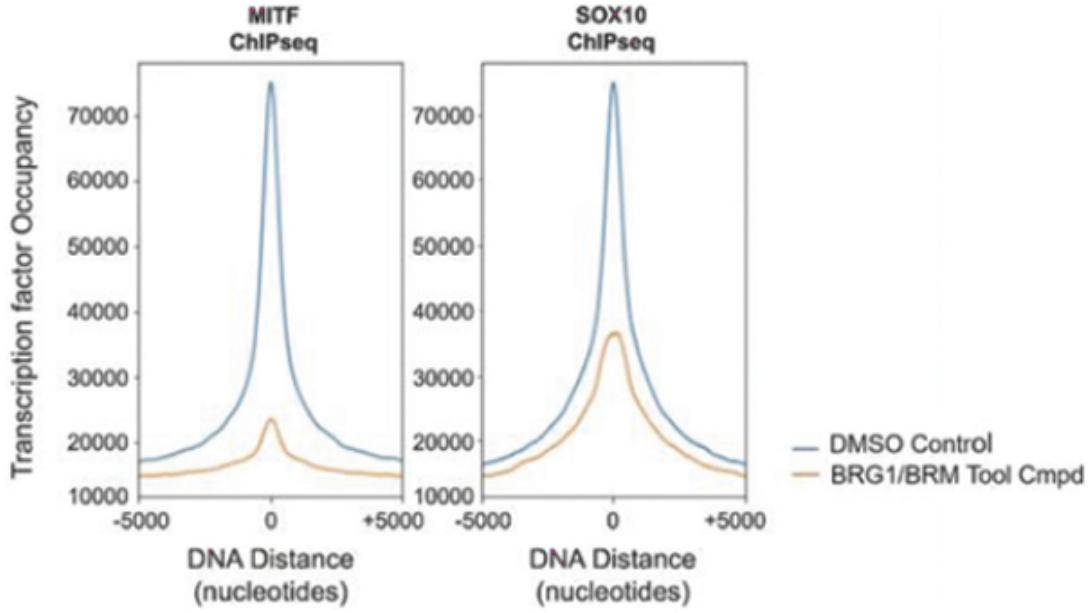
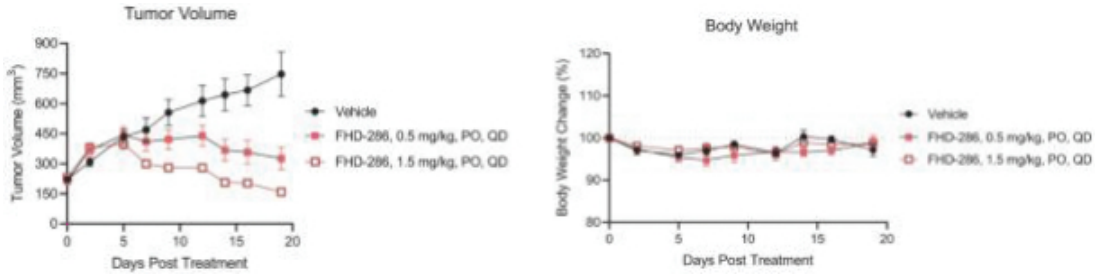


Figure 12. BRG1/BRM inhibitor blocked the ability of MITF and SOX10 to bind to their target sequences as determined by ChIP-seq.

We have generated *in vivo* proof of concept data that demonstrated antitumor activity of FHD-286 in multiple uveal melanoma CDX and PDX models. In two uveal melanoma models, 92-1 and MP-46, oral dosing of FHD-286 at 1.5 mg/kg as monotherapy resulted in tumor growth regression and inhibition, respectively. Importantly, doses of FHD-286 of up to 1.5 mg/kg were well-tolerated in that FHD-286 at these doses did not lead to changes in body weight considered to be clinically meaningful compared to controls (e.g., changes greater than 10 percent of body weight), a commonly used measure of safety.

92-1 Uveal Melanoma Model



MP-46 Uveal Melanoma Model

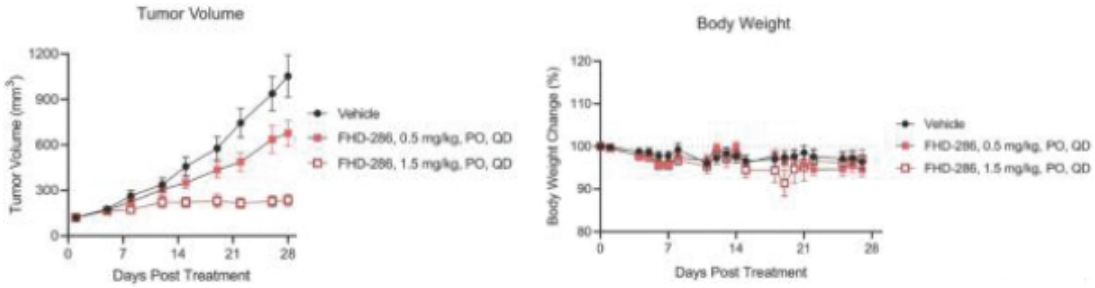


Figure 13. FHD-286 led to dose-dependent tumor growth inhibition in two uveal melanoma xenograft models 92-1 and MP-46.

Clinical Plans for FHD-286 in AML and Uveal Melanoma

We submitted two separate INDs FHD-286 for metastatic uveal melanoma and relapsed and/or refractory AML in December 2020 and received IND acceptance in late December 2020 and early January 2021, respectively. We are currently initiating separate Phase 1 studies for metastatic uveal melanoma and relapsed and/or refractory AML.

The first-in-human phase I study in AML is an accelerated titration design with two parts. Part one is the dose escalation phase that will enroll a single patient per dose (n=1) until certain criteria are met. The trial will convert to a 3+3 design once relevant pharmacokinetics/pharmacodynamics, or PK/PD, safety and or clinical activity are observed. The dose escalation portion will evaluate once daily oral, multiple ascending doses of FHD-286, with a starting dose determined by our GLP toxicology studies. Dose escalation will include patients with relapsed and/or refractory AML. The second part of the study is an expansion phase. This phase may include multiple distinct cohorts of patients with AML, informed by findings from the dose escalation phase. Initially, biomarkers, such as the association of clinical activity and BRG1 expression levels, will be evaluated retrospectively.

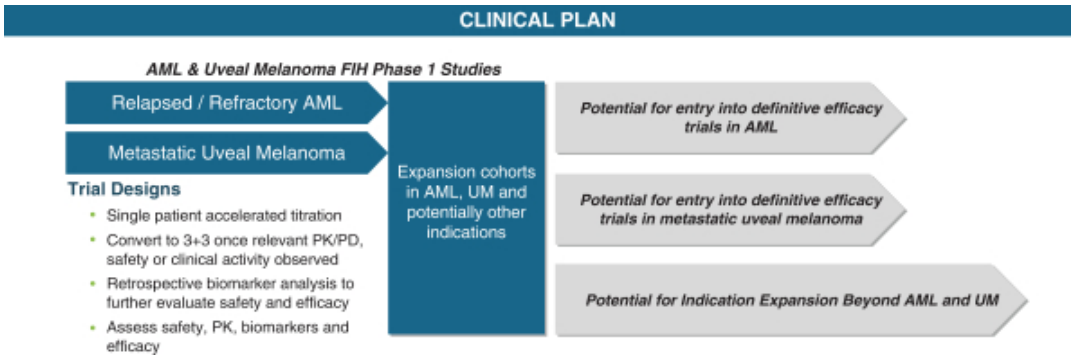
The primary objective of this first-in-human study will be the evaluation of safety and tolerability, and the identification of the maximum tolerated dose and the recommended Phase 2 dose. The secondary objectives are expected to include an evaluation of preliminary clinical activity and pharmacokinetics. Biomarkers will be evaluated in an exploratory fashion, evaluating markers associated with response. Prospective enrollment based on biomarker findings may be included in the expansion phase of the study.

The first-in-human Phase 1 study in uveal melanoma is an accelerated titration design with two parts. Part one is the dose escalation phase that will enroll a single patient per dose (n=1) until certain criteria are met. The trial will convert to a 3+3 design once relevant PK/PD, safety and or clinical activity are observed. The dose escalation portion will evaluate once daily oral, multiple ascending doses of FHD-286, with a starting dose determined by our GLP toxicology studies. Dose escalation will include patients with metastatic uveal melanoma. The second part of the study is an expansion phase, which will be informed by findings from the dose escalation phase.

The primary objective will be the evaluation of safety and tolerability and identification of the maximum tolerated dose and/or recommended Phase 2 dose. The secondary objectives are expected to include an evaluation of pharmacokinetics and preliminary clinical activity. Biomarkers will be evaluated in an exploratory fashion, evaluating target engagement as well as markers associated with response. Prospective enrollment based on biomarker findings may be included in the expansion phase of the study.

As shown in the graphic below, these two Phase 1 studies will be conducted in parallel. We intend to explore the potential value of multiple biomarkers to further understand and accelerate drug development. Biomarkers will include assessment of various tumor mutations, as well as expression levels of BRG1 and BRM. These biomarkers may be used for future patient selection, measurements of target engagement and biochemical and cellular measures associated with efficacy.

A recent data publication highlighted neuroendocrine prostate cancer as being dependent on BAF. We are evaluating multiple tumor types preclinically to determine our indication expansion strategy for FHD-286.



FHD-609

Overview

We are currently advancing FHD-609, a highly potent, selective and intravenous, small molecule protein degrader of BRD9, a subunit of a form of the BAF complex. Nearly all synovial sarcoma cancers harbor SS18-SSX mutations. These mutations render the cancer genetically dependent upon BRD9. FHD-609 has two domains: one that binds with high potency and selectivity to BRD9 and the other that binds to a receptor on the E3 ligase complex that directs proteins for destruction. Our preclinical data in synovial sarcoma animal xenograft models demonstrate anti-tumor effects that we believe support filing an IND and progressing FHD-609 into

clinical studies. We have completed the GLP toxicology studies for FHD-609. We plan to submit an IND for FHD-609 in the second quarter of 2021 and, if cleared, expect to initiate a clinical study in synovial sarcoma shortly thereafter. This multi-center Phase 1 study will primarily assess the safety and tolerability of FHD-609 in patients with synovial sarcoma. Secondary endpoints are expected to include the PK/PD properties of FHD-609 as well as clinical activity. Proof of mechanism will be based on indicators of target engagement in association with FHD-609 treatment. As we further understand the therapeutic potential of FHD-609 in the course of the initial clinical studies, we may pursue additional clinical studies in synovial sarcoma, as a single agent and/or in combination with novel or standard of care agents. In parallel, and as early as Phase 1 expansion studies, we plan to evaluate FHD-609 in other indications, including SMARCB1-deleted cancers.

Synovial Sarcoma Overview

Synovial sarcoma is a cancer of the connective tissue and most commonly originates in the arms or legs. Synovial sarcoma occurs most frequently in adolescents and young adults. There is an incidence over 1,800 new cases of synovial sarcoma in the United States, EU4, UK and Japan. Approximately 30 percent of synovial sarcomas occur in patients under 20 years of age with 84 percent of cases occurring in patients under 50 years of age.

Delay in diagnosis and treatment of synovial sarcoma is common because it is recognized simply by a lump that gradually grows over time. The primary treatment for synovial sarcoma is surgical excision of the tumor and surrounding normal tissue with the goal of sparing the limb if possible. Failure to adequately excise a sufficient area of tissue surrounding the tumor leads to recurrence rates of over 70 percent. Surgical resection is then followed by adjuvant chemotherapy or radiation therapy or both. However, there appears to be minimal benefit of these post-surgical treatments other than for palliative reasons. Radiation and chemotherapy are used in the neoadjuvant setting, or before surgery, to improve the chances of a successful limb sparing surgery.

Approximately ten percent of cases originally present as metastatic disease, and half of all cases eventually develop into metastatic disease. Eighty percent of metastases are localized in the lungs. Five-year survival rates for younger patients with early-stage disease are approximately 76 percent; however, this decreases to approximately 20 percent in patients over age 30 with advanced disease.

There are no therapies specifically approved by the FDA for synovial sarcoma patients with metastatic disease. Pazopanib, marketed as Votrient® by Novartis has been approved by the FDA for treatment of soft tissue sarcoma in patients who had received prior chemotherapy. In a Phase 3 soft tissue sarcoma trial that included a total of 369 patients, the progression-free survival time for the subset of patients with synovial sarcoma was 4.1 months (N=25) compared to 0.9 months for those who received placebo (N=13). Other chemotherapeutic agents that may be used for palliative purposes include ifosfamide.

Synovial sarcomas are characterized by a chromosomal translocation that results in the fusion of the SS18 gene to one of three genes: SSX1, SSX2 and SSX4, creating SS18-SSX gene fusions. These gene fusions are unique in synovial sarcoma and create a protein not found in healthy patients that fuels the growth and proliferation of the cancer cells. In the scientific literature, the process has been described as the gene fusion “hijacking” the BAF complex, altering its function and causing it to unpack chromatin at wrong locations.

SS18 is a component of the BAF complex. The SS18-SSX fusion protein can also be incorporated into the BAF complex, leading to synovial sarcoma. Genomic screening in synovial sarcoma cells has identified a genetic dependency between synovial sarcoma cells containing SS18-SSX fusions and BRD9, a subunit of the ncBAF complex.

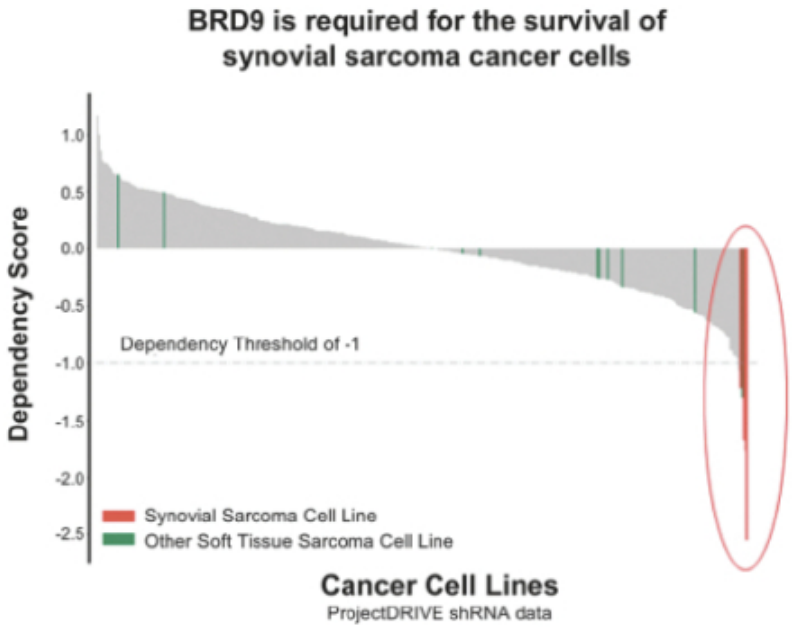


Figure 14. Synovial sarcoma cell lines were highly dependent on BRD9.

Our Solution: FHD-609

FHD-609 is a highly potent, selective and intravenous, small molecule protein degrader of BRD9. Unlike many traditional intracellular drug targets, BRD9 is not an enzyme and does not exhibit enzymatic activity. We therefore designed FHD-609 as a protein degrader, a molecule with two binding domains connected by a linker that drives the removal of targeted proteins by the cell's protein degradation system. In cells, these protein degrader molecules bring their target into proximity of the E3 ligase which marks these target proteins for destruction by the cell's proteasome system.

One domain of FHD-609 is a potent and selective binder of BRD9. This is chemically linked to a domain that binds to a receptor on the E3 ligase complex. FHD-609 led to the specific degradation of BRD9 in multiple synovial sarcoma tumor cell lines, with a DC50 of less than 1 (one) nM. This resulted in the elimination of detectable BRD9 protein and the concomitant inhibition of proliferation of these synovial sarcoma cell lines.

Our Preclinical Data for Synovial Sarcoma

We have generated *in vivo* proof of concept data that demonstrated antitumor activity of FHD-609 in synovial sarcoma CDX models. In the synovial sarcoma SYO1 CDX model containing the SS18-SSX2 mutation, dosing with FHD-609 led to potent inhibition of tumor growth. Intraperitoneal doses of FHD-609 yielded similar antitumor activity whether dosing was delivered as a once-weekly (every 7 days for three weeks) or an equivalent drug amount delivered daily over seven days for three weeks (3.5 mg/kg delivered every week versus 0.5 mg/kg delivered daily over 7 days). This suggests that sustained tumor regression can occur with a less frequent dosing regimen, which will be explored in clinical development. In the model, tumor growth inhibition levels were associated with levels of BRD9 degradation as indicated below.

SYO-1 Synovial Sarcoma CDX Model

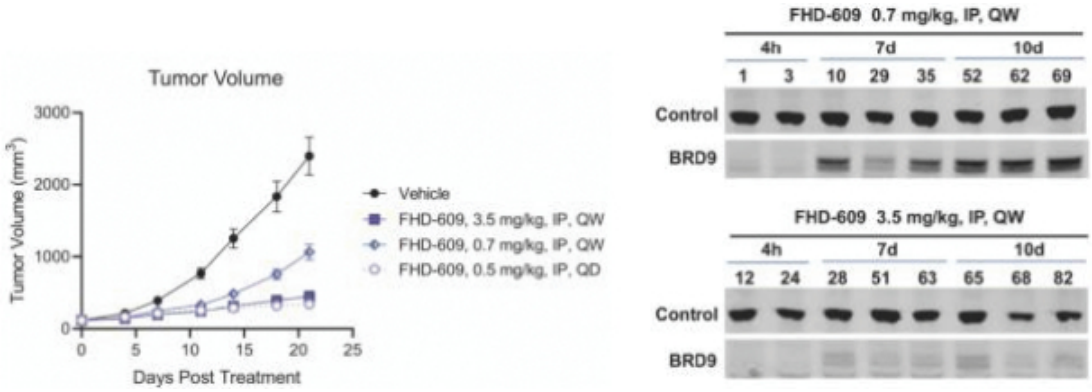


Figure 15. FHD-609 led to dose-dependent tumor growth inhibition of synovial sarcoma tumors equivalently at a once weekly or daily treatment schedule. On the right, the western blot shows dose-dependent BRD9 degradation correlating with the anti-tumor activity.

In the synovial sarcoma ASKA CDX model containing the SS18-SSX1 mutation, the antitumor activity of FHD-609 was comparable and superior to that observed for other systemic therapeutic agents. In this model FHD-609 was dosed intravenously twice per week, ifosfamide as a monotherapy intravenously on days one through three every three weeks, and pazopanib orally once daily. FHD-609 led to robust tumor suppression, with meaningful suppression observed through 40 days at the highest studied dose of 2 mg/kg.

ASKA Synovial Sarcoma CDX Model

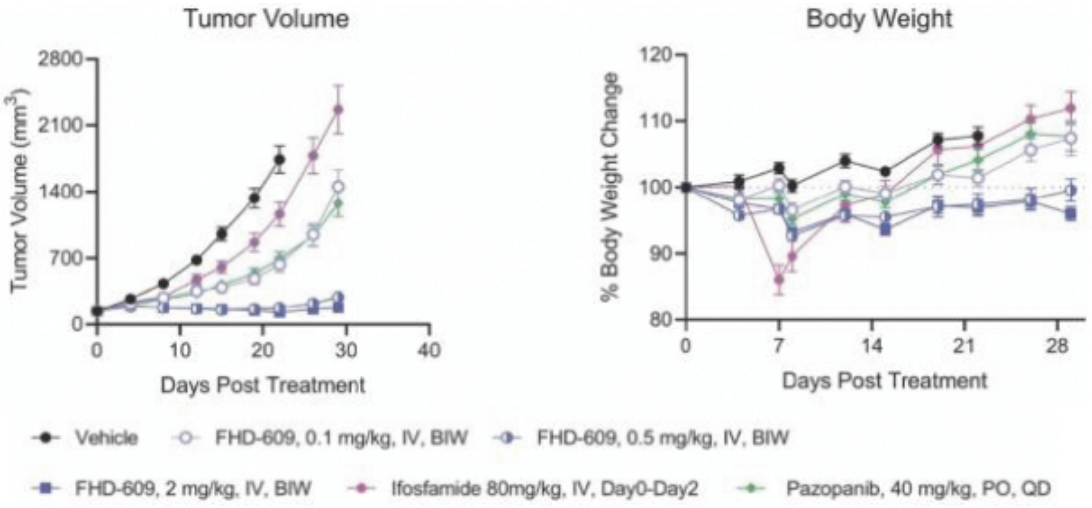


Figure 16. FHD-609 resulted in tumor regression in the ASKA synovial sarcoma xenograft model. FHD-609 demonstrated significant tumor growth inhibition compared to either ifosfamide or pazopanib.

Importantly, after discontinuation of FHD-609, treatment with FHD-609 was associated with sustained tumor growth inhibition. Following discontinuance of FHD-609 treatment at 2 mg/kg, at approximately day 21 tumor regrowth was not detectable for at least another 15 days. We believe these results support the targeted degradation of BRD9 and its importance in synovial sarcoma.

ASKA Synovial Sarcoma CDX Model

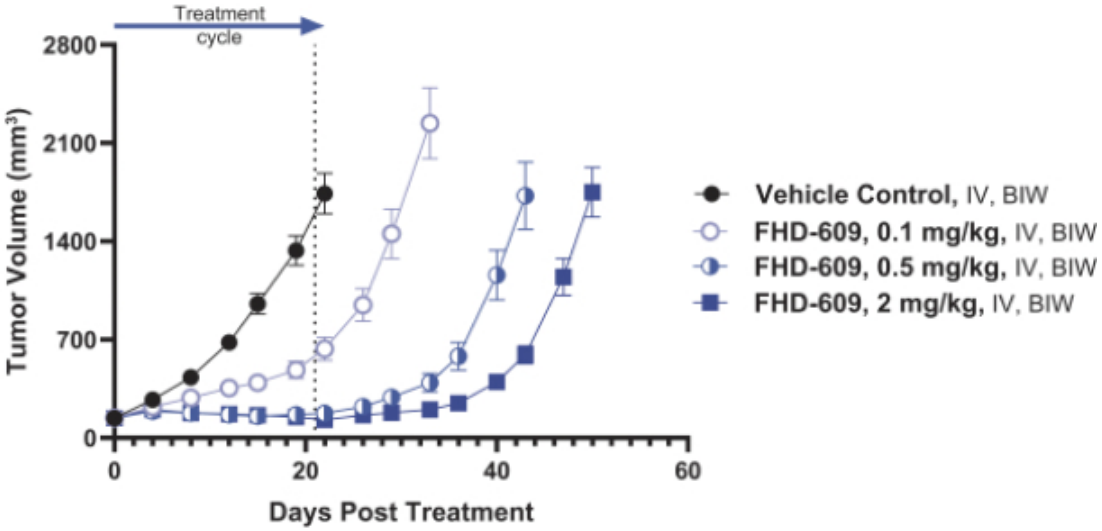


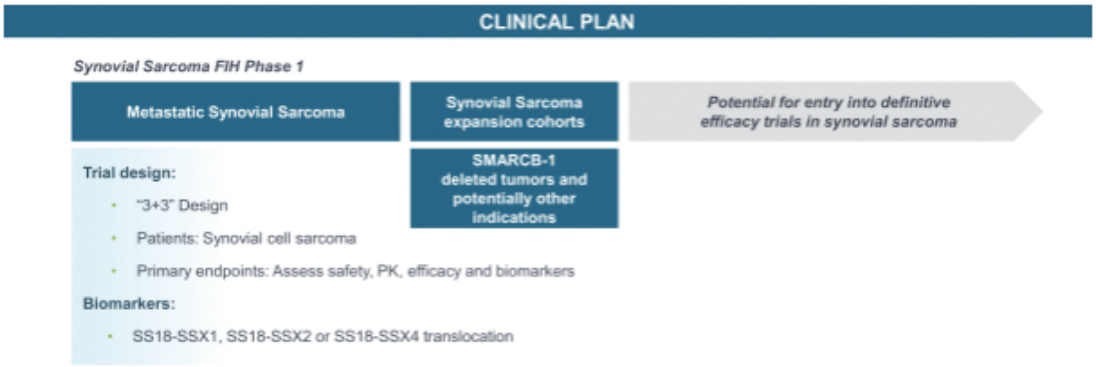
Figure 17. FHD-609 treatment was associated with sustained tumor suppression after treatment withdrawal.

Clinical Plans for FHD-609 in Synovial Sarcoma

The first-in-human study in synovial sarcoma will include a standard dose escalation and expansion phase. The dose escalation portion is a Phase 1 design with a starting dose determined by the GLP toxicology studies. Dose escalation may include treatment-naïve or treatment-experienced patients with metastatic synovial sarcoma. The expansion phase may include multiple distinct cohorts of synovial sarcoma patients, informed by findings from the dose escalation phase. Initially, biomarkers such as the association of clinical activity and SS18-SSX mutational status will be evaluated retrospectively.

The primary endpoints of this first-in-human study will be safety, the identification of any dose-limiting toxicities, the maximum tolerated dose, the recommended Phase 2 dose, and the evaluation of pharmacokinetics and pharmacodynamics. The secondary endpoints are expected to include an evaluation of clinical activity: overall response rate, duration of response and additional time to event analyses. Biomarkers will be evaluated in an exploratory fashion, evaluating target engagement as well as markers associated with response and/or resistance. Prospective enrollment based on biomarker findings may be included in the expansion phase of the study. As we further understand the therapeutic potential of FHD-609 in the course of the initial clinical studies, we may pursue additional clinical studies in synovial sarcoma, as a single agent and/or in combination with novel

or standard of care agents. In parallel, and as early as Phase 1 expansion studies, we plan to evaluate FHD-609 in other indications, including SMARCB1-deleted cancers.



BRM-Selective Modulators

Overview

Broad cancer sequencing initiatives have shown that BRG1 is one of the most highly mutated subunits of the BAF complex. BRG1 was found to be mutated in approximately five percent of tumors sequenced as part of the Memorial Sloan Kettering Cancer Center MSK-IMPACT study, and in up to ten percent of NSCLC tumors. Beyond NSCLC, the MSK-IMPACT study highlighted BRG1 mutations in over thirty different types of tumors. In many cases, these mutations lead to a loss of enzymatic activity in the BRG1 subunit, creating a genetically determined dependency on BRM. This loss of BRG1 and subsequent dependency on BRM leads to a drugging opportunity. We are currently developing selective modulators of BRM to target this genetic dependency in BRG1 mutated cancers.

12 Tumor Types with Highest Prevalence of BRG-1 Mutations

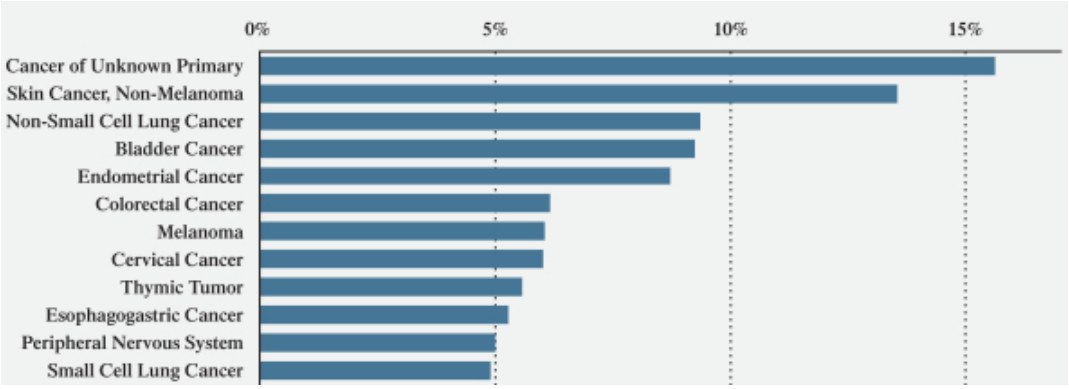


Figure 18. The above chart highlights the cancers with the highest prevalence of BRG1 mutations from the MSK-IMPACT study.

Non-Small Cell Lung Cancer (NSCLC) Overview

Lung cancer is the leading cause of cancer-related death, accounting for approximately 18 percent of all cancer deaths globally or an estimated 1.8 million deaths per year. There are an estimated 228,000 new cases of lung

cancer diagnosed and 135,000 deaths in the United States annually. NSCLC accounts for 80 to 85 percent of lung cancer cases. Genetic profiling of tumors has identified a number of genes that are altered in NSCLC. The standard of care for NSCLC has included conventional chemotherapy with or without a checkpoint inhibitor. Targeted therapies developed for the proteins encoded by some of these genes such as the epidermal growth factor receptor, or EGFR, and anaplastic lymphoma kinase gene, or ALK, have been approved and are now part of the standard of care of patents with NSCLC. However, less than 30 percent of NSCLC patients have alterations in these two genes. Up to two thirds of NSCLC patients who are ineligible for or resistant to treatment with EGFR or ALK targeted therapies have tumors that express PD-L1 and are candidates for checkpoint inhibitor therapies, which lead to significant improvements in progression free survival and overall survival compared to standard chemotherapy. Despite the availability of both targeted and conventional therapies, the prognosis in NSCLC remains poor, with an overall five-year survival for all patients diagnosed with NSCLC of 19 percent.

An analysis of genomic data in NSCLC cancer patients, collected as part of MSK-IMPACT, revealed that gene alterations in BRG1 were found in ten percent of NSCLC samples. In a retrospective analysis conducted by MSKCC it was observed that among patients with BRG1-deficient NSCLC who received first-line platinum doublet chemotherapy or chemotherapy plus immunotherapy, median progression-free survival was 38 days and 35 days, respectively. Prognosis is poor in patients with BRG1-deficient NSCLC, highlighting the importance of developing novel therapeutics that address this unmet need.

MSK-IMPACT: BRG-1 Mutated in 10% of NSCLC

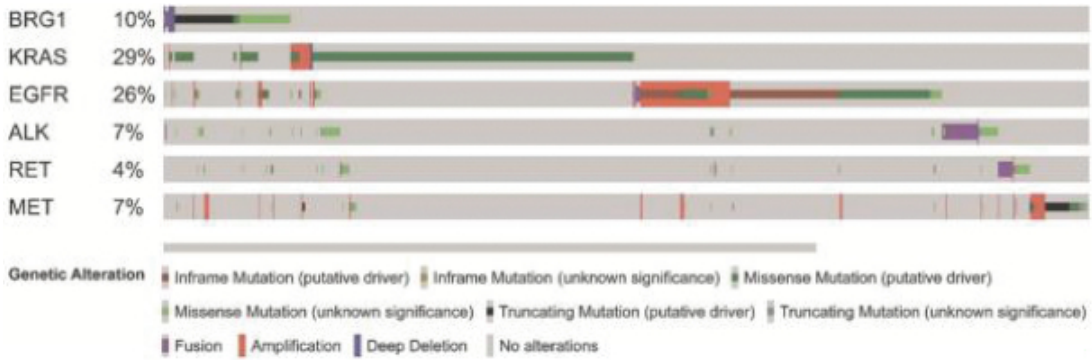


Figure 19. BRG1 gene alterations are found in 10 percent of NSCLC tumors and have minimal overlap with other actionable mutations present in NSCLC, such as EGFR and ALK.

Genomic screening of over 400 cancer cell lines that remove BRM via CRISPR revealed a genetic dependency of certain BRG1-mutated cancers on BRM. This finding suggests that selective inhibition of BRM has the potential to be therapeutically meaningful in certain cancers with BRG1 mutations.

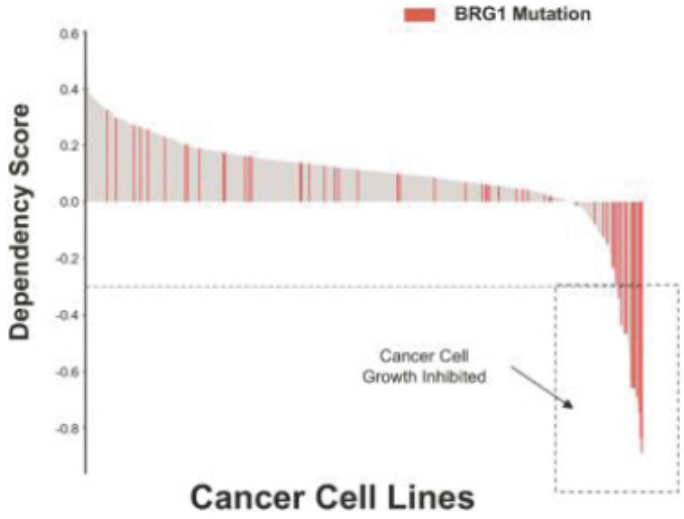


Figure 20. In a screen of over 400 cancer cell lines, inactivation of the BRM gene resulted in selective inhibition of cell lines containing mutations in BRG1.

Our Solution: Selective BRM Modulators

We are advancing two classes of molecules, an enzymatic inhibitor and a protein degrader, as selective modulators of BRM.

One class consists of selective, allosteric inhibitors of the ATPase activity of BRM. We are designing these inhibitors to be more selective for BRM than the very similar ATPase BRG1. Through our proprietary methods of isolating and screening BAF complexes that contain either BRG1 or BRM, we have identified small molecule inhibitors that are over 10 times more selective for BRM than BRG1. We have shown that this selectivity was

also observed in cellular assays. Pharmacokinetic profiles of these molecules have been consistent with the ability to potently inhibit BRM while having minimal inhibitory activity against BRG1.

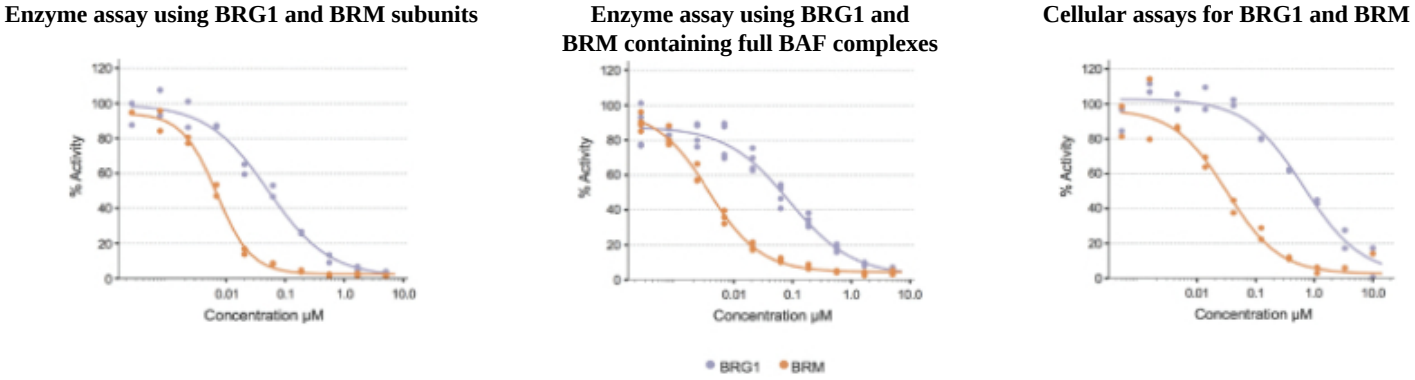


Figure 21. This panel showed biochemical (percent of ATPase activity) and cellular selectivity of a 20X selective inhibitor of BRG1 versus BRM.

Our other approach to selective BRM modulation consists of protein degrader molecules that activate the cell's protein degradation system to selectively destroy BRM. One domain of the BRM degrader molecule is a potent and selective binder of BRM. This is chemically linked to a domain that binds to a receptor on the E3 ligase complex. In cells, these protein degrader molecules bring their target into proximity of the E3 ligase which marks these target proteins for destruction by the cell's protein degradation system. We have shown that it is possible to identify protein degraders that lead to the destruction of BRM while leaving BRG1 untouched. We anticipate nominating a drug candidate in 2021.

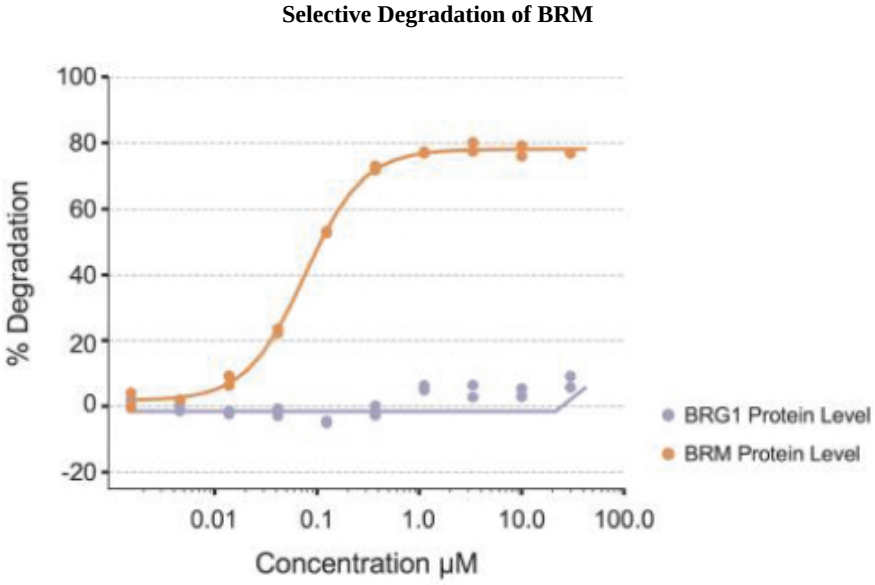


Figure 22. Selective BRM degrading molecules led to the degradation of over 75 percent of BRM while leaving the levels of BRG1 virtually unchanged.

ARID1B Selective Modulators and Other Opportunities in the Chromatin Regulatory System

The ARID1A subunit is the most mutated subunit within the BAF complex. Mutations in ARID1A confer a dependency on the ARID1B subunit of the BAF complex. ARID1A mutations are implicated in ovarian, endometrial, colorectal, bladder, and gastric cancers. Data suggest that there are over 175,000 patients with ARID1A mutations that would potentially benefit from a therapy selectively targeting ARID1B.

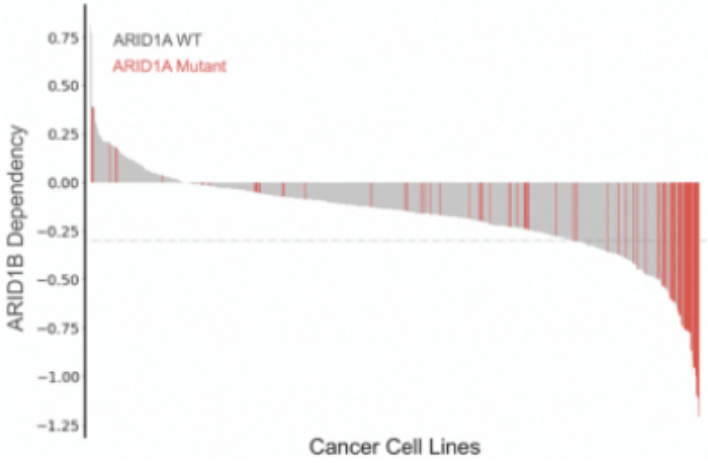


Figure 23. In a screen of over 400 cancer cell lines, inactivation of the ARID1B gene resulted in selective growth inhibition of cell lines containing mutations in ARID1A, establishing the dependency on ARID1B in these cell lines.

Since ARID1B is not an enzyme, our strategy is to selectively degrade ARID1B. Our platform allows us to generate full BAF complexes containing only ARID1A or ARID1B. Using our platform, we have conducted high throughput screens and have discovered binders to the ARID1B protein that we will seek to optimize as protein degrader product candidates.

Given the significance of mutations within the chromatin regulatory system, we are using our platform to discover and validate additional dependencies. We have several additional early programs underway. We continue to evaluate new target opportunities and intend to further expand our pipeline in oncology as well as other therapeutic areas.

Targeting Transcription Factors: Disrupting Transcription Factor Binding to Chromatin Remodeling Complexes

Transcription factors work in concert with chromatin remodeling complexes, BAF as one example, to orchestrate gene expression. In tumor cells, genes encoding transcription factors are often amplified, deleted, rearranged via chromosomal translocation or subjected to point mutations that result in a gain or loss of function. We have developed a set of tools to visualize and study the interactions between transcription factors and chromatin remodeling complexes. To our knowledge, we are the only company with these capabilities.

We are using these capabilities to drive our drug discovery efforts across multiple transcription factor programs for a variety of cancer indications. Our strategy is to disrupt the interaction between transcription factors and chromatin remodeling complexes. Our initial focus is on disrupting transcription factor interactions with the BAF complex. We believe that there are over 100 transcription factors in oncology that would be amenable to this new approach. Based on these insights, we are developing small molecule disruptors that block the interaction between transcription factors and the BAF complex. In addition to applications in cancer, we believe that such disruptors could be applied in other therapeutic areas.

Our approach to disrupting the interactions between transcription factors and the BAF complex is the basis of a collaboration signed with Merck in July 2020. In this collaboration, we intend to apply our Gene Traffic Control platform to identify disruptors of a single predetermined transcription factor. As part of the collaboration, we received an upfront payment of $15.0 million, and are also eligible to receive up to $245.0 million upon achievement of specified research, development and regulatory milestones by any product candidate generated by the collaboration, and up to $165.0 million upon achievement of specified sales-based milestones.

A prototypical example of a chromatin remodeling complex–transcription factor interaction is exemplified by the ERG transcription factor and BAF. In approximately half of all prostate cancers, the gene encoding ERG is fused to the TMPRRS2 promotor, resulting in the overexpression of ERG and the upregulation of a broad set of additional genes. Furthermore, genetic suppression of ERG expression in cells containing the TMPRRS2-ERG gene fusion has been shown to inhibit cell proliferation. These results support our approach that disrupting the interaction of over expressed transcription factors, such as ERG, with a chromatin remodeling complex has the potential to be therapeutically beneficial to patients.

Similar to ERG, the ability of individual transcription factors to interact with the BAF complex has previously been reported in the literature, but to our knowledge, there have not previously been systematic studies quantifying and describing these binding interactions. We used our Gene Traffic Control platform to produce and purify BAF complexes and multiple transcription factors to study the structural details as well as the biochemical and biophysical properties of their interactions.

We observed that different transcription factors bind to different sites on the surface of the BAF complex. This suggests that there is specificity in these interactions. Therefore, it may be possible to block the interaction of a specific transcription factor with the BAF complex without blocking the interactions of other transcription factors.

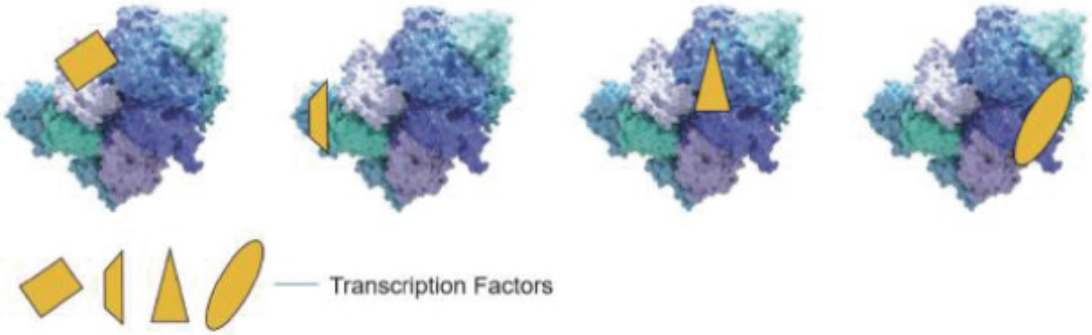


Figure 24. Illustrative locations of the binding sites of multiple transcription factors to the BAF complex.

We also observed that the binding affinities that describe how tightly transcription factors bind to the BAF complex were roughly comparable to those observed for other protein-protein interactions for which small

molecule disruptors have been developed. We found that the interactions between multiple transcription factors and the BAF complex had a K_d, a measure of binding affinity, in the range of 20 to 350 nM.

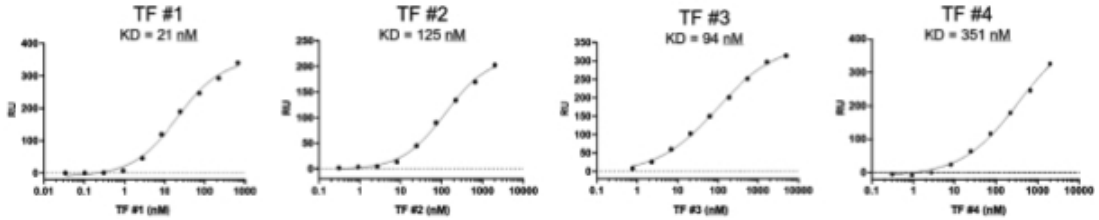


Figure 25. Interactions between transcription factors and the BAF complex had K_ds in the range of 20 to 350 nM. Smaller numbers reflected higher affinity binding.

Using the insights of where and how tightly transcription factors bind, we have developed as part of our Gene Traffic Control platform the ability to conduct high throughput screens on chromatin remodeling complex–transcription factor interactions. We have already validated eight BAF-transcription factor interactions for targets of interest in various cancers. We are applying our know-how to screen several of these BAF-transcription factor interactions to discover and develop transcription factor disruptors. We intend to use our platform to validate and drug additional transcription factors that interact with BAF and other chromatin remodeling complexes both in oncology and other therapeutic areas.

Competition

The biotechnology and pharmaceutical industries are characterized by the rapid evolution of technologies and understanding of disease etiology, intense competition and a strong emphasis on intellectual property. We believe that our approach, strategy, scientific capabilities, know-how and experience provide us with competitive advantages, including, to our knowledge, our being the only company with the ability to study the chromatin regulatory system at scale, in context, and in an integrated way. However, we expect substantial competition from multiple sources, including major pharmaceutical, specialty pharmaceutical, and existing or emerging biotechnology companies, academic research institutions and governmental agencies and public and private research institutions worldwide. Many of our competitors, either alone or through collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies may be or may become interested in the chromatin regulatory system and rapidly develop programs that may compete with ours by studying the chromatin regulatory system at scale, in context and in an integrated way. Even if they do not advance programs with the same mechanism of action as ours, these companies could develop products or product candidates that are competitive with ours or that have a superior product profile and may do so at a rapid pace. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

We face competition from segments of the pharmaceutical, biotechnology and other related markets that pursue the development of therapies that target broad genetic expression mechanisms, including the chromatin regulatory system. In addition, we may face competition from companies developing product candidates that utilize protein degradation approaches, including Arvinas, Inc., Kymera Therapeutics, Inc., Nurix Therapeutics, Inc., C4 Therapeutics, Inc., and Vividion Therapeutics, Inc. Further, several large pharmaceutical companies have disclosed preclinical investments in this field. Our competitors will also include companies that are or will

be developing other targeted therapies, including small molecule, antibody, or protein degraders for the same indications that we are targeting.

We could see a reduction or elimination in our commercial opportunity if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, are less expensive or with more favorable labeling than our product candidates, regardless of whether they target the chromatin regulatory system as a mechanism of action. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Intellectual Property

We seek to protect the intellectual property and proprietary technology that we consider important to our business, including by pursuing patent applications that cover our product candidates and methods of using the same, as well as other relevant inventions and improvements that we believe to be commercially important to the development of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. Our commercial success depends, in part, on our ability to obtain, maintain, enforce and protect our intellectual property and other proprietary rights for the technology, inventions and improvements we consider important to our business, and to defend any patents we may own or in-license in the future, prevent others from infringing any patents we may own or in-license in the future, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid and enforceable patents and proprietary rights of third parties.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our product candidates and technologies will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our pending provisional and PCT patent applications, and any patent applications that we may in the future file or license from third parties, may not result in the issuance of patents and any issued patents we may obtain do not guarantee us the right to practice our technology or commercialize our product candidates. We also cannot predict the breadth of claims that may be allowed or enforced in any patents we may own or in-license in the future. Any issued patents that we may own or in-license in the future may be challenged, invalidated, circumvented or have the scope of their claims narrowed. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting the protection such patent would afford the respective product and any competitive advantage such patent may provide.

The term of individual patents depends upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent claiming a new drug product may also be eligible for a limited patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of a clinical investigation involving human beings is begun and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. Only one patent applicable to an approved product is eligible

for the extension, and only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended. Additionally, the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The United States Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA. In the future, if our product candidates receive approval by the FDA, we expect to apply for patent term extensions on any issued patents covering those products, depending upon the length of the clinical studies for each product and other factors. There can be no assurance that patents will issue from our current or future pending patent applications, or that we will benefit from any patent term extension or favorable adjustments to the terms of any patents we may own or in-license in the future. In addition, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Patent term may be inadequate to protect our competitive position on our products for an adequate amount of time.

As of February 28, 2021, we owned 10 pending U.S. provisional patent applications, eight pending U.S. non-provisional patent applications, and 19 pending PCT applications, and ten pending ex-U.S. patent applications. We currently do not own or in-license any issued patents with respect to any of our product candidates, including FHD-286 and FHD-609, or our platform technology, and our intellectual property portfolio is in its very early stages.

FHD-286

As of February 28, 2021, we owned three pending U.S. provisional patent applications, two pending U.S. non-provisional patent applications, four pending Patent Cooperation Treaty, or PCT, patent applications, and five pending ex-U.S. patent applications that relate to FHD-286, including its composition and various methods of use. Any U.S. or ex-U.S. patent that may issue from these patent applications would be scheduled to expire between 2039-2041, excluding any additional term for patent term adjustment or patent term extension, if applicable.

FHD-609

As of February 28, 2021, we owned one pending U.S. provisional patent applications, two pending U.S. non-provisional patent applications, and three pending Patent Cooperation Treaty, or PCT, patent applications, and five pending ex-U.S. patent applications that relate to FHD-609, including its composition and various methods of use. Any U.S. or ex-U.S. patent that may issue from a non-provisional patent application claiming priority to these applications would be scheduled to expire between 2039-2041, excluding any additional term for patent term adjustment or patent term extension, if applicable.

Prosecution of most of our PCT patent applications and our provisional patent applications has not commenced and will not commence unless and until they are timely converted into U.S. non-provisional or national stage applications. Prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO or other foreign jurisdiction are often significantly narrowed by the time they issue, if they issue at all. Any of our pending PCT patent applications are not eligible to become issued patents until, among other things, we file national stage patent applications within 30 months in the countries in which we seek patent protection. If we do not timely file any national stage patent applications, we may lose our priority date with respect to our PCT patent applications and any patent protection on the inventions disclosed in such PCT patent applications. Our provisional patent applications may never result in issued patents and are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing the related provisional patent application. If we do not timely file non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional and

national stage patent applications relating to our provisional and PCT patent applications, we cannot predict whether any of our current or future patent applications related to FHD-286, FHD-609, or any of our other product candidates, will issue as patents. If we do not successfully obtain patent protection, or, even if we do obtain patent protection, if the scope of the patent protection we obtain with respect to FHD-286, FHD-609, or our other product candidates or technology is not sufficiently broad, we will be unable to prevent others from using our technology or from developing or commercializing technology and products similar or identical to ours or other competing products and technologies.

In addition to patent applications, we rely on unpatented trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and confidential know-how are difficult to protect. In particular, we consider various aspects of our Gene Traffic Control platform to constitute our trade secrets and know-how. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our collaborators and scientific advisors and non-competition, non-solicitation, confidentiality and invention assignment agreements with our employees and consultants. We cannot guarantee that we will have executed such agreements with all applicable employees and contractors, or that these agreements will afford us adequate protection of our intellectual property and proprietary information rights. In addition, our trade secrets and/or confidential know-how may become known or be independently developed by a third party or misused by any person to whom we disclose such information. These agreements may also be breached, and we may not have an adequate remedy for any such breach. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain or use information that we regard as proprietary. Although we take steps to protect our proprietary information, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information. For more information regarding the risks related to our intellectual property, please see “Risk Factors—Risks Related to our Intellectual Property.”

License Agreement with Merck

In July 2020, we entered into a Research Collaboration and Exclusive License Agreement, or the Merck Collaboration Agreement, with Merck to apply our Gene Traffic Control platform to discover and develop novel therapeutics based on disruptors of a specified transcription factor target.

Under the terms of the Merck Collaboration Agreement, we are responsible for certain preclinical research activities under a mutually agreed research plan, such as the use of our high throughput screening and compound optimization technology to identify and validate disruptors directed to this transcription factor target, up until our delivery to Merck of a hit package that identifies validated disruptors directed to the transcription factor target. Merck will be responsible for further preclinical research under the Merck Collaboration Agreement and for the clinical development and commercialization of therapeutics arising from the agreement. Merck will have a limited right to substitute the transcription factor target that is the subject of the collaboration for other transcription factors.

Under the terms of the Merck Collaboration Agreement, we have granted Merck an exclusive, worldwide, sublicensable license under certain patent rights and know-how to make, have made, use, import, offer to sell and sell therapeutics arising from the collaboration that disrupt the specified transcription factor target.

We have received an upfront payment of $15.0 million from Merck, and are eligible to receive up to $245.0 million upon achievement of specified research, development and regulatory milestones by any product candidate generated by the collaboration, and up to $165.0 million upon achievement of specified sales-based milestones per approved product from the collaboration, if any. We will be eligible to receive tiered royalties, calculated on a product-by-product basis, on net sales of approved products from the collaboration, if any, at royalty rates ranging from the mid-single digits to low tens, depending on whether the products are covered by patent rights we license to Merck.

The Merck Collaboration Agreement will expire upon expiration of all of Merck's royalty obligations under the agreement. Merck may terminate the Merck Collaboration Agreement for convenience, and either party may terminate the Merck Collaboration Agreement in the event the other party's uncured material breach or such party's bankruptcy or insolvency. If Merck terminates the Merck Collaboration Agreement as a result of our breach, the licenses and other rights granted to Merck under the agreement will remain in effect and become perpetual. If the term of the agreement expires, then such licenses and other rights will become fully paid-up.

Manufacturing

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates undergoing preclinical testing, as well as for clinical testing and commercial manufacture if our product candidates receive marketing approval.

All of our drug candidates are small molecules and are manufactured in synthetic processes from available starting materials. The chemistry appears amenable to scale up and does not currently require unusual equipment in the manufacturing process. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

We generally expect to rely on third parties for the manufacture of companion diagnostics for our products, which are assays or tests to identify an appropriate patient population. Depending on the technology solutions we choose, we may rely on multiple third parties to manufacture and sell a single test.

Commercialization

Subject to receiving marketing approvals, we expect to commence commercialization activities by building a focused sales and marketing organization in the United States to sell our products. We believe that such an organization will be able to address the community of oncologists who are the key specialists in treating the patient populations for which our product candidates are being developed. Outside the United States, we expect to enter into distribution and other marketing arrangements with third parties for any of our product candidates that obtain marketing approval.

We also plan to build a marketing and sales management organization to create and implement marketing strategies for any products that we market through our own sales organization and to oversee and support our sales force. The responsibilities of the marketing organization would include developing educational initiatives with respect to approved products and establishing relationships with researchers and practitioners in relevant fields of medicine.

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in ex-United States countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, recordkeeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs. We, along with our vendors, 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 of our product candidates. The process of obtaining regulatory approvals of drugs and ensuring subsequent compliance with appropriate federal, state, local and ex-United States statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, where we are initially focusing our drug development, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, as amended, its implementing regulations and

other laws. If we fail to comply with applicable FDA or other requirements at any time with respect to product development, clinical testing, approval or any other legal requirements relating to product manufacture, processing, handling, storage, quality control, safety, marketing, advertising, promotion, packaging, labeling, export, import, distribution, or sale, we may become subject to administrative or judicial sanctions or other legal consequences. These sanctions or consequences could include, among other things, the FDA's refusal to approve pending applications, issuance of clinical holds for ongoing studies, suspension or revocation of approved applications, warning or untitled letters, product withdrawals or recalls, product seizures, relabeling or repackaging, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution.

The process required by the FDA before our product candidates are approved as drugs for therapeutic indications and may be marketed in the United States generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice, or GLP, requirements;
- completion of the manufacture, under cGMP conditions, of the drug substance and drug product that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- submission to the FDA of an IND, which must become effective before clinical trials may begin;
- approval by an institutional review board, or IRB, or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, good clinical practice, or GCP, requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of a New Drug Application, or NDA;
- a determination by the FDA within 60 days of its receipt of an NDA, to accept the filing for review;
- 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;
- potentially, satisfactory completion of FDA audit of the clinical trial sites that generated the data in support of the NDA;
- payment of user fees for FDA review of the NDA; and
- 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.

Preclinical Studies and Clinical Trials for Drugs

Before testing any drug in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of drug chemistry, formulation and stability, as well as *in vitro* and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to United States federal and state regulation, including GLP requirements for safety/toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data, must be 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 clinical trials may begin. Some long-term preclinical testing may continue after the IND is submitted. 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 full or partial clinical hold. FDA must notify the sponsor of the grounds for the hold and any identified deficiencies must be resolved 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 clinical hold can also be imposed once a trial has already begun, thereby halting the trial until the deficiencies articulated by FDA are corrected.

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, who generally are physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent for their participation in any clinical trial. 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, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable compared to the anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subject or other grounds, such as a lack of observed efficacy. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about clinical trials, including results for clinical trials other than Phase 1 investigations, must be submitted within specific timeframes for publication on www.ClinicalTrials.gov, a clinical trials database maintained by the National Institutes of Health.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, FDA will nevertheless accept the results of the study in support of an NDA if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials to evaluate therapeutic indications to support NDAs for marketing approval are typically conducted in three sequential phases, which may overlap.

- *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 drug's potential efficacy, to determine the 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.

Post-approval trials, sometimes referred to as Phase 4 clinical trials or post-marketing studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of NDA approval.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human volunteers and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing the drug product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and manufacturers must develop, among other things, methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Marketing Approval for Drugs

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, 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 package requesting approval to market the product for one or more indications. 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 for the requested indications. The marketing application is required to include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. 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 must approve an NDA before a drug may be marketed in the United States.

The FDA reviews all submitted NDAs before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective for the indications sought and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. Under the goals and polices agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA targets ten months, from the filing date, in which to complete its initial

review of a new molecular entity NDA and respond to the applicant, and six months from the filing date of a new molecular entity NDA for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

Further, under PDUFA, as amended, each NDA must be accompanied by a substantial user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy, or REMS, if it believes that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh its risks. A REMS can include use of risk evaluation and mitigation strategies like medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk-minimization tools.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

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 in compliance with cGMP requirements and are adequate to assure consistent production of the 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 the advisory committee recommendation, if any, and 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 the 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.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug 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. 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. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity. Further, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Development and Review Programs for Drugs

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs 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 more quickly than standard FDA review timelines typically permit.

A new drug 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. Rolling review means that the agency may review portions of the marketing application before the sponsor submits the complete application. In addition, a new drug 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, once an NDA or BLA is submitted, if the drug that is the subject of the marketing application 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, the FDA's goal date to take action on the marketing application is six months compared to ten months for a standard review. 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. The FDA may withdraw approval of a drug or an indication approved under Accelerated Approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA generally requires, as a condition for Accelerated Approval, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period. After the 120-day period has passed, 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 scientific or medical standards for approval or the quality of evidence necessary to support approval, though they may expedite the development or review process.

Pediatric Information and Pediatric Exclusivity

The Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, as amended, certain NDAs and NDA supplements must contain data that can be used to assess the safety and efficacy 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 grant deferrals for submission of pediatric data or full or partial waivers. The FD&C Act requires that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

A drug can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

United States. Post-Approval Requirements for Drugs

Drugs manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the generation of additional data or the conduct of additional preclinical studies and clinical trials.

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 cGMPs, which impose certain procedural and documentation requirements. Failure to comply with statutory and regulatory requirements may subject a manufacturer to legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual prescription drug product program user fee.

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 restrictions under a REMS. Other potential consequences include, among other things:

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

Companion diagnostics are designed to identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for

the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics are regulated as medical devices by the FDA. In the United States, the FD&C Act, and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption or FDA exercise of enforcement discretion applies, diagnostic tests generally require marketing clearance or approval from the FDA prior to commercialization. The two primary types of FDA marketing authorization applicable to a medical device are clearance of a premarket notification, or 510(k), and approval of a premarket approval application, or PMA.

To obtain 510(k) clearance for a medical device, or for certain modifications to devices that have received 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or to a pre-amendment device that was in commercial distribution before May 28, 1976, or a predicate device, for which the FDA has not yet called for the submission of a PMA. In making a determination that the device is substantially equivalent to a predicate device, the FDA compares the proposed device to the predicate device and assesses whether the subject device is comparable to the predicate device with respect to intended use, technology, design and other features which could affect safety and effectiveness. If the FDA determines that the subject device is substantially equivalent to the predicate device, the subject device may be cleared for marketing. The 510(k) premarket notification pathway generally takes from three to twelve months from the date the application is completed, but can take significantly longer.

A PMA must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. The process for developing a PMA, including the gathering of clinical and preclinical data and submission to FDA can take several years or longer. For diagnostic tests, a PMA typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the quality system regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. The FDA's review of an initial PMA is required by statute to take between six to ten months, although the process typically takes longer, and may require several years to complete, and PMA approval is not guaranteed. If the FDA evaluations of both the PMA and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny the approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

On July 31, 2014, the FDA issued a final guidance document addressing the development and approval process for "*In Vitro* Companion Diagnostic Devices." According to the guidance document, for novel therapeutic products that depend on the use of a diagnostic test and where the diagnostic device could be essential for the safe and effective use of the corresponding therapeutic product, the companion diagnostic device should be developed and approved or cleared contemporaneously with the therapeutic, although the FDA recognizes that there may be cases when contemporaneous development may not be possible. However, in cases where a drug cannot be used safely or effectively without the companion diagnostic, the FDA's guidance indicates it will generally not approve the drug without the approval or clearance of the diagnostic device. The FDA also issued a draft guidance in July 2016 setting forth the principles for co-development of an *in vitro* companion diagnostic device with a therapeutic product. The draft guidance describes principles to guide the development and contemporaneous marketing authorization for the therapeutic product and its corresponding *in vitro* companion diagnostic.

Once cleared or approved, the companion diagnostic device must adhere to post-marketing requirements including the requirements of the FDA's QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging, and shipping of all medical devices, as well as adverse event reporting, recalls and corrections along with product marketing requirements and limitations. Medical devices, including companion diagnostics, may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. Like drug makers, companion diagnostic makers are subject to unannounced FDA inspections at any time during which the FDA will conduct an audit of the product(s) and the company's facilities, facility records, and manufacturing processes for compliance with its authorities.

Marketing Exclusivity

Market exclusivity provisions authorized under the FD&C Act can delay the submission or the approval of certain marketing applications. The FD&C Act provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FD&C Act alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities of product candidates following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, which may include the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, 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 business operations and any current or future 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 develop, 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, including but not limited to those described below.

- The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid; a person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.
- The federal civil and criminal false claims laws, including the civil False Claims Act, or FCA, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing 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. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs.
- The federal civil monetary penalties laws impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary, if the person knows or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies.
- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, or falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, impose, among other things, specified requirements on covered entities and their business associates relating to the privacy and

security of individually identifiable health information including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates in some cases, 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 Physician Payments Sunshine Act, which imposes annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided 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 in the previous year to certain non-physician providers such as physician assistants and nurse practitioners.
- Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.
- Analogous state and foreign laws and regulations may be broader in scope than the provisions described above and may apply regardless of payor. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and relevant federal government compliance guidance; require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers; restrict marketing practices or require disclosure of marketing expenditures and pricing information. State and foreign laws may govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts.

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. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other related governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to similar actions, penalties and sanctions. 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 its business.

Coverage and Reimbursement by Third-Party Payors

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and

establish adequate reimbursement levels for, the product. In the United States, the Medicare and Medicaid programs are increasingly used as models for how private and other governmental payors develop their coverage and reimbursement policies for drugs. No uniform policy of coverage and reimbursement for drug products exists, however, among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, which will require additional expenditure above and beyond the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Current and Future Healthcare Reform Legislation

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in March 2010, the United States Congress enacted the Affordable Care Act, which, among other things, includes changes to the coverage and payment for products under government health care programs.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. For example, various portions of the Affordable Care Act are currently facing legal and constitutional challenges in the Fifth Circuit Court of Appeals and the United States Supreme Court. Additionally, the current administration has issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices, and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the Affordable Care Act. It is unclear whether the Affordable Care Act will be overturned, repealed,

replaced, or further amended. We cannot predict what effect further changes to the Affordable Care Act would have on our business.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with a temporary suspension from May 1, 2020 through December 31, 2020, unless additional Congressional action is taken. In addition, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, including bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Although a number of these measures may require additional authorization to become effective, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

On July 24, 2020, President Trump announced a number of executive orders related to prescription drug pricing that attempt to implement several of the Administration’s proposals, including a policy that would tie Medicare Part B drug prices to international drug prices; one that directs HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; and one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for plans, pharmacies, and pharmaceutical benefit managers after HHS confirms that the action is not projected to increase federal spending, Medicare beneficiary premiums, or patients’ total out-of-pocket costs. The probability of success of these newly announced policies and their impact on the U.S. prescription drug marketplace is unknown. There are likely to be political and legal challenges associated with implementing these reforms as they are currently envisioned.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government authorities can extend well beyond the receipt of regulatory approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization. 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 products, if approved in those countries.

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 and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution would apply to any product that is approved outside the United States.

Employees

As of December 31, 2020, we had 95 full-time employees. 53 of our employees have M.D. or Ph.D. degrees. Within our workforce, 79 employees are engaged in research and development and 16 are engaged in business development, finance, legal, and general management and administration. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our Corporate Information

We were formed as a Delaware corporation in October 2015 under the name Foghorn Therapeutics Inc. Our principal executive office is located at 500 Technology Square, Suite 700, Cambridge, Massachusetts, 02139, and our phone number is 617-586-3100. Our website address is https://foghorntx.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.

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.

We are also a “smaller reporting company” as defined in the Securities and Exchange Act of 1934, as amended, or the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

Available Information

Our Internet address is https://foghorntx.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) and 15(d) of the Exchange Act are available through the “Investors” 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. In addition, our filings with the SEC may be accessed through the SEC’s Electronic Data Gathering, Analysis and Retrieval 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

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and related notes, before deciding to invest in our common stock. Some of the following risks and uncertainties are, and will be, exacerbated by the COVID-19 pandemic (including any resurgences thereof) and any worsening of the global business and economic environment as a result. If any of the events or developments described below were to occur, our business, prospects, operating results and financial condition could suffer materially, the trading price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were incorporated in October 2015, and our operations to date have been focused on building our proprietary Gene Traffic Control platform, organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, protecting our trade secrets, filing patent applications, identifying potential product candidates, undertaking preclinical studies and establishing arrangements with third parties for the manufacture of initial quantities of our product candidates and component materials. We are currently initiating Phase 1 clinical trials for FHD-286, and all of our other product candidates are in preclinical development. We have not yet demonstrated an ability to successfully conduct or complete any clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and results of operations to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

We have incurred significant losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. As of December 31, 2020, we had an accumulated deficit of $162.9 million. We have financed our operations primarily through private placements of our preferred stock and our initial public offering, as well as through a loan with Oxford Finance LLC, or Oxford Finance, and our collaboration agreement with Merck Sharp & Dohme Corp., or Merck. See “Business—License Agreement with Merck.” We have devoted all of our efforts to research and development. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if and as we:

- advance our FHD-286 and FHD-609 product candidates and continue our preclinical development of product candidates from our current research programs;
- identify additional research programs and additional product candidates;

- initiate preclinical testing for any new product candidates we identify and develop;
- obtain, maintain, expand, enforce, defend and protect our trade secrets and intellectual property portfolio and provide reimbursement of third-party expenses related to our patent portfolio;
- hire additional research and development personnel;
- add operational, legal, compliance, financial and management information systems and personnel to support our research, product development and operations as a public company;
- expand the capabilities of our platform;
- acquire or in-license product candidates, intellectual property and technologies;
- operate as a public company;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials; and
- ultimately establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval.

We have one product candidate in Phase 1 clinical development and have not initiated clinical development of any other product candidate and expect that it will be many years, if ever, before we have a product candidate ready for commercialization. To become and remain profitable, we must develop and, either directly or through collaborators, eventually commercialize a medicine or medicines with significant market potential. This will require us to be successful in a range of challenging activities, including identifying product candidates, completing preclinical testing and clinical trials of product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing, and selling those medicines for which we may obtain marketing approval, and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. We are unable to predict the extent of any future losses or when we will become profitable, if at all. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We will need substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce, or eliminate our research and product development programs or future commercialization efforts.

We expect our expenses to increase in connection with our ongoing activities, particularly as we identify, continue the research and development of, initiate clinical trials of, and seek marketing approval for, our product candidates. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce, or eliminate our research and product development programs or future commercialization efforts.

As of December 31, 2020, our cash, cash equivalents and marketable securities were $185.8 million. The net proceeds of our initial public offering were $107.9 million, after deducting underwriting discounts and commissions and other offering expenses. On November 19, 2020, we received additional net proceeds of $14.2 million in connection with the underwriters' partial exercise of their option to purchase additional shares of common stock in our initial public offering.

Additional fundraising efforts, when needed, may divert our management's attention from their day-to-day activities, which may adversely affect our ability to advance our product candidates or develop new product candidates. We cannot be certain that additional funding will be available on acceptable terms, or at all. 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 our product candidates or other research and development initiatives.

If we are unable to obtain funding on a reasonable and timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs, clinical research, or the commercialization of any product candidate. We may be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations. 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 never generated revenue from product sales and may never be profitable.

We are currently in the Phase 1 clinical development stage for our most advanced product candidate, FHD-286, and in the preclinical development stage for our other lead research programs. In addition, we expect to submit an IND to the FDA for FHD-609 in the second quarter of 2021. We expect that it will be many years, if ever, before we have a product candidate ready for commercialization. To become and remain profitable, we must succeed in developing, obtaining marketing approval for and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our current or future product candidates, establishing and maintaining arrangements with third parties for the manufacture of clinical supplies of our product candidates, obtaining marketing approval for our product candidates and manufacturing, marketing, selling and obtaining reimbursement for any products for which we may obtain marketing approval. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Our Loan Agreement with Oxford Finance contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay the outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and share price.

Pursuant to our secured loan agreement with Oxford Finance we have agreed to certain affirmative and negative covenants that, among other things, restrict our ability to:

- dispose of any property;
- consolidate or merge;
- incur additional indebtedness;
- encumber any of our property;
- make distributions, including dividends;
- make certain investments or acquisitions; or
- repay any subordinated debt.

These covenants could prevent us from taking certain actions without the consent of our lender, which may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us. The Oxford Finance agreement also includes events of default, including, among other things, payment defaults; breaches of certain covenants or agreements; certain bankruptcy or insolvency events; the occurrence of certain events that could reasonably be expected to have a “material adverse effect;” and defaults in respect of certain other indebtedness.

If an event of default were to occur and Oxford Finance declared all outstanding obligations immediately due and payable, we would be required to repay the outstanding indebtedness. If we are unable to repay this debt, Oxford Finance would be able to take remedies permitted under the agreement. Even if we are able to repay the indebtedness on an event of default, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and share price.

U.S. federal income tax reform could adversely 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. For example, on March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act, which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 coronavirus outbreak, including temporary beneficial changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters. Additionally, on December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act, or the TCJA, which significantly reformed the Internal Revenue Code of 1986, as amended, or the Code. The TCJA included significant changes to corporate and individual taxation, some of which could adversely impact an investment in our common stock. 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 future ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset a portion of future taxable income, if any, subject to expiration in the case of carryforwards generated prior to January 1, 2018. Additionally, we continue to generate business tax credits, including research and development tax credits, which generally may be carried forward to offset a portion of future taxable income, if any, subject to expiration of such credit carryforwards. Under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. Our prior equity offerings and other changes in our stock ownership may have resulted in such ownership changes. We may also experience ownership changes in the future or subsequent shifts in our stock ownership, some of which are outside of our control. As a result, if we earn net taxable income, our ability to use our pre-change NOLs or other pre-change tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. Additionally, for taxable years beginning after December 31, 2021, the deductibility of such U.S. federal NOLs is limited to 80% of our taxable income in any future taxable year. There is a risk that under existing tax laws, changes thereto, regulatory changes, or other unforeseen reasons, our existing NOLs or business tax credits could expire or otherwise be unavailable to offset future income tax liabilities. At the state level, there may also be periods during which the use of NOLs or business tax credits is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For these reasons, we may not be able to realize a tax benefit from the use of our NOLs or tax credits, even if we attain profitability.

Risks Related to Discovery and Development

We are heavily dependent on the success of our product candidates, which are in preclinical and Phase 1 clinical development. We may not be successful in our efforts to identify and develop potential product candidates. If these efforts are unsuccessful, or if we experience significant delays, we may never become a commercial stage company or generate any revenues, and our business will be materially harmed.

The success of our business depends primarily upon our ability to identify, develop, and commercialize product candidates based on our platform. All of our product development programs are still in the research or preclinical or Phase 1 clinical stage of development. Our research programs may fail to identify potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying

potential product candidates, our potential product candidates may be shown to have harmful side effects in preclinical *in vitro* experiments or animal model studies, they may not show promising signals of therapeutic effect in such experiments or studies or they may have other characteristics that may make the product candidates impractical to administer or market.

If any of these events occur, we may be forced to abandon our research or development efforts for a program or programs, which would have a material adverse effect on our business, financial condition, results of operations, and prospects. Research programs to identify new product candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful, which would be costly and time-consuming.

The success of our product candidates will depend on several factors, including but not limited to the following:

- successful completion of preclinical studies;
- successful submission of INDs and initiation of clinical trials;
- establishing an acceptable safety profile of the products and maintaining such a profile following approval;
- achieving desirable therapeutic properties for our product candidates' intended indications;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, both for clinical and commercial supplies of our product candidates;
- receipt and related terms of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity of our product candidates;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products; if and when approved, whether alone or in collaboration with others; acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- effectively competing with other therapies; and
- sufficiency of our financial and other resources.

If we do not successfully 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 could materially harm our business. Moreover, if we do not receive regulatory approvals, we may not be able to continue our operations.

We may not be able to file INDs or IND amendments to commence clinical trials of our product candidates on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

In order to commence a clinical trial in the United States, we are required to seek FDA acceptance of an IND for each of our product candidates. We cannot be sure any IND we submit to the FDA, or any similar clinical trial application we submit in other countries, will be accepted. We may also be required to conduct additional preclinical testing prior to filing or acceptance of an IND for any of our product candidates, and the results of any such additional preclinical testing may not be positive.

Further, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that even once clinical trials have begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if the FDA agrees with the design and implementation of the clinical trials set forth in

an IND, we cannot guarantee that the FDA will not change its requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory authorizations for our trials to proceed may prevent us from completing our clinical trials or commercializing our product candidates on a timely basis, if at all.

There is substantial competition in our field, which may result in others developing or commercializing products before we do.

The biotechnology and pharmaceutical industries utilize rapidly advancing technologies and are characterized by intense competition. While we believe that our scientific knowledge and platform development expertise provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceuticals, specialty pharmaceuticals and biotechnology companies, academic institutions and government agencies, and public and private research institutes that conduct research, development, manufacturing and commercialization. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, enrolling and conducting clinical trials, and seeking regulatory approvals and product marketing than we do, and have potential to advance products competitive with our product candidates or other programs addressing the chromatin regulatory system at a rapid pace. In addition, our competitors may compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our competitors may advance competing product candidates that have a more attractive product profile than our product candidates, make progress examining the chromatin regulatory system or bring a product to market before we can. Any of these developments could put us at a significant competitive disadvantage and have a material adverse effect on the prospects of our business.

Product candidates that we and our collaborators successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. While we are not aware of other companies addressing the chromatin regulatory system at scale, in context and in an integrated way, we are aware of efforts to bring products to market that could be competitive with ours if our programs are successful. Specifically, we expect that our product candidates will compete against approved drugs, including Idhifa® by Celgene Corporation, Tibsovo® by Agios Pharmaceuticals, and Rydapt® by Novartis International AG . If our drug candidates are approved for the indications for which we are currently planning clinical trials, they will likely compete with the competitor drugs mentioned above and with other drugs that are currently in development. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. Our competitors may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. For additional information regarding our competition, see “Business—Competition.”

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

We have one product in Phase 1 clinical development and all of our other product candidates are in preclinical development and their risk of failure is high. We are unable to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the United States or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or similar regulatory

authorities outside the United States will accept our proposed clinical programs or if the outcome of our preclinical testing and studies ultimately will support the further development of our programs.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. We cannot guarantee that any of our ongoing and planned clinical trials will be conducted as planned or completed on schedule, if at all. Moreover, we may experience numerous unforeseen events during, or as a result of, clinical trials, that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- delays in discussions with or obtaining alignment with regulators regarding trial design;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate, including as a result of delays in the testing, validation, manufacturing and delivery of product candidates to the clinical sites by us or by third parties with whom we have contracted to perform certain of those functions;
- we may experience delays in reaching, or may fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- we may experience delays in enrolling patients or may compete with other trials to enroll patients, including due to our targeted disease having small patient populations;
- regulators or institutional review boards 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 difficulty in designing clinical trials and in selecting endpoints for diseases that have not been well-studied and for which the natural history and course of the disease is poorly understood;
- the selection of certain clinical endpoints may require prolonged periods of clinical observation or analysis of the resulting data;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- we may fail to perform clinical trials in accordance with the FDA's or any other regulatory authority's good clinical practices, or GCP, requirements, or regulatory guidelines in other countries;
- our product candidates may have undesirable side effects or other unexpected characteristics, or adverse events associated with the product candidate may occur which are viewed to outweigh its potential benefits, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- 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;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical trials for various reasons, including noncompliance with regulatory requirements;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the cost of clinical trials of our product candidates may be greater than we anticipate;

- disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting, or completing our planned and ongoing clinical trials; and
- we could be required to conduct additional clinical trials or testing of our product candidates beyond those that we currently contemplate, which may result in a delay in our market approval, limitation of approval for patient populations, distribution limitations, or not obtaining marketing approval at all.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA or comparable foreign regulatory authorities, or recommended for suspension or termination by the data monitoring committee for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or comparable foreign regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

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

If we experience delays or difficulties in the enrollment and dosing of patients in our clinical trials, our receipt of necessary regulatory approvals for our product candidates could be delayed or prevented.

Identifying and qualifying patients to participate in clinical trials of FHD-286, FHD-609 or any other product candidates is critical to our success. The timing of our clinical trials depends on our ability to recruit patients to participate in our studies as well as the dosing of such patients and completion of required follow-up periods. Our competitors may compete for the same limited patient populations. If we or our collaborators are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other analogous regulatory authorities outside the United States, or as needed to provide appropriate statistical power for a given trial, we may not be able to initiate or continue clinical trials for our current and future product candidates. Additionally, we may face similar challenges or delays in our other or potential future clinical trials. If patients are unwilling to participate in our studies because of negative publicity from adverse events related to the biotechnology field, competitive clinical trials for similar patient populations or for other reasons, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of FHD-286 or any other product candidates may be delayed. These delays could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of the clinical trials altogether. Furthermore, our ability to enroll patients may be significantly delayed by the evolving COVID-19 pandemic and we do not know the extent and scope of such delays at this point.

Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- size of the patient population and process for identifying patients;

- design of the trial protocol;
- availability and efficacy of approved medications for the disease under investigation;
- convenience and ease of administration compared to approved medications for the disease under investigation and the willingness of patients to undergo the surgical procedures necessary to administer our product candidates, such as biopsy;
- ability to obtain and maintain patient informed consent;
- risk that enrolled patients will drop out before completion of the trial;
- eligibility and exclusion criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- factors we may not be able to control, such as current or potential pandemics that may limit patients, principal investigators or staff or clinical site availability (for example, outbreak of COVID-19).

Enrollment delays in our clinical trials may result in increased development costs for FHD-286 or any other product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit, or terminate clinical trials for FHD-286 or our other product candidates, or expand to additional jurisdictions, which could impose additional challenges on our company and expose us to risks. If we are not successful in conducting our clinical trials as planned, it would have an adverse effect on our business, financial condition, results of operations, and prospects.

Any favorable preclinical results may not be predictive of results that may be observed in clinical trials.

Data obtained from preclinical activities are subject to varying interpretations and analyses, which may delay, limit or prevent regulatory approval. Many companies that have believed their product candidates performed satisfactorily in preclinical studies have nonetheless failed to demonstrate results in clinical studies. As we generate preclinical results, such results will not ensure that later preclinical studies or clinical trials will demonstrate similar results. There is a high failure rate for drugs and biologics proceeding through clinical trials. Even if FHD-286 and FHD-609 reach the clinical trial stage, these product candidates may fail to show the desired safety and efficacy in later stage of clinical development. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later-stage clinical trials even after achieving promising results in the preclinical and early stage clinical trials.

Our product candidates utilize novel mechanisms of action, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects.

Our lead product candidates utilize novel mechanisms of action, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects. For example, FHD-609 is a protein degrader. Currently there are no approved medicines using this mechanism of action. Because FHD-609 in particular utilizes a novel mechanism of action that has not been the subject of extensive study compared to more well-known product candidates, there is also an increased risk that we may discover previously unknown or unanticipated adverse effects during our preclinical studies and clinical trials. Any such events could adversely impact our business prospects, financial condition and results of operations.

In addition, a novel mechanism of action may lengthen the regulatory review process, require us to conduct additional studies or clinical 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. The novel mechanism of action also means that fewer people are trained in or experienced with product candidates of this type, which may make it more difficult to find, hire and retain personnel for research, development and manufacturing positions.

Our approach to the discovery of product candidates is unproven, and we may not be successful in our efforts to use and expand our platform to build a pipeline of product candidates with commercial value.

A key element of our strategy is to use and expand our Gene Traffic Control platform to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of various cancers and other therapeutic areas. Although our research and development efforts to date have resulted in our discovery and preclinical development of FHD-286 and FHD-609 for the treatment of cancer, FHD-286 and FHD-609 may not be safe or effective as cancer treatments, and we may not be able to develop any other product candidates. We may not be successful in identifying further targets in the chromatin regulatory system that are relevant in cancer, or other diseases, and which can be "basketed" into a group that is large enough to present a sufficient commercial opportunity or that is druggable with one chemical compound. Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future, which likely would result in significant harm to our financial position and adversely affect our stock price.

Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, which would delay or prevent regulatory approval of the product candidates, limit the commercial potential, or result in significant negative consequences following any potential marketing approval.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that such product candidates are safe and effective for use in each targeted indication. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We have not evaluated any product candidates in human clinical trials. Moreover, we are not aware of any clinical trials involving products that interact with BAF complexes to affect the chromatin regulatory system in a similar manner to our products. It is impossible to predict when or if any product candidates we may develop will prove safe in humans. Our clinical trials may fail to demonstrate with substantial evidence from adequate and well-controlled trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. There can be no assurance that our clinical trials will not cause undesirable side effects.

If any product candidates we develop are associated with or cause serious adverse events, undesirable side effects, or unexpected characteristics, we may need to abandon their development or limit development to certain uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective, any of which would have a material adverse effect on our business, financial condition, results of operations, and prospects. Many product candidates that initially showed promise in early stage testing for treating cancer or other diseases have later been found to cause side effects that prevented further clinical development of the product candidates. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.

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

Additionally, adverse developments in clinical trials of pharmaceutical and biopharmaceutical products conducted by others may cause the FDA or other regulatory oversight bodies to suspend or terminate our clinical trials or to change the requirements for approval of any of our product candidates.

Any of these events could prevent us from achieving or maintaining market acceptance of any product candidates we may identify and develop and could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Even if our clinical trials are successfully completed, clinical data are often subject to varying interpretations and analyses, and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do. Results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. Even if regulatory is secured for a product candidate, the terms of such approval may also limit its commercial potential.

We rely on third parties to manufacture our preclinical and clinical product supplies, to produce and process clinical quantities of our product candidates and to assist with clinical trials

We currently rely on third parties to manufacture preclinical and clinical product supplies and to manufacture clinical supplies of our product candidates. We need to negotiate and maintain contractual arrangements with these outside vendors for the supply of our product candidates and we may not be able to do so on favorable terms. We have not yet caused any product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other foreign regulatory authorities following inspections that will be conducted after we submit an application to the FDA or other foreign regulatory authorities. We will be completely dependent on our contract manufacturing partners for compliance with cGMP and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have no 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, if it withdraws any approval in the future, or if it otherwise identifies noncompliance with cGMPs at these facilities, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Similarly, if any third-party manufacturers on which we will rely fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition, results of operations, and prospects could be materially and adversely affected.

In addition, we will rely on third-party clinical investigators, contract research organizations, or CROs, and consultants. Relying on third-party clinical investigators, CROs and consultants may force us to encounter delays that are outside of our control. We may be unable to identify and contract with a sufficient number of investigators, CROs and consultants on a timely basis or at all. There can be no assurance that we will be able to negotiate and enter into any additional master services agreement with other CROs, as necessary, on terms that are acceptable to us on a timely basis or at all.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, 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, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Employee Matters, Managing Growth and Information Technology

We are highly dependent on our key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

We are highly dependent on Adrian Gottschalk, our Chief Executive Officer. In addition, the loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business.

Despite our efforts to retain Mr. Gottschalk and other valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice.

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

As of December 31, 2020, we had 95 full-time employees. We intend to hire new employees to assume activities and responsibilities within the company, including conducting our research and performing development activities in the future.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We conduct our operations at our facilities in Cambridge, Massachusetts. The Massachusetts region is headquarters to many other biopharmaceutical companies and many academic and research institutions. 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. Changes to U.S. immigration and work authorization laws and regulations, including those that restrain

the flow of scientific and professional talent, can be significantly affected by political forces and levels of economic activity. Our business may be materially adversely affected if legislative or administrative changes to immigration or visa laws and regulations impair our hiring processes and goals or projects involving personnel who are not U.S. citizens.

Any delay or disruption in hiring such new employees could result in delays in our research and development activities and would harm our business. As our development 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, as well as additional facilities to expand our operations.

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

Our internal computer systems, or those used by our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of the development programs of our product candidates.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, and telecommunication and electrical failures. 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 data from completed or future preclinical studies and clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we 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.

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

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

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, 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, statutory, regulatory, and policy changes, the FDA's ability to hire and

retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global pandemic of COVID-19, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

The continuing outbreak of COVID-19 in the United States and other countries may adversely affect our business and the market price of our common stock.

The recent global pandemic of COVID-19 is impacting worldwide economic activity, particularly economic activity in the United States, and poses the risk that we or our employees, contractors, suppliers, or other partners may be prevented or delayed from conducting business activities for an indefinite period of time, including due to shutdowns that may be requested or mandated by governmental authorities. The continued prevalence of COVID-19 and the measures taken by the governments of countries affected could disrupt the supply chain and the manufacture or shipment of both drug substance and finished drug product for our product candidates for preclinical testing or clinical trials, cause diversion of healthcare resources away from the conduct of preclinical and clinical trial matters to focus on pandemic concerns, limit travel in a manner that interrupts key trial activities, such as trial site initiations and monitoring, delay regulatory filings with regulatory agencies in affected areas or adversely affect our ability to obtain regulatory approvals. These disruptions could also affect other facets of our business, including but not limited to:

- our ability to recruit employees from outside of the United States;
- the ability of our CROs to conduct preclinical studies and clinical trials in countries outside of the United States;
- our ability to important materials from outside of the United States; and
- our ability to export materials to our CROs and other third-parties located outside of the United States.

The COVID-19 outbreak and mitigation measures also may have an adverse impact on global economic conditions, which could adversely impact our business, financial condition or results of operations. Additionally, the COVID-19 outbreak has resulted in significant financial market volatility and uncertainty. A continuation or worsening of the levels of market disruption and volatility seen in the recent past as a result of the COVID-19 outbreak could have an adverse effect on our ability to access capital and on the market price of our common stock.

Risks Related to Our Intellectual Property

If we are unable to adequately protect our proprietary technology and platform or obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and products may be impaired.

Our commercial success will depend in part on our ability and the ability of our licensors to obtain and maintain proprietary or intellectual property protection in the United States and other countries for our product candidates, and our core technologies, including aspects of our Gene Traffic Control platform. We rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. In particular, our Gene Traffic Control platform is not the subject of patent applications.

We seek to protect our proprietary product candidates by filing patent applications in the United States and abroad related to our product candidates that are important to our business. If we or our licensors are unable to obtain or maintain patent protection with respect to our current and future product candidates, competitors and other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates and other product candidates that we may pursue may be impaired. As a result, our business, financial condition, results of operations and prospects could be materially harmed.

Currently, our patent portfolio, including our portfolio related to our product candidates FHD-286 and FHD-609, is in its earliest stages, primarily consisting of provisional patent applications, which do not themselves issue as patents, and patent applications filed pursuant to the Patent Cooperation Treaty, or PCT. We have no issued patents related to FHD-286 or FHD-609. In order to continue to pursue protection based on provisional patent applications, we will need to file PCT, foreign applications and/or U.S. non-provisional patent applications prior to applicable deadlines. In order to continue to pursue protection based on PCT applications, we will need to file national phase applications in the U.S. and ex-U.S. jurisdictions prior to applicable deadlines. Even then, patents may never issue from our patent applications, or the scope of any patent may not be sufficient to provide a competitive advantage.

The degree of patent protection we require to successfully commercialize our product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our pending patent applications will issue, or that any of our pending patent applications that mature into issued patents will include claims with a scope sufficient to protect FHD-286 or FHD-609 or our other current or future product candidates. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar or identical to our product candidates, including generic versions of such products.

Other parties have developed technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications, in either case that they may rely upon to dominate our patent position in the market. 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 know with certainty whether we were the first to make the inventions claimed in our owned or licensed pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty.

In addition, the patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, with respect to most of the pending patent applications covering our product candidates, prosecution has yet to commence. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the U.S. Patent and Trademark Office, or USPTO, have been significantly narrowed by the time they issue, if at all. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

Even if we acquire patent protection that we expect should enable us to maintain such competitive advantage, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party submission of prior art to the USPTO challenging the priority of an invention claimed within one of our patents, which submissions may also be made prior to a patent's issuance, precluding the granting of any of our pending patent applications. We may become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others from whom we have obtained licenses to such rights. Competitors may claim that they invented the inventions claimed in our issued patents or patent applications prior to us, or may file patent applications before we do. Competitors may also claim that we are infringing on their patents and that we therefore cannot practice our technology as claimed under our patents, if issued. Competitors may also contest our patents, if issued, by showing the patent examiner that the invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patent applications or technologies, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants and advisors and any other third parties who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, without payment to us, or could limit the duration of the patent protection covering our technology and product candidates. Such challenges may also result in our inability to manufacture or commercialize our product candidates without infringing third party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our patent portfolio is unchallenged, it may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. For example, a third party may develop a competitive product that provides benefits similar to one or more of our product candidates but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business.

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

In addition to the protection afforded by patents, we rely upon unpatented trade secret protection, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. With respect to the various aspects of our Gene Traffic Control platform, including our proprietary libraries, we consider trade secrets and know-how to be our primary intellectual property. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our collaborators, scientific advisors, employees and consultants, and invention assignment agreements with our consultants and employees. We may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements, however, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees 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. We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security on our premises, and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

Our trade secrets could otherwise become known or be independently discovered by our competitors. Competitors could purchase our product candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected so as to protect our market against competitors' products, our competitive position could be adversely affected, as could our business.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our product candidates, which would have a material adverse effect on our business.

The intellectual property landscape around our technology, including our Gene Traffic Control platform, is highly dynamic, and third parties may obtain intellectual property rights that could affect our ability to use our platform or otherwise develop and commercialize product candidates.

The field of protein modeling, especially in the area of targeting transcription factors, is still in its infancy. Due to the intense research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is evolving and in flux, and it may remain uncertain for the coming years. There may be significant intellectual property related litigation and proceedings relating to our owned and in-licensed, and other third party, intellectual property and proprietary rights in the future.

Our commercial success depends upon our ability and the ability of our collaborators and licensors to develop, manufacture, market, and sell any product candidates that we may develop and use our proprietary technologies without infringing, misappropriating, or otherwise violating the intellectual property and proprietary rights of third parties. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our Gene Traffic Control platform and related technology and product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of therapies, products or their methods of use or manufacture. There may be third-party patents of which we are currently unaware with claims to technologies, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. 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 may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. We may be unable to obtain a license to such patents held by third-parties on commercially reasonable terms or at all. In the event that we are unable to obtain licenses to such patents, our ability to develop and commercialize one or more product candidates may become severely limited. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby providing our competitors and other third parties access to the same technologies licensed to us.

We may initiate or become involved in legal proceedings involving allegations that we are infringing a third party's intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends in part upon our ability and the ability of our collaborators to develop, manufacture and sell our product candidates and use our proprietary technologies without infringing the propriety rights and intellectual property of third parties.

The biotechnology and pharmaceutical industries are characterized by extensive and frequent litigation regarding patents and other intellectual property rights. We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology. Our competitors or other third parties may assert infringement claims against us, alleging that our products or technologies are covered by their patents. Given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. If a patent holder believes our product or product candidate infringes on its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our product candidates and technology. We may choose to obtain a license, even in the absence of an action or finding of infringement. In either case, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby providing our competitors and other third

parties access to the same technologies licensed to us. Without such a license, we could be forced, including by court order, to cease developing and commercializing the infringing technology or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed such third-party patent rights. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our products in one or more foreign countries, which would have a materially adverse effect on our business.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We could in the future also be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate such technologies or features would have a material adverse effect on our business and may prevent us from successfully commercializing our product candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates, which would have an adverse effect on our business, results of operations and financial condition.

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 and other third parties may infringe, misappropriate or otherwise violate our patents, if obtained, and other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims. A court may disagree with our allegations, however, and may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the third-party technology in question. Further, such third parties could counterclaim that we infringe their intellectual property or that a patent we have asserted against them is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. In addition, third parties may initiate legal proceedings against us to assert such challenges to our intellectual property rights. The outcome of any such proceeding is generally unpredictable.

An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one of our product candidates, we would lose at least part, and perhaps all, of the patent protection covering such product candidate. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. 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. 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 adequately conduct such litigation or proceedings. 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. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights, or we may be unable to successfully defend ourselves from allegations of infringement or misappropriation. 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.

We may not be able to effectively enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, the patent laws of some foreign countries do not afford intellectual property protection to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. 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, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in the major markets for our product candidates, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

We may be subject to claims challenging the inventorship or ownership of any intellectual property, including any patents we may own or in-license in the future.

We may be subject to claims that former employees, collaborators or other third parties have an interest in any patents we may own or in-license in the future, trade secrets, or other intellectual property as an inventor

or co-inventor. We may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates or other technologies. We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to an inventorship dispute, such dispute may lead to litigation which could be expensive and time consuming. If we are unsuccessful, in addition to paying monetary damages, we could lose valuable rights in intellectual property that we regard as our own, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and our Gene Traffic Control platform. 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 do not obtain patent term extension and 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 U.S. patents, if obtained, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term 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. However, we may not be granted an extension 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 less than we request, our business, financial condition, results of operations and prospects could be materially harmed.

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:

- aspects of our Gene Traffic Control platform are protected by trade secrets, which may be inadequate to safeguard our competitive advantage, and some aspects of our platform may not be protectable by intellectual property rights at all;
- 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 any patents that may issue to us, our licensors or our collaborator;
- we or our licensors or collaborators, might not have been the first to make the inventions covered by our pending patent applications, or any patents that may issue in the future;
- we or our 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 or misappropriating our intellectual property rights;

- it is possible that our present or future pending 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;
- changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates;
- the patents of others may harm our business; and
- we may choose not to file a patent application 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.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a “first to file” system. The first-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce rights in our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce any patents that we may obtain in the future.

Risks Related to Our Reliance on Third Parties

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

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs and CDMOs, as well as potential collaboration partners to conduct certain aspects of our

discovery, preclinical studies and development and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and planned clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors, CROs and CDMOs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties, our CROs or our CDMOs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Moreover, our business may be adversely affected 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.

Further, these investigators, CROs and CDMOs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. 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 independent investigators, CROs and CDMOs fail to devote sufficient resources to the development of our product candidates, or if CROs 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, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or precluded entirely.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs 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 commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. 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 currently rely and expect to rely in the future on the use of manufacturing suites in third-party facilities or third parties to manufacture our product candidates. Our business could be harmed if we are unable to use third-party manufacturing suites or if the third-party manufacturers fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must currently rely on outside vendors to manufacture our product candidates in clinical quantities.

Our reliance on third parties for clinical quantities exposes us to a number of risks, including:

- our third-party manufacturers might be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately and incompliance with cGMP; and
- our third-party manufacturers could breach or terminate their agreements with us.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA or result in higher costs. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA could place significant restrictions on our company until deficiencies are remedied.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are subject to numerous environmental, health and safety laws and regulations, including those governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks Related to Regulatory and Other Legal Compliance Matters

Our clinical trials may fail to demonstrate adequately the safety and efficacy of any of our product candidates, which would delay or prevent further clinical development of those candidates.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, including FHD-286 and FHD-609, and any other future product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective in humans.

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

Even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or other comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA or other comparable foreign regulatory authorities will view our product candidates as having sufficient efficacy to support the indication studied in the clinical trial even if positive results are observed in early clinical trials. To the extent that the results of the trials are not satisfactory to the FDA or other comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Additionally, any safety or efficacy concerns observed in any tumor-specific subgroup of our

clinical trials could limit the prospects for regulatory approval of our product candidates for a tumor-agnostic indication, which could have a material adverse effect on our business, financial condition and results of operations.

We may in the future seek orphan drug status for FHD-286 and FHD-609 and some of our other future product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our future revenue, if any, to be reduced.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug 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 if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We may seek orphan drug designation for some or all of our other future product candidates, where applicable, in addition to orphan indications in which there is a medically plausible basis for the use of these products. Even when we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we intend to seek orphan drug designation for other product candidates, we may never receive such designations. For example, the FDA has expressed concerns regarding the regulatory considerations for orphan drug designation as applied to tissue agnostic therapies, and the FDA may interpret the federal Food, Drug and Cosmetic Act, as amended, or the FD&C Act, and regulations promulgated thereunder in a way that limits or blocks our ability to obtain orphan drug designation or orphan drug exclusivity, if our product candidates are approved, for our targeted indications.

A Breakthrough Therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek Breakthrough Therapy designation from the FDA for FHD-286 and FHD-609, and for some or all of our future product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life- threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic 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 product candidates 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. Drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including 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 candidate products considered for approval under non-expedited FDA review 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 the product no longer meets the conditions for qualification. Thus, even though we intend to seek Breakthrough Therapy designation for some or all of our future product candidates for the treatment of various cancers, there can be no assurance that we will receive breakthrough therapy designation.

Our relationships with healthcare providers, physicians, and third-party payors will be subject to applicable anti-kickback, fraud and abuse, anti-bribery, physician payment transparency 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.

Our future arrangements with third-party payors and customers 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 research, market, sell, and distribute our medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- federal Anti-Kickback Statute, which prohibits, among other things, persons from offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the purchasing or ordering of, a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- federal false claims, false statements and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement material to a false claim;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- the Physician Payments Sunshine Act, which requires pharmaceutical and medical device companies to report information related to certain payments and transfers of value to certain healthcare providers to the Center for Medicare & Medicaid Services, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback, anti-bribery and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers, as well as other state laws that require companies to comply with specific compliance standards, restrict financial interactions between companies and healthcare providers and require companies to report information related to payments to health care providers or marketing expenditures.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices may not comply with healthcare laws and regulations, including, without limitation, certain of our advisory board agreements with physicians who receive stock or stock options as compensation for services provided to us. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects.

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

The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our current or future product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. In particular, in the U.S., there have been and continue to be a number of legislative initiatives at the federal and state level to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, of collectively, the ACA, was enacted, which substantially changed the way healthcare is financed by both government and private payors. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. It is unclear how any efforts to challenge, repeal, or replace the ACA will impact the ACA or our business.

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. Further, healthcare reform may result in changes to payment methodologies, the implementation of pharmaceutical and biological product price controls, and reductions in Medicare and other healthcare funding. If any such changes were to be imposed, they could adversely affect the operation of our business.

The successful commercialization of our product candidates will depend in part on the extent to which third-party payors establish coverage, adequate reimbursement levels and pricing policies.

Our ability to obtain coverage and adequate reimbursement for our product candidates by governmental healthcare programs, private health insurers, and other third-party payors will have an effect on our ability to successfully commercialize our product candidates. We cannot be sure that coverage and reimbursement will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future. No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our product candidates.

We are subject to U.S. and international restrictive regulations governing the use, processing and cross-border transfer of data and personal information.

The conduct of our clinical trials may be subject to privacy restrictions based on U.S. and non-U.S. regulations. For example, we may be subject to the California Consumer Privacy Act, or CCPA. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Additionally, the collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the EU General Data Protection Regulation, or GDPR. See "Business—Government Regulation." Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Further, the United Kingdom's vote in favor of exiting the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated.

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

General Risk Factors

The market price of our common stock may be volatile, which could result in substantial losses for our stockholders.

Our stock price has been and may continue to be volatile. Since our initial public offering in October 2020, the price of our common stock as reported on the Nasdaq Global Market has ranged from a low of $12.38 on March 10, 2021 to a high of $25.88 on December 18, 2020. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the success of existing or new competitive product candidates or technologies;
- the timing and results of preclinical studies and clinical trials for any product candidates that we may develop;
- failure or discontinuation of any of our product development and research programs;
- results of preclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- commencement or termination of collaborations for our product development and research programs;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our research programs or product candidates that we may develop;

- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- expiration of market stand-off or lock-up agreement;
- effects of public health crises, pandemics and epidemics, such as COVID-19;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions; and
- the other factors described in this “Risk Factors” section.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company’s securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future.

Securities litigation could result in substantial costs and divert management’s attention and resources from our business.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

A significant portion of our total outstanding shares is eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Certain holders of shares of our common stock have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under

Securities Act Rule 144 or until the rights terminate pursuant to the terms of the investors' rights agreement between us and such holders. If additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Insiders have substantial influence over us, which could limit your ability to affect the outcome of key transactions, including a change of control.

Our directors and executive officers and their affiliates beneficially own shares representing approximately 56% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or SOX Section 404, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. In this annual report, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we 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.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" 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 will adopt the new or revised standard at the time private companies adopt the new or revised standard and will 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. Therefore, the reported results of operations contained in our consolidated financial statements may not be directly comparable to those of other public companies.

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

In October 2020, we completed our initial public offering. As a public company, and particularly after we are no longer an "emerging growth company," we incur significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of

effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance, and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We are currently evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to SOX Section 404, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K with the SEC after we become a public company. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with SOX Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by SOX Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn, or additional global financial crises, could result in a variety of risks to our business, including weakened demand for our product candidates, if approved, or our ability to raise additional capital when needed on acceptable terms, if at all. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets. Similarly, the recent significant volatility associated with the COVID-19 outbreak has caused significant instability and disruptions in the capital and credit markets. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Provisions in our amended and restated certificate of incorporation, our amended and restated by-laws and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation, amended and restated by-laws and Delaware law contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which you might

otherwise receive a premium for your shares. Our amended and restated certificate of incorporation and by-laws include provisions that:

- authorize “blank check” preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed only for cause;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our amended and restated by-laws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated by-laws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated by-laws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation designates the state or federal courts within the State of Delaware as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, subject to limited exceptions, the state or federal courts (as appropriate) within the State of Delaware will be exclusive forums for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated by-laws, (4) action against us or any of our directors or officers involving a claim or defense arising pursuant to the Exchange Act or the Securities Act or (5) any other action asserting a claim

against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters is located at 500 Technology Square, Suite 700, Cambridge, MA 02139, where we lease and occupy approximately 81,441 square feet of office and laboratory space. The current term of our 500 Technology Square lease expires in September 2028, with an option to extend the term five additional years with 12 months' notice at an agreed upon market rate.

We believe our existing facilities are sufficient for our needs for the foreseeable future. To meet the future needs of our business, we may lease additional or alternate space, and we believe suitable additional or alternative space will be available in the future on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Certain Information Regarding the Trading of Our Common Stock

Our common stock trades under the symbol "FHTX" on the Nasdaq Global Market and has been publicly traded since October 23, 2020. Prior to this time, there was no public market for our common stock.

Holders of Our Common Stock

As of January 31, 2021, there were approximately 90 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.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Recent Sales of Unregistered Securities

None.

Use of Proceeds from Initial Public Offering

On October 27, 2020, we closed our initial public offering, or IPO, of our common stock pursuant to which we issued and sold 7,500,000 shares of our common stock at a price to the public of $16.00 per share for aggregate gross proceeds of $120.0 million, before deducting underwriting discounts and commissions and other offering expenses. On November 19, 2020, we sold an additional 951,837 shares of our common stock pursuant to the underwriters' option to purchase additional shares in the IPO at the public offering price for an additional $15.2 million in gross proceeds.

All of the shares issued and sold in the IPO were registered under the Securities Act pursuant to the Registration Statement, which was declared effective by the SEC on October 22, 2020. Goldman Sachs & Co. LLC, Morgan Stanley & Co. LLC and Cowen and Company, LLC acted as joint book-running managers and Wedbush Securities Inc. acted as lead manager of our IPO.

We received aggregate net proceeds of approximately $122.1 million after deducting underwriting discounts and commissions and other offering expenses. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10 percent or more of our common stock or to any of our affiliates.

We have used approximately $12.1 million of the net proceeds from the IPO as of December 31, 2020 to advance FHD-286 and FHD-609 towards the clinic, to further invest in our pipeline and platform targeting the chromatin regulatory system and for working capital and other general corporate purposes. There has been no material change in our planned use of the net proceeds from the offering as described in our Registration Statement.

Issuer Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. SELECTED FINANCIAL DATA

We are a smaller reporting company, as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, for this reporting period and are not required to provide the information required 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 the related notes to those statements included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Some of the numbers included herein have been rounded for the convenience of presentation. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Overview

We are pioneering the discovery and development of a new class of medicines targeting genetically determined dependencies within the chromatin regulatory system, an untapped opportunity for therapeutic intervention. Our proprietary Gene Traffic Control platform gives us an integrated, mechanistic understanding of how the various components of the chromatin regulatory system interact, allowing us to identify, validate and potentially drug targets within the system. Breakdowns in the chromatin regulatory system are associated with over 50 percent of all cancers. Addressing these breakdowns could potentially provide therapies for over 2.5 million patients. Consequently, we are initially focused in oncology. We are developing FHD-286, a selective, allosteric ATPase inhibitor and are currently initiating separate Phase 1 studies in metastatic uveal melanoma and relapsed and/or refractory acute myeloid leukemia, or AML. The investigational new drug applications for metastatic uveal melanoma and relapsed and/or refractory AML were accepted by the FDA in late December and early January, respectively. We are developing FHD-609, a targeted protein degrader, to treat synovial sarcoma, for which we plan to submit an investigational new drug application, or IND, in the second quarter of 2021. Our vision is to use our Gene Traffic Control platform to discover and develop drugs in oncology and other therapeutic areas, including virology, autoimmune disease and neurology.

Since our inception in October 2015, we have focused substantially all of our resources on building our Gene Traffic Control platform, organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, protecting our trade secrets, filing patent applications, identifying potential product candidates, undertaking preclinical studies and clinical trial start-up activities, establishing arrangements with third parties for the manufacture of initial quantities of our product candidates and component materials. We do not have any products approved for sale and have not generated any revenue from product sales.

On October 27, 2020, we completed our initial public offering, or IPO, pursuant to which we issued and sold 7,500,000 shares of our common stock at a public offering price of $16.00 per share, resulting in net proceeds of $107.9 million, after deducting underwriting discounts and commissions and other offering expenses. On November 19, 2020, we issued and sold an additional 951,837 shares of common stock at the IPO price of $16.00 per share pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $14.2 million after deducting underwriting discounts and commissions. Prior to our IPO, we have funded our operations with proceeds from sales of preferred stock, term loans and an upfront payment of $15.0 million we received in July 2020 under our collaboration agreement with Merck Sharp & Dohme Corp., or Merck.

We have incurred significant operating losses since our inception. For the years ended December 31, 2020 and 2019, we reported net losses of $68.8 million and $51.1 million, respectively. As of December 31, 2020, we had an accumulated deficit of $162.9 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. Our ability to generate any product revenue or product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more product candidates we may develop.

We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- advance our FHD-286 and FHD-609 product candidates and continue our preclinical development of product candidates from our current research programs;
- identify additional research programs and additional product candidates;
- initiate preclinical testing for any new product candidates we identify and develop;
- obtain, maintain, expand, enforce, defend and protect our trade secrets and intellectual property portfolio and provide reimbursement of third-party expenses related to our patent portfolio;
- hire additional research and development personnel;
- add operational, legal, compliance, financial and management information systems and personnel to support our research, product development and operations as a public company;
- expand the capabilities of our platform;
- acquire or in-license product candidates, intellectual property and technologies;
- operate as a public company;
- seek marketing approvals for any product candidates that successfully complete clinical trials; and
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval.

We will not generate revenue from product sales unless and until we successfully commercialize one of our product candidates, after completing clinical development and obtaining regulatory approval. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, and distribution. Further, we expect to incur additional costs associated with operating as a public company.

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 our collaboration agreement with Merck and a combination of equity offerings, debt financings and collaborations or licensing arrangements. 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, scale back our development or commercialization plans for one or more of our product candidates.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately 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.

COVID-19

In March 2020, COVID-19 was declared a global pandemic by the World Health Organization, and to date the COVID-19 pandemic continues to present a substantial public health and economic challenge around the world. The length of time and full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain, subject to change and are difficult to predict. While we continue to conduct our research and development activities, the COVID-19 pandemic may cause disruptions that affect our ability to initiate and complete preclinical studies, ongoing and future clinical trials or to procure items that are essential for our research and development activities.

We plan to continue to closely monitor the ongoing impact of the COVID-19 pandemic on our employees and our business operations. In an effort to provide a safe work environment for our employees, we have, among other things, increased the cadence of sanitization of our office and lab facilities, implemented various social distancing measures in our office and labs including replacing in-person meetings with virtual interactions, and are providing personal protective equipment for our employees present in our office and lab facilities. We expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees and other business partners in light of the pandemic.

Components of Our Results of Operations

Collaboration Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. If our development efforts for our product candidates are successful and result in regulatory approval or licenses with third parties, we may generate revenue in the future from product sales, milestone payments under our existing collaboration agreement or payments from other license agreements that we may enter into with third parties.

In July 2020, we entered into a strategic research collaboration and license agreement, or the Collaboration Agreement, with Merck, pursuant to which we will apply our proprietary Gene Traffic Control platform to discover and develop novel therapeutics. Under the Collaboration Agreement, we granted Merck exclusive global rights to develop and commercialize drugs that target dysregulation of a single transcription factor. Under the terms of the Collaboration Agreement, we received a nonrefundable upfront payment of $15.0 million from Merck, and are eligible to receive up to $245.0 million upon achievement of specified research, development and regulatory milestones by any product candidate generated by the collaboration, and up to $165.0 million upon achievement of specified sales-based milestones per approved product from the collaboration, if any, as well as royalties on sales of any approved product from the collaboration. We cannot provide assurance as to the timing of future milestone or royalty payments or that we will receive any of these payments at all.

We record revenue over the research term as we satisfy our performance obligation under the Collaboration Agreement. Accordingly, the upfront payment of $15.0 million is being recognized as revenue using the cost-to-cost method, which we believe best depicts the transfer of control to the customer over time. Under the cost-to-cost method, the extent of progress towards completion is measured based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the identified single performance obligation. We expect revenue to fluctuate as the achievement of milestones becomes probable and as our efforts to satisfy our performance obligation vary from period to period. In estimating the total costs to satisfy our performance obligation pursuant to the Collaboration Agreement, we are required to make significant estimates including an estimate of the number of transcription factor substitutions and the expected time and expected costs to fulfill the performance obligation. The cumulative effect of revisions to the total estimated costs to complete our performance obligation will be recorded in the period in which the changes are identified, and amounts can be reasonably estimated. While such revisions will have no impact on our cash flows, a significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods. As of December 31, 2020, we recorded $14.6 million of the upfront payment as deferred revenue and recognized $0.4 million of revenue under the Collaboration Agreement.

Operating Expenses

Our operating expenses are comprised of research and development expenses and general and administrative expenses.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts, and progressing our programs, which include:

- personnel-related costs, including salaries, benefits and stock-based compensation expense, for employees engaged in research and development functions;
- expenses incurred in connection with our research programs and preclinical and clinical development of our product candidates, including under agreements with third parties, such as consultants and contractors and contract research organizations, or CROs;
- the cost of manufacturing drug substance and drug product for use in our research and preclinical studies and clinical trials under agreements with third parties, such as consultants and contractors and contract development and manufacturing organizations, or CDMOs;
- laboratory supplies and research materials;
- facilities, depreciation and amortization and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and insurance; and
- payments made under third-party licensing agreements.

We track our direct external research and development expenses on a program-by-program basis. These consist of costs that include fees, reimbursed materials, and other costs paid to consultants, contractors, CDMOs, and CROs in connection with our preclinical, clinical 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 and, as such, are not separately classified.

We expect that our research and development expenses will increase substantially as we advance our programs into clinical development and expand our discovery, research and preclinical 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 product candidates we may develop. A change in the outcome of any number of variables with respect to product candidates we may develop could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any product candidates we may develop.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries, benefits and stock-based compensation, for employees engaged in executive, legal, finance and accounting and other administrative functions. General and administrative expenses also include professional fees for legal, patent, consulting, investor and public relations and accounting and audit services as well as direct and allocated facility-related 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 programs and platform. We also anticipate that we will continue to incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance costs and investor and public relations expenses associated with operating as a public company.

Other Income (Expense)

Interest Expense

Interest expense consists of interest expense associated with outstanding borrowings under our loan agreements as well as the amortization of debt discount associated with such agreements.

Interest Income and Other Income (Expense), Net

Interest income consists of interest earned on our invested cash balances. Other income (expense) consists of sublease income and miscellaneous expense unrelated to our core operations.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred or for the research and development tax credits earned in each period, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credit carryforwards will not be realized.

As of December 31, 2020, we had federal and state net operating loss carryforwards of $147.3 million and $132.3 million, respectively, which may be available to offset future taxable income. The federal net operating loss carryforwards include $12.5 million which expire at various dates beginning in 2035 and $134.8 million which carryforward indefinitely but in some circumstances may be limited to offset 80% of annual taxable income. The state net operating loss carryforwards expire at various dates beginning in 2036. As of December 31, 2020, we also had federal and state research and development tax credit carryforwards of $3.4 million and $2.0 million, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2036 and 2031, respectively. Due to our history of cumulative net losses since inception and uncertainties surrounding our ability to generate future taxable income, we have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

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, or GAAP. 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, revenue, costs and expenses and the disclosure of contingent assets and liabilities in our consolidated 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 appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

We account for our one collaboration arrangement, entered into in July 2020, under ASC Topic 606, *Revenue From Contracts With Customers* (ASC 606). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services we transfer to the customer.

We assess the goods or services promised within each contract and determine those that are performance obligations. The promised goods or services in our arrangements would likely consist of licenses, rights to our intellectual property, research and development services and related supporting activities. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. We assess if these options provide a material right to the customer and if so, they are considered performance obligations.

We assess whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct, we consider factors such as the research, development, manufacturing and commercialization capabilities of the customer and the availability of the associated expertise in the general marketplace. We also consider the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

The transaction price is then determined and allocated to the identified performance obligations in proportion to their standalone selling prices ("SSP") on a relative SSP basis. SSP is determined at contract inception and is not updated to reflect changes between contract inception and when the performance obligations are satisfied. Determining the SSP for performance obligations requires significant judgment. In developing the SSP for a performance obligation, we consider applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. We validate the SSP for performance obligations by evaluating whether changes in the key assumptions used to determine the SSP will have a significant effect on the allocation of arrangement consideration between multiple performance obligations.

If the consideration promised in a contract includes a variable amount, we estimate the amount of consideration to which we will be entitled to in exchange for transferring the promised goods or services to a customer. We determine the amount of variable consideration by using the expected value method or the most likely amount method. We include the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, we re-evaluate the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

If an arrangement includes development and regulatory milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

For arrangements with licenses of intellectual property that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

We record amounts as accounts receivable when the right to consideration is deemed unconditional. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded for deferred revenue.

In determining the transaction price, we adjust consideration for the effects of the time value of money if the timing of payments provides us with a significant benefit of financing. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between the transfer of the promised goods or services to the customer and the payment by the customer will be one year or less. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied, either at a point in time or over time, and if over time, recognition is based on the use of an output or input method.

Under the cost-to-cost method, the extent of progress towards completion is measured based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the identified single performance obligation. In estimating the total costs to satisfy our performance obligation, we are required to make significant estimates including an estimate of the expected time and expected costs to fulfill the performance obligation. The cumulative effect of revisions to the total estimated costs to complete our performance obligation will be recorded in the period in which the changes are identified, and amounts can be reasonably estimated. While such revisions will have no impact on our cash flows, a significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate certain accrued research and development expenses. This process involves 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. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include those related to fees paid to:

- vendors in connection with discovery, preclinical and clinical development activities;
- CROs in connection with preclinical studies and testing and clinical trials; and
- CDMOs in connection with the process development and scale up activities and the production and manufacturing of materials.

We base the expense recorded related to contract research and manufacturing on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs and CDMOs that conduct services and produce and supply materials. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. 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 accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. While the majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; some require advance payments. 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. We record these as prepaid expenses on our consolidated balance sheet.

Stock-based Compensation

We measure all stock-based awards granted to employees, non-employees and directors based on their fair value on the date of the grant using the Black-Scholes option-pricing model for options or the difference between the purchase price, if any, and the fair value of our common stock for restricted stock awards. Compensation expense for awards with service-based vesting is generally recognized over the vesting period of the award using the straight-line method to record the expense. We use the graded-vesting method to record the expense of awards with both service-based and performance-based vesting conditions, commencing once achievement of the performance condition becomes probable. The Black-Scholes option-pricing model uses as inputs the fair value of our common stock and assumptions we make for the expected volatility of our common stock, the expected term of stock options, the risk-free interest rate for a period that approximates the expected term of our common stock options and our expected dividend yield. We account for forfeitures of share-based awards as they occur.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

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

	Year Ended December 31,		
	2020	2019	Change
	(in thousands)		
Collaboration revenue	$ 430	$ —	$ 430
Operating expenses:			
Research and development	57,715	44,362	13,353
General and administrative	11,246	6,722	4,524
Total operating expenses	68,961	51,084	17,877
Loss from operations	(68,531)	(51,084)	(17,447)
Other income (expense):			
Interest expense	(979)	(540)	(439)
Interest income and other income (expense), net	1,001	495	506
Change in fair value of preferred stock warrant liability	(69)	1	(70)
Loss on debt extinguishment	(222)	—	(222)
Total other expense, net	(269)	(44)	(225)
Net loss	$ (68,800)	$ (51,128)	$(17,672)

Collaboration Revenue

Collaboration revenue recognized during the year ended December 31, 2020 of $0.4 million was related to our Collaboration Agreement. The upfront payment of $15.0 million was initially recorded as deferred revenue and is being recognized as revenue under the cost-to-cost method.

Research and Development Expenses

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

	Year Ended December 31,		
	2020	2019	Change
	(in thousands)		
Research and development program expenses:			
FHD-286	$ 5,570	$ 5,458	$ 112
FHD-609	7,137	5,266	1,871
Platform, research and discovery, and unallocated expenses:			
Platform and other early stage research external costs	13,707	13,522	185
Personnel related (including stock-based compensation)	17,822	13,176	4,646
Facility related and other	13,479	6,940	6,539
Total research and development expenses	$ 57,715	$ 44,362	$13,353

Research and development expenses were $57.7 million for the year ended December 31, 2020, compared to $44.4 million for the year ended December 31, 2019. The increase in our FHD-286 program costs of $0.1 million was due to an increase in preclinical, manufacturing, and clinical trial start-up costs, partially offset by a decrease in research costs as we progressed towards an IND submission in December 2020. The increase in our FHD-609 program costs of $1.9 million was due to an increase in preclinical and manufacturing costs, partially offset by a decrease in research costs as we progressed our program candidate into IND-enabling studies. Platform and other early-stage research external costs, which include our selective BRM and selective ARID1B early-stage programs, increased by $0.2 million, primarily as a result of an increase in selective BRM costs as a result of our ongoing hit-to-lead efforts. Personnel-related costs increased by $4.6 million due primarily to increased headcount in our research and development function. The increase in facility-related expenses and other of $6.5 million was due to the increased costs of supporting a larger group of research and development personnel and their research efforts, including increased rent expense related to our new facility lease, which commenced in January 2020.

General and Administrative Expenses

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

	Year Ended December 31,		
	2020	2019	Change
	(in thousands)		
Personnel related (including stock-based compensation)	$ 6,026	$ 3,732	$2,294
Professional and consultant	3,388	2,235	1,153
Facility related and other	1,832	755	1,077
Total general and administrative expenses	$ 11,246	$ 6,722	$4,524

General and administrative expenses were $11.2 million for the year ended December 31, 2020, compared to $6.7 million for the year ended December 31, 2019. The increase in personnel-related costs of $2.3 million was a result of an increase in headcount in our general and administrative function to support our business. The increase in professional and consultant fees of $1.2 million was primarily due to higher costs associated with

operating as a public company. The increase in facility-related expenses and other of $1.1 million was due to the increased rent expense related to our new facility lease, which commenced in January 2020 as well as an increase due to directors and officers insurance.

Other Income (Expense)

Interest expense was $1.0 million for the year ended December 31, 2020, compared to $0.5 million for the year ended December 31, 2019. The increase was due primarily to increased borrowings under our loan facility.

Interest income and other income (expense), net was $1.0 million for the year ended December 31, 2020 and consisted primarily of sublease income of $1.0 million related to the sublease that began in July 2020 and $0.1 million of interest income. Interest income and other income (expense), net of $0.5 million for the year ended December 31, 2019 consisted primarily of $0.5 million of interest income. Interest income decreased from the year ended December 31, 2019 to the same period in 2020 primarily due to lower interest rates on invested balances.

We recorded a loss on debt extinguishment of $0.2 million for the year ended December 31, 2020. We used proceeds from a new loan and security agreement entered into in November 2020 to repay the balance of our prior loan outstanding at the time including a final payment fee.

Liquidity and Capital Resources

Since our inception in October 2015, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we support our continued research activities and development of our programs and platform. Through December 31, 2020, we have funded our operations with proceeds from our IPO in October 2020, sales of preferred stock, term loans and an upfront payment of $15.0 million we received in July 2020 under our Collaboration Agreement. As of December 31, 2020, we had cash, cash equivalents and marketable securities of $185.8 million.

Cash Flows

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

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Cash used in operating activities	$ (31,286)	$(46,335)
Cash used in investing activities	(108,914)	(964)
Cash provided by financing activities	217,473	23,969
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 77,273	$(23,330)

Operating Activities

During the year ended December 31, 2020, operating activities used $31.3 million of cash, resulting from our net loss of $68.8 million, partially offset by net non-cash charges of $8.8 million and net cash provided by changes in our operating assets and liabilities of $28.7 million. Net cash provided by changes in our operating assets and liabilities for the year ended December 31, 2020 consisted primarily of a $15.1 million increase in operating lease liabilities resulting from our landlord incentives received, a $14.6 million increase in deferred revenue resulting from the upfront payment received in connection with our Collaboration Agreement and an increase of $3.7 million in accounts payable and accrued expenses and other current liabilities, partially offset by an increase of $4.7 million in prepaid expenses and other assets.

During the year ended December 31, 2019, operating activities used $46.3 million of cash, resulting from our net loss of $51.1 million, partially offset by net non-cash charges of $3.6 million and net cash provided by changes in our operating assets and liabilities of $1.2 million. Net cash provided by changes in our operating assets and liabilities for the year ended December 31, 2019 consisted primarily of a $3.3 million increase in accounts payable and accrued expenses and other current liabilities, partially offset by a $1.2 million decrease in operating lease liabilities and a $1.0 million increase in prepaid expenses and other assets.

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

Investing Activities

During the year ended December 31, 2020, net cash used in investing activities was $108.9 million primarily due to the purchases of marketable securities of $93.0 million and the acquisition of property and equipment of $16.2 million. Property and equipment purchases for the year ended December 31, 2020 were primarily related to leasehold improvements for our new facility in Cambridge, Massachusetts.

During the year ended December 31, 2019, net cash used by investing activities was $1.0 million due to the acquisition of property and equipment during the year.

Financing Activities

During the year ended December 31, 2020, net cash provided by financing activities was $217.5 million, consisting primarily of proceeds from our IPO, net of underwriting discounts and commissions and other offering expenses of $122.1 million, net proceeds from the sale of our Series B preferred stock of $89.9 million, net borrowings of $4.3 million and proceeds from the exercise of common stock options of $1.2 million.

During the year ended December 31, 2019, net cash provided by financing activities was $24.0 million, consisting of proceeds from the sale of our Series B preferred stock of $15.3 million, proceeds from borrowings under our loan and security agreement of $8.0 million and proceeds from the exercise of common stock options of $0.7 million.

Loan and Security Agreement with Oxford

On November 19, 2020, we entered into a new loan and security agreement, or the Oxford Loan, with Oxford Finance LLC, or Oxford, for an aggregate principal amount of $20.0 million (Oxford Term Loan A) and up to an additional $5.0 million (Oxford Term Loan B). The Term Loan bears interest at a floating per annum rate equal to the greater of (i) 8.0% and (ii) the sum of (a) thirty-day U.S. DOLLAR LIBOR rate reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 7.84%. In addition, upon loan maturity or prepayment, we are reqired to make a final payment fee equal to 5.0% of the aggregate principal amount borrowed. We are required to make monthly interest only payments under the Oxford Loan on the first calendar day of each month beginning on January 1, 2021. Beginning on December 1, 2023, we are required to make consecutive equal monthly payments of principal, together with applicable interest, in arrears, based upon a repayment schedule equal to 24 months, with a final maturity date of November 1, 2025.

Our obligations under the Oxford Loan Agreement are secured by a security interest in all of our assets, other than our intellectual property. We are also subject to certain affirmative and negative covenants.

On November 19, 2020, we used the proceeds from the Oxford Loan Agreement to pay in full the outstanding amounts under the Loan and Security Agreement with Comerica.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and initiate clinical trials for our product candidates in development. We believe that the net proceeds from our IPO in October 2020, together with our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses, capital expenditure requirements and debt service payments into the third quarter of 2022. We have based these estimates as to how long we expect we will be able to fund our operations on assumptions that may prove to be inaccurate. We could use our available capital resources sooner than we currently expect, in which case we would be required to obtain additional financing sooner than planned, which may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources.

If we are unable to raise sufficient capital as and when needed, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate we may develop, or be unable to expand our operations or otherwise capitalize on our business opportunities. If we raise additional funds through collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to future revenue streams or product candidates or grant licenses on terms that may not be favorable to us.

Off-balance Sheet Arrangements

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

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company, as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, for this reporting period and are not required to provide the information required under this item.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

FOGHORN THERAPEUTICS INC.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Foghorn Therapeutics Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Foghorn Therapeutics Inc. and its subsidiary (the "Company"), as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (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, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 18, 2021

We have served as the Company's auditor since 2018.

Foghorn Therapeutics Inc.

Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 92,795	$ 14,981
Marketable securities	92,975	—
Restricted cash	—	541
Prepaid expenses and other current assets	4,917	1,363
Total current assets	190,687	16,885
Property and equipment, net	19,528	2,683
Restricted cash	1,733	1,733
Other assets	842	11
Operating lease right-of-use assets	42,804	1,030
Total assets	$ 255,594	$ 22,342
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,680	$ 3,439
Accrued expenses	9,161	3,701
Operating lease liabilities	3,981	1,360
Notes payable, net of discount	—	4,152
Deferred revenue	2,024	—
Total current liabilities	18,846	12,652
Notes payable, net of discount and current portion	19,654	10,960
Operating lease liabilities, net of current portion	58,361	157
Deferred revenue, net of current portion	12,546	—
Preferred stock warrant liability	—	45
Total liabilities	109,407	23,814
Commitments and contingencies (Note 13)		
Convertible preferred stock (Series A-1, A-2 and B), $0.0001 par value; no shares and 28,629,622 shares authorized at December 31, 2020 and 2019, respectively; no shares and 28,615,546 shares issued and outstanding at December 31, 2020 and 2019, respectively	—	86,544
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 25,000,000 shares authorized as of December 31, 2020; no shares issued or outstanding	—	—
Common stock, $0.0001 par value; 175,000,000 and 46,600,000 shares authorized at December 31, 2020 and 2019, respectively; 36,790,946 shares issued and outstanding at December 31, 2020 and 5,762,745 shares issued and 4,870,851 shares outstanding at December 31, 2019	4	—
Additional paid-in capital	309,126	6,120
Accumulated other comprehensive loss	(7)	—
Accumulated deficit	(162,936)	(94,136)
Total stockholders' equity (deficit)	146,187	(88,016)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 255,594	$ 22,342

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

Foghorn Therapeutics Inc.

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2020	2019
Collaboration revenue	$ 430	$ —
Operating expenses:		
Research and development	57,715	44,362
General and administrative	11,246	6,722
Total operating expenses	68,961	51,084
Loss from operations	(68,531)	(51,084)
Other income (expense):		
Interest expense	(979)	(540)
Interest income and other income (expense), net	1,001	495
Change in fair value of preferred stock warrant liability	(69)	1
Loss on debt extinguishment	(222)	—
Total other expense, net	(269)	(44)
Net loss	$ (68,800)	$ (51,128)
Net loss per share attributable to common stockholders—basic and diluted	$ (6.23)	$ (12.20)
Weighted average common shares outstanding—basic and diluted	11,046,802	4,191,793
Comprehensive loss:		
Net loss	$ (68,800)	$ (51,128)
Other comprehensive loss:		
Unrealized losses on marketable securities	(7)	—
Total other comprehensive loss	(7)	—
Total comprehensive loss	$ (68,807)	$ (51,128)

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

Foghorn Therapeutics Inc.

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

(In thousands, except share amounts)

	Series A-1, A-2 and B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances at December 31, 2018	26,575,544	$ 71,250	3,475,152	$ —	$ 3,735	$ —	$ (43,008)	$ (39,273)
Issuance of Series B convertible preferred stock, net of issuance costs of $6	2,040,002	15,294	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	503,808	—	691	—	—	691
Vesting of restricted stock	—	—	891,891	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	1,694	—	—	1,694
Net loss	—	—	—	—	—	—	(51,128)	(51,128)
Balances at December 31, 2019	28,615,546	86,544	4,870,851	—	6,120	—	(94,136)	(88,016)
Issuance of Series B convertible preferred stock, net of issuance costs of $198	12,007,867	89,861	—	—	—	—	—	—
Conversion of preferred stock to common stock	(40,623,413)	(176,405)	21,958,588	3	176,402	—	—	176,405
Issuance of common stock upon initial public offering net of underwriting discounts, commissions and offering costs			8,451,837	1	122,120	—	—	122,121
Conversion of warrant liability to equity upon closing of initial public offering			—	—	114	—	—	114
Issuance of common stock in connection with the cashless exercise of warrants	—	—	6,728	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	611,048	—	1,221	—	—	1,221
Issuance of warrants in connection with notes payable	—	—	—	—	188	—	—	188
Vesting of restricted stock	—	—	891,894	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	2,961	—	—	2,961
Unrealized losses on marketable securities	—	—	—	—	—	(7)	—	(7)
Net loss	—	—	—	—	—	—	(68,800)	(68,800)
Balances at December 31, 2020	—	—	36,790,946	$ 4	$ 309,126	$ (7)	$ (162,936)	$ 146,187

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

Foghorn Therapeutics Inc.

Consolidated Statements of Cash Flows

(In thousands)

	Year ended December 31, 2020	2019
Cash flows from operating activities:		
Net loss	$ (68,800)	$(51,128)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,961	1,694
Depreciation and amortization expense	1,327	693
(Gain) loss on disposal of property and equipment	(206)	11
Loss on debt extinguishment	222	—
Change in fair value of preferred stock warrant liability	69	(1)
Noncash lease expense	4,201	1,100
Noncash interest expense	238	99
Accretion of discount on marketable securities	(1)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(4,670)	(991)
Accounts payable	474	1,211
Accrued expenses and other current liabilities	3,194	2,137
Operating lease liabilities	15,135	(1,160)
Deferred revenue	14,570	—
Net cash used in operating activities	(31,286)	(46,335)
Cash flows from investing activities:		
Purchases of property and equipment	(16,183)	(968)
Proceeds from sale of property and equipment	250	4
Purchases of marketable securities	(92,981)	—
Net cash used in investing activities	(108,914)	(964)
Cash flows from financing activities:		
Proceeds from initial public offering, net of underwriting discounts, commissions and offering costs	122,121	—
Proceeds from issuance of convertible preferred stock, net of issuance costs	89,861	15,294
Proceeds from issuance of common stock upon exercise of stock options	1,221	691
Proceeds from issuance of notes payable, net of issuance costs	19,800	7,984
Repayments of notes payable	(15,530)	—
Net cash provided by financing activities	217,473	23,969
Net increase (decrease) in cash, cash equivalents and restricted cash	77,273	(23,330)
Cash, cash equivalents and restricted cash at beginning of period	17,255	40,585
Cash, cash equivalents and restricted cash at end of period	$ 94,528	$ 17,255
Supplemental cash flow information:		
Cash paid for interest	$ 660	$ 420
Supplemental disclosure of noncash investing and financing information:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 2,400	$ 367
Conversion of redeemable convertible preferred stock to common stock	$ 176,405	$ —
Conversion of warrant liability to equity upon closing of initial public offering	$ 114	$ —
Issuance of warrants in connection with notes payable	$ 188	$ —
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 92,795	$ 14,981
Restricted cash (current and non-current)	1,733	2,274
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 94,528	$ 17,255

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

Foghorn Therapeutics Inc.

Notes to Consolidated Financial Statements

1. Nature of Business and Basis of Presentation

Foghorn Therapeutics Inc. (the "Company") is a clinical-stage biopharmaceutical company discovering and developing a new class of medicines targeting genetically determined dependencies within the chromatin regulatory system. The Company uses its proprietary Gene Traffic Control platform to identify, validate and potentially drug targets within the system. The Company was founded in October 2015 as a Delaware corporation. The Company is headquartered in Cambridge, Massachusetts.

The Company is subject to risks similar to those of other early-stage companies in the biopharmaceutical industry, including dependence on key individuals, the need to develop commercially viable products, competition from other companies, many of whom are larger and better capitalized, the impact of the COVID-19 pandemic and the need to obtain adequate additional financing to fund the development of its products. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be maintained, that any products developed will obtain required regulatory approval or that any approved products will be commercially viable. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from the sale of its products.

In March 2020, the World Health Organization declared the global novel coronavirus disease 2019 ("COVID-19") outbreak a pandemic. The Company's operations have not been significantly impacted by the COVID-19 pandemic. However, the Company cannot at this time predict the specific extent, duration, or full impact that the COVID-19 pandemic will have on its financial condition and operations, including ongoing and planned clinical trials. The impact of the COVID-19 outbreak on the Company's financial performance will depend on future developments, including the duration and spread of the pandemic and related governmental advisories and restrictions. These developments and the impact of COVID-19 on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, the Company's results may be materially adversely affected.

On October 27, 2020, the Company completed its initial public offering ("IPO") pursuant to which it issued and sold 7,500,000 shares of its common stock at a public offering price of $16.00 per share, resulting in net proceeds of $107.9 million, after deducting underwriting discounts and commissions and other offering expenses. On November 19, 2020, the Company issued and sold an additional 951,837 shares of common stock at the IPO price of $16.00 per share pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $14.2 million after deducting underwriting discounts and commissions. Upon the closing of the IPO, all of the Company's outstanding convertible preferred stock automatically converted into shares of common stock and the Company's outstanding warrants to purchase Series A Preferred Stock automatically became warrants to purchase an aggregate of 7,608 shares of common stock (see Note 7).

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. Since inception, the Company has funded its operations primarily with proceeds from sales of preferred stock, debt financing and an upfront payment of $15.0 million the Company received in July 2020 under a collaboration agreement with Merck Sharp & Dohme Corp. (see Note 10), and most recently, with proceeds from the sale of common stock in the IPO completed in October 2020. The Company has incurred recurring losses, including net losses of $68.8 million and $51.1 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, the Company had an accumulated deficit of $162.9 million. The Company expects to continue to generate operating losses in the foreseeable future. As of the issuance date of these consolidated

financial statements the Company expects that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months.

The Company will need to obtain additional funding through public or private equity offerings, debt financings, collaborations, strategic alliances and/or licensing arrangements. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborative or strategic alliances or licensing arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. Arrangements with collaborators or others may require the Company to relinquish rights to certain of its technologies or programs. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, pipeline expansion or commercialization efforts, which could adversely affect its business prospects. Although management will continue to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations when needed or at all.

Basis of presentation

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

2. Summary of Significant Accounting Policies

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 expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, revenue recognition, the valuation of stock-based awards and the accrual of research and development expenses. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Actual results may differ from those estimates or assumptions.

Concentrations of credit risk and of significant suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. As of December 31, 2020, the Company maintained cash, cash equivalents and marketable securities at financial institutions in excess of federally insured limits. 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 provide services, supplies and materials for certain activities related to its programs. These programs could be adversely affected by a significant interruption in these services or the availability of materials.

Cash equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents.

Marketable Securities

The Company's marketable securities are classified as available-for-sale and are carried at fair value with the unrealized gains and losses reported as a component of accumulated other comprehensive loss in stockholders' equity (deficit). Realized gains and losses and declines in value judged to be other than temporary are included as a component of interest income and other income (expense), net based on the specific identification method. The Company classifies its marketable securities with maturities beyond one year as short-term, based on their highly liquid nature and because such marketable securities are available for current operations.

Restricted cash

Amounts included in restricted cash represent amounts pledged as collateral for letters of credit required for security deposits on the Company's leased facilities and credit cards. These amounts are classified as restricted cash (current and non-current) in the Company's consolidated balance sheets.

Property and equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

	Estimated Useful Life
Laboratory equipment	5 years
Furniture and fixtures	5 years
Computer equipment and software	3 years
Leasehold improvements	Shorter of useful life or remaining term of lease

Costs for capital assets not yet placed into service are depreciated once placed into service. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance are charged to expense as incurred.

Impairment of long-lived assets

The Company evaluates its long-lived assets, which consist primarily of property and equipment and operating lease right-of-use assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. The Company did not record any impairment losses on long-lived assets during the years ended December 31, 2020 or 2019.

Fair value measurements

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

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

- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and marketable securities are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of the Company's accounts payable and accrued expenses approximate their fair values due to the short-term nature of these liabilities. The carrying value of the Company's long-term debt approximates its fair value (a level 2 measurement) due to its variable interest rate.

Revenue recognition

The Company accounts for its one collaboration arrangement, entered into in July 2020, under ASC Topic 606, *Revenue From Contracts With Customers* (ASC 606). For additional information on the Company's collaboration agreement, see Note 10, Collaboration Agreement, to these consolidated financial statements. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

The Company assesses the goods or services promised within each contract and determines those that are performance obligations. The promised goods or services in the Company's arrangements would likely consist of licenses, rights to the Company's intellectual property, research and development services and related supporting activities. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations.

The Company assesses whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the customer and the availability of the associated expertise in the general marketplace. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

The transaction price is then determined and allocated to the identified performance obligations in proportion to their standalone selling prices ("SSP") on a relative SSP basis. SSP is determined at contract inception and is not

updated to reflect changes between contract inception and when the performance obligations are satisfied. Determining the SSP for performance obligations requires significant judgment. In developing the SSP for a performance obligation, the Company considers applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. The Company validates the SSP for performance obligations by evaluating whether changes in the key assumptions used to determine the SSP will have a significant effect on the allocation of arrangement consideration between multiple performance obligations.

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

If an arrangement includes development and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

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

The Company records amounts as accounts receivable when the right to consideration is deemed unconditional. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded for deferred revenue.

In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if the timing of payments provides the Company with a significant benefit of financing. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between the transfer of the promised goods or services to the customer and the payment by the customer will be one year or less. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied, either at a point in time or over time, and if over time, recognition is based on the use of an output or input method.

Classification of convertible preferred stock

The Company classified its convertible preferred stock outstanding prior to the IPO outside of stockholders' equity (deficit) on the consolidated balance sheet because the holders of such shares had redemption rights in the event of a deemed liquidation that, in certain situations, is not solely within the control of the Company.

Research and development costs

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, and external costs of vendors engaged to conduct research, preclinical and clinical development activities 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 over the period to which they relate. Costs for research and development activities are expensed in the period in which they are incurred. Payments for such activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid expense or accrued research and development expense. Determining the prepaid and accrued balances at the end of any reporting period incorporate certain judgments and estimates by management that are based on information available to the Company including information provided by vendors regarding the progress to completion of specific tasks or costs incurred.

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.

Leases

In accordance with ASC 842, *Leases*, the Company accounts for a contract as a lease when it has the right to control the asset for a period of time while obtaining substantially all of the asset's economic benefits. The Company determines if an arrangement is a lease or contains an embedded lease at inception. For arrangements that meet the definition of a lease, the Company determines the initial classification and measurement of its right-of-use asset and lease liability at the lease commencement date and thereafter if modified. The lease term includes any renewal options that the Company is reasonably assured to exercise. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its estimated secured incremental borrowing rate for that lease term. The Company's policy is to not record leases with an original term of twelve months or less on its consolidated balance sheets and recognizes those lease payments in the income statement on a straight-line basis over the lease term. The Company's existing leases are for office and laboratory space and an equipment lease.

In addition to rent, the leases may require the Company to pay additional costs, such as utilities, maintenance and other operating costs, which are generally referred to as non-lease components. The Company has elected to not separate lease and non-lease components. Only the fixed costs for lease components and their associated non-lease components are accounted for as a single lease component and recognized as part of a right-of-use asset and liability. Rent expense for operating leases is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in operating expense in the consolidated statements of operations and comprehensive loss.

Stock-based compensation

The Company measures stock options with service-based vesting or performance-based vesting granted to employees, non-employees and directors based on the fair value on the date of grant using the Black-Scholes option-pricing model. The Company measures restricted common stock awards using the difference between the purchase price per share of the award, if any, and the fair value of the Company's common stock at the date of grant. Compensation expense for the awards is recognized over the requisite service period for employees and directors and as services are delivered for non-employees, both of which are generally the vesting period of the respective award. The Company uses the straight-line method to record the expense of awards with only service-based vesting conditions. The Company uses the graded-vesting method to record the expense of awards with both service-based and performance-based vesting conditions, commencing once achievement of the performance condition becomes probable. The Company accounts for forfeitures of share-based awards as they occur.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Net loss per share

In October 2020, upon the closing of the IPO, all outstanding shares of the Company's convertible preferred stock automatically converted into 21,958,588 shares of the Company's common stock. Prior to this conversion, the Company followed the two-class method when computing net income (loss) per share as the Company had issued shares that meet 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 (loss) available to common stockholders for the period to be allocated between common stock and participating securities based upon their respective rights to share in the earnings as if all income (loss) for the period had been distributed.

Basic net income (loss) per share attributable to common stockholders is computed by dividing net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net income (loss) per share attributable to common stockholders is computed by adjusting net income (loss) attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares.

The Company's participating securities contractually entitled the holders of such shares to participate in dividends but did not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reported a net loss, such losses were not allocated to such participating securities. In periods in which the Company reported a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

The Company reported a net loss attributable to common stockholders for the years ended December 31, 2020 and 2019.

The following common stock equivalents presented based on amounts outstanding at each period end, have been excluded from the calculation of diluted net loss per share because including them would have had an anti-dilutive impact:

	December 31,	
	2020	2019
Stock options to purchase common stock	5,016,460	3,886,489
Warrants to purchase common stock	18,445	—
Convertible preferred stock (as converted to common stock)	—	15,467,863
Unvested restricted common stock	—	891,894
Warrants to purchase convertible preferred stock (as converted to common stock)	—	7,608
	5,034,905	20,253,854

Segments

Operating segments are defined as components of an entity for which separate discrete financial information is made available and that is regularly evaluated by the chief operating decision maker ("CODM") in making decisions regarding resource allocation and assessing performance. The Company's CODM is its chief executive officer and the Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company is focused on pioneering the discovery and development of a new class of medicines targeting genetically determined dependencies within the chromatin regulatory system.

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. For the year ended December 31, 2020, the Company's only element of other comprehensive loss was unrealized losses on available for sale debt securities. For the year ended December 31, 2019, there was no difference between net loss and comprehensive loss.

Income taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to the provision for income taxes. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. Any resulting unrecognized tax benefits are recorded within the provision for income taxes.

Recently issued accounting pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company can adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and can do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326)*. The new standard adjusts the accounting for assets held at amortized costs basis, including marketable securities accounted for as available for sale. The standard eliminates the probable initial recognition threshold and requires

an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. For public entities, the guidance was effective for annual reporting periods beginning after December 15, 2019 and for interim periods within those fiscal years. For nonpublic entities and emerging growth companies that choose to take advantage of the extended transition period, the guidance is effective for annual reporting periods beginning after December 15, 2020. Early adoption is permitted for all entities. In November 2019, the FASB issued ASU No. 2019-10, which deferred the effective date for nonpublic entities to annual reporting periods beginning after December 15, 2022, including interim periods within those fiscal years. The Company is evaluating when to adopt this standard and the effect the adoption will have on its consolidated financial statements.

3. Marketable Securities and Fair Value Measurements

As of December 31, 2020, available for sale marketable securities by security type consisted of (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. treasury notes (due within one year)	$ 92,982	$ —	$ (7)	$ 92,975
Total	$ 92,982	$ —	$ (7)	$ 92,975

The Company had no marketable securities as of December 31, 2019.

The following tables present the Company's fair value hierarchy for its assets and liabilities, which are measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements at December 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 48,770	$ —	$ —	$ 48,770
U.S. treasury notes	—	42,997	—	42,997
Marketable securities:				
U.S. treasury notes	—	92,975	—	92,975
Total	$ 48,770	$ 135,972	$ —	$ 184,742

	Fair Value Measurements at December 31, 2019 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 14,951	$ —	$ —	$ 14,951
Liabilities:				
Preferred stock warrant liability	$ —	$ —	$ 45	$ 45

The preferred stock warrant liability as of December 31, 2019 consisted of the fair value of warrants to purchase 14,076 shares of Series A-1 convertible preferred stock at $1.00 per share and was based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy. The Company's valuation of the preferred stock warrants utilized the Black-Scholes option-pricing model, which incorporated assumptions and estimates to value the preferred stock warrants. The Company assessed these

assumptions and estimates at the end of each reporting period. Changes in the fair value of the preferred stock warrants were recognized within other income (expense) in the consolidated statements of operations and comprehensive loss and were not material during the years ended December 31, 2020 and 2019.

In October 2020, upon closing of the IPO, the warrants to purchase 14,076 shares of Series A-1 convertible preferred stock automatically became warrants to purchase an aggregate of 7,608 shares of common stock. The Company remeasured the warrants as of the IPO date and reclassified the carrying value of the warrants from a non-current liability to additional paid-in capital in its consolidated balance sheet. During the year ended December 31, 2020, these warrants were exercised in full.

4. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2020	2019
Laboratory equipment	$ 3,740	$ 3,202
Furniture and fixtures	815	337
Computer equipment and software	100	81
Leasehold improvements	16,961	75
Assets not yet placed in service	15	280
	21,631	3,975
Less: Accumulated depreciation and amortization	(2,103)	(1,292)
	$19,528	$ 2,683

Depreciation and amortization expense was $1.3 million and $0.7 million for the years ended December 31, 2020 and 2019, respectively.

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2020	2019
Accrued employee compensation and benefits	$3,513	$1,867
Accrued construction in progress	2,385	119
Accrued external research and development expenses	2,146	1,384
Accrued professional fees	979	274
Other	138	57
	$9,161	$3,701

6. Notes Payable

Long-term debt consisted of the following (in thousands):

	December 31,	
	2020	2019
Principal amount of long-term debt	$20,000	$15,000
Less: Current portion of long-term debt	—	(4,152)
Long-term debt, net of current portion	20,000	10,848
Final payment fee	1,000	530
Debt discount, net of accretion	(1,346)	(418)
Long-term debt, net of discount and current portion	$19,654	$10,960

Loan and Security Agreements

As of December 31, 2019, the Company had outstanding loans under its amended loan and security agreement with Comerica Bank (the "Loan") of $7.0 million ("Term Loan A") and $8.0 million ("Term Loan B"). Borrowings under both Term Loan A and Term Loan B were repayable in monthly payments of interest-only through February 2020, to be followed by monthly payments of equal principal plus interest until the loan maturity date of February 1, 2023. In April 2020, the Company amended the Loan to extend the interest only period through May 31, 2020 and in June 2020 the Loan was further amended to extend the interest-only period through August 31, 2020. Interest for Term Loan A was the greater of 1) Comerica's Prime Rate or 2) LIBOR plus 2.5%, and for Term Loan B, 1.0% plus the greater of 1) Comerica's Prime Rate or 2) LIBOR plus 2.5%.

A final payment fee of 3.0% of the aggregate amounts drawn under Term Loan A and 4.0% under Term Loan B was due upon the earlier of the maturity date, the repayment date if paid early, whether voluntary or upon acceleration due to default, the sale of substantially all of the Company's assets, or the Company's IPO. The Company may repay the Loan at any time by paying the outstanding principal balance in full, along with any unpaid accrued interest and the final payment fee. The final payment fee of $0.5 million was being amortized to interest expense over the term of the debt using the effective interest method. Upon closing of the Company's IPO in October 2020, the final payment fee became due. In November 2020, the Company used a portion of the proceeds from its new loan and security agreement described below to repay the outstanding principal balance under Term Loan A and Term Loan B plus unpaid accrued interest and the final payment fee. The Company recorded a loss on debt extinguishment of $0.2 million related to this repayment.

On November 19, 2020, the Company entered into a new loan and security agreement, or the Oxford Loan, with Oxford Finance LLC, or Oxford, for an aggregate principal amount of $20.0 million (Oxford Term Loan A) and up to an additional $5.0 million (Oxford Term Loan B). On November 19, 2020, the Company borrowed $20.0 million under the Oxford Term Loan A. The Term Loan bears interest at a floating per annum rate equal to the greater of (i) 8.0% and (ii) the sum of (a) thirty-day LIBOR rate plus (b) 7.84%. In addition, upon loan maturity or prepayment, the Company is reqired to make a final payment fee equal to 5.0% of the aggregate principal amount borrowed which is being amortized to interest expense over the term of the debt using the effective interest method.

The Company is required to make monthly interest only payments under the Oxford Loan each month beginning on January 1, 2021. Beginning on December 1, 2023, the Company is required to make consecutive equal monthly payments of principal, together with applicable interest, in arrears, based upon a repayment schedule equal to 24 months, with a final maturity date of November 1, 2025 (the "Maturity Date"). At the Company's option, the Company may elect to prepay the loans subject to a prepayment fee equal to the following percentage of the principal amount being prepaid: 2% if an advance is prepaid during the first 12 months following the applicable advance date, 1% if an advance is prepaid after 12 months but prior to 24 months following the

applicable advance date, and 0.5% if an advance is prepaid any time after 24 months following the applicable advance date but prior to the Maturity Date.

The Company's obligations under the Oxford Loan Agreement are secured by a security interest in all of its assets, other than its intellectual property. The Company is also subject to certain affirmative and negative covenants including limitations on dispositions, mergers or acquisitions; encumbering its intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; and engaging in certain other business transactions. The obligations under the Loan are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in the Company's business, operations or financial or other condition. Upon the occurrence of an event of default and until such event of default is no longer continuing, the annual interest rate will be 5.0% above the otherwise applicable rate. As of December 31, 2020, the Company believes an event of default would be remote.

In addition, in connection with the Oxford Loan Agreement, the Company granted warrants to purchase 18,445 shares of the Company's common stock at $16.26 per share. The issued warrants are exerciseable for 10 years. The Company valued the warrants using the Black-Scholes option pricing model and determined the fair value of the warrants to be $0.2 million. The Company determined the warrants met the criteria for equity classification, and, as such, the fair value of the warrants were recorded as additional paid-in capital and as a discount to the debt which is being amortized to interest expense over the term of the Oxford Loan of five years. In addition, the Company incurred debt issuance costs of $0.2 million.

As of December 31, 2020, the interest rate applicable to outstanding borrowings under the Oxford Loan was 8.0%. During the years ended December 31, 2020 and 2019, the weighted average effective interest rate on outstanding borrowings was approximately 6.4% and 6.9%, respectively.

As of December 31, 2020, future principal payments due are as follows (in thousands):

2021	$ —
2022	—
2023	833
2024	10,000
2025	9,167
	$ 20,000

7. Convertible Preferred Stock and Preferred Stock Warrants

Convertible Preferred Stock

The Company issued Series A-1 convertible preferred stock (the "Series A-1"), Series A-2 convertible preferred stock (the "Series A-2") and Series B convertible preferred stock (the "Series B"). The Series A-1 and Series A-2 are collectively referred to as the "Series A" and the Series A and Series B are collectively referred to as the "Preferred Stock."

In July and August 2020, in two separate closings, the Company sold 5,600,000 shares of Series B preferred stock at a purchase price of $7.50 per share resulting in gross proceeds to the Company of $42.0 million.

In April 2020, in two separate closings, the Company sold 6,407,867 shares of Series B preferred stock at a purchase price of $7.50 per share resulting in gross proceeds to the Company of $48.1 million.

As of December 31, 2019, Preferred Stock consisted of the following (in thousands, except share amounts):

	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A-1 Preferred Stock	9,707,826	9,693,750	$ 9,609	$ 9,694	5,239,865
Series A-2 Preferred Stock	10,804,165	10,804,165	16,179	16,206	5,840,089
Series B Preferred Stock	8,117,631	8,117,631	60,756	60,882	4,387,909
	28,629,622	28,615,546	$ 86,544	$ 86,782	15,467,863

Upon the closing of the IPO in October 2020, the Company's Preferred Stock automatically converted into 21,958,588 shares of common stock.

Warrants to Purchase Preferred Stock

In connection with the issuance of notes payable, the Company issued warrants to purchase 14,076 shares of Series A-1 preferred stock at an exercise price of $1.00 per share. In October 2020, upon closing of the IPO, the warrants automatically became warrants to purchase an aggregate of 7,608 shares of common stock and were then cashless exercised in full for 6,728 shares of common stock.

8. Common Stock

On October 27, 2020, the Company completed its initial public offering ("IPO") pursuant to which it issued and sold 7,500,000 shares of its common stock at a public offering price of $16.00 per share, resulting in net proceeds of $107.9 million, after deducting underwriting discounts and commissions and other offering expenses. On November 19, 2020, the Company issued and sold an additional 951,837 shares of common stock at the IPO price of $16.00 per share pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $14.2 million after deducting underwriting discounts and commissions. Upon the closing of the IPO, all of the Company's outstanding convertible preferred stock automatically converted into shares of common stock (see Note 7).

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.

9. Stock-Based Compensation

2016 Stock incentive plan

The Company's 2016 Stock Incentive Plan, (the "2016 Plan") provided for the Company to grant incentive stock options or nonqualified stock options and other equity awards to employees, directors and consultants of the Company. Upon the effectiveness of the 2020 Equity Incentive Plan (the "2020 Plan") in October 2020, the Company ceased granting additional awards under the 2016 Plan.

2020 Equity Incentive Plan

On October 21, 2020, the Company's board of directors adopted and its stockholders approved the 2020 Plan, which became effective on October 21, 2020. The 2020 Plan provides for the grant of incentive stock options, non-qualified options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares initially reserved for issuance under the 2020 Plan was (i) 2,200,000 shares (the "share pool"), plus (ii) the number of shares of common stock available for issuance under the 2016 Plan as of the effective date of the 2020 Plan, plus the number of shares of common stock underlying

awards under the 2016 Plan that on or after the date of adoption expire or become unexercisable without delivery of shares, are forfeited to, or repurchased for cash, are settled in cash, or otherwise become available again for grant under the 2016 Plan, in each case, in accordance with its terms (up to an aggregate of 5,078,295 shares). As of December 31, 2020, 2,213,094 shares remained available for future grants under the 2020 Plan.

The share pool will automatically increase on January 1 of each year from 2021 to 2030 by the lesser of (i) four percent of the number of shares of our common stock outstanding as of the close of business on the immediately preceding December 31 and (ii) the number of shares determined by the board of directors on or prior to such date for such year. The number of shares reserved for issuance under the 2020 Plan was increased by 1,471,576 shares effective January 1, 2021.

The 2020 Plan and 2016 Plan are administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or its committee if so delegated. Stock options granted with service-based vesting conditions generally vest over four years and expire after ten years. The exercise price for stock options granted is not less than the fair value of common stock on the date of grant. The Company bases fair value of common stock on the quoted market price. Prior to the IPO, the board of directors determined the value the Company's common stock, taking into consideration its most recently available valuation of common stock performed by third parties as well as additional relevant factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant.

2020 Employee Stock Purchase Plan

On October 21, 2020, the Company's board of directors adopted and its stockholders approved the 2020 Employee Stock Purchase Plan (the "ESPP"), which became effective on October 21, 2020. The aggregate number of shares of common stock available for purchase pursuant to the exercise of options under the ESPP is 360,000 shares, plus an automatic annual increase, as of January 1 of each year from 2021 to 2030, equal to the lesser of (i) one percent of the number of shares of common stock outstanding as of the close of business on the immediately preceding December 31 and (ii) the number of shares determined by the board of directors on or prior to such date for such year (up to a maximum of 3,220,520 shares). The number of shares reserved for issuance under the ESPP was increased by 367,894 shares effective January 1, 2021.

As of December 31, 2020, no offering periods have commenced under the ESPP.

Stock option valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. Prior to the IPO, the Company was 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. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table presents, on a weighted average basis, the assumptions used in the Black-Scholes option-pricing model to determine the grant-date fair value of stock options granted in 2020 and 2019:

	Year Ended December 31,	
	2020	2019
Risk-free interest rate	0.4%	2.2%
Expected volatility	78.5%	78.2%
Expected dividend yield	—	—
Expected term (in years)	6.1	6.0

The following table summarizes the Company's option activity during the year ended December 31, 2020:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2019	3,886,489	$ 2.39		
Granted	1,922,377	8.87		
Exercised	(611,048)	1.99		
Forfeited	(181,358)	2.10		
Outstanding as of December 31, 2020	5,016,460	$ 4.93	8.5	$ 76,941
Vested and expected to vest as of December 31, 2020	5,016,460	$ 4.93	8.5	$ 76,941
Options exercisable as of December 31, 2020	1,508,122	$ 1.91	7.4	$ 27,683

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2020 and 2019 was $3.5 million and $1.2 million, respectively.

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2020 and 2019 was $6.01 per share and $2.54 per share, respectively.

Restricted common stock

During 2015, the Company issued and sold 4,459,459 shares of restricted common stock at par value to the scientific founders of the Company. The shares were subject to vesting over a period of five years and began vesting upon the closing of the Series A-1 Preferred Stock in April 2016 and were fully vested as of December 31, 2020. The following table summarizes the Company's restricted common stock activity during the year ended December 31, 2020:

	Shares
Unvested restricted common stock as of December 31, 2019	891,894
Issued	—
Vested	(891,894)
Unvested restricted common stock as of December 31, 2020	—

The aggregate fair value of restricted stock that vested during the years ended December 2020 and 2019 was $4.8 million and $3.3 million, respectively.

Stock-based compensation

The Company recorded stock-based compensation expense related to common stock options and restricted common stock in the following expense categories of its consolidated statements of operations and comprehensive loss (in thousands):

	Year Ended December 31,	
	2020	2019
Research and development expenses	$ 1,724	$ 1,140
General and administrative expenses	1,237	554
	$2,961	$1,694

As of December 31, 2020, total unrecognized compensation cost was $13.5 million, which is expected to be recognized over a weighted average period of 3.6 years.

10. Collaboration Agreement

In July 2020, the Company entered into a research collaboration and license agreement (the "Collaboration Agreement") with Merck Sharp & Dohme Corp. ("Merck"). The Company and Merck will apply Foghorn's proprietary Gene Traffic Control platform to discover and develop novel therapeutics. Under the Collaboration Agreement, the Company granted Merck exclusive global rights to develop and commercialize drugs that target dysregulation of a single transcription factor. Under the terms of the Collaboration Agreement, the Company and Merck are each responsible to perform certain research activities in accordance with a mutually agreed upon research plan. Merck may substitute the selected transcription factor during certain stages of the research program, subject to certain limitations. Following completion of the research program, Merck is responsible for the development and commercialization of the compounds developed pursuant to the research program and any product containing such compounds. Pursuant to the Collaboration Agreement, the Company will also participate on a joint steering committee.

Under the terms of the agreement, Foghorn received a nonrefundable upfront payment of $15.0 million from Merck, and is eligible to receive up to $245.0 million upon achievement of specified research, development and regulatory milestones by any product candidate generated by the collaboration, and up to $165.0 million upon achievement of specified sales-based milestones per approved product from the collaboration, if any. The Company will be eligible to receive tiered royalties, calculated on a product-by-product and country-by-country basis, on net sales of approved products from the collaboration, if any, at royalty rates ranging from the mid-single digits to low tens, depending on whether the products are covered by patent rights it licenses to Merck.

Unless terminated earlier, the Collaboration Agreement will continue in full force and effect until one or more products has received marketing authorization and, thereafter, until expiration of all royalty obligations under the Collaboration Agreement. The Company or Merck may terminate the Collaboration Agreement upon an uncured material breach by the other party or insolvency of the other party. Merck may also terminate the Merck Collaboration Agreement for any reason upon certain notice to the Company.

The Company determined that the (1) research, development, manufacture and commercialization licenses, (2) the research activities performed by the Company and (3) service on the joint committees represent a single performance obligation under the Collaboration Agreement. The Company determined that Merck cannot benefit from licenses separately from the research activities and participation on the joint steering committee as these services are specialized and rely on the Company's expertise such that these activities are highly interrelated and therefore not distinct. Accordingly, the promised goods and services represent one combined performance obligation and the entire transaction price was allocated to that single combined performance obligation. The performance obligation will be satisfied over the research term as the Company performs the research activities and participates in a joint steering committee to oversee research activities.

The upfront payment of $15.0 million was initially recorded as deferred revenue and is being recognized as revenue as the performance obligation is satisfied. The Company recognizes revenue using the cost-to-cost method, which it believes best depicts the transfer of control to the customer over time. Under the cost-to-cost method, the extent of progress towards completion is measured based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the identified performance obligation. Under this method, revenue is recorded as a percentage of the estimated transaction price based on the extent of progress towards completion. As of December 31, 2020, the potential research, development and regulatory milestone payments that the Company is eligible to receive were excluded from the transaction price as they were fully constrained by uncertain events. The Company will reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and if necessary,

the Company will adjust its estimate of the transaction price. Any additions to the transaction price would be reflected in the period as a cumulative revenue catch-up based on the ratio of costs incurred to the total estimated costs expected applied to the revised transaction price. Sales-based royalties and milestone payments, which predominantly relate to the license, will be recognized if and when the related sales occur.

As of December 31, 2020, the aggregate amount of the transaction price related to the unsatisfied portion of the performance obligation is $14.6 million, which is expected to be recognized as revenue through 2028. The Company does not expect collaboration revenue to be recognized evenly over this period as it will be recognized on a percentage of completion basis (using cost-to-cost method) as the Company performs the research activities and participates on the joint steering committee, which will likely vary from period to period. In estimating the total costs to satisfy its single performance obligation pursuant to the Collaboration Agreement, the Company is required to make significant estimates including an estimate of the number of transcription factor substitutions and the expected time and expected costs to fulfill the performance obligation. The cumulative effect of revisions to the total estimated costs to complete the Company's single performance obligation will be recorded in the period in which the changes are identified, and amounts can be reasonably estimated. While such revisions will have no impact on the Company's cash flows, a significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

The Company assessed the Collaboration Agreement to determine whether a significant financing component exists and concluded that a significant financing component does not exist. Through December 31, 2020, the Company had recorded $0.4 million of revenue under the Collaboration Agreement.

11. Income Taxes

During the years ended December 31, 2020 and 2019, the Company recorded no income tax benefits for the net deferred tax assets comprised primarily of net operating losses incurred and research and development tax credits generated in each year, due to its uncertainty of realizing a benefit from these items.

All of the Company's operating losses since inception have been generated in the United States.

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

	Year Ended December 31,	
	2020	2019
Federal statutory income tax rate	(21.0)%	(21.0)%
State taxes, net of federal benefit	(6.4)	(7.1)
Federal and state research and development tax credits	(3.7)	(2.2)
Other	(0.5)	0.4
Change in deferred tax asset valuation allowance	31.6	29.9
Effective income tax rate	0.0%	0.0%

Net deferred tax assets consisted of the following (in thousands):

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 39,289	$ 23,769
Research and development tax credit carryforwards	4,955	2,415
Capitalized start-up costs	174	190
Accrued expenses	1,010	522
Stock-based compensation	436	74
Operating lease liabilities	17,032	414
Total deferred tax assets	62,896	27,384
Deferred tax liabilities:		
Depreciation	(2,819)	(482)
Operating lease right-of-use assets	(11,694)	(281)
Total deferred tax liabilities	(14,513)	(763)
Valuation allowance	(48,383)	(26,621)
Net deferred tax assets	$ —	$ —

As of December 31, 2020, the Company had U.S. federal and state net operating loss carryforwards of $147.3 million and $132.3 million, respectively, which may be available to offset future taxable income. The federal net operating loss carryforwards include $12.5 million which expire at various dates beginning in 2035 and $134.8 million which carryforward indefinitely but in some circumstances may be limited to offset 80% of annual taxable income. The state net operating loss carryforwards expire at various dates beginning in 2036. As of December 31, 2020, the Company also had U.S. federal and state research and development tax credit carryforwards of $3.4 million and $2.0 million, respectively, which may be available to offset future tax liabilities and expire at various dates beginning in 2036 and 2031, respectively.

Utilization of the U.S. federal and state net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income or tax liabilities. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed by the Company and any limitation is known, no amounts are being recorded as an uncertain tax position.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company’s history of cumulative net losses incurred since inception and its lack of commercialization of any products that would generate revenue from product sales and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2020 and 2019. Management reevaluates the positive and negative evidence at each reporting period.

The valuation allowance increased by $21.8 million and $15.3 million during the years ended December 31, 2020 and 2019, respectively, primarily as a result of the increase in net operating loss carryforwards.

As of December 31, 2020 and 2019, the Company had not recorded any amounts for unrecognized tax benefits. The Company files income tax returns in the U.S. and Massachusetts, 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. Since the Company is in a loss carryforward position, it is generally subject to examination by the U.S. federal, state, and local income tax authorities for all tax years in which a loss carryforward is available.

12. Leases

In October 2019, the Company entered into a lease for 81,441 square feet of office and laboratory space in Cambridge, Massachusetts, commencing in January 2020 (the “New Lease”). The initial term of the New Lease was eight years with a five-year option to extend at fair-market rent at the time of the extension. The base rent payments escalate annually over the eight-year lease term and totaled approximately $60.3 million. In connection with the New Lease, the landlord agreed to fund up to $3.0 million in tenant improvements to the leased facility as well as up to an additional $16.3 million, which resulted in additional rent payments to the landlord over the lease term. During the year ended December 31, 2020, $15.4 million of leasehold improvements were reimbursed by the landlord, which resulted in an increase to operating lease liabilities. The Company is obligated to pay its portion of real estate taxes and costs related to the premises, including costs of operations and management of the leased premises. The Company is required to maintain a cash balance of $1.7 million to secure a letter of credit associated with the lease. This amount was classified as restricted cash (non-current) on the consolidated balance sheet as of December 31, 2020 and 2019. On January 1, 2020, the lease commencement date, the Company recorded an operating lease asset of $38.6 million and corresponding lease liability of $38.3 million.

In June 2020, the Company amended the New Lease to defer payment of a portion of the base rent and operating expenses and to extend the lease term by nine months to September 2028. The amendment was accounted for as a lease modification and the right-of-use asset and lease liability were remeasured at the modification date of June 29, 2020 resulting in an increase of $7.4 million to both the right-of-use asset and lease liabilities.

The Company had a lease for office and laboratory facilities in Cambridge, Massachusetts under a noncancelable operating lease that began in August 2017 and expired in March 2025. In April 2020, this lease was assigned and assumed by a related party which became effective in October 2020.

The components of lease expense were as follows (in thousands):

	Year Ended December 31,	
	2020	2019
Operating lease cost	$ 7,032	$ 1,671
Short-term lease cost	61	60
Variable lease cost	1,217	547
	$ 8,310	$ 2,278

Supplemental disclosure of cash flow information related to leases was as follows (in thousands):

	Year Ended December 31, 2020	2019
Cash paid for amounts included in the measurement of operating lease liabilities	$ 3,086	$ 1,731
Operating lease liabilities arising from obtaining right-of-use assets	$ 38,306	$ 271
Increase in operating lease liabilities and right-of-use assets due to lease remeasurement	$ 7,384	$ 6,513

The weighted-average remaining lease term and discount rate were as follows:

	2020	2019
Weighted-average remaining lease term—operating leases (in years)	7.7	1.1
Weighted-average discount rate—operating leases	5.35%	7.53%

Future annual minimum lease payments under operating leases as of December 31, 2020 were as follows (in thousands):

2021	$ 9,814
2022	10,016
2023	10,107
2024	10,347
2025	10,595
Thereafter	30,500
Total future minimum lease payments	81,379
Less: imputed interest	(15,104)
Less: estimated lease incentives	(3,933)
Total operating lease liabilities	$ 62,342

Included in the consolidated balance sheet (in thousands):	December 31, 2020
Current operating lease liabilities	$ 3,981
Operating lease liabilities, net of current portion	58,361
Total operating lease liabilities	$ 62,342

Sublease agreement

In April 2020, the Company entered into a two-year sublease of approximately 16,843 square feet of office space under the New Lease, as amended, which began in July 2020. As of December 31, 2020, the remaining base rent payments due to the Company under the subleases was $2.5 million. The Company recorded other income of $1.0 million during the year ended December 31, 2020 related to this sublease.

13. Commitments and Contingencies

Leases

The Company’s commitments under its leases are described in Note 12.

License agreements

Dana-Farber Cancer Institute

In 2016, the Company entered into a license agreement with the Dana-Farber Cancer Institute, Inc. (“Dana Farber”) for an exclusive license for certain biological materials as well as patent rights to methods of identifying compounds to treat prostate cancer. In consideration for the right to develop, manufacture, and commercialize products based on certain of Dana Farber’s intellectual property, the Company is obligated to reimburse Dana Farber for patent expenses and pay low single-digit sales-based royalties upon the occurrence of specific events as outlined in the license agreement. Unless terminated earlier, in accordance with the provisions of the agreement, the agreement will terminate on the expiration date of the last to expire of the applicable Dana Farber patents. None of the Company’s product candidates utilize technology covered by this license.

Stanford

In July 2017, the Company entered into a license agreement with the Board of Trustees of the Leland Stanford Junior University (“Stanford”) for a non-exclusive license for patent rights to certain diseases associated with chromatin remodeling. In consideration for the right to develop, manufacture, and commercialize products based on certain of Stanford’s intellectual property, the Company paid a one-time, non-refundable license fee of less than $0.1 million and reimbursed Stanford for $0.1 million of costs incurred related to the patented technology. The Company also issued 42,781 shares of the Company’s common stock upon execution of a share purchase agreement. In addition to annual license maintenance fees of less than $0.1 million, the Company will reimburse Stanford for patent expenses, pay low single-digit sales-based royalties, and pay up to $1.1 million in regulatory milestones on each licensed product upon the occurrence of specific events as outlined in the license agreement. None of the Company’s product candidates utilize technology covered by this license.

Indemnification agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, contract research organizations, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. The Company has not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

Legal Proceedings

From time to time, the Company may become involved in litigation or other legal proceedings. The Company is not currently a party to any material litigation or legal proceedings.

14. Defined Contribution Plan

The Company has a 401(k) defined contribution plan (the “401(k) Plan”) for its employees. Eligible employees may make pretax contributions to the 401(k) Plan up to statutory limits. There was no discretionary match made under the 401(k) Plan as of December 31, 2020 and 2019.

15. Related Parties

In October 2015, the Company entered into a five-year service agreement with Flagship Pioneering (“Flagship”), an affiliate of one of its stockholders, to provide general and administrative services to the Company, including

certain consulting services and the provision of employee health and dental benefit plans for the Company's employees. The Company made cash payments for services received under this agreement of $1.2 million and $0.9 million during the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020 and 2019, the Company had no accounts payable to Flagship for costs related to the service agreement. This agreement expired in 2020.

In October 2015, the Company entered into a five-year consulting agreement with a scientific founder of the Company who is also a board member and a shareholder. In October 2020, this agreement was extended to January 1, 2022, with an option to renew. During the years ended December 31, 2020 and 2019, the Company paid the scientific founder $0.2 million and $0.2 million, respectively. As of December 31, 2020 the Company had less than $0.1 million in accounts payable to this scientific founder.

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, under the supervision and with the participation of our Principal Executive Officer (our Chief Executive Officer) and Principal Financial and Accounting Officer (our Chief Financial Officer), has evaluated the effectiveness of our disclosure controls and procedures as of period end. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company 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 a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any disclosure 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, 2020, our Principal Executive Officer and Principal 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 does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's independent registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended December 31, 2020 that has materially affected, or is 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 information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. Financial Statements

For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page 103 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 immediately preceding the signature page of this Annual Report on Form 10-K. The exhibits listed in the Exhibit Index are incorporated by reference herein.

ITEM 16. FORM 10-K SUMMARY

None.

Exhibit Index

Exhibit number	Description of document
3.1	Third Amended and Restated Certificate of Incorporation of Foghorn Therapeutics Inc.(Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39634), filed on October 27, 2020).
3.2	Amended and Restated By-laws of Foghorn Therapeutics Inc. (Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-39634), filed on October 27, 2020).
4.1	Specimen stock certificate evidencing shares of common stock (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
4.2	Amended and Restated Investors' Rights Agreement, by and among Foghorn Therapeutics Inc. and the investors party thereto, dated as of December 18, 2018 (Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
4.3	Amendment to the Investors' Rights Agreement and the Voting Agreement, dated December 18, 2018, by and among Foghorn Therapeutics Inc. and the investors party thereto, dated as of April 17, 2020 (Incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 2, 2020).
4.4	Form of Warrant to Purchase Series A-2 Preferred Stock of the Registrant issued to Silicon Valley Bank, dated November 29, 2016 (Incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 2, 2020).
4.5	Form of Warrant to Purchase Common Stock of the Registrant issued to Oxford Finance LLC (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-39634), filed on November 25, 2020.
4.6*	Description of Registrant's Securities
10.1	Lease Agreement by and between ARE-Tech Square, LLC and Foghorn Therapeutics Inc., dated October 23, 2019 (Incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 2, 2020).
10.2++	Exclusive Collaboration and License Agreement, by and between Merck Sharp & Dohme Corp. and Foghorn Therapeutics Inc., dated as of July 2, 2020 (Incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 2, 2020).
10.3^	Foghorn Therapeutics Inc. 2016 Stock Incentive Plan, as amended (Incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 2, 2020).
10.4^	Form of Stock Restriction Agreement under the Foghorn Therapeutics Inc. 2016 Stock Incentive Plan (Incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 2, 2020).
10.5^	Form of Incentive Stock Option Grant Notice under the Foghorn Therapeutics Inc. 2016 Stock Incentive Plan (Incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264) filed on October 2, 2020).
10.6^	Form of Non-Qualified Stock Option Grant Notice under the Foghorn Therapeutics Inc. 2016 Stock Incentive Plan (Incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 2, 2020).

Exhibit number	Description of document
10.7	Form of Indemnification Agreement between Foghorn Therapeutics Inc. and its directors and officers (Incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 2, 2020).
10.8^	Amended and Restated Letter Agreement between Foghorn Therapeutics Inc. and Adrian Gottschalk, dated October 14, 2020 (Incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
10.9^	Amended and Restated Letter Agreement between Foghorn Therapeutics Inc. and Samuel Agresta, M.D., M.P.H. & T.M., dated October 14, 2020 (Incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
10.10^	Amended and Restated Letter Agreement between Foghorn Therapeutics Inc. and Carl P. Decicco, Ph.D., dated October 14, 2020 (Incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
10.11^	Foghorn Therapeutics Inc. 2020 Equity Incentive Plan (Incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
10.12^	Form of Incentive Stock Option Agreement under the Foghorn Therapeutics Inc. 2020 Equity Incentive Plan (Incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
10.13^	Form of Non-Statutory Stock Option Agreement (Employees) under the Foghorn Therapeutics Inc. 2020 Equity Incentive Plan (Incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
10.14^	Form of Non-Statutory Stock Option Agreement (Non-Employee Directors) under the Foghorn Therapeutics Inc. 2020 Equity Incentive Plan (Incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
10.15^	Foghorn Therapeutics Inc. 2020 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
10.16^	Foghorn Therapeutics Inc. 2020 Cash Incentive Plan (Incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
10.17^	Consulting Agreement between Foghorn Therapeutics Inc. and Cigall Kadoch, dated October 1, 2015 (Incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
10.18*^	Amendment to Consulting Agreement between Foghorn Therapeutics Inc. and Cigall Kadoch dated October 29, 2020.
10.19	Loan and Security Agreement dated as of November 19, 2020, among Oxford Finance LLC, and the Registrant (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-39634), filed on November 25, 2020).
21.1	List of Subsidiaries of Foghorn Therapeutics Inc. (Incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 2, 2020).

Exhibit number	Description of document
23.1*	Consent of Deloitte & Touche LLP
31.1*	Rule 13a—14(a) / 15d—14(a) Certification—Principal Executive Officer.
31.2*	Rule 13a—14(a) / 15d—14(a) Certification—Principal Financial Officer.
32.1**	Section 1350 Certification—Principal Executive Officer.
32.2**	Section 1350 Certification—Principal Financial Officer.
101*	Financial statements from the Annual Report on Form 10-K of the Company as of and for the period ended December 31, 2020, formatted in Extensible Business Reporting Language (XBRL): (i) Balance Sheets; (ii) Statements of Operations; (iii) Statements of Changes in Redeemable Preferred Stock and Stockholders' Equity; (iv) Statements of Cash Flows; and (v) Notes to Financial Statements.

* Filed herewith
** Furnished herewith
^ Indicates management contract or compensatory plan, contract or arrangement.
++ Portions of this exhibit (indicated by asterisks) have been omitted because the Registrant has determined they are not material and would likely cause competitive harm to the Registrant if publicly disclosed.

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.

FOGHORN THERAPEUTICS INC.

Date: March 18, 2021

By: /s/ Allan Reine
Allan Reine
Chief Financial Officer
(Principal Accounting and Financial Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Adrian Gottschalk and Allan Reine, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

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.

Signature	Title	Date
/s/ Adrian Gottschalk Adrian Gottschalk	President, Chief Executive Officer and Director (Principal Executive Officer)	March 18, 2021
/s/ Allan Reine Allan Reine, M.D.	Chief Financial Officer (Principal Accounting and Financial Officer)	March 18, 2021
/s/ José Baselga José Baselga, M.D., Ph.D.	Director	March 18, 2021
/s/ Scott Biller Scott Biller, Ph.D.	Director	March 18, 2021
/s/ Douglas Cole Douglas Cole, M.D.	Director	March 18, 2021
/s/ Simba Gill Simba Gill, Ph.D.	Director	March 18, 2021
/s/ Cigall Kadoch Cigall Kadoch, Ph.D.	Director	March 18, 2021
/s/ Adam Koppel Adam Koppel, M.D., Ph.D.	Director	March 18, 2021
/s/ Michael Mendelsohn Michael Mendelsohn, M.D.	Director	March 18, 2021

Exhibit 4.6

DESCRIPTION OF THE REGISTRANT'S SECURITIES

REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following summary describes all material provisions of the common stock, par value $0.0001 per share, of Foghorn Therapeutics Inc. The description of our common stock is qualified by reference to our certificate of incorporation, bylaws, and investor rights agreement, which are included as exhibits to the Annual Report on Form 10-K of which this Exhibit 4.6 is a part. The summary below is also qualified by provisions of applicable law.

General

Our authorized capital stock consists of 175,000,000 shares of common stock, par value $0.0001 per share, and 25,000,000 shares of preferred stock, par value $0.0001 per share. Our common stock is registered under Section 12 of the Securities Exchange Act of 1934, as amended, and is listed on The Nasdaq Global Market under the symbol "FHTX."

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are validly issued, fully paid and nonassessable. 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.

Preferred Stock

Under the terms of our amended and restated certificate of incorporation, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from seeking to acquire, a majority of our outstanding voting stock.

Anti-Takeover Effects of our Certificate of Incorporation and our By-Laws

Our certificate of incorporation and by-laws contains certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of our board of directors but which may have the effect of delaying, deferring or preventing a future takeover or change in control of us unless such takeover or change in control is approved by our board of directors.

These provisions include:

Classified board. Our certificate of incorporation provides that our board of directors will be divided into three classes of directors, with the classes as nearly equal in number as possible. As a result, approximately one-third of our board of directors are elected each year. The classification of directors has the effect of making it more difficult for stockholders to change the composition of our board. Our certificate of incorporation also provides that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors will be fixed exclusively pursuant to a resolution adopted by our board of directors.

Action by written consent; special meetings of stockholders. Our certificate of incorporation provides that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. Our certificate of incorporation and the by-laws also provides that, except as otherwise required by law, special meetings of the stockholders can only be called pursuant to a resolution adopted by a majority of our board of directors. Except as described above, stockholders are not permitted to call a special meeting or to require our board of directors to call a special meeting.

Removal of directors. Our certificate of incorporation provides that our directors may be removed only for cause by the affirmative vote of at least 75% of the voting power of our outstanding shares of capital stock, voting together as a single class. This requirement of a supermajority vote to remove directors could enable a minority of our stockholders to prevent a change in the composition of our board.

Advance notice procedures. Our by-laws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting are only able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our Secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the by-laws do not give our board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the by-laws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of us.

Supermajority approval requirements. The DGCL generally provides that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or by-laws, unless either a corporation's certificate of incorporation or by-laws requires a greater percentage. Our certificate of incorporation and by-laws provide that the affirmative vote of holders of at least 75% of the total votes eligible to be cast in the election of directors is required to amend, alter, change or repeal specified provisions. This requirement of a supermajority vote to approve amendments to our certificate of incorporation and by-laws could enable a minority of our stockholders to exercise veto power over any such amendments.

Authorized but unissued shares. Our authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

Exclusive forum. Our certificate of incorporation requires, to the fullest extent permitted by law, that derivative actions brought in the name of the Company, actions against directors, officers and employees for breach of a fiduciary duty and other similar actions may be brought only in specified courts in the State of Delaware. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers. See "Risk Factors —Our amended and restated certificate of incorporation designates the state or federal courts within the State of Delaware as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees."

Section 203 of the DGCL

We are subject to the provisions of Section 203 of the DGCL. 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. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

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; or at or after the time the stockholder became interested, the business combination was approved by our board of directors of the corporation 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.

A Delaware corporation may “opt out” of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or by-laws resulting from a stockholders’ amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

Exhibit 10.18

Execution Version

October 29, 2020

Cigall Kadoch, Ph.D.
By Email Delivery

Dear Dr. Kadoch:

Reference is made to that certain letter agreement dated October 1, 2015, by and between you and Foghorn Therapeutics Inc. (the "Company"), as amended by that certain fee increase letter dated January 22, 2019 (such agreement, as so amended, the "Consulting Agreement"). The purpose of this letter (this "Amendment") is to amend certain terms of the Consulting Agreement, as described below.

A. Term of Consulting Agreement

Section 6(a) of the Consulting Agreement is hereby amended and replaced in its entirety as follows:

> The "Term" shall commence on the Effective Date and shall continue until January 1, 2022, unless earlier terminated in accordance with this Section 6. Notwithstanding the foregoing, from and after January 1, 2022, the Term shall be extended automatically for each successive one- (1) year period unless the Company provides you written notice no later than the immediately preceding December 1 of its intention not to renew the Term.

B. Compensation

Section 8(b) of the Consulting Agreement is hereby amended and replaced in its entirety as follows:

> Effective as of October 1, 2020, and continuing until the expiration or termination of this Agreement, the Company will pay you consulting fees, payable monthly in arrears, in a monthly amount as set forth below.

Month	Monthly Consulting Fee
October 2020	$ 18,750
November 2020	$ 16,000
December 2020	$ 16,000
January 2021	$ 14,000
February 2021	$ 14,000
March 2021	$ 12,000
April 2021	$ 12,000
May 2021 and thereafter	$ 9,580

C. Confidentiality

Section 3(c) of the Consulting Agreement is hereby amended to include the following at the end of the Section:

> Further, (i) nothing contained in this Agreement limits, restricts or in any other way affects your communicating with any governmental agency or entity, or communicating with any official or staff person of a governmental agency or entity, concerning matters relevant to such governmental agency or entity; and (ii) you will not be held criminally or civilly liable under any federal or state trade secret law for disclosing a trade secret (A) in confidence to a federal, state or local government official, directly or indirectly, or to an attorney, solely for the purpose of reporting or investigating a suspected violation of law, or (B) in a complaint or other document filed under seal in a lawsuit or other proceeding, *provided*, *however*, that notwithstanding this immunity from liability, you may be held liable if you unlawfully access trade secrets by unauthorized means.

D. Limits on Competition

Section 5(a)(i) is hereby deleted from the Consulting Agreement (with the defined term "Restricted Territory" surviving).

In order to protect the Company's legitimate business interests, you agree, as a condition of the extension of the Term as provided herein and in exchange for the compensation and benefits provided hereunder, to which you are not otherwise entitled, to enter into the Non-Competition, Non-Solicitation, Confidentiality and Assignment of Inventions Agreement (the "Confidentiality Agreement") attached as Exhibit A hereto. You must sign and return the Confidentiality Agreement in connection with the execution of this Amendment.

You acknowledge and agree that references to employment or termination of employment included in the Confidentiality Agreement will be deemed to refer, respectively, to your services to the Company, under the Consulting Agreement or otherwise, or the termination thereof.

Notwithstanding anything to the contrary in the Confidentiality Agreement, the restrictions set forth in Sections 8 (Non-Competition) and 9 (Non-Solicitation) of the Confidentiality Agreement will not apply to activities conducted on behalf of DFCI (as defined in the Consulting Agreement) or any other academic, hospital, governmental or not-for-profit institution or entity that employs you or for which you consult or otherwise provide services, now or in the future, including the Broad Institute, Harvard University, Stanford University and the Howard Hughes

Medical Institute (collectively, "Institutions"), or to any seminars, talks or other educational activities you may undertake in your capacity as an employee or consultant of an Institution, *provided* that you comply with the other terms of the Consulting Agreement and the Confidentiality Agreement.

E. Miscellaneous

Except as expressly amended by this Amendment, the Consulting Agreement will remain in full force and effect in accordance with its terms. This Amendment will be governed by and construed and enforced in accordance with the laws of the Commonwealth of Massachusetts, without giving effect to the conflict of law principles of any jurisdiction. This Amendment may be executed in one or more counterparts (and may be delivered by email or other electronic means), each of which will be deemed an original but all of which together will constitute one and the same instrument.

[*Remainder of Page Intentionally Left Blank*]

Please sign below to acknowledge your acceptance of the terms of this letter. Keep one copy for your files and return one executed copy to the Company.

Very truly yours,

FOGHORN THERAPEUTICS INC.

By: /s/ Adrian Gottschalk
Name: Adrian Gottschalk
Title: President and CEO

Accepted and agreed:

/s/ Cigall Kadoch
Cigall Kadoch

Exhibit A

NON-COMPETITION, NON-SOLICITATION, CONFIDENTIALITY AND ASSIGNMENT OF INVENTIONS AGREEMENT

(attached)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-252119 on Form S-8 of our report dated March 18, 2021, relating to the consolidated financial statements of Foghorn Therapeutics Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2020.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 18, 2021

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Adrian Gottschalk, certify that:

1. I have reviewed this Annual Report on Form 10-K of Foghorn Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (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; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 18, 2021

/s/ Adrian Gottschalk
Adrian Gottschalk
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Allan Reine, certify that:

1. I have reviewed this Annual Report on Form 10-K of Foghorn Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (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; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 18, 2021

/s/ Allan Reine
Allan Reine, M.D.
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Foghorn Therapeutics Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) 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 result of operations of the Company.

Date: March 18, 2021

/s/ Adrian Gottschalk
Adrian Gottschalk
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Foghorn Therapeutics Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) 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 result of operations of the Company.

Date: March 18, 2021

/s/ Allan Reine
Allan Reine, M.D.
Chief Financial Officer
(Principal Accounting and Financial Officer)