

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

**Amendment No. 2**  
**to**  
**FORM S-1**  
**REGISTRATION STATEMENT**  
*UNDER*  
*THE SECURITIES ACT OF 1933*

**Foghorn Therapeutics Inc.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

2834  
(Primary Standard Industrial  
Classification Code Number)

47-5271393  
(I.R.S. Employer  
Identification No.)

500 Technology Square, Ste 700  
Cambridge MA 02139  
617-586-3100

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Adrian Gottschalk  
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**Approximate date of commencement of proposed sale to the public:**  
**As soon as practicable after the effective date of this Registration Statement.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 7(a)(2)(B) of the Securities Act.

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

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

Subject to completion, dated October 22, 2020

Preliminary prospectus

7,500,000 shares



## Foghorn Therapeutics Inc.

### Common stock

This is an initial public offering of shares of common stock of Foghorn Therapeutics Inc. We are selling 7,500,000 shares of our common stock. The initial public offering price is expected to be between \$15.00 and \$17.00 per share.

We have applied for listing of our common stock on the Nasdaq Global Market under the symbol "FHTX."

We are an "emerging growth company" under federal securities laws and are subject to reduced public company reporting requirements. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

	Per share	Total
Initial public offering price	\$	\$
Underwriting discounts and commissions(1)	\$	\$
Proceeds to Foghorn Therapeutics Inc., before expenses	\$	\$

(1) See "Underwriting" for additional disclosure regarding underwriting compensation.

We have granted the underwriters an option for a period of 30 days to purchase up to 1,125,000 additional shares of common stock from us at the initial public offering price, less underwriting discounts and commissions.

**Investing in our common stock involves a high degree of risk. See "[Risk Factors](#)" beginning on page 12 of this prospectus.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

The underwriters expect to deliver the shares to purchasers on or about \_\_\_\_\_, 2020.

Goldman Sachs & Co. LLC

Morgan Stanley  
Wedbush PacGrow

Cowen

, 2020.

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Neither we nor the underwriters have authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

Through and including \_\_\_\_\_, 2020 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

### **Industry Terms**

<b>“cGMP”</b>	Current Good Manufacturing Practice – minimum requirements of the FDA and other regulatory authorities for the methods, facilities, and controls used in the manufacturing, processing, and packing of a drug product that is intended for human use to ensure that the product is safe for use and has the ingredients and strength that it claims to have.
<b>“FDA”</b>	United States Food and Drug Administration.
<b>“GLP”</b>	Good Laboratory Practices – regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in preclinical development. Regulatory authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators, trial sites and other contractors.
<b>“IND”</b>	Investigational New Drug (Application) – an application to test an experimental drug in human beings and that requires clearance by the FDA for clinical trials to be initiated.
<b>“Preclinical”</b>	Drug development studies performed outside of a human living organism or cell, using living cells, or appropriate animal models. The studies begin before trials in humans and assess safety, toxicity, and efficacy. Since drug development is dynamic, preclinical studies are performed throughout the drug development lifecycle.

### **Trademarks**

We use Gene Traffic Control™, Foghorn™, and GTCT™ as trademarks in the United States and/or in other countries. This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

### **Market and Industry Data**

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations, market position and market opportunity, is based on our management’s estimates and research, as well as industry and general publications and research, surveys and

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studies conducted by third parties. We believe that the information from these third-party publications, research, surveys and studies included in this prospectus is reliable. Management's estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable. This data involves a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates.

## PROSPECTUS SUMMARY

*This summary highlights information included elsewhere in this prospectus. This summary does not contain all the information you should consider before investing in our common stock. You should read and consider this entire prospectus carefully, including the sections titled “Risk Factors,” “Cautionary Note Regarding Forward-Looking Statements” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes included elsewhere in this prospectus, before making any investment decision. 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.*

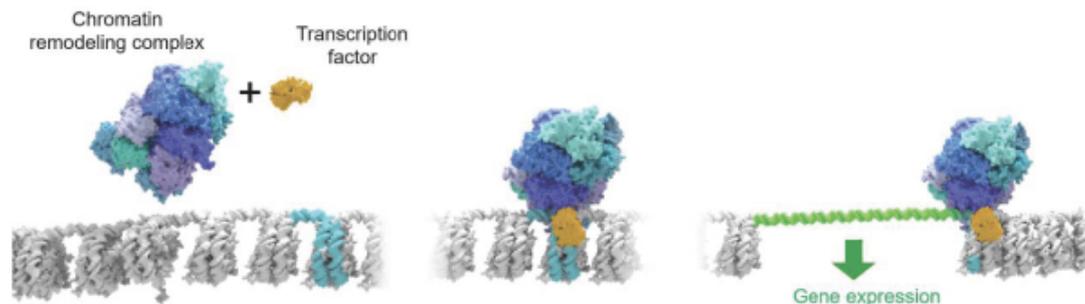
### Overview

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 FHD-609, a protein degrader, to treat hematologic cancers and solid tumors, for which we plan to file INDs in the fourth quarter of 2020 and in the first half of 2021, respectively. Our product candidates are in preclinical development, and so we currently do not have any products approved for commercial sale. 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. The left portion of the figure below shows “packed” or closed chromatin and the right portion of the figure shows “unpacked” or open chromatin with DNA highlighted in green.



### ***Our Gene Traffic Control Platform***

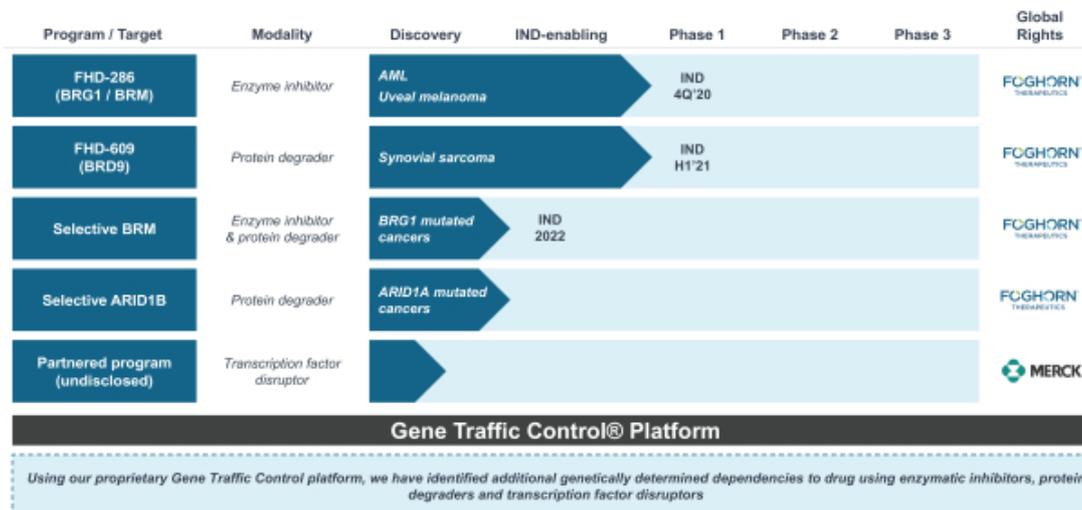
We have built our proprietary Gene Traffic Control platform to give us an integrated and mechanistic understanding of how the various components of the chromatin regulatory system interact, allowing us to identify, validate and potentially drug targets within the system. We are initially using our Gene 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.

## Our Programs

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.

### FHD-286

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 acute myeloid leukemia, or 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 that we believe support filing an IND and progressing FHD-286 into clinical studies. We have successfully completed our GLP toxicology studies for FHD-286. We plan to file our IND for FHD-286 in the fourth quarter of 2020 and, if cleared, expect to initiate separate clinical studies in AML and uveal melanoma in parallel during the first quarter of 2021. As FHD-286 progresses through clinical testing, our intention is to expand into other indications beyond AML and uveal melanoma.

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 evaluation of 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 with FHD-286 as a single agent and/or in combination with novel or standard of care agents.

### *FHD-609*

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 filing an IND and progressing FHD-609 into clinical studies. We have completed the in-life portion of our GLP toxicology studies for FHD-609. We plan to file our IND for FHD-609 in the first half 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, including SMARCB1-deleted cancers.

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 an evaluation of the pharmacokinetic and pharmacodynamic 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 these initial clinical studies, we may pursue additional clinical studies in these and other indications with FHD-609 as a single agent and/or in combination with novel or standard of care agents.

### *Our Additional Preclinical and Discovery Programs*

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. For our selective BRM modulator, we are initially targeting non-small-cell lung cancer with the goal of eventually expanding into other cancers. For our selective ARID1B modulator, initial indications may include bladder, ovarian, and endometrial cancer with the goal of eventually expanding into other cancers. 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 the BAF complex. We have over ten transcription factor targets in our pipeline. We have completed initial screening on two transcription factors and anticipate to complete screening on another two transcription factors in the next six months. Other transcription factors are at various stages of biophysical validation using our platform. We believe that there are more than 100 transcription factors that could be amenable to our approach of disrupting the interaction of the transcription factor with the BAF complex. Preclinical activities of these early programs are underway.

### **Our Collaborations**

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 first 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 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.
- Expand our precision oncology pipeline by developing proprietary enzymatic inhibitors, degraders and disruptors that target genetically defined dependencies within the chromatin regulatory system.
- Harness our platform to develop novel product candidates to address therapeutic areas beyond oncology.
- Continue to enhance our platform to extend our leading position in developing novel therapeutics targeting the chromatin regulatory system.
- Selectively enter into additional strategic partnerships to maximize the potential of our pipeline and our platform.

### **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. 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.

### **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. 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.

### **Risks Associated with Our Business**

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the “Risk Factors” section of this prospectus immediately following this prospectus summary. These risks include the following:

- We have a limited operating history, have not submitted any INDs or initiated any clinical trials, 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, and there is substantial doubt about our ability to continue as a going concern. 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 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.
- 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.

The foregoing is only a summary of some of our risks. For a more detailed discussion of these and other risks you should consider before making an investment in our common stock, see “Risk Factors.”

### **Implications of Being an Emerging Growth Company**

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies, including reduced disclosure about our executive compensation arrangements, exemption from the requirements to hold non-binding advisory votes on executive compensation and golden parachute payments and exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until the last day of the fiscal year following the fifth anniversary of this offering or such earlier time that we are no longer an emerging growth company. We would cease to be an

emerging growth company earlier if we have more than \$1.07 billion in annual revenue, we have more than \$700.0 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) or we issue more than \$1.0 billion of non-convertible debt securities over a three-year period. For so long as we remain an emerging growth company, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. We may choose to take advantage of some, but not all, of the available exemptions.

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.

#### **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://foghornrx.com>. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

## THE OFFERING

<b>Common stock offered by us</b>	7,500,000 shares.
<b>Common stock to be outstanding after this offering</b>	35,694,802 shares (36,819,802 shares if the underwriters exercise their option to purchase additional shares in full).
<b>Underwriters' option to purchase additional shares of common stock from us</b>	We have granted the underwriters an option to purchase up to an aggregate of 1,125,000 additional shares of common stock from us at the initial public offering price, less the estimated underwriting discounts and commissions, for a period of 30 days after the date of this prospectus.
<b>Use of proceeds</b>	<p>We estimate that our net proceeds from the sale of our common stock in this offering will be approximately \$107.8 million, assuming an initial public offering price of \$16.00 per share, which is the midpoint of the range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We currently expect to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows: approximately \$35.0 million to advance FHD-286, including our planned Phase 1 clinical trials for AML and uveal melanoma; approximately \$20.0 million to advance FHD-609, including our planned Phase 1 clinical trial for synovial sarcoma; approximately \$70.0 million for other research and development activities, including continued development of our Gene Traffic Control platform; and the remainder, if any, for working capital and other general corporate purposes. See "Use of Proceeds."</p>
<b>Dividend policy</b>	We do not anticipate declaring or paying any cash dividends on our capital stock in the foreseeable future. See "Dividend Policy."
<b>Risk factors</b>	You should carefully read the "Risk Factors" section of this prospectus and the other information included in this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.
<b>Directed Share Program</b>	At our request, the underwriters have reserved up to 5% of the shares of common stock offered hereby, at the initial public offering price, to offer to directors, officers, employees, business associates and related persons of Foghorn. The number of shares of common stock available for sale to the general public will be reduced to the extent these individuals purchase such reserved shares. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus. Except for any shares acquired by our directors and officers, shares purchased pursuant to the directed share program will not be subject to lock-up agreements with the underwriters. See "Underwriting" beginning on page 164.
<b>Proposed trading symbol</b>	"FHTX"

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The number of shares of our common stock to be outstanding after this offering is based on 6,236,214 shares of our common stock outstanding as of August 31, 2020, which includes 222,977 shares of unvested restricted stock subject to repurchase by us, and after giving effect to the conversion of all outstanding shares of our preferred stock into an aggregate of 21,958,588 shares of common stock upon the closing of this offering, and excludes:

- 4,828,768 shares of common stock issuable upon the exercise of stock options outstanding as of August 31, 2020 under our 2016 Stock Incentive Plan, as amended, or the 2016 Plan, at a weighted average exercise price of \$4.22 per share;
- 7,608 shares of common stock issuable upon the exercise of warrants outstanding as of August 31, 2020 to purchase shares of preferred stock that will become warrants to purchase shares of common stock, at an exercise price of \$1.85 per share, in connection with this offering;
- 338,287 shares of common stock available for future issuance as of August 31, 2020 under our 2016 Plan, which will become available for issuance under our 2020 Plan, and will no longer be available for issuance under our 2016 Plan, at the time our 2020 Equity Incentive Plan, or the 2020 Plan, becomes effective;
- 2,200,000 shares of common stock that will become available for future issuance under our 2020 Plan upon the effectiveness of the registration statement of which this prospectus is a part; and
- 360,000 shares of common stock that will become available for future issuance under our 2020 Employee Stock Purchase Plan, or the ESPP, upon the effectiveness of the registration statement of which this prospectus is a part.

Unless otherwise noted, the information in this prospectus assumes:

- a 1-for-1.85 reverse stock split effected on October 21, 2020;
- the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 21,958,588 shares of common stock upon the closing of this offering;
- no exercise of the outstanding stock options or warrants described above;
- no exercise by the underwriters of their option to purchase additional shares; and
- the filing and effectiveness of our restated certificate of incorporation and the adoption of our amended and restated bylaws upon the closing of this offering.

## SUMMARY CONSOLIDATED FINANCIAL DATA

You should read the following summary consolidated financial data together with the sections titled “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes included elsewhere in this prospectus. We have derived the statement of operations data for the years ended December 31, 2018 and 2019 from our audited consolidated financial statements included elsewhere in this prospectus. We have derived the statement of operations data for the six months ended June 30, 2019 and 2020 and the balance sheet data as of June 30, 2020 from our unaudited consolidated financial statements included elsewhere in this prospectus. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial information in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future.

	Year Ended December 31,		Six Months Ended June 30,	
	2018	2019	2019	2020
(in thousands, except share and per share data)				
<b>Consolidated Statement of Operations Data:</b>				
Operating expenses:				
Research and development	\$ 21,225	\$ 44,362	\$ 19,550	\$ 25,131
General and administrative	4,824	6,722	3,248	4,132
Total operating expenses	<u>26,049</u>	<u>51,084</u>	<u>22,798</u>	<u>29,263</u>
Loss from operations	<u>(26,049)</u>	<u>(51,084)</u>	<u>(22,798)</u>	<u>(29,263)</u>
Other income (expense):				
Interest expense	(371)	(540)	(249)	(456)
Interest income and other expense, net	113	495	303	43
Change in fair value of preferred stock warrant liability	(30)	1	—	1
Total other income (expense), net	<u>(288)</u>	<u>(44)</u>	<u>54</u>	<u>(412)</u>
Net loss	<u>\$ (26,337)</u>	<u>\$ (51,128)</u>	<u>\$ (22,744)</u>	<u>\$ (29,675)</u>
Net loss per share attributable to common stockholders—basic and diluted(1)	<u>\$ (8.94)</u>	<u>\$ (12.20)</u>	<u>\$ (5.91)</u>	<u>\$ (5.61)</u>
Weighted average common shares outstanding—basic and diluted(1)	<u>2,947,093</u>	<u>4,191,793</u>	<u>3,851,643</u>	<u>5,286,537</u>
Pro forma net loss per share attributable to common stockholders—basic and diluted(1)		<u>\$ (2.60)</u>		<u>\$ (1.34)</u>
Pro forma weighted average common shares outstanding—basic and diluted(1)		<u>19,629,444</u>		<u>22,127,383</u>

- (1) See Note 12 to our audited consolidated financial statements and Note 8 to our unaudited consolidated financial statements appearing elsewhere in this prospectus for details on the calculation of basic and diluted net loss per share attributable to common stockholders and the calculation of unaudited pro forma net loss per share attributable to common stockholders.

	At June 30, 2020		
	Actual	Pro Forma(2)	Pro Forma As Adjusted(3)
(in thousands)			
<b>Consolidated Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 36,563	\$ 78,563	\$ 185,833
Working capital(1)	23,102	65,102	172,447
Total assets	94,314	136,314	243,509
Long-term debt, net of discount, including current portion	15,238	15,238	14,708
Preferred stock warrant liability	44	—	—
Convertible preferred stock	134,480	—	—
Total stockholders' equity (deficit)	(116,411)	60,113	167,913

- (1) We define working capital as current assets less current liabilities.
- (2) The pro forma consolidated balance sheet data give effect to (i) our issuance and sale in July and August 2020 of 5,600,000 shares of Series B preferred stock for gross proceeds of \$42.0 million, (ii) outstanding warrants to purchase shares of preferred stock becoming warrants to purchase shares of common stock upon the closing of this offering, and (iii) the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 21,958,588 shares of common stock upon the closing of this offering.
- (3) The pro forma as adjusted consolidated balance sheet data give further effect to (i) our issuance and sale of 7,500,000 shares of our common stock in this offering at an assumed initial public offering price of \$16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and (ii) payment of the final payment fee of \$0.5 million related to our loan and security agreement, as amended, which amount is due and payable upon the closing of this offering.

The pro forma as adjusted information discussed above is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed initial public offering price of \$16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity (deficit) by \$7.0 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase or decrease of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity (deficit) by \$14.9 million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

## 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 prospectus, including our consolidated financial statements and related notes appearing at the end of this prospectus, 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, have not initiated any clinical trials, 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 development-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. All of our product candidates are still in preclinical development. We have not yet demonstrated an ability to successfully initiate, 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 June 30, 2020, we had an accumulated deficit of \$123.8 million. We have financed our operations primarily through private placements of our preferred stock as well as through our loan with Comerica Bank, or Comerica, 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 into Phase 1 clinical development and continue our preclinical development of product candidates from our current research programs;
- identify additional research programs and additional product candidates;

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- 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 not initiated clinical development of any 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 June 30, 2020, our cash and cash equivalents were \$36.6 million. We estimate that the net proceeds of this offering will be approximately \$107.8 million, assuming an initial public offering price of \$16.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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.

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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.

### ***There is substantial doubt about our ability to continue as a going concern.***

As a result of our recurring operating losses and negative cash flows from operations combined with our anticipated use of cash to fund operations and debt service requirements, we have concluded that there is substantial doubt about our ability to continue as a going concern beyond the 12-month period from the issuance date of our audited financial statements for the year ended December 31, 2019. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the fiscal year ended December 31, 2019 with respect to this uncertainty. Our future viability as an ongoing business is dependent on our ability to generate cash from our operating activities and to raise additional capital to finance our operations.

Without giving effect to the anticipated net proceeds from this offering, we expect that our existing cash and cash equivalents will not be sufficient to fund our planned operating expenses, capital expenditure and debt service requirements beyond one year from the issuance date of our consolidated financial statements. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, 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 on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, or discontinue the further development and commercialization efforts of one or more of our product candidates, or may be forced to reduce or terminate our operations.

There is no assurance that we will succeed in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all. The perception that we might be unable to continue as a going concern may also make it more difficult to obtain financing for the continuation of our operations on terms that are favorable to us, or at all, and could result in the loss of confidence by investors and employees. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that our investors will lose all or a part of their investment.

### ***We have never generated revenue from product sales and may never be profitable.***

We are currently only in the preclinical testing stages for our most advanced product candidates and research programs and expect to submit INDs to the FDA for FHD-286 and FHD-609 in the fourth quarter of 2020 and the first half of 2021, respectively. 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.

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***Our Loan Agreement with Comerica 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 Comerica 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 Comerica 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 Comerica 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, Comerica 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

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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 as a result of this offering 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, 2020, 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 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 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;

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- 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 FHD-286, FHD-609, or our other product candidates on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.***

We have not yet initiated clinical trials of any of our product candidates. 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 testing may not be positive. We expect to file our IND for FHD-286 in the fourth quarter of 2020 and our IND for FHD-609 in the first half of 2021 with the goal of initiating Phase 1 clinical trials in the first quarter of 2021 for FHD-286, with preliminary proof-of-concept data by year-end 2021.

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, 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

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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.***

All of our 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;

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- 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.

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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.

### ***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

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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 product supplies, and we will likely rely on third parties 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 product supplies and expect to rely on outside vendors to manufacture clinical supplies of our product candidates. We will 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 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.

***Difficulty in enrolling patients could delay clinical trials of our product candidates.***

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of completion of our clinical studies depends in part on the speed at which we can recruit patients to participate in testing our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. Because we are focused on patients with specific mutations, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. We cannot be certain how many patients will have each of the genetic mutations that our platform is designed to target or that the number of patients enrolled for each mutation will suffice for regulatory approval and inclusion of each such mutation in the approved label. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

In addition to the potentially small populations, the eligibility criteria of our planned clinical trials will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure to assure their disease is either severe enough or not too advanced to include them in a study. Additionally, the process of finding and diagnosing patients may prove costly. We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical studies because of the

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perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical study sites for prospective patients, the availability of genetic sequencing information for patient tumors so that we can identify patients with the targeted genetic mutations, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed.

***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 August 31, 2020, we had 85 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.

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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 in countries outside of the United States;
- our ability to import 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.

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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 parties 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.

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### ***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, 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;

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- 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.

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***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 in compliance 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,

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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;

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- 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.

***Risks related to this offering and ownership of our common stock***

***We do not know whether a market will develop for our common stock or what the market price of our common stock will be, and, as a result, it may be difficult for you to sell your shares of our common stock.***

Before this offering, there was no public trading market for our common stock. If a market for our common stock does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at an attractive price or at all. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall.

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### ***You will incur immediate and substantial dilution as a result of this offering.***

If you purchase common stock in this offering, you will incur immediate and substantial dilution of \$11.25 per share, representing the difference between the assumed initial public offering price of \$16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, and our pro forma net tangible book value per share after giving effect to this offering and the automatic conversion of all outstanding shares of our preferred stock upon the closing of this offering. Moreover, we issued options in the past that allow the holders to acquire common stock at prices significantly below the assumed initial public offering price. As of August 31, 2020, there were 4,828,768 shares subject to outstanding options with a weighted-average exercise price of \$4.22 per share. To the extent that these outstanding options are ultimately exercised or the underwriters exercise their option to purchase additional shares, you will incur further dilution. For a further description of the dilution you will experience immediately after this offering, see “Dilution.”

### ***The market price of our common stock may be volatile, which could result in substantial losses for investors purchasing shares in this offering.***

The initial public offering price for our common stock was determined through negotiations with the underwriters. This initial public offering price may vary from the market price of our common stock after the offering. As a result, you may not be able to sell your common stock at or above the initial public offering price. 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 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;

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- 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. These fluctuations may be even more pronounced in the trading market for our stock shortly following this offering. 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 will rely 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 restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. After this offering and after giving effect to the conversion of all outstanding shares of our preferred stock into 21,958,588 shares of our common stock upon the closing of this offering, we will have 35,694,802 shares of common stock outstanding, or 36,819,802 shares if the underwriters exercise their option to purchase additional shares in full, in each case based on the 6,236,214 shares of our common stock outstanding as of August 31, 2020. Of these shares, the 7,500,000 shares (or 8,625,000 shares if the underwriters exercise their option to purchase additional shares in full) we are selling in this offering may be resold in the public market immediately, unless purchased by our affiliates. The remaining 28,194,802 shares are currently restricted under securities laws or as a result of lock-up or other agreements, but will be able to be sold after this offering as described in the “Shares Eligible for Future Sale” section of this prospectus. Moreover, after this offering, holders of an aggregate of 21,958,588 shares of our common stock will have rights, subject to 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. We also plan to register all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up agreements described in the “Underwriting” section of this prospectus. If any of these 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 will continue to have substantial influence over us after this offering, which could limit your ability to affect the outcome of key transactions, including a change of control.***

After this offering, our directors and executive officers and their affiliates will 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 prospectus, 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 will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.***

As a public company, and particularly after we are no longer an “emerging growth company,” we will 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

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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.

### ***We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.***

We cannot specify with certainty the particular uses of the net proceeds we will receive from this offering. Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in “Use of Proceeds.” Accordingly, you will have to rely upon the judgment of our management with respect to the use of the proceeds, with only limited information concerning management’s specific intentions. Our management may spend a portion or all of the net proceeds from this offering in ways that our stockholders may not desire or that may not yield a favorable return. The failure by our management to apply these funds effectively could harm our business, financial condition, results of operations and prospects. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

### ***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.

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***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, which will become effective upon the closing of this offering, 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.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus 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 prospectus 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 studies and clinical trials, including the timing and clearance of our IND filings for FHD-286 and FHD-609;
- 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 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 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 CDMOs and 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;
- 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; and
- our use of proceeds from this offering, estimates of our expenses, capital requirements and needs for additional financing.

The forward-looking statements in this prospectus 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 prospectus and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this prospectus entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this prospectus. 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.

## USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the shares of common stock in this offering will be approximately \$107.8 million, or approximately \$124.5 million if the underwriters exercise their option to purchase additional shares in full, based upon an assumed initial price to the public of \$16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$16.00 per share would increase (decrease) the net proceeds to us from this offering by approximately \$7.0 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) the net proceeds to us from this offering by approximately \$14.9 million, assuming that the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We currently expect to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately \$35.0 million to advance FHD-286, including our planned Phase 1 clinical trials for AML and uveal melanoma;
- approximately \$20.0 million to advance FHD-609, including our planned Phase 1 clinical trial for synovial sarcoma;
- approximately \$70.0 million for other research and development activities, including continued development of our Gene Traffic Control platform; and
- the remainder, if any, for working capital and other general corporate purposes.

Based on our planned use of the net proceeds from this offering and our existing cash and cash equivalents, we estimate that such funds will be sufficient to fund our operating expenses, capital expenditure requirements and debt service payments into the third quarter of 2022. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. The expected net proceeds from this offering, together with our existing cash and cash equivalents, will not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise additional capital to complete the development and commercialization of our product candidates.

We may also use a portion of the net proceeds from this offering to acquire, in-license or invest in products, technologies or businesses that are complementary to our business. The amounts and timing of our actual expenditures will depend on numerous factors, including the progress of our preclinical development efforts, our operating costs and other factors described under “Risk Factors” in this prospectus.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with complete certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the actual amounts that we will spend on the uses set forth above.

We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds. Pending the uses described above, we plan to invest the net proceeds from this offering in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

## **DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, pursuant to our loan and security agreement with Comerica Bank, or Comerica, we are prohibited from paying cash dividends without the prior written consent of Comerica and future debt instruments may materially restrict our ability to pay dividends on our common stock. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors our board of directors deems relevant, and subject to the restrictions contained in our current and any future financing instruments. Our ability to pay cash dividends on our capital stock in the future may also be limited by the terms of any preferred securities we may issue or agreements governing any indebtedness we may incur.

## CAPITALIZATION

The following table summarizes our cash and cash equivalents and capitalization as of June 30, 2020:

- on an actual basis;
- on a pro forma basis to give effect to (i) our issuance and sale in July and August 2020 of 5,600,000 shares of Series B preferred stock for gross proceeds of \$42.0 million, (ii) outstanding warrants to purchase shares of preferred stock becoming warrants to purchase shares of common stock upon the closing of this offering, (iii) the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 21,958,588 shares of common stock upon the closing of this offering, and (iv) the filing and effectiveness of our amended and restated certificate of incorporation; and
- on a pro forma as adjusted basis to give further effect to (i) our issuance and sale of 7,500,000 shares of our common stock in this offering at an assumed initial public offering price of \$16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and (ii) payment of the final payment fee of \$0.5 million related to our loan and security agreement, as amended, which amount is due and payable upon the closing of this offering.

You should read the information in this table together with the consolidated financial statements and related notes to those statements, as well as the information set forth under the headings “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	As of June 30, 2020		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share data)		
Cash and cash equivalents	\$ 36,563	\$ 78,563	\$ 185,833
Preferred stock warrant liability	\$ 44	\$ —	\$ —
Long-term debt, net of discount, including current portion	15,238	15,238	14,708
Convertible preferred stock (Series A and B), \$0.0001 par value; 36,629,622 shares authorized, 35,023,413 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	134,480	—	—
Stockholders’ equity (deficit)			
Preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding, actual; 25,000,000 shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, \$0.0001 par value; 55,000,000 shares authorized, 5,880,598 shares issued and 5,434,649 shares outstanding, actual; 175,000,000 shares authorized, 27,839,186 shares issued and 27,393,237 shares outstanding, pro forma; 175,000,000 shares authorized, 35,339,186 shares issued and 34,893,237 shares outstanding, pro forma as adjusted	1	3	3
Additional paid-in capital	7,399	183,921	291,721
Accumulated deficit	(123,811)	(123,811)	(123,811)
Total stockholders’ equity (deficit)	(116,411)	60,113	167,913
<b>Total capitalization</b>	<b>\$ 33,351</b>	<b>\$ 75,351</b>	<b>\$ 182,621</b>

The pro forma as adjusted information above is illustrative only, and our capitalization following the closing of this offering will depend on the actual initial public offering price and other terms of this offering determined at

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pricing. Each \$1.00 increase or decrease in the assumed initial public offering price of \$16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit), and total capitalization by \$7.0 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase or decrease of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit), and total capitalization by \$14.9 million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The outstanding share information in the table above excludes as of June 30, 2020:

- 3,990,475 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2020 under the 2016 Plan at a weighted average exercise price of \$2.54 per share (which does not include options to purchase an aggregate of 1,356,981 shares of common stock, at an exercise price of \$8.90 per share, that were granted subsequent to June 30, 2020);
- 7,608 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2020 to purchase shares of preferred stock that will become warrants to purchase shares of common stock, at an exercise price of \$1.85 per share, in connection with this offering;
- 45,710 shares of common stock available for future issuance as of June 30, 2020 under our 2016 Plan, which will become available for issuance under our 2020 Plan, and will no longer be available for issuance under our 2016 Plan, at the time our 2020 Plan becomes effective; and
- 2,200,000 shares of common stock that will become available for future issuance under the 2020 Plan upon the effectiveness of the registration statement of which this prospectus is a part; and
- 360,000 shares of common stock that will become available for future issuance under our ESPP upon the effectiveness of the registration statement of which this prospectus is a part.

## DILUTION

If you invest in our common stock in this offering, you will experience immediate and substantial dilution in the pro forma as adjusted net tangible book value of your shares of common stock. Dilution in pro forma as adjusted net tangible book value represents the difference between the assumed initial price to the public per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value (deficit) as of June 30, 2020 was \$(116.5) million, or \$(19.81) per share of common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and the carrying value of our preferred stock, which is not included within stockholders' equity (deficit). Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by the 5,880,598 shares of common stock outstanding as of June 30, 2020, which includes 445,949 shares of unvested restricted stock subject to repurchase by us.

Our pro forma net tangible book value as of June 30, 2020 was \$60.0 million, or \$2.16 per share of common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to (i) our issuance and sale in July and August 2020 of 5,600,000 shares of Series B preferred stock for gross proceeds of \$42.0 million, (ii) the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 21,958,588 shares of common stock upon the closing of this offering, and (iii) outstanding warrants to purchase shares of preferred stock becoming warrants to purchase shares of common stock upon the closing of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of June 30, 2020, after giving effect to the pro forma adjustments described above.

After giving further effect to (i) our issuance and sale of 7,500,000 shares of our common stock in this offering at an assumed initial public offering price of \$16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus and (ii) payment of the final payment fee of \$0.5 million related to our loan and security agreement, as amended, which amount is due and payable upon the closing of this offering, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2020 would have been \$167.9 million, or \$4.75 per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of \$2.59 to existing stockholders and immediate dilution of \$11.25 in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors.

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

Assumed initial public offering price per share	\$16.00
Historical net tangible book value (deficit) per share as of June 30, 2020	\$(19.81)
Increase per share attributable to the pro forma adjustments described above	<u>21.97</u>
Pro forma net tangible book value per share as of June 30, 2020	2.16
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing common stock in this offering	<u>2.59</u>
Pro forma as adjusted net tangible book value per share after this offering	<u>4.75</u>
Dilution per share to new investors purchasing common stock in this offering	<u>\$11.25</u>

The dilution information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. A \$1.00 increase (decrease) in the assumed

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initial public offering price of \$16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value per share after this offering by \$0.20 and dilution per share to new investors purchasing common stock in this offering by \$0.80, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase our pro forma as adjusted net tangible book value per share after this offering by \$0.28 and decrease the dilution per share to new investors purchasing common stock in this offering by \$0.28, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A decrease of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease our pro forma as adjusted net tangible book value per share after this offering by \$0.29 and increase the dilution per share to new investors purchasing common stock in this offering by \$0.29, assuming no change in the assumed initial public offering price and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares in full, our pro forma as adjusted net tangible book value per share after this offering would be \$5.06, representing an immediate increase in pro forma as adjusted net tangible book value per share of \$2.90 to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per share of \$10.94 to new investors purchasing common stock in this offering, assuming an initial public offering price of \$16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, as of June 30, 2020, on the pro forma as adjusted basis described above, the total number of shares of common stock purchased from us on an as converted to common stock basis, the total consideration paid or to be paid and the average price per share paid or to be paid by existing stockholders and by new investors in this offering at an assumed initial public offering price of \$16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percentage	
Existing stockholders	27,839,186	78.8%	\$178,244,000	59.8%	\$ 6.40
Investors participating in this offering	7,500,000	21.2	120,000,000	40.2	\$ 16.00
Total	<u>35,339,186</u>	<u>100.0%</u>	<u>\$298,244,000</u>	<u>100.0%</u>	

A \$1.00 increase (decrease) in the assumed initial public offering price of \$16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by \$7.5 million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by 1.5 percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by 1.5 percentage points, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by \$16.0 million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by 3.1 percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by 3.4 percentage points, assuming no change in the assumed initial public offering price.

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The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to 56.4% of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors purchasing common stock in this offering would be increased to 43.6% of the total number of shares of our common stock outstanding after this offering.

The tables and discussion above are based on the number of shares of our common stock outstanding as of June 30, 2020, and exclude:

- 3,990,475 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2020 under the 2016 Plan at a weighted average exercise price of \$2.54 per share (which does not include options to purchase an aggregate of 1,356,981 shares of common stock, at an exercise price of \$8.90 per share, that were granted subsequent to June 30, 2020);
- 7,608 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2020 to purchase shares of preferred stock that will become warrants to purchase shares of common stock, at an exercise price of \$1.85 per share, in connection with this offering;
- 45,710 shares of common stock available for future issuance as of June 30, 2020 under the 2016 Plan, which will become available for issuance under our 2020 Plan, and will no longer be available for issuance under our 2016 Plan, at the time our 2020 Plan becomes effective; and
- 2,200,000 shares of common stock that will become available for future issuance under the 2020 Plan upon the effectiveness of the registration statement of which this prospectus is a part; and
- 360,000 shares of common stock that will become available for future issuance under our ESPP upon the effectiveness of the registration statement of which this prospectus is a part.

To the extent that outstanding stock options or warrants are exercised, new stock options or warrants are issued, or we issue additional shares of common stock in the future, there will be further dilution to new investors. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

## SELECTED FINANCIAL DATA

The following tables set forth our selected financial data for the periods indicated. We have derived the consolidated statements of operations data for the years ended December 31, 2018 and 2019, and the consolidated balance sheet data as of December 31, 2018 and 2019, from our audited consolidated financial statements included elsewhere in this prospectus and the consolidated statements of operations data for the six months ended June 30, 2019 and 2020, and the consolidated balance sheet data as of June 30, 2020, from our unaudited consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that should be expected for any future period. You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes included elsewhere in this prospectus and the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of this prospectus.

	Year Ended December 31,		Six Months Ended June 30,	
	2018	2019	2019	2020
(in thousands, except share and per share data)				
<b>Consolidated Statement of Operations Data:</b>				
Operating expenses:				
Research and development	\$ 21,225	\$ 44,362	\$ 19,550	\$ 25,131
General and administrative	4,824	6,722	3,248	4,132
Total operating expenses	<u>26,049</u>	<u>51,084</u>	<u>22,798</u>	<u>29,263</u>
Loss from operations	<u>(26,049)</u>	<u>(51,084)</u>	<u>(22,798)</u>	<u>(29,263)</u>
Other income (expense):				
Interest expense	(371)	(540)	(249)	(456)
Interest income and other expense, net	113	495	303	43
Change in fair value of preferred stock warrant liability	(30)	1	—	1
Total other income (expense), net	<u>(288)</u>	<u>(44)</u>	<u>54</u>	<u>(412)</u>
Net loss	<u>\$ (26,337)</u>	<u>\$ (51,128)</u>	<u>\$ (22,744)</u>	<u>\$ (29,675)</u>
Net loss per share attributable to common stockholders—basic and diluted(1)	<u>\$ (8.94)</u>	<u>\$ (12.20)</u>	<u>\$ (5.91)</u>	<u>\$ (5.61)</u>
Weighted average common shares outstanding—basic and diluted(1)	<u>2,947,093</u>	<u>4,191,793</u>	<u>3,851,643</u>	<u>5,286,537</u>
Pro forma net loss per share attributable to common stockholders—basic and diluted(1)		<u>\$ (2.60)</u>		<u>\$ (1.34)</u>
Pro forma weighted average common shares outstanding—basic and diluted(1)		<u>19,629,444</u>		<u>22,127,383</u>

- (1) See Note 12 to our audited consolidated financial statements and Note 8 to our unaudited consolidated financial statements appearing elsewhere in this prospectus for details on the calculation of basic and diluted net loss per share attributable to common stockholders and the calculation of unaudited pro forma net loss per share attributable to common stockholders.

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	December 31,		June 30,
	2018	2019	2020
(in thousands)			
<b>Consolidated Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 40,019	\$ 14,981	\$ 36,563
Working capital(1)	36,943	4,233	23,102
Total assets	43,058	22,342	94,314
Long-term debt, net of discount, including current portion	7,029	15,112	15,238
Preferred stock warrant liability	46	45	44
Convertible preferred stock	71,250	86,544	134,480
Total stockholders' deficit	(39,273)	(88,016)	(116,411)

(1) We define working capital as current assets less current liabilities.

## 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 prospectus. 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 prospectus.*

### 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 FHD-609, a protein degrader, to treat hematologic cancers and solid tumors, for which we plan to file INDs in the fourth quarter of 2020 and in the first half of 2021, respectively. Our product candidates are in preclinical development, and so we currently do not have any products approved for commercial sale. 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 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. To date, we have funded our operations with proceeds from sales of preferred stock, our \$15.0 million 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. Through June 30, 2020, we had received gross proceeds of \$134.8 million from sales of preferred stock. In July and August 2020, we received additional gross proceeds of \$42.0 million from sales of Series B preferred stock.

We have incurred significant operating losses since our inception. For the year ended December 31, 2019, we reported net losses of \$51.1 million, and for the six months ended June 30, 2020, we reported net losses of \$29.7 million. As of June 30, 2020, we had an accumulated deficit of \$123.8 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 into Phase 1 clinical development 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;

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- hire additional clinical, regulatory and scientific 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, following the completion of this offering, 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 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, 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

### *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, 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 future 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 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 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.

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### **Other Income (Expense)**

#### *Interest Expense*

Interest expense consists of interest expense associated with outstanding borrowings under our existing loan agreement with Comerica Bank, or Comerica, as well as the amortization of debt discount associated with such agreement.

#### *Interest Income and Other Expense, Net*

Interest income consists of interest earned on our invested cash balances. Other expense consists of 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, 2019, we had federal and state net operating loss carryforwards of \$87.6 million and \$84.9 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 \$75.1 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, 2019, we also had federal and state research and development tax credit carryforwards of \$1.5 million and \$1.2 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.

### **Results of Operations**

#### **Comparison of the Six Months Ended June 30, 2019 and 2020**

The following table summarizes our results of operations for the six months ended June 30, 2019 and 2020:

	<b>Six Months Ended June 30,</b>		
	<b>2019</b>	<b>2020</b>	<b>Change</b>
	<b>(in thousands)</b>		
Operating expenses:			
Research and development	\$ 19,550	\$ 25,131	\$ 5,581
General and administrative	3,248	4,132	884
Total operating expenses	<u>22,798</u>	<u>29,263</u>	<u>6,465</u>
Loss from operations	<u>(22,798)</u>	<u>(29,263)</u>	<u>(6,465)</u>
Other income (expense):			
Interest expense	(249)	(456)	(207)
Interest income and other expense, net	303	43	(260)
Change in fair value of preferred stock warrant liability	—	1	1
Total other income (expense), net	<u>54</u>	<u>(412)</u>	<u>(466)</u>
Net loss	<u>\$ (22,744)</u>	<u>\$ (29,675)</u>	<u>\$ (6,931)</u>

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### *Research and Development Expenses*

The following table summarizes our research and development expenses for the six months ended June 30, 2019 and 2020:

	<u>Six Months Ended June 30,</u>		<u>Change</u>
	<u>2019</u>	<u>2020</u>	
	(in thousands)		
Research and development program expenses:			
FHD-286	\$ 2,843	\$ 3,069	\$ 226
FHD-609	2,337	1,969	(368)
Platform, research and discovery, and unallocated expenses:			
Platform and other early stage research external costs	5,507	6,386	879
Personnel related (including stock-based compensation)	5,642	8,278	2,636
Facility related and other	3,221	5,429	2,208
Total research and development expenses	<u>\$ 19,550</u>	<u>\$ 25,131</u>	<u>\$5,581</u>

Research and development expenses were \$25.1 million for the six months ended June 30, 2020, compared to \$19.6 million for the six months ended June 30, 2019. The increase in our FHD-286 program costs of \$0.2 million was due to an increase in preclinical and manufacturing costs, partially offset by a decrease in research costs as we progressed our candidate into IND-enabling studies. FHD-609 program costs decreased by \$0.4 million as a result of a decrease in research costs, partially offset by an increase in preclinical and manufacturing costs as we progressed our candidate into IND-enabling studies. Platform and other early stage research external costs, which include our selective BRM and selective ARID 1B early-stage programs, increased by \$0.9 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 \$2.6 million due to increased headcount in our research and development function. The increase in facility-related expenses and other of \$2.2 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 six months ended June 30, 2019 and 2020:

	<u>Six Months Ended June 30,</u>		<u>Change</u>
	<u>2019</u>	<u>2020</u>	
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 1,713	\$ 2,472	\$ 759
Professional and consultant	1,170	1,217	47
Facility related and other	365	443	78
Total general and administrative expenses	<u>\$ 3,248</u>	<u>\$ 4,132</u>	<u>\$ 884</u>

General and administrative expenses were \$4.1 million for the six months ended June 30, 2020, compared to \$3.2 million for the six months ended June 30, 2019. The increases in personnel-related costs of \$0.8 million was a result of an increase in headcount in our general and administrative function to support our business.

### *Other Income (Expense)*

Interest expense was \$0.5 million for the six months ended June 30, 2020, compared to \$0.2 million for the six months ended June 30, 2019. The increase was due to increased borrowings under our loan facility.

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Interest income and other expense, net was less than \$0.1 million for the six months ended June 30, 2020, compared to \$0.3 million for the six months ended June 30, 2019 and consisted primarily of interest earned on invested cash balances. Interest income decreased as a result of lower invested balances and lower interest rates on invested balances.

### *Comparison of the Years Ended December 31, 2018 and 2019*

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

	<u>Year Ended December 31,</u>		<u>Change</u>
	<u>2018</u>	<u>2019</u>	
	(in thousands)		
Operating expenses:			
Research and development	\$ 21,225	\$ 44,362	\$ 23,137
General and administrative	4,824	6,722	1,898
Total operating expenses	<u>26,049</u>	<u>51,084</u>	<u>25,035</u>
Loss from operations	<u>(26,049)</u>	<u>(51,084)</u>	<u>(25,035)</u>
Other income (expense):			
Interest expense	(371)	(540)	(169)
Interest income and other expense, net	113	495	382
Change in fair value of preferred stock warrant liability	(30)	1	31
Total other income (expense), net	<u>(288)</u>	<u>(44)</u>	<u>244</u>
Net loss	<u>\$ (26,337)</u>	<u>\$ (51,128)</u>	<u>\$ (24,791)</u>

### *Research and Development Expenses*

The following table summarizes our research and development expenses for the years ended December 31, 2018 and 2019:

	<u>Year Ended December 31,</u>		<u>Change</u>
	<u>2018</u>	<u>2019</u>	
	(in thousands)		
Direct research and development expenses by program:			
FHD-286	\$ 2,520	\$ 5,458	\$ 2,938
FHD-609	821	5,266	4,445
Platform, research and discovery, and unallocated expenses:			
Platform and other early stage research external costs	6,218	13,522	7,304
Personnel related (including stock-based compensation)	6,379	13,176	6,797
Facility related and other	5,287	6,940	1,653
Total research and development expenses	<u>\$ 21,225</u>	<u>\$ 44,362</u>	<u>\$23,137</u>

Research and development expenses were \$44.4 million for the year ended December 31, 2019, compared to \$21.2 million for the year ended December 31, 2018. The increase in our FHD-286 program costs of \$2.9 million was due to an increase in research costs as our program advanced from hit-to-lead to lead optimization. Preclinical costs also increased as a result of initiating toxicology studies in 2019. The increase in our FHD-609 program costs of \$4.4 million were due to an increase in research costs as our program advanced from hit-to-lead to lead optimization. Preclinical costs also increased as a result of initiating toxicology studies towards the end of 2019. Platform and other early stage research external costs, which includes our selective BRM and selective ARID1B early-stage research programs, increased by \$7.3 million, as a result of our target validation, assay development and hit-validation efforts for our discovery programs. Personnel-related costs increased by

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\$6.8 million due to increased headcount in our research and development function. The increase in facility-related expenses and other of \$1.7 million was due to the increased costs of supporting a larger group of research and development personnel and their research efforts.

### *General and Administrative Expenses*

The following table summarizes our general and administrative expenses for the years ended December 31, 2018 and 2019:

	<u>Year Ended December 31,</u>		
	<u>2018</u>	<u>2019</u>	<u>Change</u>
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 2,666	\$ 3,732	\$1,066
Professional and consultant	1,632	2,235	603
Facility related and other	526	755	229
Total general and administrative expenses	<u>\$ 4,824</u>	<u>\$ 6,722</u>	<u>\$1,898</u>

General and administrative expenses were \$6.7 million for the year ended December 31, 2019, compared to \$4.8 million for the year ended December 31, 2018. The increase in personnel-related costs of \$1.1 million was a result of an increase in headcount in our general and administrative function to support our business. Professional and consultant fees increased by \$0.6 million due to increased patent costs and professional fees relating to accounting, audit and legal services as well as costs associated with ongoing business activities and our preparations to operate as a public company.

### *Other Income (Expense)*

Interest expense was \$0.5 million for the year ended December 31, 2019 compared to \$0.4 million for the year ended December 31, 2018. The increase was due to increased borrowings under our loan facility.

Interest income and other expense, net was \$0.5 million for the year ended December 31, 2019, compared to \$0.1 million and consisted primarily of interest earned on invested cash balances. Interest income increased primarily as a result of higher invested balances.

Other expense was not significant for either of the years ended December 31, 2019 or 2018.

### **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 June 30, 2020, we have funded our operations with proceeds from sales of preferred stock and debt financing. Through June 30, 2020, we had received gross proceeds of \$134.8 million from sales of preferred stock and gross proceeds of \$15.0 million from our secured term loan facility with Comerica.

As of June 30, 2020, we had cash and cash equivalents of \$36.6 million. In July and August 2020, we received additional gross proceeds of \$42.0 million from sales of Series B preferred stock. We also received an upfront payment of \$15.0 million in July 2020 under our collaboration agreement with Merck.

**Cash Flows**

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

	<u>Year Ended December 31,</u>		<u>Six Months Ended June 30,</u>	
	<u>2018</u>	<u>2019</u>	<u>2019</u>	<u>2020</u>
	(in thousands)			
Cash used in operating activities	\$ (22,648)	\$ (46,335)	\$ (20,861)	\$ (23,357)
Cash used in investing activities	(1,541)	(964)	(794)	(3,269)
Cash provided by financing activities	51,770	23,969	15,331	48,210
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ 27,581</u>	<u>\$ (23,330)</u>	<u>\$ (6,324)</u>	<u>\$ 21,584</u>

**Operating Activities**

During the six months ended June 30, 2020, operating activities used \$23.4 million of cash, resulting from our net loss of \$29.7 million, partially offset by net non-cash charges of \$3.3 million and net cash provided by changes in our operating assets and liabilities of \$3.0 million. Net cash provided by changes in our operating assets and liabilities for the six months ended June 30, 2020 consisted primarily of a \$3.3 million increase in operating lease liabilities resulting from our landlord incentives and an increase of \$0.5 million in accounts payable and accrued expenses and other current liabilities, both partially offset by an increase of \$0.8 million in prepaid expenses and other current assets.

During the six months ended June 30, 2019, operating activities used \$20.9 million of cash, resulting from our net loss of \$22.7 million, partially offset by net non-cash charges of \$1.5 million and net cash provided by changes in our operating assets and liabilities of \$0.3 million. Net cash provided by changes in our operating assets and liabilities for the six months ended June 30, 2019 consisted primarily of a \$0.9 million increase in accounts payable and accrued expenses and other current liabilities, partially offset by a \$0.5 million decrease in operating lease liabilities.

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 current assets.

During the year ended December 31, 2018, operating activities used \$22.6 million of cash, resulting from our net loss of \$26.3 million, partially offset by net non-cash charges of \$1.3 million and net cash provided by changes in our operating assets and liabilities of \$2.4 million. Net cash provided by changes in our operating assets and liabilities for the year ended December 31, 2018 consisted primarily of a \$2.4 million increase in accounts payable and accrued expenses and other current liabilities.

Changes in accounts payable, accrued expenses and other current liabilities and prepaid expenses and other current 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 six months ended June 30, 2020 and 2019, net cash used in investing activities was \$3.3 million and \$0.8 million, respectively, due to the acquisition of property and equipment during the periods. Property and equipment purchases for the six months ended June 30, 2020 were primarily related to leasehold improvements for our new facility in Cambridge, Massachusetts.

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During the years ended December 31, 2019 and 2018, net cash used by investing activities was \$1.0 million and \$1.5 million, respectively, due to the acquisition of property and equipment during the year.

### *Financing Activities*

During the six months ended June 30, 2020, net cash provided by financing activities was \$48.2 million, consisting of proceeds from the sale of our Series B preferred stock of \$47.9 million and proceeds from the exercise of common stock options.

During the six months ended June 30, 2019, net cash provided by financing activities was \$15.3 million, consisting of proceeds from the sale of our Series B preferred stock of \$15.3 million and proceeds from the exercise of common stock options.

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.

During the year ended December 31, 2018, net cash provided by financing activities was \$51.8 million, consisting of proceeds from the sale of our Series B preferred stock of \$40.4 million, proceeds from convertible notes of \$5.0 million, proceeds from borrowings under our loan and security agreement of \$7.0 million and proceeds from the exercise of common stock options, all partially offset by repayments of notes payable of \$0.8 million.

### *Loan and Security Agreement*

In February 2018, we entered into a loan and security agreement with Comerica Bank, or Comerica, for up to \$7.0 million in available debt financing to be used toward funding our operations, or the Loan, and an option for an additional \$1.0 million pending receipt of a term sheet for a qualified financing as defined in the agreement.

In March 2019, we amended the Loan to increase the maximum borrowing capacity available to \$15.0 million. Under the Loan, as amended, \$7.0 million was drawn down as Term Loan A and \$8.0 million was drawn down as 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. Interest for Term Loan A is 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, which amounts to \$0.5 million, is 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 our assets, or our initial public offering, or IPO. In April 2020 and June 2020, we further amended the Loan to extend the interest-only period first to May 31, 2020 and then to August 31, 2020. Borrowings under both Term Loan A and Term Loan B are repayable in monthly payments of interest-only through August 31, 2020 to be followed by monthly payments of equal principal plus interest until the loan maturity date of February 1, 2023. As of June 30, 2020, the interest rate applicable to outstanding borrowings under the Loan, as amended, are 3.8%.

Borrowings under the Loan, as amended, are collateralized by substantially all of our assets, other than our intellectual property. There are no financial covenants associated with the Loan, as amended; however, we are subject to certain affirmative and negative covenants restricting our activities, including limitations on dispositions, mergers or acquisitions; encumbering our intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; and engaging in certain other business transactions. The obligations under the Loan, as amended, are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in our 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. We believe an event of default would be remote.

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### **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 this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses, capital expenditure requirements and debt service payments into the third quarter of 2022. We have based our estimates as to how long we expect we will be able to fund our operations on assumptions that may prove to be wrong. We could use our available capital resources sooner than we currently expect, in which case we would be required to obtain additional financing, 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.

Without giving effect to the anticipated net proceeds from this offering, we expect that our existing cash and cash equivalents will not be sufficient to fund our planned operating expenses and capital expenditure and debt service requirements beyond one year from the issuance date of our consolidated financial statements. To finance our operations, we will need to raise additional capital, which cannot be assured. We have concluded that this circumstance raises substantial doubt about our ability to continue as a going concern. See Notes 1 to our consolidated financial statements and unaudited consolidated financial statements included elsewhere in this prospectus for additional information on our assessment.

Similarly, in its report on our consolidated financial statements for the year ended December 31, 2019, our independent registered public accounting firm included an explanatory paragraph stating that our recurring losses from operations since inception and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern.

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.

See “Risk Factors” for additional risks associated with our substantial capital requirements.

### **Contractual Obligations and Commitments**

The following table summarizes our contractual obligations as of June 30, 2020 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due By Period				
	Total	Less Than 1 Year	1 to 3 Years (in thousands)	3 to 5 Years	More Than 5 Years
Operating leases(1)	\$83,361	\$ 6,810	\$ 20,008	\$ 20,716	\$ 35,827
Notes payable obligations(2)	16,322	5,488	6,259	4,575	—
Total	<u>\$99,683</u>	<u>\$ 12,298</u>	<u>\$ 26,267</u>	<u>\$ 25,291</u>	<u>\$ 35,827</u>

- (1) Amounts in table reflect payments due for our leases of office and laboratory space in Cambridge, Massachusetts and equipment under three operating lease agreements.
- (2) Amounts in table reflect the contractually required principal, final payment fee and interest payments payable under the Loan and Security Agreement, as amended, under which borrowings bear interest in part

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at a variable rate. For purposes of this table, the interest due under the Loan and Security Agreement was calculated using an assumed weighted average interest rate of 3.8% per annum, which was the stated interest rate in effect as of June 30, 2020.

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

We have also entered into license agreements under which we are obligated to make specified milestone and royalty payments. We have not included future payments under these agreements in the table of contractual obligations above since the payment obligations under these agreements are contingent upon future events such as regulatory milestones or generating product sales. We are unable to estimate the timing or likelihood of achieving these milestones or generating future product sales. For additional information about our licenses agreements and amounts that could become payable in the future under such agreements, see our consolidated financial statements appearing elsewhere in this prospectus.

### **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 prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

### ***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 and preclinical development activities;
- CROs in connection with preclinical studies and testing; 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

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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. We account for forfeitures of share-based awards as they occur. 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.

### ***Determination of fair value of common stock***

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuations of common stock, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Our common stock valuations were prepared using a hybrid method which used market approaches to estimate our enterprise value. The hybrid method is a probability-weighted expected return method, or PWERM, where the equity value in one or more scenarios is allocated using an option pricing method, or OPM. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for the company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. These third-party valuations were performed at various dates, which resulted in valuations of our common stock of \$3.72 per share as of December 15, 2018, \$3.93 per share as of April 15, 2020, \$8.77 per share as of August 4, 2020 and \$10.38 per share as of August 31, 2020. In addition to considering the results of

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

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

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

Once a public trading market for our common stock has been established in connection with the completion of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

### *Awards granted*

The following table summarizes by grant date the number of stock-based awards, consisting of common stock options, granted between January 1, 2019 and October 19, 2020, the per share exercise price of options, the per share fair value of common stock on each grant date, and the per share estimated fair value of the options:

<u>Grant Date</u>	<u>Number of Shares Subject to Option</u>	<u>Per Share Exercise Price of Options</u>	<u>Per Share Fair Value of Common Stock on Grant Date</u>	<u>Per Share Estimated Fair Value of Options on Grant Date</u>
February 13, 2019	504,405	\$ 3.72	\$ 3.72	\$2.56
February 20, 2019	828,749	\$ 3.72	\$ 3.72	\$2.56
June 5, 2019	137,702	\$ 3.72	\$ 3.72	\$2.54
September 17, 2019	857,864	\$ 3.72	\$ 3.72	\$2.52
June 4, 2020	351,073	\$ 3.93	\$ 3.93	\$2.52
August 18, 2020	1,135,633	\$ 8.77	\$ 8.77	\$5.91
August 20, 2020	108,107	\$ 8.77	\$ 8.77	\$5.91
September 24, 2020	113,241	\$10.38	\$10.38	\$6.92

### **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 prospectus.

### **Quantitative and Qualitative Disclosures about Market Risks**

As of December 31, 2019 and June 30, 2020, we had cash and cash equivalents of \$15.0 million and \$36.6 million, respectively, which consisted of cash and money market funds. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in market interest rates would not have a material effect on the fair market value of our investment portfolio.

As of December 31, 2019 and June 30, 2020, we had \$15.0 million of borrowings outstanding under our loan and security agreement, as amended, with Comerica. Outstanding borrowings bear interest at a variable rate based on the bank's prime rate and LIBOR. An immediate 10% change in the prime rate or LIBOR would not have had a material impact on our debt-related obligations, financial position or results of operations.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

We do not believe that inflation had a material effect on our business, financial condition or results of operations during the year ended December 31, 2019 or the six months ended June 30, 2020.

### **JOBS Act**

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies, including reduced disclosure about our executive compensation arrangements, exemption from the requirements to hold non-binding advisory votes on executive compensation and golden parachute payments and exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until the last day of the fiscal year following the fifth anniversary of this offering or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company earlier if we have more than \$1.07 billion in annual revenue, we have more than \$700.0 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) or we issue more than \$1.0 billion of non-convertible debt securities over a three-year period. For so long as we remain an emerging growth company, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. We may choose to take advantage of some, but not all, of the available exemptions.

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.

## 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 FHD-609, a protein degrader, to treat hematologic cancers and solid tumors, for which we plan to file INDs in the fourth quarter of 2020 and in the first half of 2021, respectively. Our product candidates are in preclinical development, and so we currently do not have any products approved for commercial sale. 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.

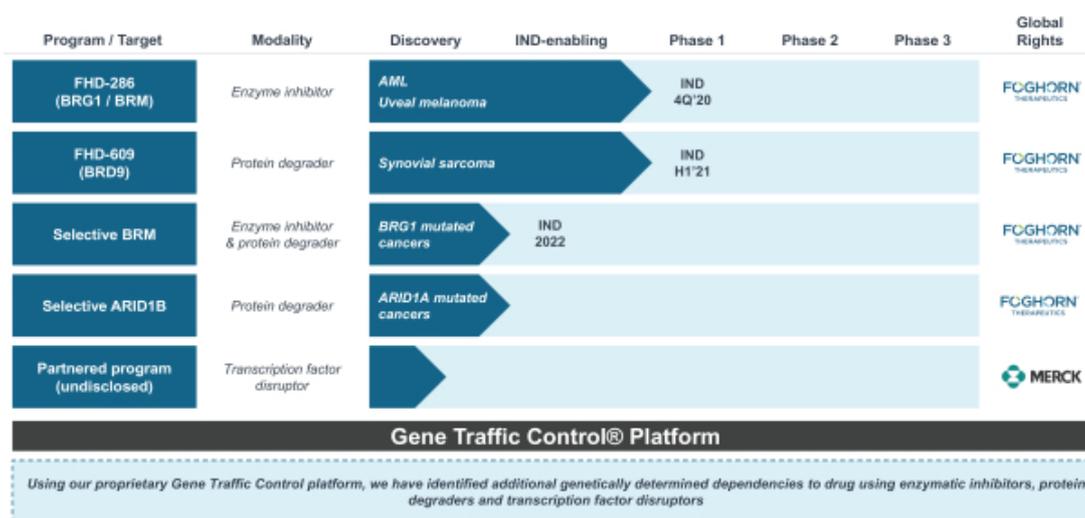
Our Gene Traffic Control platform encompasses the following:

- **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.

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- **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

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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 that we believe support filing an IND and progressing FHD-286 into clinical studies. We have successfully completed our GLP toxicology studies for FHD-286. We plan to file our IND for FHD-286 in the fourth quarter of 2020 and, if cleared, expect to initiate separate clinical studies in AML and uveal melanoma in parallel during the first quarter of 2021. 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 filing an IND and progressing FHD-609 into clinical studies. We have completed the in-life portion of our GLP toxicology studies for FHD-609. We plan to file our IND for FHD-609 in the first half 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 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 first 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 approximately 85 employees, approximately 80 percent of whom hold Ph.D., M.D., J.D., or Master's degrees.

### **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:

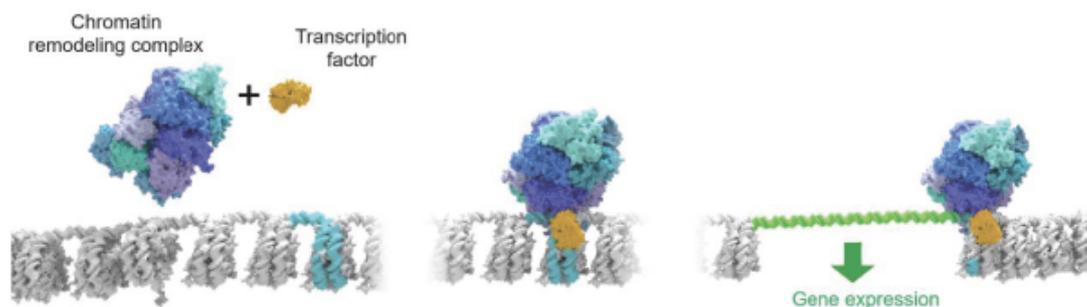
- **Advance our lead precision oncology product candidates, FHD-286 and FHD-609, through clinical development in patients with select solid tumors and hematological cancers.** FHD-286 and FHD-609 are a highly selective and potent enzymatic inhibitor and protein degrader, respectively, that target two 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 plan to file an IND for FHD-286 in the fourth quarter of 2020 for the treatment of AML and uveal melanoma and, if cleared, expect to initiate separate Phase 1 clinical trials in the first quarter of 2021 with preliminary clinical proof-of-concept data expected by year-end 2021. We also

plan to file an IND for FHD-609 in the first half 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 upon 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

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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.

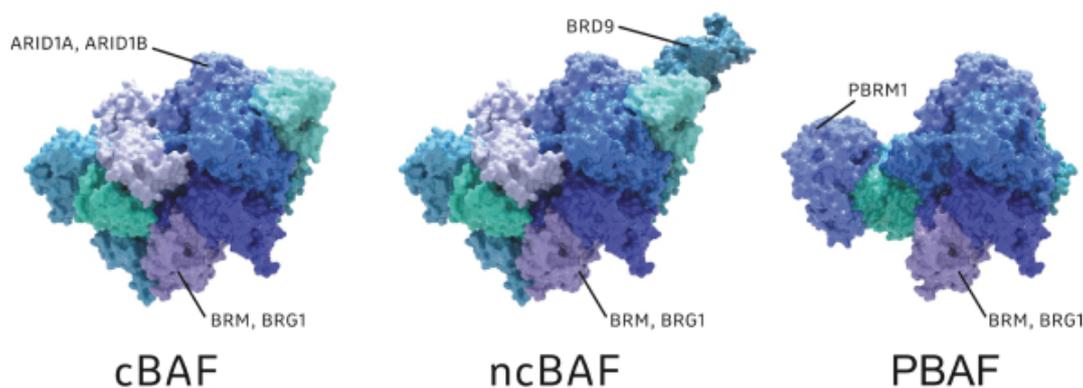
### *Our Initial Focus—BAF Complexes and Associated Transcription Factors*

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.

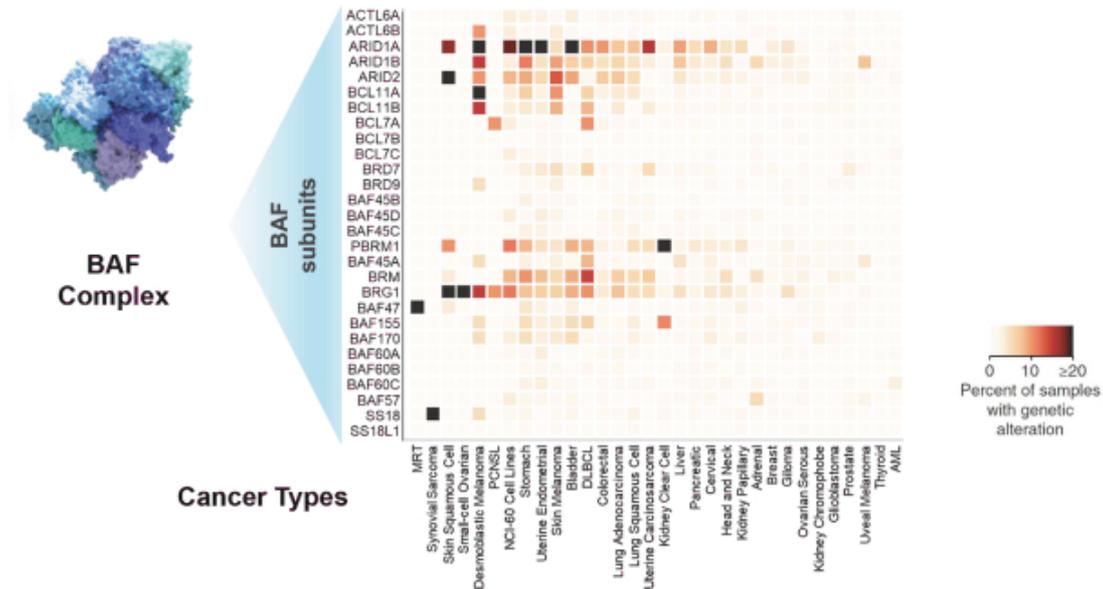
BAF, which stands for BRG1/BRM-associated factors, one type of chromatin remodeling complex, is mutated in approximately 20 percent of cancers, thus being the most mutated in the family of ATPase chromatin remodelers and among the most mutated targets in cancer. Given the breadth of mutations in cancer,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

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- 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.

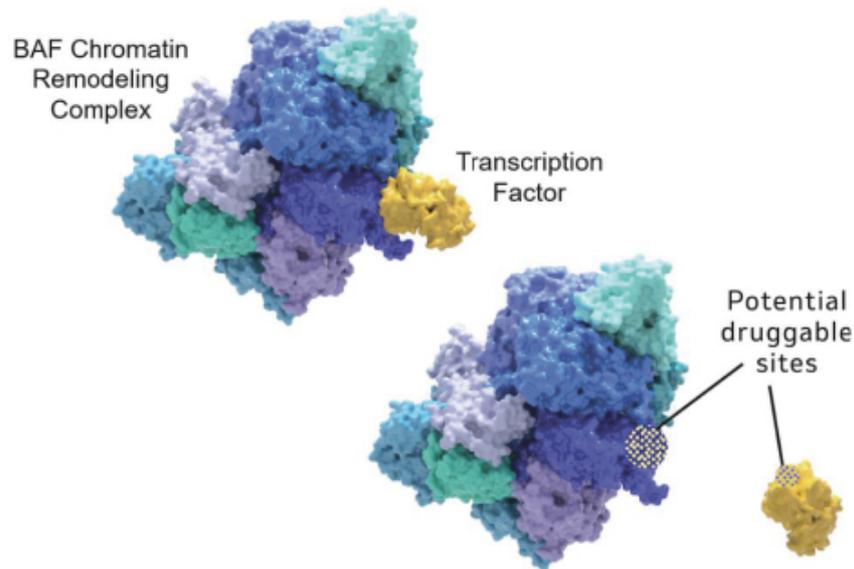
- **Enzyme inhibitors.** These candidates have the potential to act on targets such as the ATPases BRG1 and BRM of the BAF complex. Our screening capabilities enable us to find allosteric inhibitors which afford additional selectivity over orthosteric, or direct, inhibitors.
- **Protein degraders.** 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.

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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

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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 & 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 & 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.

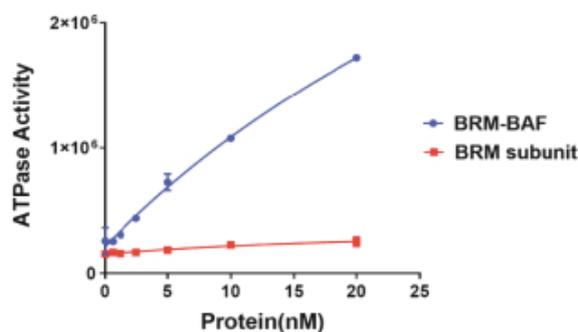
### *Production of Chromatin Regulatory System Components at Scale & Proprietary Assays*

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.

**ATPase activity using nucleosome substrate**



**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

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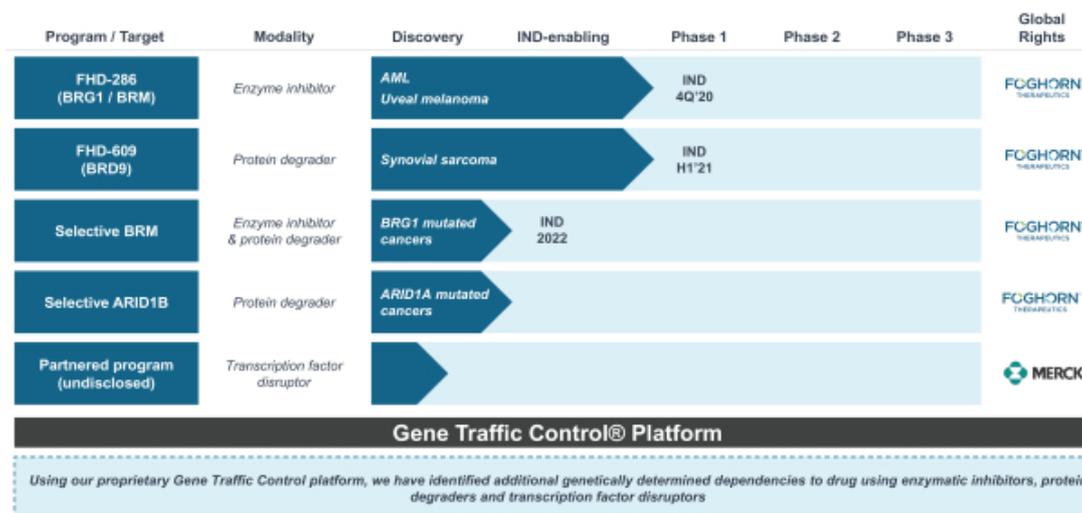
### Translation to Clinic and Identification of Biomarkers

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. We plan to file an IND for our lead product candidate, FHD-286, in the fourth quarter of 2020, and for our second product candidate, FHD-609, in the first half 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. Our preclinical data in both AML and uveal melanoma animal xenograft models have demonstrated anti-tumor effects that we believe support filing an IND and progressing FHD-286 into clinical studies. We have successfully completed our GLP toxicology studies for FHD-286. We plan to file our IND for FHD-286 in the fourth quarter of 2020 and, if cleared, expect to initiate separate clinical studies in AML and uveal melanoma in parallel during the first quarter of 2021. 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

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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, EU5 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, 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***

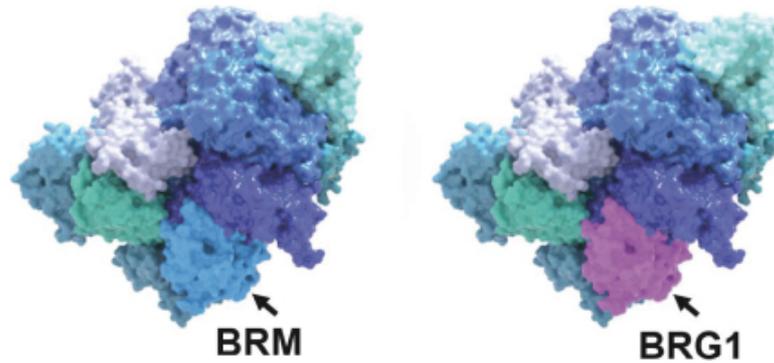
Uveal melanoma is the most frequent type of ocular cancer with approximately 5,000 cases each year in the major markets (United States, EU5 and Japan), typically presenting upon a routine eye exam in patients without specific symptoms. Local treatment, primarily with radiation therapy, is effective in 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**

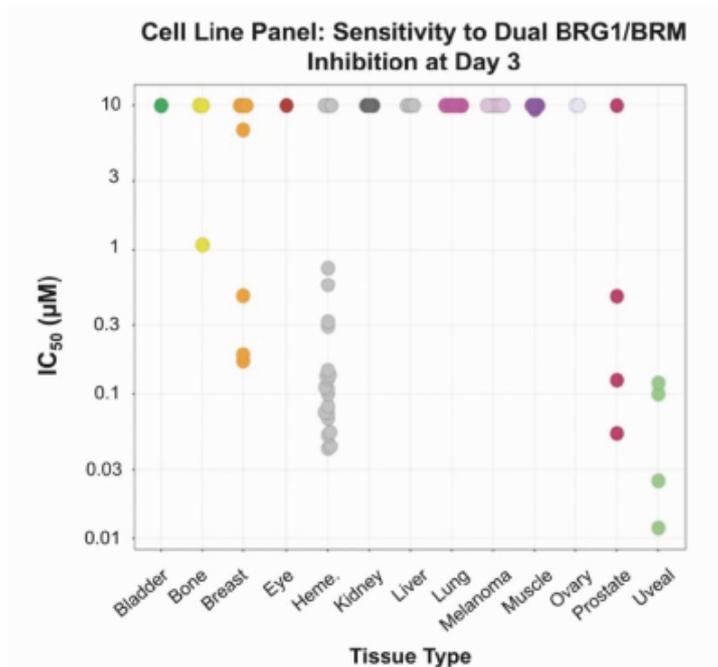
FHD-286 is a highly potent, selective, allosteric and orally available, small molecule inhibitor of the enzymatic activity of both BRG1 and BRM. In established AML cell line-derived xenograft, or CDX, models MV4-11 and OCI-AML2, we observed robust tumor growth inhibition. In established uveal melanoma CDX models, specifically MP-46 and 92-1, we observed significant tumor growth inhibition and tumor regression, respectively. We have completed GLP-toxicology studies with FHD-286 and we believe the data support filing an IND with the FDA. We plan to file an IND in the fourth quarter of 2020.

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.



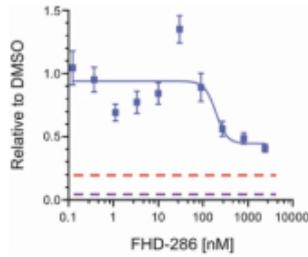
**Figure 7. Certain cell lines, including those derived from uveal melanoma, hematological cancers, prostate cancer, and breast cancer were highly sensitive to BRG1/BRM inhibition.**

***Our Preclinical Data for AML***

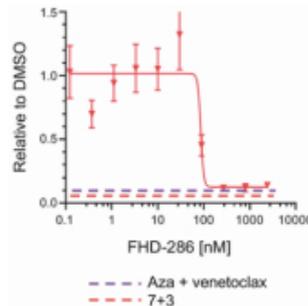
Genetic studies have identified a critical role of BRG1 in the maintenance of the undifferentiated state of AML cells. Knockdown of the expression of BRG1 was found both to inhibit the expression of genes associated with high proliferation and to induce the expression of genes associated with mature 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. 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.

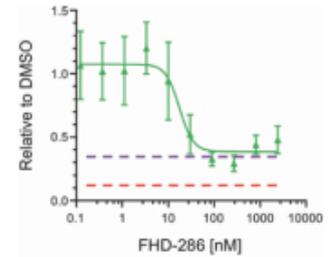
**Patient #1 Sample  
BM-de novo AML**



**Patient #2 Sample  
BM-secondary AML**

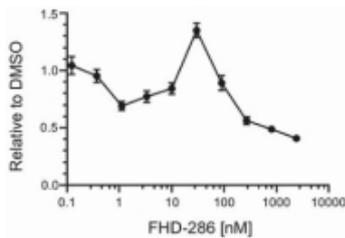


**Patient #3 Sample  
BM-secondary AML**

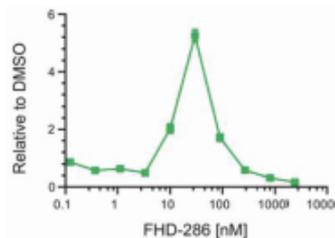


**Figure 8. Treatment of patient-derived AML tumor samples with FHD-286 stimulated differentiation and cell death. Dose-dependent reduction of blast counts in samples from three patients. The blast count was normalized and plotted as relative to the level in vehicle DMSO-treated samples. The level of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

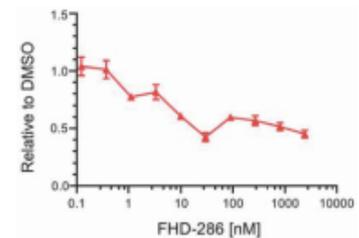
**Total Blasts**



**Differentiation-like Blasts**



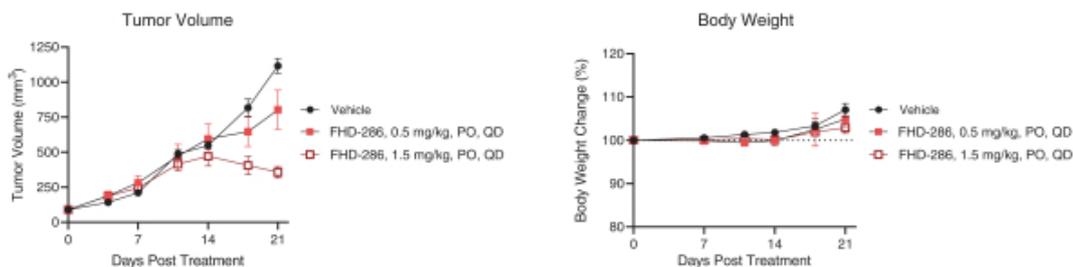
**Immature Blasts**



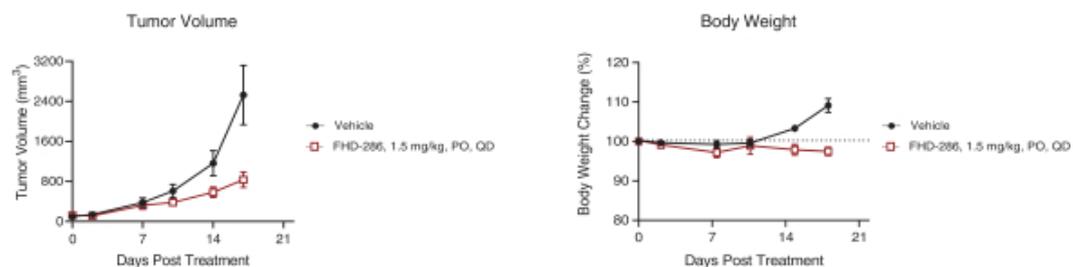
**Figure 9: Evidence of a dose-dependent differentiation effect in patient #1 sample.**

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.**

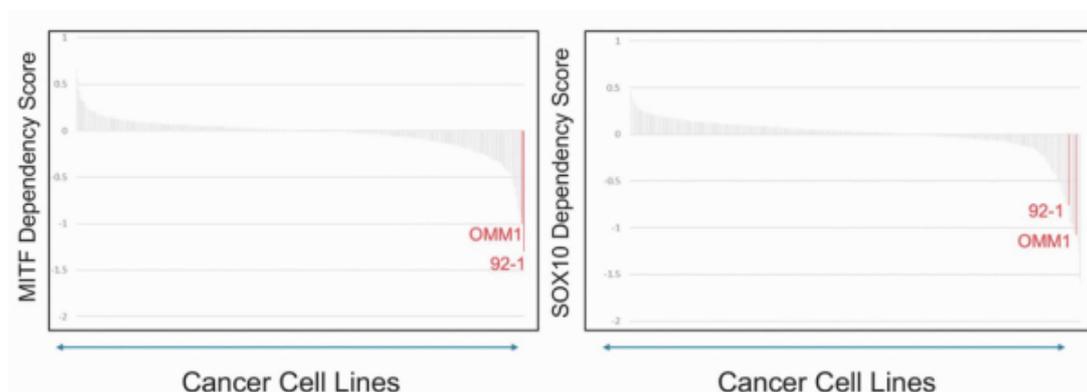


**Figure 10. FHD-286, dosed as monotherapy, led to tumor growth inhibition in two AML xenograft models MV4-11 and OCI-AML-2.**

***Our Preclinical Data for Uveal Melanoma***

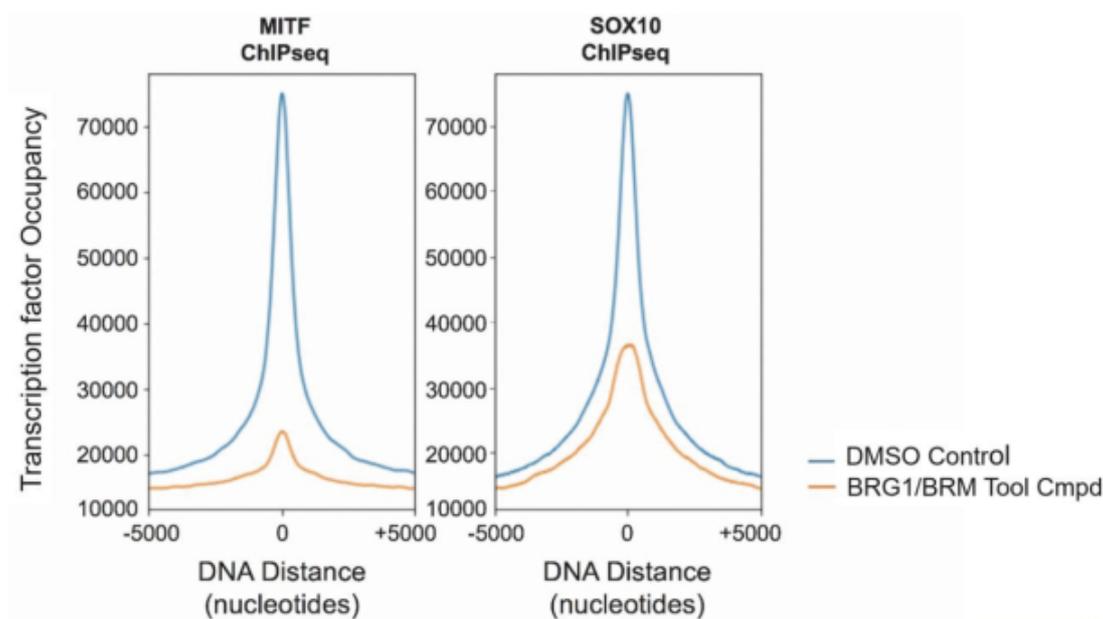
In uveal melanoma cell lines that contain GNAQ/GNA11 mutations, genetic studies have revealed that these cells overexpressed two transcription factors, MITF and SOX10. Our data showed that the MITF and SOX10 transcription factors abnormally over-interacted with the BAF complex in uveal melanoma cell 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.**

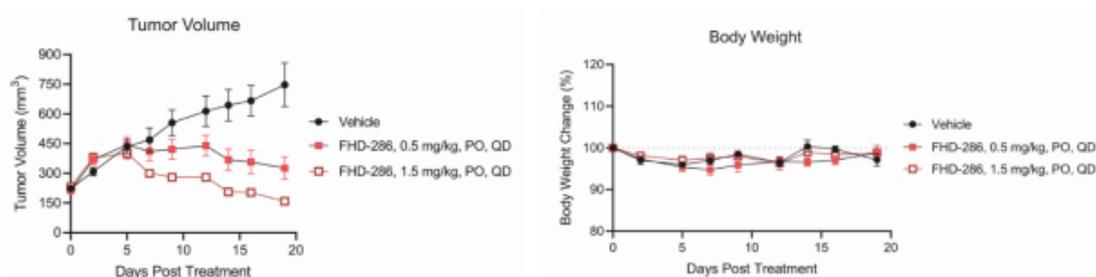
We found that inhibition of BRG1 and BRM led to suppression of gene expression from several MITF and SOX10-dependent genes. A broader measure of the effect of dual inhibition of BRG1 and BRM on transcription of MITF and SOX10-dependent genes was obtained using a technique known as chromatin immunoprecipitation 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.



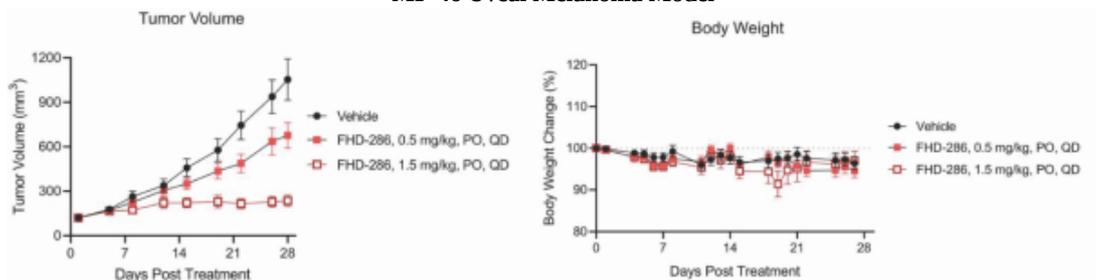
**Figure 12. BRG1/BRM inhibitor blocked the ability of MITF and SOX10 to bind to their target sequences as determined by ChIP-seq.**

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 intend to file an IND with the FDA for FHD-286 in the fourth quarter of 2020, and, if cleared, expect to initiate two separate Phase 1 clinical trials of FHD-286 in the first quarter of 2021 in patients with AML and uveal melanoma.

The first-in-human study Phase 1 in AML will include a standard dose escalation and expansion phase. 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 may include patients with relapsed and/or refractory AML. The expansion 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.

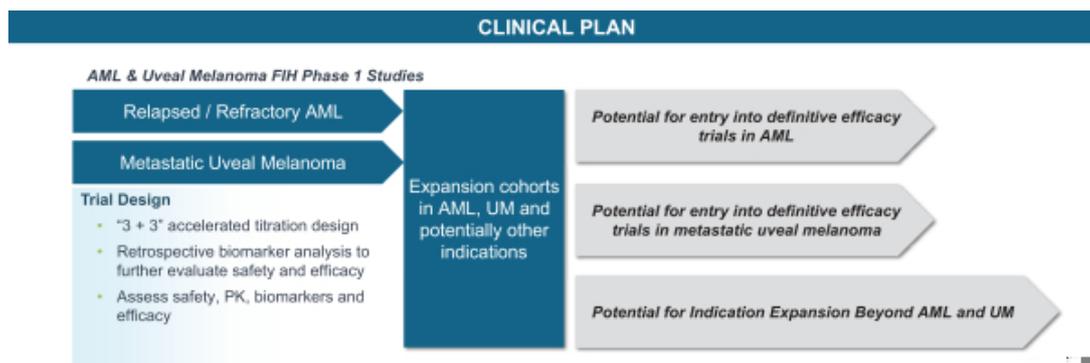
The primary objective of this first-in-human study will be the evaluation of safety and tolerability, and the identification of the maximum tolerated dose and the recommended Phase 2 dose. The secondary objectives are expected to include an evaluation of preliminary clinical activity and pharmacokinetics. 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.

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The first human Phase 1 study in uveal melanoma will include a standard dose escalation and expansion phase. The dose escalation portion will evaluate once daily, multiple ascending doses of FHD-286 with a starting dose determined by our GLP toxicology studies. Dose escalation may include patients with metastatic uveal melanoma. The expansion phase may include multiple distinct cohorts of uveal melanoma patients, 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 are expected to 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.



## 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 dosing portion of our GLP toxicology studies for FHD-609. We plan to file our IND for FHD-609 in the first half 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 pharmacokinetic and pharmacodynamic 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, EU5 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.

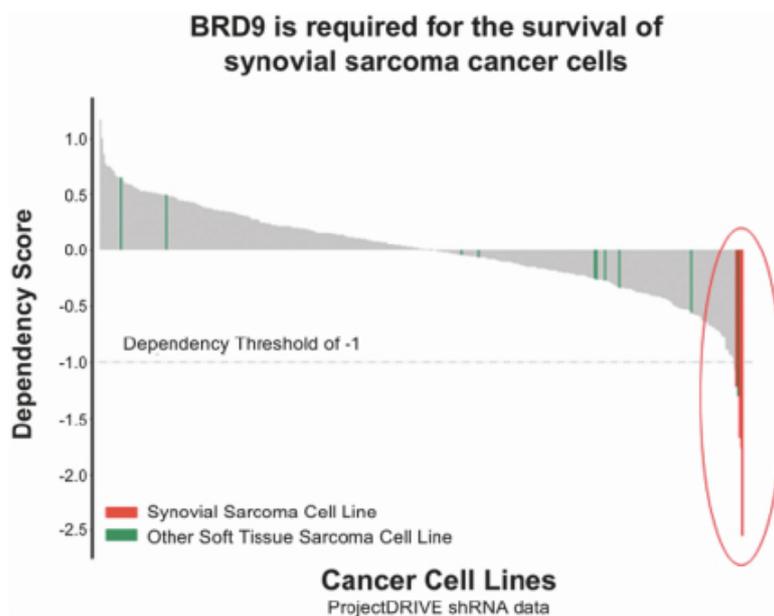
Delay in diagnosis and treatment of synovial sarcoma is common because it is recognized simply by a lump that gradually grows over time. The primary treatment for synovial sarcoma is surgical excision of the tumor and surrounding normal tissue with the goal of sparing the limb if possible. Failure to 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.

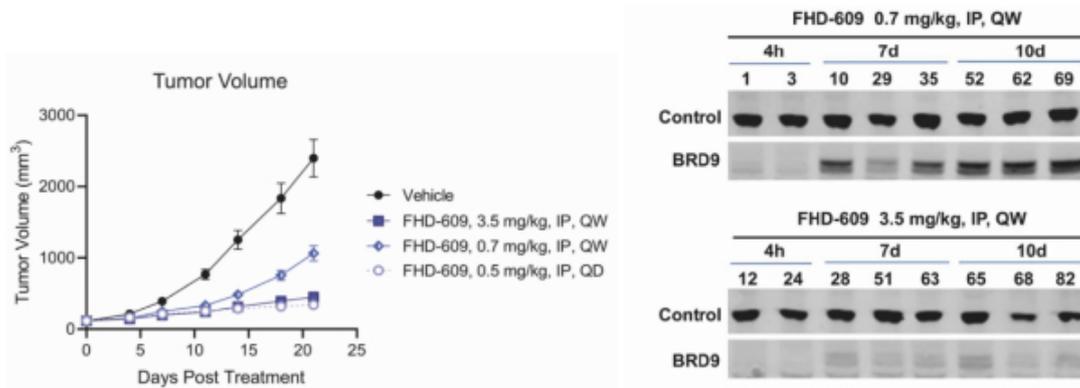
One domain of FHD-609 is a potent and selective binder of BRD9. This is chemically linked to a domain that binds to a receptor on the E3 ligase complex. FHD-609 led to the specific degradation of BRD9 in multiple synovial sarcoma tumor cell lines, with a DC50 of less than 1 (one) nM. This resulted in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

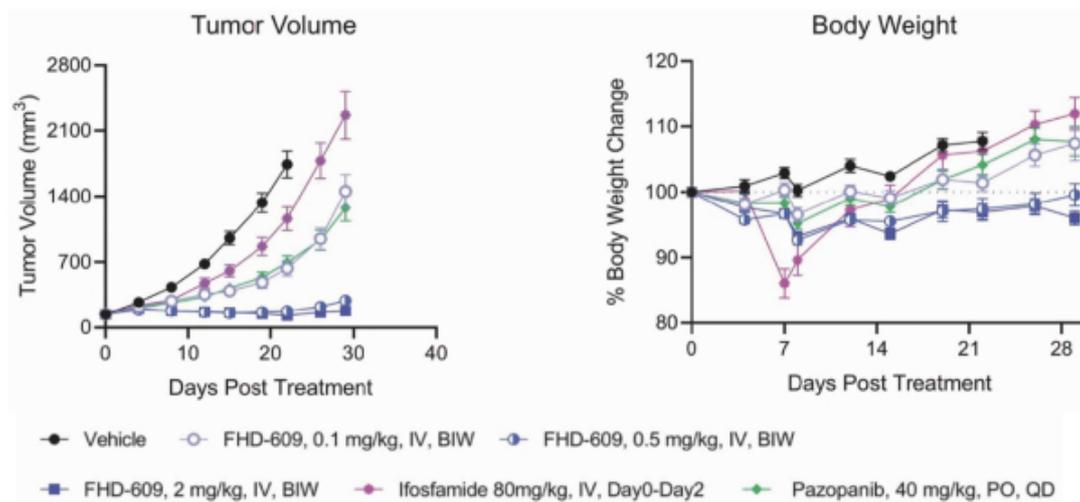
### SYO-1 Synovial Sarcoma CDX Model



**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.

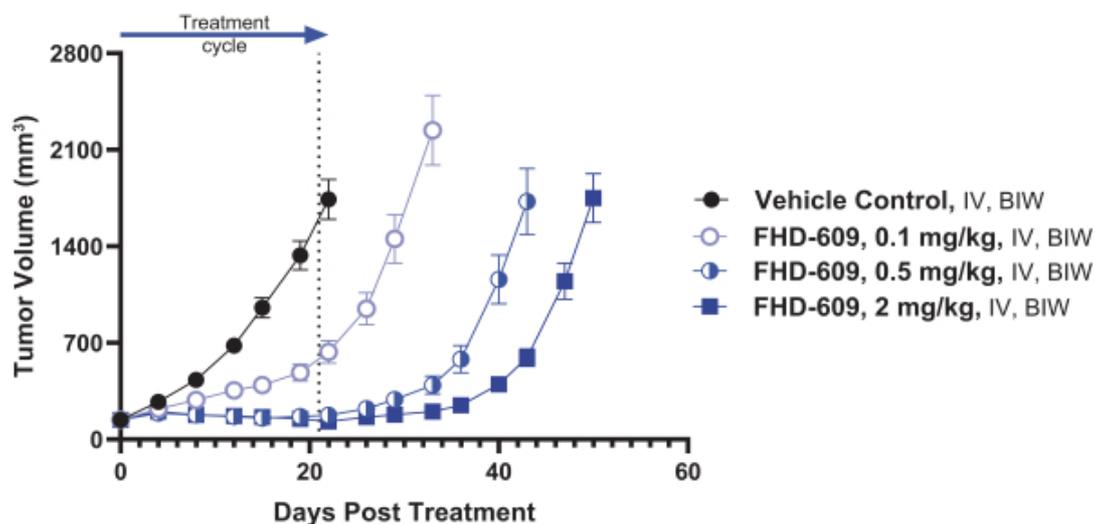
### ASKA Synovial Sarcoma CDX Model



**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



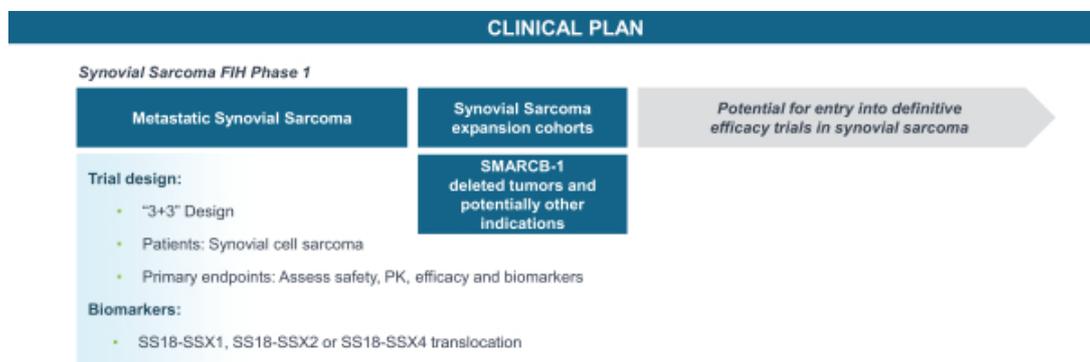
**Figure 17. FHD-609 treatment was associated with sustained tumor suppression after treatment withdrawal.**

#### 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.

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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

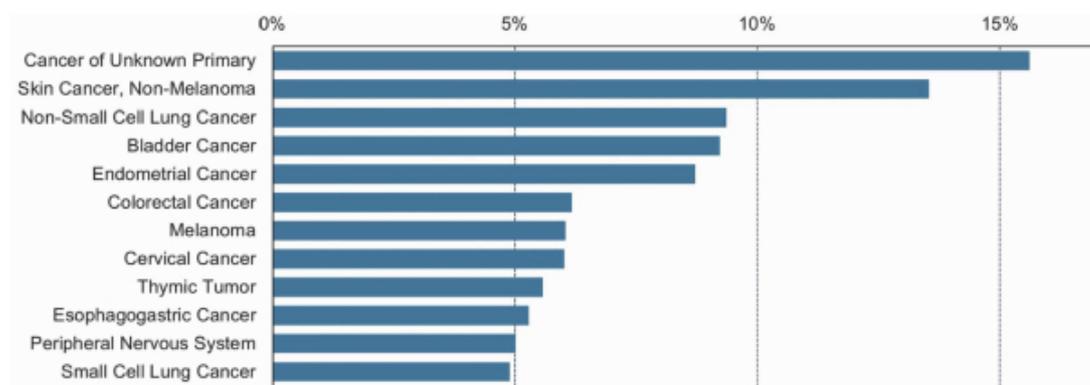


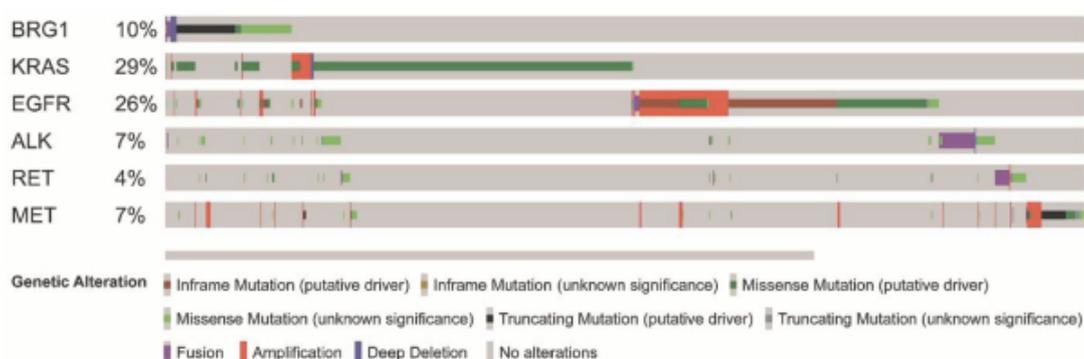
Figure 18. The above chart highlights the cancers with the highest prevalence of BRG1 mutations from the MSK-IMPACT study.

### **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 patients 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.

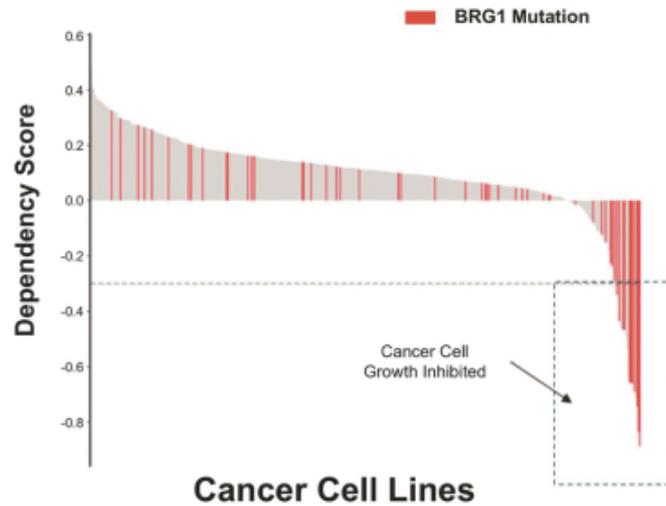
An analysis of genomic data in NSCLC cancer patients, collected as part of MSK-IMPACT, revealed that gene alterations in BRG1 were found in ten percent of NSCLC samples. In a retrospective analysis conducted by MSKCC it was observed that among patients with BRG1-deficient NSCLC who received first-line 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***

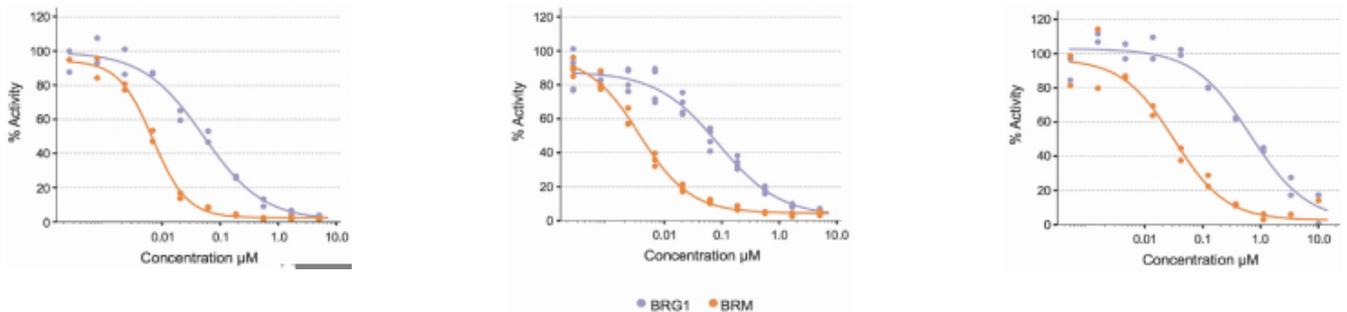
We are advancing two classes of molecules, an enzymatic inhibitor and a protein degrader, as selective modulators of BRM.

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.

**Enzyme assay using BRG1 and BRM subunits**

**Enzyme assay using BRG1 and BRM containing full BAF complexes**

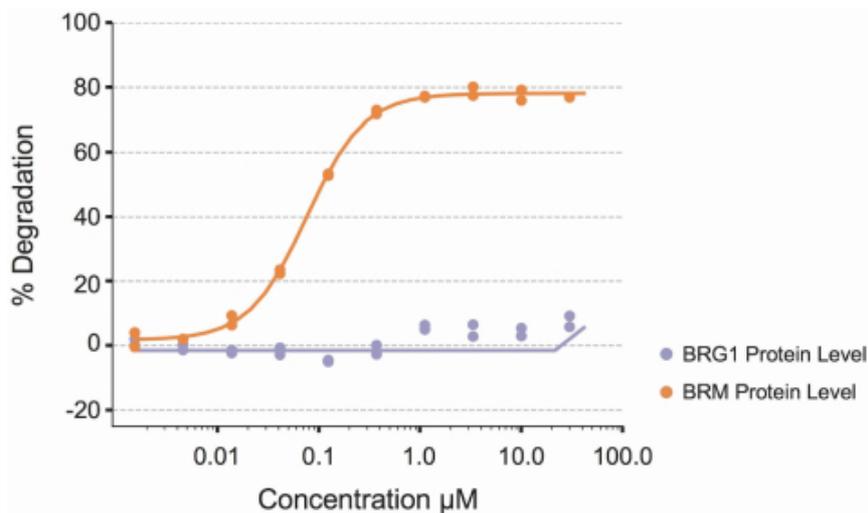
**Cellular assays for BRG1 and BRM**



**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.

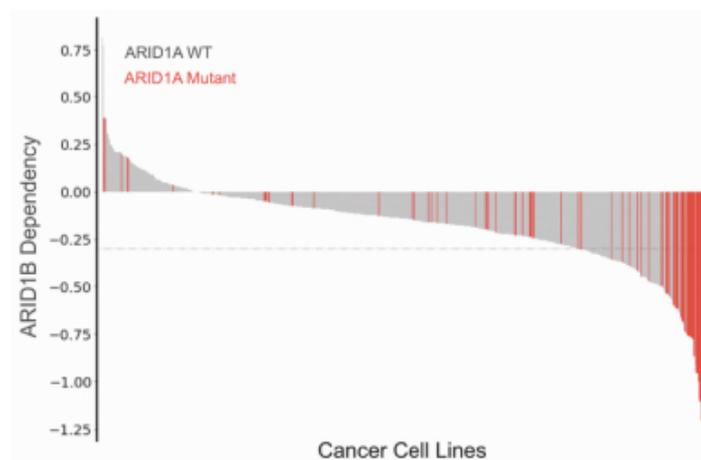
### Selective Degradation of BRM



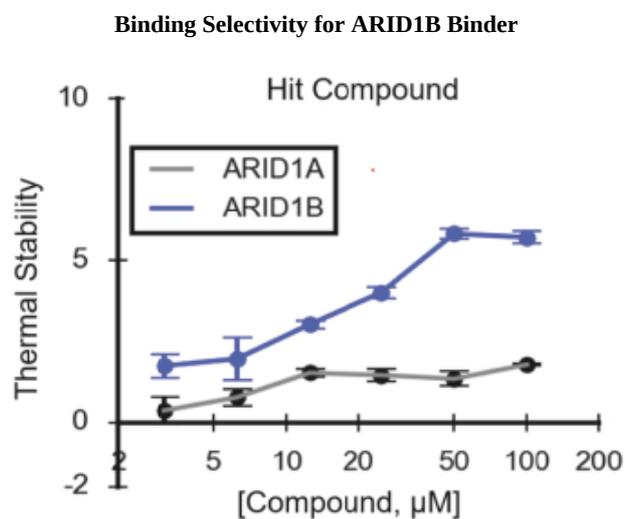
**Figure 22. Selective BRM degrading molecules led to the degradation of over 75 percent of BRM while leaving the levels of BRG1 virtually unchanged.**

### 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.



**Figure 24.** Dose response by DSF (Differential scanning fluorimetry) demonstrated selective binding to ARID1B over ARID1A with an initial screening hit compound.

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.

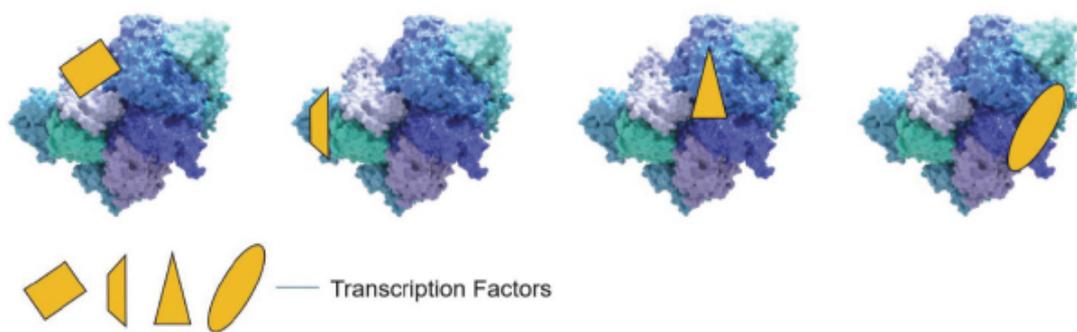
We are using these capabilities to drive our drug discovery efforts across multiple transcription factor programs for a variety of cancer indications. Our strategy is to disrupt the interaction between transcription factors and chromatin remodeling complexes. Our initial focus is on disrupting transcription 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 first 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 TMPRSS2 promoter, 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 TMPRSS2-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.

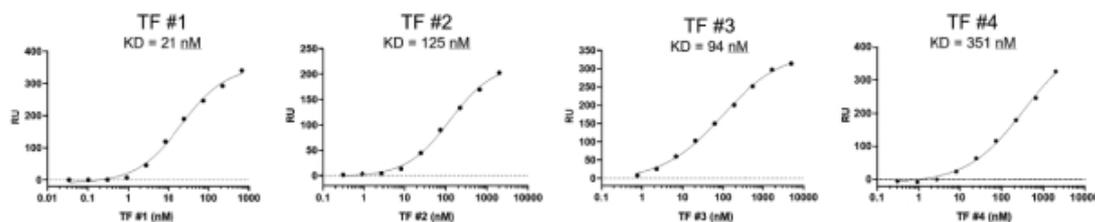
Similar to ERG, the ability of individual transcription factors to interact with the BAF complex has previously been reported in the literature, but to our knowledge, there have not previously been systematic studies quantifying and describing these binding interactions. We used our Gene Traffic Control 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 25. 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 26. Interactions between transcription factors and the BAF complex had  $K_D$ s 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

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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

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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 August 31, 2020, we owned 16 pending U.S. provisional patent applications, four pending U.S. non-provisional patent applications, and 16 pending PCT applications, and four 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 August 26, 2020, we owned five pending U.S. provisional patent applications, one pending U.S. non-provisional patent applications, four pending Patent Cooperation Treaty, or PCT, patent applications, and two 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 August 26, 2020, we owned two pending U.S. provisional patent applications, one pending U.S. non-provisional patent applications, and two pending Patent Cooperation Treaty, or PCT, patent applications, and two 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

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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 Sharp & Dohme Corp., or 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.

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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 first 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 if our INDs for FHT-286 and FHT-609 are accepted 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 foreign 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 foreign 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 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](http://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

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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

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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 policies 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.

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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

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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

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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.

### ***U.S. 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;

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- 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.

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- 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.

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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

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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.

### **Facilities**

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.

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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.

**Employees**

As of August 31, 2020, we had 85 full-time employees. 45 of our employees have M.D. or Ph.D. degrees. Within our workforce, 72 employees are engaged in research and development and 13 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.

**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.

## MANAGEMENT

### Executive Officers and Directors

Our executive officers and directors, and their ages and positions as of August 31, 2020, are as set forth below:

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
<b>Executive Officers</b>		
Adrian Gottschalk	45	Chief Executive Officer, Director
Allan Reine, M.D.	45	Chief Financial Officer
Samuel Agresta, M.D.	47	Chief Medical Officer
Carl P. Decicco, Ph.D.	59	Chief Scientific Officer
Steven F. Bellon, Ph.D.	55	Senior Vice President, Drug Discovery
<b>Non-Employee Directors</b>		
Douglas G. Cole, M.D.	60	Director
José Baselga, M.D., Ph.D.	61	Director
Scott Biller, Ph.D.	64	Director
Balkrishan (Simba) Gill, Ph.D.	56	Director
Cigall Kadoch, Ph.D.	35	Director
Adam M. Koppel, M.D., Ph.D.	50	Director
Michael Mendelsohn, M.D.	65	Director

### Executive Officers

*Adrian Gottschalk* has served as our President, Chief Executive Officer and as a member of our board of directors since May 2017. Prior to joining Foghorn and since 2004, Mr. Gottschalk worked at Biogen Inc. where he was most recently a Senior Vice President and Neurodegeneration Therapeutic Area Head from November 2015 to May 2017. In this role, he was responsible for the late-stage development and commercialization of medicines for Alzheimer's disease, Parkinson's disease, and amyotrophic lateral sclerosis, or ALS. Mr. Gottschalk holds a B.S. from Texas A&M University, an MBA from the Sloan School of Management at the Massachusetts Institute of Technology and an M.S. from the joint Harvard Medical School / Massachusetts Institute of Technology Division of Health Sciences & Technology (HST) Biomedical Enterprise Program. We believe that Mr. Gottschalk's experience as our President and Chief Executive Officer along with over 15 years of experience in the biotechnology field provides him with the qualifications and skills necessary to serve as a member of our board of directors.

*Allan Reine, M.D.* has served as our Chief Financial Officer since September 2019. Prior to joining Foghorn, Dr. Reine served as Chief Financial Officer of Pieris Pharmaceuticals from August 2017 to September 2019. From August 2012 through August 2017, Dr. Reine was a portfolio manager at Lombard Odier Asset Management, where he ran a healthcare portfolio focused on biotechnology and pharmaceutical companies. Before joining Lombard Odier, from 2003 through August 2012, Dr. Reine served as a healthcare portfolio manager at various funds, including Citi Principal Strategies, SAC Capital, Trivium Capital and Alexandra Investment Management. Dr. Reine began his career in 2001 at CIBC World Markets where he worked in both biotechnology investment banking and biotechnology equity research. Dr. Reine received his M.D. from the University of Toronto and his B.S. in Statistical Sciences from the University of Western Ontario.

*Samuel Agresta, M.D., M.P.H. & T.M.* has served as our Chief Medical Officer since September 2019. Prior to joining Foghorn, Dr. Agresta served as Chief Medical Officer of Infinity Pharmaceuticals from August 2018 to August 2019. Prior to that, Dr. Agresta was Vice President, Clinical Development of Agios Pharmaceuticals from December 2011 to August 2018. During that time, he led the development of the IDH inhibitors from drug candidate stage to FDA approval. Dr. Agresta is currently a member of the board of directors of Infinity Pharmaceuticals where he served since September 2019. Dr. Agresta received his B.S. from Georgetown University and his M.D. and M.P.H. & T.M. from Tulane University.

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*Carl P. Decicco, Ph.D.* has served as our Chief Scientific Officer since December 2018. Prior to joining Foghorn, Dr. Decicco served as Senior Vice President, Research at Bristol-Myers Squibb from May 2013 to November 2018, where he was responsible for all research and reported directly to the Chief Scientific Officer. Prior to that as Senior Vice President, Molecular Sciences from November 2008 to May 2013. Dr. Decicco received his B.Sc. and Ph.D. from the University of Guelph, and also completed post-doctoral studies in organic chemistry at Harvard University.

*Steven F. Bellon, Ph.D.* has served as our Senior Vice President, Drug Discovery since October 2019, and previously served in the role of Vice President, Drug Discovery since June 2016. Prior to joining Foghorn, Dr. Bellon was Senior Director and Executive Director of Constellation Pharmaceuticals, starting in September 2008. At Constellation Pharmaceuticals, Dr. Bellon built the structural biology group and the bromodomain platform. Dr. Bellon has also held positions at Amgen and Vertex Pharmaceuticals and has more than 20 years of experience in drug discovery. Dr. Bellon received his B.S. from Haverford College and his Ph.D. from the Massachusetts Institute of Technology.

### **Non-Employee Directors**

*Douglas Cole, M.D.* has served as a member of our board of directors since October 2015. Dr. Cole joined Flagship Pioneering, which conceives, creates, resources and develops first-in-category life sciences companies, in 2001, and is currently a Managing Partner focused on life science investments. Dr. Cole currently serves on the board of directors of Denali Therapeutics and a number of private companies. In the past five years, Dr. Cole served on the boards of directors of a number of public companies including Quanterix Corporation, Agios Pharmaceuticals, Receptos, AVEO Pharmaceuticals, Editas Medicine, Tetrphase Pharmaceuticals and Concert Pharmaceuticals. Dr. Cole received his M.D. from the University of Pennsylvania School of Medicine and his B.A. in English from Dartmouth College. We believe Dr. Cole is qualified to sit on our board of directors given his substantial experience as an investor in emerging biopharmaceutical and life sciences companies as well as his experience serving on the boards of directors of multiple public and private biopharmaceutical companies.

*José Baselga, M.D., Ph.D.* has served as a member of our board of directors since April 2017. Dr. Baselga is currently Executive Vice President of Research & Development Oncology at AstraZeneca, which position he has held since January 2019. Prior to joining AstraZeneca, Dr. Baselga was Physician-in-Chief and Chief Medical Officer at Memorial Sloan Kettering Cancer Center, or MSKCC, from January 2013 to September 2018. He also served as Professor of Medicine at Weill Cornell Medical College and as Attending Physician, Department of Medicine and as member, Human Oncology and Pathogenesis Program at MSKCC since January 2013. Previously, Dr. Baselga served as Chief of Division of Hematology & Oncology and Associate Director of the Massachusetts General Hospital Cancer Center and Professor of Medicine at Harvard Medical School from January 2010 to December 2012, and President of the American Association for Cancer Research from 2016 to 2017. He also served in various roles at Vall d'Hebron University Hospital in Barcelona, Spain, including as Founding Director, Vall d'Hebron Institute of Oncology from 2007 to 2012 and Director, Division of Medical Oncology, Hematology & Radiation Oncology and Founding Director and Chairman, Medical Oncology Service from 1996 to 2010. He previously served on the boards of directors of Aura Biosciences, Infinity Pharmaceuticals, GRAIL, Varian Medical Systems and Bristol Myers Squibb. He is a co-founder of Tango Therapeutics, Northern Biologics (formerly, Mosaic Biomedicals) and Venthera. Dr. Baselga received his M.D. and Ph.D. from the Universitat Autònoma de Barcelona. We believe Dr. Baselga is qualified to serve on our board of directors due to his extensive executive experience at a leading cancer hospital as well as his comprehensive expertise as a physician and clinical researcher in the area of oncology drug discovery and development.

*Scott Biller, Ph.D.* has served as a member of our board of directors since January 2020. Dr. Biller currently serves as a Senior Advisor for Agios Pharmaceuticals, where he previously served as the company's Chief Scientific Officer from September 2010 to December 2019. Dr. Biller is also currently the sole proprietor of Biller Consulting, a consulting company serving the biopharmaceutical industry. From 2003 to 2010, Dr. Biller was Vice President and Head of Global Discovery Chemistry at the Novartis Institutes for Biomedical Research. Prior to that, Dr. Biller held the positions of Vice President, Pharmaceutical Candidate Optimization at the

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Bristol Myers Squibb, or BMS, Pharmaceutical Research Institute and Executive Director of Drug Discovery chemistry for the BMS research site in Lawrenceville, New Jersey. Since June 2020, Dr. Biller has served on the board of directors of Remix Therapeutics. Dr. Biller earned a S.B. degree from the Massachusetts Institute of Technology, a Ph.D. from Caltech and was an NIH Postdoctoral Fellow at Columbia University in natural product synthesis. We believe Dr. Biller is qualified to serve on our board of directors because of his extensive experience in drug discovery and development and his significant leadership experience in the biotechnology industry.

*Balkrishan (Simba) Gill, Ph.D.* has served as a member of our board of directors since July 2017. Dr. Gill is the President, Chief Executive Officer and a member of the board of directors of Evelo Biosciences, which positions he has held since June 2015. Dr. Gill has also served as a venture partner at Flagship Pioneering, an innovation enterprise that conceives, creates, resources and grows first-in-category life sciences companies, since 2015. From 2016 to 2019, Dr. Gill served on the board of directors of Realm Therapeutics PLC. Dr. Gill received his Ph.D. from King's College, London and his MBA from INSEAD. We believe Dr. Gill is qualified to serve on our board of directors due to his knowledge and experience in the venture capital and pharmaceutical industries.

*Cigall Kadoch, Ph.D.* our academic co-founder, has served as a member of our board of directors since March 2016. She is currently Associate Professor of Pediatric Oncology at the Dana-Farber Cancer Institute, which position she has held since January 2014. Dr. Kadoch also currently serves as Associate Professor of Pediatrics, Harvard Medical School, which she has held since April 2014 and as Institute Member and Epigenomics Program Co-Director at the Broad Institute of Massachusetts Institute of Technology and Harvard University, which she has held since April 2014. Dr. Kadoch received her B.A. from the University of California, Berkeley and her Ph.D. from Stanford University School of Medicine. We believe that Dr. Kadoch is qualified to serve on our board of directors due to her expertise and experience as our academic co-founder and her deep understanding of the role of chromatin regulation in human cancer and other serious diseases.

*Adam M. Koppel, M.D., Ph.D.* has served as a member of our board of directors since July 2017. Dr. Koppel currently serves as Managing Director of Bain Capital Life Sciences, which position he has held since June 2016. He had initially joined Bain Capital Public Equity in 2003 where he was a leader within the healthcare sector until mid-2014. During the period between mid-2014 and mid-2016, Dr. Koppel was at Biogen, where he served as Executive Vice President of Corporate Development and Chief Strategy Officer. Prior to initially joining Bain Capital in 2003, Dr. Koppel was an Associate Principal at McKinsey & Co. in New Jersey where he served a variety of healthcare companies. Dr. Koppel currently sits on the boards of directors of Solid BioSciences, Dicerna Pharmaceuticals, Cerevel Therapeutics, Aptinyx and Viacyte. He has also previously served on the boards of Trevena and PTC Therapeutics. Dr. Koppel received an M.D. and Ph.D. in Neuroscience from the University of Pennsylvania School of Medicine. He also received an MBA from The Wharton School at the University of Pennsylvania, where he was a Palmer Scholar. He graduated magna cum laude from Harvard University with an A.B. and A.M. in History and science. We believe Dr. Koppel is qualified to serve on our board of directors due to his background as an executive officer, director and venture capital investor in biopharmaceutical companies, as well as his scientific and medical background.

*Michael Mendelsohn, M.D.* has served as a member of our board of directors since April 2017. Dr. Mendelsohn is also member of the board of directors of Cycleron Pharmaceuticals, where he has served since April 2019, as well as the Executive Chairman and President of Cardurion Pharmaceuticals, where he has served since May 2016. Since April 2015, Dr. Mendelsohn has also been a senior advisor and consultant to the chief medical and scientific officer of Takeda Pharmaceutical Co. Ltd. From December 2014 to December 2018, he served as senior advisor and consultant and a member of the pharmaceuticals advisory committee for the chief scientific officer and president of research and development at Ironwood Pharmaceuticals. From May 2014 to July 2017, Dr. Mendelsohn was a venture partner for SV Health Investors. Prior to that, from June 2010 to November 2013, Dr. Mendelsohn served as Senior Vice President and Global Head of Cardiovascular Research at Merck Research Laboratories. From 1993 to 2010, Dr. Mendelsohn was a faculty member at Tufts Medical Center and Tufts University School of Medicine, where he founded and was the executive director of the Molecular Cardiology

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Research Institute from 1997 to 2010 and served as Chief Scientific Officer from 2008 to 2010. Dr. Mendelsohn was previously a member of the cardiovascular faculty at Brigham and Women's Hospital and Harvard Medical School. Dr. Mendelsohn received a B.A. from Amherst College and M.D. from Harvard Medical School. We believe Dr. Mendelsohn is qualified to serve on our board of directors because of his extensive experience as a clinician and scientist, along with experience and insights as an active advisor and consultant to leadership in research and development for multinational biopharmaceutical companies.

### **Board Composition and Election of Directors**

#### ***Classified Board of Directors***

In accordance with our amended and restated certificate of incorporation, which will be in effect upon the closing of this offering, our board of directors will be divided into three classes of directors. At each annual meeting of stockholders, a class of directors will be elected for a three-year term to succeed the class whose terms are then expiring, to serve from the time of election and qualification until the third annual meeting following their election or until their earlier death, resignation or removal. Upon the closing of this offering, our directors will be divided among the three classes as follows:

The Class I directors will be Scott Biller, Cigall Kadoch and Michael Mendelsohn, and their terms will expire at our first annual meeting of stockholders following this offering.

The Class II directors will be Adrian Gottschalk and Adam Koppel, and their terms will expire at our second annual meeting of stockholders following this offering.

The Class III directors will be José Baselga, Douglas Cole and Simba Gill, and their terms will expire at our third annual meeting of stockholders following this offering.

Our amended and restated certificate of incorporation will provide that the authorized number of directors may be changed only by resolution of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control. See the section of this prospectus captioned "Description of Capital Stock—Anti-takeover Effects of Our Certificate of Incorporation and By-laws" for a discussion of these and other anti-takeover provisions found in our amended and restated certificate of incorporation and amended and restated by-laws, which will become effective immediately prior to the closing of this offering.

#### ***Director Independence***

Under the rules of the Nasdaq Stock Market, independent directors must comprise a majority of a listed company's board of directors within one year of the completion of its initial public offering. In addition, the Nasdaq Stock Market rules require that, subject to specified exceptions, each member of a listed company's audit and compensation committees be independent and that director nominees be selected or recommended for the board's selection by independent directors constituting a majority of the independent directors or by a nominating and corporate governance committee comprised solely of independent directors. Under the Nasdaq Stock Market rules, a director will only qualify as "independent" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that such person is "independent" as defined under Nasdaq Stock Market rules and the Exchange Act rules.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the

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board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that each of our directors, with the exception of Dr. Kadoch and Mr. Gottschalk, is an “independent director” as defined under applicable rules of the Nasdaq Stock Market, including, in the case of all the members of our audit committee with the exception of Dr. Cole, the independence criteria set forth in Rule 10A-3 under the Exchange Act, and in the case of all the members of our compensation committee, the independence criteria set forth in Rule 10C-1 under the Exchange Act and are “non-employee directors” as defined in Section 16b-3 of the Exchange Act. In making such determination, our board of directors considered the relationships that each such non-employee director has with our Company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director. Mr. Gottschalk is not an independent director under these rules because he is our President and Chief Executive Officer. Dr. Kadoch is not an independent director under these rules because of the amount she has been paid pursuant to her consulting agreement with us. See “Certain relationships and related party transactions—Consulting Agreement with Cigall Kadoch, Ph.D.”

### ***Board Committees***

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which will operate pursuant to a charter adopted by our board of directors and which will be effective prior to the consummation of this offering. The board of directors may also establish other committees from time to time to assist us and the board of directors in their duties. Upon the effectiveness of the registration statement of which this prospectus forms a part, the composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act, the Nasdaq Stock Market and the Exchange Act. Upon our listing on the Nasdaq Global Market, each committee’s charter will be available on the corporate governance section of our website at <https://foghorntx.com>. Information contained on our website is not incorporated by reference into this prospectus, and you should not consider information contained on our website to be part of this prospectus or in deciding whether to purchase shares of our common stock.

### ***Audit Committee***

The audit committee’s responsibilities upon completion of this offering will include:

- appointing, approving the compensation of, and evaluating the qualifications, performance and independence of our independent registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from such firm, and pre-approving all audit and permitted non-audit services to be performed by our independent registered public accounting firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures, including earnings releases;
- reviewing and discussing with management and our independent registered public accounting firm any material issues regarding accounting principles and financial statement presentations;
- coordinating our board of directors’ oversight of our internal control over financial reporting, disclosure controls and procedures, code of business conduct and ethics, procedures for complaints and legal and regulatory matters;
- discussing our risk management policies with management;

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- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our independent registered public accounting firm and management;
- reviewing and approving any related person transactions;
- overseeing our guidelines and policies governing risk assessment and risk management;
- overseeing the integrity of our information technology systems, process and data;
- preparing the audit committee report required by SEC rules;
- reviewing and assessing, at least annually, the adequacy of the audit committee's charter; and
- performing, at least annually, an evaluation of the performance of the audit committee.

All audit services and all non-audit services, other than *de minimis* non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

The members of our audit committee are Adam Koppel, Simba Gill and Douglas Cole. Dr. Koppel chairs the audit committee. Our board of directors has determined that each member of our audit committee has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has also determined that Drs. Koppel and Gill are "audit committee financial experts," as defined under Item 407 of Regulation S-K.

We expect to satisfy the member independence requirements for the audit committee prior to the end of the transition period provided under current Nasdaq Listing Rules and SEC rules and regulations for companies completing their initial public offering.

### **Compensation Committee**

Our compensation committee's responsibilities upon completion of this offering will include:

- assisting our board of directors in developing and reviewing potential candidates for executive positions;
- reviewing our overall compensation strategy, including base salary, incentive compensation and equity-based grants;
- reviewing, determining and approving corporate, individual and other goals and objectives relevant to compensation of our chief executive officer and approving the compensation of the CEO;
- reviewing and approving the compensation of our other executive officers;
- reviewing and making recommendations to the board of directors with respect to director compensation;
- overseeing and administering our cash and equity incentive plans;
- reviewing, considering and selecting, to the extent determined to be advisable, a peer group of appropriate companies for purposing of benchmarking and analysis of compensation for our executive officers and directors;
- reviewing and approving all employment contract and other compensation, severance and change-in-control arrangements for our executive officers;
- recommending to our board of directors any stock ownership guidelines for our executive officers and non-employee directors;
- retaining, appointing or obtaining advice of a compensation consultant, legal counsel or other advisor, and determining the compensation and independence of such consultant or advisor;

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- preparing, if required, the compensation committee report on executive compensation for inclusion in our annual proxy statement in accordance with the proxy rules;
- monitoring our compliance with the requirements of Sarbanes-Oxley relating to loans to directors and officers;
- overseeing our compliance with applicable SEC rules regarding shareholder approval of certain executive compensation matters;
- reviewing the risks associated with our compensation policies and practices;
- reviewing and assessing, at least annually, the adequacy of the compensation committee's charter; and
- performing, on an annual basis, an evaluation of the performance of the compensation committee.

The members of our compensation committee are Simba Gill, Douglas Cole and Michael Mendelsohn. Dr. Gill chairs the compensation committee. Prior to establishing a compensation committee, our board of directors made decisions relating to the compensation of our executive officers.

### ***Nominating and Governance Committee***

Our nominating and corporate governance committee's responsibilities upon completion of this offering will include:

- identifying individuals qualified to become members of our board of directors consistent with criteria approved by the board and receiving nominations for such qualified individuals;
- recommending to our board of directors the persons to be nominated for election as directors and to each committee of the board;
- establishing a policy under which our shareholders may recommend a candidate to the nominating and corporate governance committee for consideration for nomination as a director;
- reviewing and recommending committee slates on an annual basis;
- recommending to our board of directors qualified candidates to fill vacancies on our board of directors;
- developing and recommending to our board of directors a set of corporate governance principals applicable to us and reviewing the principles on at least an annual basis;
- reviewing and making recommendations to our board with respect to our board leadership structure and board committee structure;
- reviewing, in concert with our board of directors, our policies with respect to significant issues of corporate public responsibility;
- making recommendations to our board of directors processes for annual evaluations of the performance of our board of directors, our chief executive officer and committees of our board of directors;
- overseeing the process for annual evaluations of our board of directors, chief executive officer and committees of our board of directors and certifying that performance of our chief executive officer and other members of executive management is being properly evaluated;
- considering and reporting to our board of directors any questions of possible conflicts of interest of members of our board of directors;
- providing new director orientation and continuing education for existing directors on a periodic basis;
- overseeing the maintenance and presentation to our board of directors of management's plans for succession to senior management positions in the Company;
- reviewing and assessing, at least annually, the adequacy of the nominating and corporate governance committee's charter; and

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- performing, on an annual basis, an evaluation of the performance of the nominating and corporate governance committee.

The members of our nominating and corporate governance committee are Douglas Cole, Adam Koppel, and José Baselga. Dr. Cole chairs the nominating and corporate governance committee. Our board of directors has determined that each member of the nominating and corporate governance committee satisfies the independence standards of the applicable rules of the Nasdaq Stock Market.

Our board of directors may establish other committees from time to time.

### **Role of the Board in Risk Oversight**

Our board of directors has an active role, as a whole and also at the committee level, in overseeing the management of our risks. Our board of directors is responsible for general oversight of risks and regular review of information regarding our risks, including liquidity risks and operational risks. The compensation committee is responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. The audit committee is responsible for overseeing the management of risks relating to accounting matters and financial reporting. The nominating and governance committee is responsible for overseeing the management of risks associated with the independence of our board of directors and potential conflicts of interest. Although each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors is regularly informed through discussions from committee members about such risks. Our board of directors believes its administration of its risk oversight function has not negatively affected our board of directors' leadership structure.

### **Code of Business Conduct and Ethics**

Prior to the closing of this offering, we will adopt a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part. Following this offering, a current copy of the code will be posted on the investor section of our website. In addition, we intend to post on our website all disclosures that are required by law or listing rules concerning any amendments to, or waivers from, any provision of the code.

**EXECUTIVE AND DIRECTOR COMPENSATION**

The following discussion and analysis of compensation arrangements should be read with the compensation tables and related disclosures set forth below. This discussion contains forward looking statements that are based on our current plans and expectations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from the programs summarized in this discussion.

**Introduction**

This section provides an overview of the compensation awarded to, earned by, or paid to our principal executive officer and our next two most highly compensated executive officers, listed below, in respect of their service to us for the fiscal year ended December 31, 2019. We refer to these individuals as our named executive officers. Our named executive officers are:

Adrian Gottschalk, our President and Chief Executive Officer;

Carl Decicco, Ph.D., our Chief Scientific Officer; and

Samuel Agresta, M.D., our Chief Medical Officer.

The compensation committee of our board of directors was responsible for determining the compensation of our executive officers during fiscal year 2019 and will generally continue to be responsible for making such determinations following this offering, subject, in the case of our Chief Executive Officer, to the approval of our board of directors. Our Chief Executive Officer made recommendations to the compensation committee about the compensation of his direct reports in respect of fiscal years 2019 and 2020.

**Summary Compensation Table**

The following table sets forth the compensation awarded to, earned by, or paid to our named executive officers in respect of their service to us for the fiscal year ended December 31, 2019:

<u>Name and principal position</u>	<u>Year</u>	<u>Salary \$(1)</u>	<u>Bonus \$(2)</u>	<u>Option awards \$(3)</u>	<u>Non-equity incentive plan compensation \$(4)</u>	<u>All other compensation \$(5)</u>	<u>Total (\$)</u>
Adrian Gottschalk <i>President and Chief Executive Officer</i>	2019	\$465,000	—	\$ 642,918	\$ 197,625	—	\$1,305,543
Carl Decicco, Ph.D. <i>Chief Scientific Officer</i>	2019	\$400,000	—	\$1,474,337	\$ 136,000	\$ 60,000	\$2,070,337
Samuel Agresta, M.D. <i>Chief Medical Officer(6)</i>	2019	\$116,667	\$300,000	\$ 785,607	—	—	\$1,202,274

- (1) The amount reported for Mr. Gottschalk includes employee contributions made to our 401(k) plan.
- (2) The amount reported for Dr. Agresta reflects a sign-on bonus (\$75,000), a transition payment (\$65,000) and a one-time payment (\$160,000), each as described below under "Agreements With Our Named Executive Officers."
- (3) The amounts reported represent the aggregate grant date fair value of options to purchase our common stock granted to Mr. Gottschalk and Drs. Decicco and Agresta in fiscal year 2019, computed in accordance with FASB ASC 718, excluding the effect of estimated forfeitures. The assumptions used to value the stock options for this purpose are set forth in Note 10 to our consolidated financial statements included elsewhere in this prospectus.

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- (4) The amounts reported represent the annual bonus earned by each of Mr. Gottschalk and Dr. Decicco with respect to fiscal year 2019, based on the attainment of corporate performance goals as described below under “Annual Bonuses.” Dr. Agresta was not paid a bonus for fiscal year 2019.
- (5) The amount reported for Dr. Decicco reflects a travel and lodging allowance.
- (6) Dr. Agresta commenced employment with us on September 16, 2019.

### **Narrative Disclosure to Summary Compensation Table**

#### ***Base Salary***

The letter agreement with each named executive officer, described below, establishes a base salary for the officer. For 2019, Mr. Gottschalk’s base salary was increased to \$465,000. For 2020, Mr. Gottschalk’s base salary was increased to \$478,950, Dr. Decicco’s base salary was increased to \$412,000 and Dr. Agresta’s base salary was increased to \$412,000.

#### ***Annual Bonuses***

With respect to fiscal year 2019, each of Mr. Gottschalk and Drs. Decicco and Agresta was eligible to receive an annual bonus, with the initial target amount of such bonus for each named executive officer set forth in his letter agreement with us, described below. For fiscal year 2019, the target bonus amount, expressed as a percentage of base salary, for each of Mr. Gottschalk, Dr. Decicco and Dr. Agresta was as follows: up to 50%, up to 40% and up to 40%, respectively. Annual bonuses for fiscal year 2019 for our named executive officers were based on the attainment of certain corporate performance goals as determined by the compensation committee, including those related to capital raising and financing, senior management recruitment, development of pipeline candidates, and research and development targets. For 2019, the compensation committee determined that, based on the level of attainment of the applicable corporate performance goals and other factors determined relevant by the committee, each eligible executive would be eligible to earn 85% of his bonus target. As a result, Mr. Gottschalk earned a bonus of \$197,625 and Dr. Decicco earned a bonus of \$136,000. Dr. Agresta was not paid an annual bonus for fiscal year 2019 pursuant to the terms of his letter agreement, as described below.

#### ***Agreements With Our Named Executive Officers***

Each named executive officer is party to an amended and restated letter agreement with us that sets forth the terms and conditions of his employment. The material terms of the agreements are described below. The terms “cause,” “good reason event” and “change of control” referred to below are defined in the respective named executive officer’s agreement.

*Mr. Gottschalk.* In connection with this offering, we entered into an amended and restated letter agreement with Mr. Gottschalk that provides for an initial base salary of \$478,950 per year and an initial target annual bonus of 50% of his annual base salary. The amended and restated letter agreement provides that, as long as he is our Chief Executive Officer, we will nominate Mr. Gottschalk to serve on our board of directors and he will serve as a member of our board of directors if elected.

Mr. Gottschalk also entered into an Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment of Inventions Agreement under which he has agreed not to compete with us during his employment and for 12 months following the termination of his employment, except for any termination due to layoff or without cause (as defined in this agreement), in exchange for garden leave pay during the post-employment non-competition period equal to 50% of his highest annual base salary during the two years prior to termination of his employment. We may elect to waive the post-employment non-competition period, in which case no garden leave pay would be due. Pursuant to the terms of this agreement, Mr. Gottschalk also has agreed to a perpetual obligation of confidentiality, the assignment of intellectual property, the protection and return of documents and other materials, and not to solicit our customers or business partners, or solicit or hire our employees or independent contractors, during his employment and for 12 months following termination of his employment.

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*Dr. Decicco.* In connection with this offering, we entered into an amended and restated letter agreement with Dr. Decicco that provides for an initial base salary of \$412,000 per year and a target annual bonus of 40% of his annual base salary.

Dr. Decicco also entered into an Employee Non-Competition Agreement and an Employee Non-Solicitation, Confidentiality and Assignment of Inventions Agreement, which together have terms substantially similar to Mr. Gottschalk's Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment of Inventions Agreement, as described above.

*Dr. Agresta.* In connection with this offering, we entered into an amended and restated letter agreement with Dr. Agresta that provides for an initial base salary of \$412,000 per year and a target annual bonus of 40% of his annual base salary. The amended and restated letter agreement also provided for repayment by Dr. Agresta if we terminate his employment for cause or if he resigns without good reason, in each case, prior to September 16, 2021, of a one-time transition payment of \$65,000 previously paid to him. Pursuant to the terms of the amended and restated letter agreement, we will reduce annual bonus amounts that otherwise could have been earned by Dr. Agresta by the amount of a one-time payment of \$160,000 previously paid to him. This payment, less the amount of any reductions as described above, will be repayable by Dr. Agresta if we terminate his employment for cause or if he resigns without good reason, in each case, prior to September 16, 2021.

Dr. Agresta also entered into an Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment of Inventions Agreement, which has terms substantially similar to Mr. Gottschalk's Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment of Inventions Agreement, as described above.

### *Severance Upon Termination of Employment; Change in Control.*

*Mr. Gottschalk.* If Mr. Gottschalk's employment is terminated by us without cause or if he resigns for good reason outside of a change of control, he will be entitled to receive (i) severance in an amount equal to 12 months of his then-current base salary, payable in installments over six months; (ii) payment of the employer portion of COBRA premiums for 12 months, subject to his eligibility for, and timely election of, COBRA coverage; and (iii) any earned but unpaid bonus relating to the calendar year prior to the year of termination, payable at the same time bonuses otherwise are paid to active employees.

If Mr. Gottschalk's employment is terminated by us without cause or if he resigns for good reason within the four months prior to or 12 months following a change of control, he will be entitled to receive (i) severance in an amount equal to 1.5 times the sum of (A) his then-current base salary plus (B) his target annual bonus for the year of termination, payable in installments over 12 months; (ii) payment of the employer portion of COBRA premiums for 18 months, subject to his eligibility for, and timely election of, COBRA coverage; (iii) any earned but unpaid bonus relating to the calendar year prior to the year of termination, payable at the same time bonuses otherwise are paid to active employees; and (iv) full acceleration of time-based stock options and other time-based equity awards.

*Dr. Decicco.* If Dr. Decicco's employment is terminated by us without cause or if he resigns for good reason outside of a change of control, he will be entitled to receive (i) severance in an amount equal to nine months of his then-current base salary, payable in installments over nine months; (ii) payment of the employer portion of COBRA premiums for nine months, subject to his eligibility for, and timely election of, COBRA coverage; and (iii) any earned but unpaid bonus relating to the calendar year prior to the year of termination, payable at the same time bonuses otherwise are paid to active employees.

If Dr. Decicco's employment is terminated by us without cause or if he resigns for good reason within the three months prior to or 12 months following a change of control, he will be entitled to receive (i) severance in an amount equal to the sum of (A) his then-current base salary plus (B) his target annual bonus for the year of termination, payable in installments over 12 months; (ii) payment of the employer portion of COBRA premiums for 12 months, subject to his eligibility for, and timely election of, COBRA coverage; (iii) any earned but unpaid

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bonus relating to the calendar year prior to the year of termination, payable at the same time bonuses otherwise are paid to active employees; and (iv) full acceleration of time-based stock options and other time-based equity awards.

*Dr. Agresta.* If Dr. Agresta's employment is terminated by us without cause or if he resigns for good reason outside of a change of control, he will be entitled to receive (i) severance in an amount equal to nine months of his then-current base salary, payable in installments over nine months; (ii) payment of the employer portion of COBRA premiums for nine months, subject to his eligibility for, and timely election of, COBRA coverage; and (iii) any earned but unpaid bonus relating to the calendar year prior to the year of termination, payable at the same time bonuses otherwise are paid to active employees.

If Dr. Agresta's employment is terminated by us without cause or if he resigns for good reason within the three months prior to or 12 months following a change of control, he will be entitled to receive (i) severance in an amount equal to the sum of (A) his then-current base salary plus (B) his target annual bonus for the year of termination, payable in installments over 12 months; (ii) payment of the employer portion of COBRA premiums for 12 months, subject to his eligibility for, and timely election of, COBRA coverage; (iii) any earned but unpaid bonus relating to the calendar year prior to the year of termination, payable at the same time bonuses otherwise are paid to active employees; and (iv) full acceleration of time-based stock options and other time-based equity awards.

*Severance Subject to Compliance with Restrictive Covenant Obligations and Release of Claims.* Our obligation to provide severance payments and other benefits under each of the named executive officers' amended and restated letter agreements is conditioned on (i) the executive providing a timely and effective separation agreement containing a release of claims in favor of us; and (ii) the executive's continued compliance with applicable restrictive covenant obligations, including any non-competition, non-solicitation and confidentiality restrictions.

### **Equity Compensation**

Each our of named executive officers received a grant of options to purchase our common stock in each of the fiscal years 2019 and 2020 pursuant to the terms of the 2016 Plan.

On February 20, 2019, Mr. Gottschalk was granted an option to purchase 250,697 shares of our common stock, which vested as to 25% of the underlying shares on January 30, 2020, and vests as to 6.25% of the underlying shares on the first day of each calendar quarter thereafter, for the subsequent 12 calendar quarters, generally subject to his continued employment with us through the applicable vesting date.

On February 20, 2019, Dr. Decicco was granted an option to purchase 468,378 shares of our common stock, which vested as to 25% of the underlying shares on December 10, 2019, and vests as to 6.25% of the underlying shares on the first day of each calendar quarter thereafter, for the subsequent 12 calendar quarters, generally subject to his continued employment with us through the applicable vesting date. On February 20, 2019, Dr. Decicco also was granted an option to purchase 109,673 shares of our common stock, which vested as to 25% of the underlying shares on January 30, 2020, and vests as to 6.25% of the underlying shares on the first day of each calendar quarter thereafter, for the subsequent 12 calendar quarters, generally subject to his continued employment with us through the applicable vesting date.

On September 17, 2019, Dr. Agresta was granted an option to purchase 311,297 shares of our common stock, which vested as to 25% of the underlying shares on September 16, 2020, and vests as to 6.25% of the underlying shares on the first day of each calendar quarter thereafter, for the subsequent 12 calendar quarters, generally subject to his continued employment with us through the applicable vesting date.

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On August 18, 2020, Mr. Gottschalk and Drs. Decicco and Agresta were granted options to purchase 310,810, 91,891 and 91,891 shares of our common stock, respectively, each of which option vests as to 25% of the underlying shares on August 17, 2021, and vests as to 6.25% of the underlying shares on the first day of each calendar quarter thereafter, for the subsequent 12 calendar quarters, generally subject to the applicable executive's continued employment with us through the applicable vesting date.

### **Severance and Change of Control Payments and Benefits**

Each of our named executive officers is entitled to severance and change of control benefits pursuant to the terms of his amended and restated letter agreement as described above under "Agreements With Our Named Executive Officers."

### **Employee and Retirement Benefits**

We currently provide broad-based health and welfare benefits, and certain commuter benefits, that are available to our full-time employees, including our named executive officers, including health, life, disability, vision and dental insurance. In addition, we maintain a 401(k) retirement plan for our full-time employees. The 401(k) plan permits us to make discretionary employer contributions. We did not make any employer contributions to the 401(k) plan in 2019. Other than the 401(k) plan, we do not provide any qualified or non-qualified retirement or deferred compensation benefits to our employees, including our named executive officers.

### **Outstanding Equity Awards at Fiscal Year-end Table**

The following table sets forth information about outstanding equity awards held by each of our named executive officers as of December 31, 2019:

Option awards				
<u>Name</u>	<u>Number of securities underlying unexercised options exercisable (#)</u>	<u>Number of securities underlying unexercised options unexercisable (#)</u>	<u>Option exercise price (\$/share)</u>	<u>Option expiration date</u>
Adrian Gottschalk	201,858	339,527	\$ 0.54	5/29/2027(1)
	—	250,697	\$ 3.72	2/20/2029(2)
Carl Decicco, Ph.D.	—	351,283	\$ 3.72	2/20/2029(3)
	—	109,673	\$ 3.72	2/20/2029(4)
Samuel Agresta, M.D.	—	311,297	\$ 3.72	9/16/2029(5)

- (1) Represents an option to purchase 905,405 shares of our common stock, granted on May 30, 2017, which vested as to 25% of the underlying shares on May 30, 2018, and vests as to 6.25% of the underlying shares on the first day of each calendar quarter thereafter, for the subsequent 12 calendar quarters, generally subject to Mr. Gottschalk's continued employment with us through the applicable vesting date.
- (2) Represents an option to purchase 250,697 shares of our common stock, granted on February 20, 2019, which vested as to 25% of the underlying shares on January 30, 2020, and vests as to 6.25% of the underlying shares on the first day of each calendar quarter thereafter, for the subsequent 12 calendar quarters, generally subject to Mr. Gottschalk's continued employment with us through the applicable vesting date.
- (3) Represents an option to purchase 468,378 shares of our common stock, granted on February 20, 2019, which vested as to 25% of the underlying shares on December 10, 2019, and vests as to 6.25% of the underlying shares on the first day of each calendar quarter thereafter, for the subsequent 12 calendar quarters, generally subject to Dr. Decicco's continued employment with us through the applicable vesting date.

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- (4) Represents an option to purchase 109,673 shares of our common stock, granted on February 20, 2019, which vested as to 25% of the underlying shares on January 30, 2020, and vests as to 6.25% of the underlying shares on the first day of each calendar quarter thereafter, for the subsequent 12 calendar quarters, generally subject to Dr. Decicco's continued employment with us through the applicable vesting date.
- (5) Represents an option to purchase 311,297 shares of our common stock, granted on September 17, 2019, which vested as to 25% of the underlying shares on September 16, 2020, and vests as to 6.25% of the underlying shares on the first day of each calendar quarter thereafter, for the subsequent 12 calendar quarters, generally subject to Dr. Agresta's continued employment with us through the applicable vesting date.

### **Director Compensation**

The following table sets forth information concerning the compensation awarded to, earned by, or paid to our non-employee directors during the fiscal year ended December 31, 2019. Mr. Gottschalk's compensation for 2019 is included with that of our other named executive officers above. None of our non-employee directors was granted any stock options or other equity-based awards during fiscal year 2019 and we did not provide cash retainer fees to our non-employee directors prior to this offering.

<u>Name</u>	<u>Stock Awards \$(1)</u>	<u>Option Awards \$(2)</u>	<u>All other compensation \$(3)</u>	<u>Total (\$)</u>
Jose Baselga, M.D., Ph.D.	—	—	—	—
Douglas Cole, M.D. (4)	—	—	—	—
Simba Gill, Ph.D.	—	—	—	—
Cigall Kadoch, Ph.D.	—	—	\$ 225,000	\$225,000
Adam Koppel, M.D., Ph.D.	—	—	—	—
Michael Mendelsohn, M.D.	—	—	—	—

- (1) As of December 31, 2019, Dr. Kadoch held 790,694 unvested restricted shares of our common stock.
- (2) As of December 31, 2019, each of Drs. Baselga, Koppel, and Mendelsohn held an option to purchase 94,594 shares of our common stock and Dr. Gill held an option to purchase 189,188 shares of our common stock.
- (3) The amount reported in this column represents consulting fees earned by Dr. Kadoch in fiscal year 2019.
- (4) Directors who are affiliated with our investors did not receive compensation in respect of their service as members of our board of directors during fiscal year 2019.

### **Director Compensation**

Each of Drs. Baselga, Gill, Koppel, and Mendelsohn is party to a letter agreement with us that sets forth the terms and conditions of his service on our board of directors. In addition, each of Drs. Gill and Kadoch is party to a consulting agreement with us that sets forth the terms and conditions of the consulting services provided by the director.

*Drs. Baselga and Mendelsohn.* We entered into letter agreements with Drs. Baselga and Mendelsohn, each of which provided for the grant of an option to purchase 94,594 shares of our common stock, which option was immediately exercisable in full in exchange for the receipt of restricted shares. The restrictions on such restricted shares lapsed, pursuant to the terms of a stock restriction agreement, as to 25% of the underlying shares on the date of grant and as to 6.25% of the underlying shares on the first day of each calendar quarter thereafter, for the subsequent 12 calendar quarters, generally subject to the director's continued service on the board of directors through the applicable vesting date. Each letter agreement also contains a perpetual confidentiality obligation.

*Dr. Gill.* We entered into a letter agreement with Dr. Gill, which provided for the grant of an option to purchase 94,594 shares of our common stock, which vested as to 25% of the underlying shares on July 25, 2018, and as to

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6.25% of the underlying shares on the first day of each calendar quarter thereafter, for the subsequent 12 calendar quarters, generally subject to continued service with us through the applicable vesting date. The letter agreement also contains a perpetual confidentiality obligation.

In addition, we entered into a consulting agreement with Dr. Gill, which provides for a grant of an option to purchase 94,594 shares of our common stock in respect of Dr. Gill's consulting services, which vested as to 25% of the underlying shares on July 25, 2018, and as to 6.25% of the underlying shares on the first day of each calendar quarter thereafter, for the subsequent 12 calendar quarters, generally subject to continued service with us through the applicable vesting date. The consulting agreement also contains a perpetual confidentiality obligation and provides for the assignment of intellectual property.

*Dr. Kadoch.* We entered into a consulting agreement with Dr. Kadoch, which provided for an initial consulting fee of \$150,000 per year in respect of Dr. Kadoch's consulting services. Beginning in 2019, Dr. Kadoch's consulting fee was increased to \$225,000. Pursuant to the terms of the consulting agreement, Dr. Kadoch has agreed to a 10-year post-termination obligation of confidentiality, an assignment of intellectual property covenant, and not to compete with us or solicit our customers, business partners, employees or independent contractors during the term of the consulting agreement and for 12 months thereafter. We also entered into a stock restriction agreement with Dr. Kadoch providing for the grant of 3,953,469 restricted shares of our common stock, which vested in full as of October 1, 2020.

*Dr. Koppel.* We entered into a letter agreement with Dr. Koppel, which provided for the grant of an option to purchase 94,594 shares of our common stock, which option was immediately exercisable in full in exchange for the receipt of restricted shares. The restrictions on such restricted shares lapsed, pursuant to the terms of a stock restriction agreement, as to 25% of the underlying shares on July 19, 2018, and as to 6.25% of the underlying shares on the first day of each calendar quarter thereafter, for the subsequent 12 calendar quarters, generally subject to continued service on the board of directors through the applicable vesting date. The letter agreement also contains a perpetual confidentiality obligation.

### ***Director Compensation Policy***

In connection with this offering, our board of directors adopted a non-employee director compensation policy. Under the non-employee director compensation policy, our non-employee directors will be compensated as follows following this offering:

- each non-employee director will receive an annual cash fee of \$35,000 (\$65,000 for the chair of our board of directors);
- each non-employee director who is a member of the audit committee will receive an additional annual cash fee of \$7,500 (\$15,000 for the audit committee chair);
- each non-employee director who is a member of our compensation committee will receive an additional annual cash fee of \$5,000 (\$10,000 for our compensation committee chair);
- each non-employee director who is a member of the nominating and corporate governance committee will receive an additional annual cash fee of \$4,000 (\$8,000 for the nominating and corporate governance committee chair);
- each non-employee director who is first elected or appointed to our board of directors after the completion of this offering will be granted an option under the Foghorn Therapeutics Inc. 2020 Equity

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Incentive Plan, or the 2020 Plan, to purchase 25,060 shares of our common stock (but in no event will a non-employee director's initial grant have a grant date fair value, determined in accordance with FASB ASC 718, that exceeds \$600,000); and

- each non-employee director who has served as a member of our board of directors for at least a six-month period prior to the first meeting of our board of directors following the annual meeting of our stockholders will annually be granted an option under the 2020 Plan to purchase 12,530 shares of our common stock (but in no event will a non-employee director's annual grant have a grant date fair value, determined in accordance with FASB ASC 718, that exceeds \$300,000).

The stock options granted to our non-employee directors will have a per share exercise price at least equal to the fair market value of a share of our common stock on the date of grant and will expire not later than ten years after the date of grant. The stock option granted to a non-employee director upon his or her initial election to our board of directors will vest as to one-third of the underlying shares on each of the first three anniversaries of the date of grant, subject to such director's continued service on our board of directors. The annual stock options granted to our non-employee directors will vest in full on the first anniversary of the date of grant, subject to the director's continued service on our board of directors.

Each non-employee director is entitled to reimbursement for reasonable travel and other expenses incurred in connection with attending meetings of our board of directors and any committee on which he or she serves.

Pursuant to the terms of the 2020 Plan, the aggregate value of all compensation granted or paid to any director with respect to any calendar year, including awards granted under the 2020 Plan and cash fees or other compensation paid by us to such director outside of the 2020 Plan for his or her services as a director during such calendar year, is subject to a limit of \$750,000 in the aggregate (\$1,000,000 in the aggregate with respect to a director's first year of service on our board of directors).

## **Equity and Cash Plans**

### ***2016 Stock Incentive Plan***

In 2016, our board of directors adopted, and our stockholders approved, the 2016 Plan. The 2016 Plan has been amended from time to time to increase the aggregate number of shares of our common stock reserved for issuance under it, and was most recently amended on August 18, 2020. The 2016 Plan permits the grant of incentive stock options to our employees and the grant of nonqualified stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock-based awards to our employees, officers and directors, as well as consultants and advisors. Subject to adjustment, the maximum number of shares that may be granted under the 2016 Plan is 6,513,512. As of August 31, 2020, options to purchase 4,828,768 shares of our common stock were outstanding under the 2016 Plan and 338,287 shares remained available for future awards. Shares underlying awards that are terminated, surrendered or cancelled without having been exercised, that result in any common stock not being issued, or that are forfeited to or repurchased by the Company, and shares that are withheld in payment of an exercise price of an award or in satisfaction of tax withholding requirements, will become available for subsequent awards under the 2016 Plan. It is anticipated that no further awards will be made under the 2016 Plan following the completion of this offering. In connection with this offering, we intend to adopt a new omnibus equity incentive plan under which we will grant equity and equity-based awards following this offering, as described below under "2020 Equity Incentive Plan". This summary is not a complete description of all provisions of the 2016 Plan and is qualified in its entirety by reference to the 2016 Plan, which is filed as an exhibit to the registration statement of which this prospectus is part.

### ***Plan Administration***

Our board of directors, or a committee of our board of directors, administers the 2016 Plan. As used in this summary, the term "administrator" refers to our board of directors and its authorized delegate, as applicable. Subject to the provisions of the 2016 Plan, the administrator has the authority to, among other things, interpret

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the 2016 Plan, determine eligibility for and grant awards under the 2016 Plan, adopt, amend and repeal such administrative rules, guidelines and practices relating to the 2016 Plan as it shall deem advisable, and otherwise do all things necessary to carry out the purposes of the 2016 Plan.

### *Non-transferability of Awards*

The 2016 Plan generally does not allow for the transfer of awards and awards generally may be exercised only by the holder of an award during his or her lifetime.

### *Adjustments Upon Changes in Capitalization, Merger, or Certain Other Transactions*

The 2016 Plan provides that in the event of a stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of our common stock other than an ordinary cash dividend, the administrator will make equitable adjustments to the number and class of securities available under the 2016 Plan, the number and class of securities and exercise price per share of each outstanding stock option, the share and per-share provisions and the measurement price of each outstanding stock appreciation right, the number of shares subject to and the repurchase price per share subject to each outstanding restricted stock award, and the share and per-share-related provisions and the purchase price, if any, of each other outstanding stock-based award.

In the case of a reorganization event (which does not include this offering), except to the extent specifically provided otherwise in an award agreement or another agreement between us and the grantee, or with respect to restricted stock units as limited by the requirements of Section 409A of the Code, the administrator may provide for any one or more of the following as to all or any (or any portion of) outstanding awards, other than restricted stock awards: (i) the assumption or substitution of outstanding awards by the acquiring or succeeding corporation; (ii) the termination of unexercised awards immediately prior to the consummation of such reorganization event; (iii) the acceleration of vesting and exercisability, or the lapse of applicable restrictions, in whole or in part, prior to or upon such reorganization event; (iv) the cash-out of outstanding awards; (v) the conversion of outstanding awards into the right to receive liquidation proceeds, in connection with a liquidation or dissolution of the Company; and (vi) any combination of the foregoing.

With respect to restricted stock awards, upon the occurrence of a reorganization event other than a liquidation or dissolution of the Company, the repurchase and other rights we have with respect to outstanding restricted stock awards will inure to the benefit of our successor and apply to the cash, securities or other property into which the restricted stock was converted or for which it was exchanged in connection with such reorganization event, except to the extent otherwise provided by the administrator. Upon the occurrence of a reorganization event involving the liquidation or dissolution of the Company, except to the extent specifically provided otherwise in an award agreement or other agreement between us and the grantee, all restrictions and conditions on all restricted stock awards then outstanding will automatically be deemed terminated or satisfied.

### *Amendment and Termination*

The administrator may amend, suspend or terminate the 2016 Plan or any portion thereof at any time, subject to any required stockholder approval with respect to incentive stock options under Section 422 of the Code and provided that any such amendment will apply to then-outstanding awards only to the extent the administrator determines that such amendment does not materially and adversely affect the rights of the award holders. The administrator may also amend, modify or terminate any outstanding award, including by substituting another award of the same or different type, changing the date of exercise or realization, and converting an incentive stock option to a nonqualified stock option, provided that the award holder's consent will be required unless the administrator determines that such action does not materially and adversely affect the award holder's rights under the 2016 Plan.

### *Lock-Up*

Pursuant to the terms of the stock option award agreements under the 2016 Plan, the award holders have agreed not to offer, pledge, sell or otherwise transfer or dispose of any of our common stock or other securities, or enter into any swap or other agreement with the effect of transferring the economic consequences of ownership thereof, within the 180 days following the date of the final prospectus in connection with this offering, plus up to an additional 34 days to the extent requested by the managing underwriters of this offering in order to address certain listing rules.

### *2020 Equity Incentive Plan*

In connection with this offering, our board of directors adopted the 2020 Plan, and, in connection with and following this offering, all equity-based awards will be granted under the 2020 Plan. The following summary describes what we expect to be the material terms of the 2020 Plan. This summary is not a complete description of all provisions of the 2020 Plan and is qualified in its entirety by reference to the 2020 Plan, which is filed as an exhibit to the registration statement of which this prospectus is a part. In connection with this offering, our board of directors expects to grant options to purchase an aggregate of approximately 45,945 shares of our common stock to certain non-executive employees. These options will generally vest as to 25% of the underlying shares on the first anniversary of the vesting commencement date and in quarterly installments thereafter, such that they will become fully vested on the fourth anniversary of the vesting commencement date, generally subject to the individual's continued employment with us through the applicable vesting date. These options will have a per share exercise price equal to the initial public offering price.

### *Purpose*

The purpose of the 2020 Plan is to advance our interests by providing for the grant to our employees, directors and consultants of stock and stock-based awards.

### *Plan Administration*

The 2020 Plan will be administered by our compensation committee, except with respect to matters that are not delegated to our compensation committee by our board of directors. Our compensation committee (or our board of directors, as applicable) will have the discretionary authority to interpret the 2020 Plan and any awards granted under it, determine eligibility for and grant awards, determine the exercise price, base value from which appreciation is measured or purchase price, if any, applicable to any award, determine, modify, accelerate and waive the terms and conditions of any award, determine the form of settlement of any award, prescribe forms, rules and procedures relating to the 2020 Plan and awards and otherwise do all things necessary or desirable to carry out the purposes of the 2020 Plan or any award. Our compensation committee may delegate such of its duties, powers and responsibilities as it may determine to one or more of its members, members of our board of directors and, to the extent permitted by law, our officers, and may delegate to employees and other persons such ministerial tasks as it deems appropriate. As used in this summary, the term "Administrator" refers to our compensation committee and its authorized delegates, as applicable.

### *Eligibility*

Our employees, directors, consultants and advisors are eligible to participate in the 2020 Plan. Eligibility for stock options intended to be incentive stock options, or ISOs, is limited to our employees or employees of certain affiliates. Eligibility for stock options, other than ISOs, and stock appreciation rights, or SARs, is limited to individuals who are providing direct services to us or certain affiliates on the date of grant of the award.

### *Authorized Shares*

Subject to adjustment as described below, the maximum number of shares of our common stock that may be delivered in satisfaction of awards under the 2020 Plan is (i) 2,200,000 shares (the "share pool"), plus (ii) the

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number of shares of our common stock available for issuance under the 2016 Plan as of the date the 2020 Plan is adopted, plus the number of shares of our 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 by, us, 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). 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 our board of directors on or prior to such date for such year. Up to 4,000,000 shares may be delivered in satisfaction of ISOs. The number of shares of our common stock delivered in satisfaction of awards under the 2020 Plan is determined (i) by excluding shares withheld by us in payment of the exercise price or purchase price of the award or in satisfaction of tax withholding requirements with respect to the award, (ii) by including only the number of shares delivered in settlement of a SAR that is settled in shares of our common stock, and (iii) by excluding any shares underlying awards settled in cash or that expire, become unexercisable, terminate or are forfeited to or repurchased by us without the delivery of shares of our common stock (or retention, in the case of restricted stock or unrestricted stock). The number of shares available for delivery under the 2020 Plan will not be increased by any shares that have been delivered under the 2020 Plan and are subsequently repurchased using proceeds directly attributable to stock option exercises.

Shares that may be delivered under the 2020 Plan may be authorized but unissued shares, treasury shares or previously issued shares acquired by us.

### *Types of Awards*

The 2020 Plan provides for the grant of stock options, SARs, restricted and unrestricted stock and stock units, performance awards and other awards that are convertible into or otherwise based on our common stock. Dividend equivalents may also be provided in connection with awards under the 2020 Plan.

- *Stock options and SARs.* The Administrator may grant stock options, including ISOs, and SARs. A stock option is a right entitling the holder to acquire shares of our common stock upon payment of the applicable exercise price. A SAR is a right entitling the holder upon exercise to receive an amount (payable in cash or shares of equivalent value) equal to the excess of the fair market value of the shares subject to the right over the base value from which appreciation is measured. The exercise price per share of each stock option, and the base value of each SAR, granted under the 2020 Plan will be no less than 100% of the fair market value of a share on the date of grant (110% in the case of certain ISOs). Other than in connection with certain corporate transactions or changes to our capital structure, stock options and SARs granted under the 2020 Plan may not be repriced, amended, or substituted for with new stock options or SARs having a lower exercise price or base value, nor may any consideration be paid upon the cancellation of any stock options or SARs that have a per share exercise or base price greater than the fair market value of a share on the date of such cancellation, in each case, without shareholder approval. Each stock option and SAR will have a maximum term of not more than ten years from the date of grant (or five years, in the case of certain ISOs).
- *Restricted and unrestricted stock and stock units.* The Administrator may grant awards of stock, stock units, restricted stock and restricted stock units. A stock unit is an unfunded and unsecured promise, denominated in shares, to deliver shares or cash measured by the value of shares in the future, and a restricted stock unit is a stock unit that is subject to the satisfaction of specified performance or other vesting conditions. Restricted stock are shares subject to restrictions requiring that they be forfeited, redelivered or offered for sale to us if specified performance or other vesting conditions are not satisfied.
- *Performance awards.* The Administrator may grant performance awards, which are awards subject to the achievement of performance criteria.
- *Other share-based awards.* The Administrator may grant other awards that are convertible into or otherwise based on shares of our common stock, subject to such terms and conditions as it determines.

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- *Substitute awards.* The Administrator may grant substitute awards in connection with certain corporate transactions, which may have terms and conditions that are different from the terms and conditions of the 2020 Plan.

### *Director Limits*

The aggregate value of all compensation granted or paid to any director with respect to any calendar year, including awards granted under the 2020 Plan and cash fees or other compensation paid by us to such director outside of the 2020 Plan for his or her services as a director during such calendar year (which, for the avoidance of doubt, will not include compensation granted or paid to a director for services other than as a director, including, without limitation, for services as a consultant or adviser to the company), is subject to a limit of \$750,000 in the aggregate (\$1,000,000 in the aggregate with respect to a director's first year of service on our board of directors).

### *Vesting; Terms of Awards*

The Administrator determines the terms and conditions of all awards granted under the 2020 Plan, including the time or times an award vests or becomes exercisable, the terms and conditions on which an award remains exercisable, and the effect of termination of a participant's employment or service on an award. The Administrator may at any time accelerate the vesting or exercisability of an award.

### *Non-transferability of Awards*

Except as the Administrator may otherwise determine, awards may not be transferred other than by will or by the laws of descent and distribution.

### *Adjustments Upon Certain Covered Transactions*

In the event of certain covered transactions (including the consummation of a consolidation, merger or similar transaction, the sale of all or substantially all of our assets or shares of our common stock, or our dissolution or liquidation), the Administrator may, with respect to outstanding awards, provide for (in each case, on such terms and subject to such conditions as it deems appropriate):

- The assumption, substitution or continuation of some or all awards (or any portion thereof) by the acquiror or surviving entity;
- The acceleration of exercisability or delivery of shares in respect of any award, in full or in part; and/or
- The cash payment in respect of some or all awards (or any portion thereof) equal to the difference between the fair market value of the shares subject to the award and its exercise or base price, if any.

Except as the Administrator may otherwise determine, each award will automatically terminate or be forfeited immediately upon the consummation of the covered transaction, other than awards that are substituted for, assumed, or that continue following the covered transaction.

### *Adjustments Upon Changes in Capitalization*

In the event of certain corporate transactions, including a stock dividend, stock split or combination of shares (including a reverse stock split), recapitalization or other change in our capital structure, the Administrator shall make appropriate adjustments to the maximum number of shares that may be delivered under the 2020 Plan, the number and kind of securities subject to, and, if applicable, the exercise or purchase prices (or base values) of outstanding awards, and any other provisions affected by such event.

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### *Recovery of Compensation*

The Administrator may provide that any outstanding award, the proceeds of any award or shares acquired thereunder and any other amounts received in respect of any award or shares acquired thereunder will be subject to forfeiture and disgorgement to us, with interest and other related earnings, if the participant to whom the award was granted is not in compliance with any provision of the 2020 Plan or any award, any non-competition, non-solicitation, no-hire, non-disparagement, confidentiality, invention assignment or other restrictive covenant, or any Company policy that relates to trading on non-public information and permitted transactions with respect to shares of our common stock or provides for forfeiture, disgorgement or clawback, or as otherwise required by law or applicable stock exchange listing standards.

### *Amendment and Termination*

The Administrator may at any time amend the 2020 Plan or any outstanding award and may at any time terminate the 2020 Plan as to future awards. However, except as expressly provided in the 2020 Plan, the Administrator may not alter the terms of an award so as to materially and adversely affect a participant's rights without the participant's consent (unless the Administrator expressly reserved the right to do so in the 2020 Plan or at the time the award was granted). Any amendments to the 2020 Plan will be conditioned on shareholder approval to the extent required by applicable law or stock exchange requirements.

### **2020 Employee Stock Purchase Plan**

In connection with this offering, our board of directors adopted the Foghorn Therapeutics Inc. 2020 Employee Stock Purchase Plan (the "ESPP"). The following summary describes what we expect to be the material terms of the ESPP. This summary is not a complete description of all provisions of the ESPP and is qualified in its entirety by reference to the ESPP, which is filed as an exhibit to the registration statement of which this prospectus is a part.

#### *Purpose*

The purpose of the ESPP is to enable eligible employees of us and our participating subsidiaries to use payroll deductions to purchase shares of our common stock, and thereby acquire an interest in us. The ESPP is intended to qualify as an "employee stock purchase plan" under Section 423 of the Code.

#### *Plan Administration*

The ESPP will be administered by our compensation committee, which will have the discretionary authority to interpret the ESPP, determine eligibility under the ESPP, prescribe forms, rules and procedures relating to the ESPP, and otherwise do all things necessary or desirable to carry out the purposes of the ESPP. Our compensation committee may delegate such of its duties, powers and responsibilities as it may determine to one or more of its members, members of our board of directors and our officers and employees, in each case, to the extent permitted by law. As used in this summary, the term "Administrator" refers to our compensation committee and its authorized delegates, as applicable.

#### *Shares Subject to the ESPP*

Subject to adjustment as described below, the aggregate number of shares of our 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 our common stock outstanding as of the close of business on the immediately preceding December 31 and (ii) the number of shares determined by our board of directors on or prior to such date for such year (up to a maximum of 3,220,520 shares). Shares to be delivered upon exercise of options under the ESPP may be authorized but unissued shares, treasury shares, or previously issued shares acquired by us. If any option granted under the

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ESPP expires or terminates for any reason without having been exercised in full or ceases for any reason to be exercisable in whole or in part, the unpurchased shares subject to such option will again be available for purchase under the ESPP.

### *Eligibility*

Participation in the ESPP generally will be limited to our employees and employees of our subsidiaries who satisfy the requirements for eligibility as set forth in the ESPP. The Administrator may establish additional or other eligibility requirements, or change the requirements described in this paragraph, to the extent consistent with Section 423 of the Code. Any employee who owns (or is deemed under statutory attribution rules to own) shares possessing five percent or more of the total combined voting power or value of all classes of shares of us or our parent or subsidiaries, if any, will not be eligible to participate in the ESPP.

### *General Terms of Participation*

The ESPP allows eligible employees to purchase shares of our common stock during specified offering periods. Unless otherwise determined by the Administrator, offering periods under the ESPP will be six months in duration and commence on the first business day of January and July of each year. During each offering period, eligible employees will be granted an option to purchase shares of our common stock on the last business day of the offering period. A participant may purchase a maximum of 1,500 shares with respect to any offering period (or such lesser number as the Administrator may prescribe). No participant will be granted an option under the ESPP that permits the participant's right to purchase shares of our common stock under the ESPP and under all other employee stock purchase plans of us or our parent or subsidiaries, if any, to accrue at a rate that exceeds \$25,000 in fair market value (or such other maximum as may be prescribed by the Code) for each calendar year during which any option granted to the participant is outstanding at any time, determined in accordance with Section 423 of the Code.

The purchase price of each share issued pursuant to the exercise of an option under the ESPP on an exercise date will be 85% (or such greater percentage as specified by the Administrator) of the lesser of: (i) the fair market value of a share of our common stock on the date the option is granted, which will be the first day of the offering period; and (ii) the fair market value of a share of our common stock on the exercise date, which will be the last business day of the offering period.

The Administrator has the discretion to change the commencement and exercise dates of offering periods, the purchase price, the maximum number of shares that may be purchased with respect to any offering period, the duration of any offering periods and other terms of the ESPP, in each case, without shareholder approval, except as required by law.

Participants in the ESPP will pay for shares purchased under the ESPP through payroll deductions. Participants may elect to authorize payroll deductions between one and fifteen percent of the participant's eligible compensation each payroll period.

### *Transfer Restrictions*

Shares of our common stock purchased under our ESPP may not be transferred, sold, pledged or alienated by a participant, other than by will or by the laws of descent and distribution, for a period of six months following the date on which such shares were purchased, or such other period as may be determined by the Administrator.

### *Adjustments Upon Certain Covered Transactions*

In the event of a (i) sale of all or substantially all of our then-outstanding common stock or a sale of all or substantially all of our assets, or (ii) merger or similar transaction in which we are not the surviving corporation or which results in the acquisition of us by another person, the Administrator may provide that each outstanding

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option will be assumed or substituted for or will be cancelled and the balances of participants' accounts returned, or that the option period will end before the date of the proposed corporate transaction.

### *Adjustments Upon Changes in Capitalization*

In the event of a stock dividend, stock split or combination of shares (including a reverse stock split), recapitalization, or other change in our capital structure that constitutes an equity restructuring, the Administrator will make appropriate adjustments to the aggregate number and type of shares available for purchase under the ESPP, the number and type of shares granted under any outstanding options, the maximum number and type of shares purchasable under any outstanding option and/or the purchase price per share under any outstanding option.

### *Amendment and Termination*

The Administrator has discretion to amend the ESPP to any extent and in any manner it may deem advisable, provided that any amendment that would be treated as the adoption of a new plan for purposes of Section 423 of the Code will require shareholder approval. The Administrator may suspend or terminate the ESPP at any time.

### **2020 Cash Incentive Plan**

In connection with this offering, our board of directors adopted the Foghorn Therapeutics Inc. 2020 Cash Incentive Plan, or the Cash Incentive Plan. The Cash Incentive Plan will provide for the grant of cash-based incentive awards to our executive officers and key employees. The following summary describes what we expect to be the material terms of the Cash Incentive Plan. This summary is not a complete description of all provisions of the Cash Incentive Plan and is qualified in its entirety by reference to the Cash Incentive Plan, which is filed as an exhibit to the registration statement of which this prospectus is a part.

### *Plan Administration*

The Cash Incentive Plan will be administered by our compensation committee and its delegates. As used in this summary, the term "Administrator" refers to our compensation committee and its authorized delegates, as applicable.

The Administrator will have the discretionary authority to interpret the Cash Incentive Plan and any awards; determine eligibility for and grant awards; adjust the performance criterion or criteria applicable to awards; determine, modify or waive the terms and conditions of any award; prescribe forms, rules and procedures relating to the Cash Incentive Plan and awards, and otherwise do all things necessary or desirable to carry out the purposes of the Cash Incentive Plan.

### *Eligibility*

Executive officers and key employees of us and our subsidiaries will be eligible to participate in the Cash Incentive Plan and will be selected from time to time by the Administrator to participate in the Cash Incentive Plan.

### *Awards; Performance Criteria*

Awards under the Cash Incentive Plan will be made based on, and subject to achieving, specified criteria established by the Administrator. For each award granted under the Cash Incentive Plan, the Administrator will establish the performance criteria applicable to the award, the amount or amounts payable if the performance criteria are achieved and such other terms and conditions as the Administrator deems appropriate.

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### *Payments Under an Award*

A participant will be entitled to payment under an award only if all conditions to payment have been satisfied in accordance with the Cash Incentive Plan and the terms of the award. Following the end of a performance period, the Administrator will determine whether and to what extent the applicable performance criteria have been satisfied and will determine the amount payable under each award. The Administrator has the discretionary authority to increase or decrease the amount actually paid under any award.

### *Recovery of Compensation*

Payments in respect of an award will be subject to forfeiture and disgorgement to us if the participant violates a non-competition, non-solicitation, confidentiality or other restrictive covenant or to the extent provided in any applicable Company policy that provides for forfeiture or disgorgement, or as otherwise required by law or applicable stock exchange listing standards.

### *Amendment and Termination*

The Administrator may amend the Cash Incentive Plan or any outstanding award for any purpose, and may at any time terminate the Cash Incentive Plan as to any future grant of awards.

**CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS**

The following is a summary of transactions since January 1, 2017 to which we have been a party in which the amount involved exceeded \$120,000 and in which any of our executive officers, directors, promoters or beneficial holders of more than 5% of our capital stock had or will have a direct or indirect material interest, other than compensation arrangements which are described under the section of this prospectus captioned “Executive and Director Compensation.”

**Equity Financings****Series A-2 Convertible Preferred Stock**

In April 2017, we completed the sale of an aggregate of 10,804,165 shares of our Series A-2 convertible preferred stock at a purchase price of \$1.50 per share for an aggregate purchase price of \$16,206,247.50. Each share of our A-2 convertible preferred stock will convert into 0.5405 (when rounded to the nearest ten-thousandth) shares of our common stock upon the closing of this offering.

The following table summarizes purchases of shares of our Series A-2 convertible preferred stock by holders of more than 5% of our capital stock and entities affiliated with our executive officers and members of our board of directors.

<b>Name of Stockholder</b>	<b>Director(s)/Executive Officer(s)</b>	<b>Number of series A-2 convertible preferred stock</b>	<b>Approximate purchase price</b>
Funds affiliated with Flagship Pioneering, Inc.	Douglas Cole, M.D.	8,333,333	\$ 12,500,000
Klarman Family Foundation	Not applicable	2,083,333	\$ 3,125,000
Adrian H. Gottschalk Living Trust	Adrian Gottschalk	33,333	\$ 50,000

**Series B Convertible Preferred Stock**

In December 2018, we completed the sale of an aggregate of 6,077,629 shares of our Series B convertible preferred stock, of which 669,625 shares were issued upon conversion of a Convertible Promissory Note held by Flagship Ventures Fund V, L.P., at a purchase price of \$7.50 per share for an aggregate purchase price of \$45,582,217.50. We completed an additional closing in January 2019, with the sale of an additional aggregate of 2,040,002 shares of our Series B convertible preferred stock for an aggregate purchase price of \$15,300,015.00. In 2020, we completed additional closings for an additional aggregate of 12,007,867 shares of our Series B convertible preferred stock for an aggregate purchase price of \$90,059,002.50. Each share of our Series B convertible preferred stock will convert into 0.5405 (when rounded to the nearest ten-thousandth) shares of our common stock upon the closing of this offering.

The following table summarizes purchases of shares of our Series B convertible preferred stock by holders of more than 5% of our capital stock and entities affiliated with our executive officers and members of our board of directors.

<b>Name of Stockholder</b>	<b>Director(s)/Executive Officer(s)</b>	<b>Number of series B convertible preferred stock</b>	<b>Approximate purchase price</b>
Funds affiliated with Flagship Pioneering, Inc.	Douglas Cole, M.D.	7,336,292	\$ 55,022,190
Adrian H. Gottschalk Living Trust	Adrian Gottschalk	13,334	\$ 100,005

**Flagship Service Agreement**

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

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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 \$0.4 million and \$0.6 million during the six months ended June 30, 2019 and 2020, respectively. As of December 31, 2019, the Company had no accounts payable to Flagship related to this service agreement. At June 30, 2020, the Company had less than \$0.1 million in accounts payable to Flagship for costs related to the service agreement. Our director who is affiliated with Flagship Pioneering is set forth in the table above.

### **Consulting Agreement with Cigall Kadoch, Ph.D.**

In October 2015, we entered into a consulting agreement with Cigall Kadoch, Ph.D., our academic co-founder and a member of our board of directors, pursuant to which Dr. Kadoch provides advisory services related to the manufacturing and sale of products and services related to chromatin remodeling. Under the terms of the consulting agreement, Dr. Kadoch received a grant of 3,953,469 shares of our common stock. Additionally, we agreed to pay Dr. Kadoch a consulting fee of \$150,000 per year payable in monthly installments in arrears beginning with the effective date of the consulting agreement, and we agreed to reimburse her for reasonable business expenses incurred in connection with the performance of the services under the agreement. In January 2019, we agreed to increase the consulting fee payable to Dr. Kadoch to \$225,000 per year, payable in monthly installments in arrears.

### **Investor Rights Agreement**

We are party to an amended and restated investor rights agreement, or the Investor Rights Agreement, with each holder of our convertible preferred stock, which includes each holder of more than 5% of our capital stock and certain of our directors (or, in some cases, entities affiliated therewith). The Investor Rights Agreement imposes certain affirmative obligations on us, and also grants certain rights to the holders, including certain registration rights with respect to the registrable securities held by them. See "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights. Other provisions of the Investor Rights Agreement will terminate upon completion of this offering.

### **Voting Agreement**

We are party to an Amended and Restated Voting Agreement, dated as of December 18, 2018, or the Voting Agreement, with the Flagship Funds, and certain of our other stockholders, pursuant to which the following directors were elected to serve as members on our board of directors and, as of the date of this prospectus, continue to so serve: Dr. Cole, Dr. Kadoch, Mr. Gottschalk, Dr. Baselga, Dr. Gill, Dr. Koppel, and Dr. Mendelsohn.

The Amended and Restated Voting Agreement will terminate upon the closing of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by the holders of our common stock. The composition of our board of directors after this offering is described in more detail under "Management—Composition of the Board of Directors."

### **Director and Officer Indemnification and Insurance**

We have agreed to indemnify each of our directors and executive officers against certain liabilities, costs and expenses, and have purchased directors' and officers' liability insurance. We also maintain a general liability insurance policy which covers certain liabilities of directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

### **Related Person Transaction Policy**

Our board of directors intends to adopt a written related person transaction policy, to be effective upon the effectiveness of the registration statement of which this prospectus forms a part, setting forth the policies and

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procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, or the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds \$120,000 in any fiscal year and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked with considering all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

## PRINCIPAL STOCKHOLDERS

The following table sets forth certain information with respect to the beneficial ownership of our common stock at August 31, 2020, as adjusted to reflect the sale of common stock offered by us in this offering, for:

- each person who we know beneficially owns more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, a person is deemed to be a “beneficial” owner of a security if that person has or shares voting power or investment power, which includes the power to dispose of or to direct the disposition of such security. Except as indicated in the footnotes below, we believe, based on the information furnished to us, that the individuals and entities named in the table below have sole voting and investment power with respect to all shares of common stock beneficially owned by them, subject to any applicable community property laws.

The following table does not reflect any shares of common stock that may be purchased pursuant to our directed share program described under “Underwriting—Directed Share Program.”

Percentage ownership of our common stock before this offering is based on 28,194,802 shares of our common stock outstanding as of August 31, 2020, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 21,958,588 shares of our common stock immediately prior to the closing of this offering, assuming an initial public offering price of \$16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus. Percentage ownership of our common stock after this offering is based on shares of our common stock outstanding as of August 31, 2020, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock as described above and our issuance of 7,500,000 shares of our common stock in this offering. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or that will become exercisable within 60 days of August 31, 2020, are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless noted otherwise, the address of all listed stockholders is 500 Technology Square, Ste 700 Cambridge MA 02139.

Name of Beneficial Owner	Number of shares beneficially owned	Percentage of shares beneficially owned	
		Before Offering	After Offering
<b>5% or greater stockholders</b>			
Funds affiliated with Flagship Pioneering, Inc. (1)	12,524,120	44.42%	35.09%
Klarman Family Foundation (2)	2,139,639	7.59%	5.99%
<b>Directors and Named Executive Officers</b>			
Adrian Gottschalk (3)	927,134	3.23%	2.56%
Douglas G. Cole, M.D. (4)	—	—	—%
José Baselga, M.D., Ph.D.	94,594	*	*%
Scott Biller, Ph.D.	—	—	—%
Balkrishan (Simba) Gill, Ph.D. (5)	153,714	*	*%
Cigall Kadoch, Ph.D.	3,957,712	14.04%	11.09%
Adam M. Koppel, M.D., Ph.D. (6)	94,594	*	*%
Michael Mendelsohn, M.D. (7)	94,594	*	*%
Samuel Agresta, M.D., M.P.H. & T.M. (8)	97,280	*	*%
Carl P. Decicco, Ph.D. (9)	282,170	*	*%
All executive officers and directors as a group (11 persons) (10)	5,799,072	19.83%	15.78%

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\* Less than 1%

- (1) Consists of 9,280,878 shares of common stock issuable upon the conversion of 7,500,000 shares of Series A-1 convertible preferred stock, 8,333,333 shares of Series A-2 convertible preferred stock, and 1,336,293 shares of Series B convertible preferred stock held by Flagship Ventures Fund V, L.P. (“Flagship Fund V”); (ii) 1,441,441 shares of common stock issuable upon conversion of 2,666,666 shares of Series B convertible preferred stock held by Flagship Ventures Opportunities Fund I, L.P. (“Flagship Opportunities Fund I”); and (iii) 1,801,801 shares of common stock issuable upon conversion of 3,333,333 shares of Series B convertible preferred stock held by Flagship Pioneering Special Opportunities Fund II, L.P. (“Flagship Opportunities Fund II,” and together with Flagship Opportunities Fund I and Flagship Fund V, the “Flagship Funds”). Flagship Ventures Fund V General Partner LLC (“Fund V GP”) is the general partner of Flagship Fund V. Flagship Ventures Opportunities Fund I General Partner LLC (“Opportunities Fund I GP”) is the general partner of Flagship Opportunities Fund I. Flagship Ventures Opportunities Fund II General Partner LLC (“Opportunities Fund II GP”) is the general partner of Flagship Opportunities Fund II. Flagship Pioneering, Inc. (“Flagship Pioneering” and together with Opportunities Fund I GP, Opportunities Fund II GP, and Fund V GP, the “Flagship General Partners”) is the manager of Opportunities Fund II GP. Noubar B. Afeyan, Ph.D. is sole director of Flagship Pioneering and may be deemed to have sole voting and investment control over all shares held by Opportunities Fund II. In addition, Noubar B. Afeyan Ph.D. serves as the sole manager of Fund V GP and Opportunities Fund I GP and may be deemed to possess sole voting and investment control over all the shares held by Flagship Fund V and Opportunities Fund I. Neither Noubar B. Afeyan Ph.D. or the Flagship General Partners directly own any of the shares held by the Flagship Funds and each of the Flagship General Partners and Noubar B. Afeyan Ph.D. disclaims beneficial ownership of such shares except to the extent of his or its pecuniary interest therein. The mailing address of the Flagship Funds is 55 Cambridge Parkway, Suite 800E, Cambridge, Massachusetts 02142.
- (2) Consists of 2,139,639 shares of common stock issuable upon the conversion of 1,875,000 shares of Series A-1 convertible preferred stock and 2,083,333 shares of Series A-2 convertible preferred stock held by the Klarman Family Foundation. The mailing address for the Klarman Family Foundation is P.O. Box 171627, Boston, Massachusetts 02117.
- (3) Consists of 25,225 shares of common stock issuable upon the conversion of (i) 33,333 Series A-2 convertible preferred stock held by the Adrian Gottschalk Trust, of which Mr. Gottschalk is the trustee, (ii) 13,334 shares of Series B convertible preferred stock held by the Adrian H. Gottschalk Living Trust dated September 8, 2009, of which Mr. Gottschalk is the trustee, and (iii) 423,479 shares of common stock and options to purchase 478,430 shares of common stock that are exercisable within 60 days of August 31, 2020 held directly by Mr. Gottschalk.
- (4) Dr. Cole is a managing partner of Flagship Pioneering but has no voting or investment power with respect to the securities described in footnote 1.
- (5) Consists of options to purchase 153,714 shares of common stock that are exercisable within 60 days of August 31, 2020.
- (6) Consists of options to purchase 94,594 shares of common stock that are exercisable within 60 days of August 31, 2020.
- (7) Consists of options to purchase 94,594 shares of common stock that are exercisable within 60 days of August 31, 2020.
- (8) Consists of options to purchase 97,280 shares of common stock that are exercisable within 60 days of August 31, 2020.
- (9) Includes options to purchase 36,128 shares of common stock that are exercisable within 60 days of August 31, 2020.
- (10) Includes options to purchase an aggregate of 1,052,020 shares of common stock exercisable within 60 days of August 31, 2020.

## DESCRIPTION OF CAPITAL STOCK

### Capital Structure

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated by-laws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated by-laws that will be in effect upon the closing of this offering. Copies of these documents will be filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of our common stock and preferred stock reflect changes to our capital structure that will occur upon the closing of this offering.

### General

Upon completion of this offering, our authorized capital stock will consist of 200,000,000 shares, all with a par value of \$0.0001 per share, of which:

- 175,000,000 shares are designated as common stock; and
- 25,000,000 shares are designated as preferred stock.

### Common Stock

As of August 31, 2020, we had outstanding 6,236,214 shares of common stock held of record by 45 stockholders.

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, and the shares offered by us in this offering will be, when issued and paid for, 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

As of August 31, 2020 there were 40,623,413 shares of our convertible preferred stock outstanding. Upon the closing of this offering, all outstanding shares of our convertible preferred stock will convert into 21,958,588 shares of our common stock.

Under the terms of our amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering, 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

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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. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

### **Options**

As of August 31, 2020, options to purchase 4,828,768 shares of our common stock were outstanding under our 2016 Plan, of which 1,177,911 options were vested as of that date.

### **Registration Rights**

The Investor Rights Agreement grants the parties thereto certain registration rights in respect of the “registrable securities” held by them, which securities include (i) the shares of our common stock issuable or issued upon conversion of our preferred stock; (ii) any common stock held by investors party to the Investor Rights Agreement at the time of this offering; (iii) any common stock issued or issuable, directly or indirectly, upon conversion and/or exercise of any of our other securities held by the investors party to the Investor Rights Agreement at the time of this offering; and (iv) any common stock issued as, or issuable upon the conversion or exercise of any warrant, right, or other security that is issued as, a dividend or other distribution with respect to, or in exchange for or in replacement of, the securities in clauses (i), (ii) and (iii) above. The registration of shares of our common stock pursuant to the exercise of these registration rights would enable the holders thereof to sell such shares without restriction under the Securities Act when the applicable registration statement is declared effective. Under the Investor Rights Agreement, we will pay all expenses relating to such registrations, including the fees of one counsel for the participating holders, and the holders will pay all underwriting discounts and commissions relating to the sale of their shares. The Investor Rights Agreement also includes customary indemnification and procedural terms.

Holders of 21,958,588 shares of our common stock (including shares issuable upon the conversion of our convertible preferred stock) are entitled to such registration rights pursuant to the Investor Rights Agreement. These registration rights will expire on the earlier of (i) immediately before the closing of a deemed liquidation event, as defined in the Investor Rights Agreement; (ii) such time after this offering as SEC Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such holder’s shares without limitation during a three-month period without registration; and (iii) the fifth anniversary of this offering.

### ***Demand Registration Rights***

At any time beginning 180 days after the effective date of the registration statement of which this prospectus forms a part, the holders of not less than a majority of the registrable securities then outstanding may request that we file a registration statement on Form S-1 with respect to all requested registrable securities held by such holders, if the aggregate offering price of the registrable securities requested to be registered is expected to exceed \$10.0 million.

Once we are eligible to use a registration statement on Form S-3, the holders of not less than 30% of the registrable shares then outstanding may request that we file a registration statement on Form S-3 with respect to such holders’ registrable securities then outstanding, if the aggregate offering price of the registrable securities requested to be registered would exceed \$5.0 million.

### ***Piggyback Registration Rights***

In the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the stockholders party to the Investor Rights Agreement will be

entitled to certain “piggyback” registration rights allowing them to include their registrable securities in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act other than with respect to a demand registration or a registration statement on Form S-4 or S-8, these holders will be entitled to notice of the registration and will have the right to include their registrable securities in the registration subject to certain limitations.

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

Our certificate of incorporation and by-laws will contain 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 will provide 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 will be elected each year. The classification of directors will have the effect of making it more difficult for stockholders to change the composition of our board. Our certificate of incorporation will also provide 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. Upon completion of this offering, we expect that our board of directors will have members.

*Action by written consent; special meetings of stockholders.* Our certificate of incorporation will provide 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 will also provide 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 will not be 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 will provide 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 will 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 will only be 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 will 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 will provide that the affirmative vote of holders of at least 75% of the

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total votes eligible to be cast in the election of directors will be 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 will be 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 will require, 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**

Upon completion of this offering, we will be 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.

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**Transfer Agent and Registrar**

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

**Listing**

We have applied to have our common stock approved for listing on the Nasdaq Global Market under the symbol “FHTX.”

## SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock, and no predictions can be made about the effect, if any, that market sales of our common stock or the availability of such shares for sale will have on the market price prevailing from time to time. Nevertheless, future sales of our common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock and could impair our ability to raise capital through future sales of our securities. See “Risk Factors—Risks Related to This Offering and Ownership of Our Common Stock—A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.” Furthermore, although we have applied to have our common stock approved for listing on the Nasdaq Global Market, we cannot assure you that there will be an active public trading market for our common stock.

Upon the closing of this offering, based on the number of shares of our common stock outstanding as of August 31, 2020 and after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 21,958,588 shares of our common stock immediately prior to the closing of this offering, we will have an aggregate of 35,694,802 shares of our common stock outstanding (or 36,819,802 shares of our common stock if the underwriters exercise in full their option to purchase additional shares). Of these shares of our common stock (excluding any shares sold to our director or officers in the directed share program), all of the 7,500,000 shares sold in this offering (or 8,625,000 shares if the underwriters exercise in full their option to purchase additional shares) will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our “affiliates,” as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

All remaining shares of common stock held by existing stockholders immediately prior to the completion of this offering will be “restricted securities” as such term is defined in Rule 144. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below. Upon expiration of the lock-up period, we estimate that approximately 35,694,802 shares of our common stock will be available for sale in the public market, subject in some cases to applicable volume limitations under Rule 144.

### **Lock-Up Agreements**

We and each of our directors and executive officers and holders of substantially all of our outstanding capital stock, who collectively own 28,194,802 shares of our common stock prior to the closing of this offering (based on our shares outstanding as of August 31, 2020 and after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock immediately prior to the closing of this offering), have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of the representatives.

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above. For a further description of these lock-up agreements, please see “Underwriting.”

### **Rule 144**

#### ***Affiliate Resales of Restricted Securities***

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who

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has beneficially owned shares of our common stock for at least six months would be entitled to sell in “broker’s transactions” or certain “riskless principal transactions” or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 356,948 shares (or 368,198 shares if the underwriters exercise their option to purchase additional shares in full) of our common stock immediately after this offering; or
- the average weekly trading volume in shares of our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of \$50,000, the seller must file a notice on Form 144 with the SEC and the Nasdaq Global Market concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

### ***Non-Affiliate Resales of Restricted Securities***

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

### **Rule 701**

In general, under Rule 701, any of an issuer’s employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The SEC has indicated that Rule 701 will apply to typical options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

### **Equity Plans**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of our common stock subject to outstanding options and shares of our common stock issued or issuable under our incentive plans. We expect to file the registration statement covering shares offered pursuant to our incentive plans shortly after the date of this prospectus, permitting the resale of such shares by nonaffiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144.

**Registration Rights**

Upon the closing of this offering, the holders of 21,958,588 shares of our common stock (including shares of our common stock issuable upon the conversion of all outstanding shares of our convertible preferred stock) or their transferees will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See “Description of Capital Stock—Registration Rights” for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement.

**MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES  
TO NON-U.S. HOLDERS OF OUR COMMON STOCK**

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case, in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder’s particular circumstances, including the impact of the alternative minimum tax or the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies and other financial institutions;
- brokers, dealers or traders in securities;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans;
- “qualified foreign pension funds” as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds; and
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an applicable financial statement.

This discussion does not address the tax treatment of partnerships or other pass-through entities, or arrangements, or persons who hold our common stock through partnerships or other pass-through entities or arrangements, for U.S. federal income tax purposes. If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

**THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS, AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.**

#### **Definition of a Non-U.S. Holder**

For purposes of this discussion, a “Non-U.S. Holder” is any beneficial owner of our common stock that is neither a “U.S. person” nor an entity or arrangement treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code) or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

#### **Distributions**

As described in the section entitled “Dividend Policy,” we do not anticipate declaring or paying any distributions to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder’s adjusted tax basis in its common stock, but not below zero. Any remaining excess will be treated as capital gain and will be treated as described below under “—Sale or Other Taxable Disposition.”

Subject to the discussion below on effectively connected income, FATCA, and backup withholding, dividends paid to a Non-U.S. Holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate. A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a

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rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits attributable to such dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

### **Sale or Other Taxable Disposition**

Subject to the discussion below on backup withholding and FATCA, a Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits attributable to such gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and we do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we are not currently a USRPHC or will not become a USRPHC in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded" (as defined by applicable Treasury Regulations) on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

### **Information Reporting and Backup Withholding**

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our common stock paid to the Non-U.S. Holder, regardless of whether any distributions constitute dividends or of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable

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withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

### **Additional Withholding Tax on Payments Made to Foreign Accounts**

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code and related Treasury Regulations and guidance, or FATCA, on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would have also applied to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

## UNDERWRITING

The company and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated. Goldman Sachs & Co. LLC, Morgan Stanley & Co. LLC and Cowen and Company, LLC are the representatives of the underwriters (the “representatives”).

<u>Underwriters</u>	<u>Number of Shares</u>
Goldman Sachs & Co. LLC	
Morgan Stanley & Co. LLC	
Cowen and Company, LLC	
Wedbush Securities Inc.	
<b>Total</b>	<b>7,500,000</b>

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional 1,125,000 shares from the company to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by the company. Such amounts are shown assuming both no exercise and full exercise of the underwriters’ option to purchase 1,125,000 additional shares.

<u>Paid by the Company</u>	<u>No Exercise</u>	<u>Full Exercise</u>
Per Shares		
Total		

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to \$ \_\_\_\_\_ per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters’ right to reject any order in whole or in part.

The company and its officers, directors, and holders of substantially all of the company’s common stock have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of the representatives.

Our directors, executive officers and the holders of substantially all of our common stock, and securities convertible into, exchangeable for or that represent the right to receive common stock, have entered into lock-up agreements with the underwriters under which they have agreed that during the lock-up period, without the prior written consent of the representatives, they will not, and will not cause or direct any of its affiliates to, (i) offer, sell, contract to sell, pledge, grant any option to purchase, lend or otherwise dispose of any common stock or such other securities, (ii) engage in any hedging or other transaction or arrangement (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) which is designed to or which reasonably could be expected to lead to or result in a sale, loan, pledge or other disposition or transfer

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of any of the economic consequences of ownership, in whole or in part, directly or indirectly, of any common stock or such other securities, even if any such sale or disposition transaction or transactions would be made or executed by or on behalf of someone other than the holder (whether such transaction or arrangement is to be settled by delivery of common stock or such other securities, in cash or otherwise) or (iii) publicly announce any intention to do any of the foregoing.

The restrictions described in the immediately preceding paragraph do not apply to:

- (i) transfers (a) as a bona fide gift or gifts or to a charitable organization or educational institution, (b) by will or intestacy, (c) to a trust, partnership, limited liability company or other entity for the direct or indirect benefit of the holder or the immediate family thereof, or if the holder is a trust, to a beneficiary of such trust, (d) to an immediate family member, investment fund or other entity controlled or managed by the holder or (e) if the holder is a corporation, partnership, limited liability company, trust or other business entity, (1) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate (as defined in Rule 405 promulgated under the Securities Act) of such holder, or (2) as part of a distribution of common stock or such other securities to limited partners, limited liability company members or stockholders of such holder; provided in each case that (x) the transferee, donee or distributee will agree in writing to be bound by the restrictions set forth in the lock-up agreement, and there will be no further transfer of such capital stock except in accordance with such lock-up agreement, and that any such transfer will not involve a disposition for value and (y) such transfer, disposition or distribution is not required to be reported with the SEC on Form 4 in accordance with Section 16 under the Exchange Act and no other public announcement will be voluntarily made during the lock-up period other than Schedule 13 filings filed with the SEC;
- (ii) transfers to us in connection with the repurchase of common stock or such other securities upon termination of service of the holder pursuant to any contractual arrangement in effect on the date of this prospectus that provides for the repurchase of common stock or such other securities, provided that such transfer or other disposition is not required to be reported with the SEC on Form 4 in accordance with Section 16 under the Exchange Act and no other public announcement will be voluntarily made during the lock-up period other than (a) Schedule 13 filings filed with the SEC and (b) any Form 4 or Form 5 required to be filed under the Exchange Act with respect to the Company, which will indicate by footnote disclosure the nature of the transfer or disposition;
- (iii) transfers to us (a) upon exercise of outstanding options, warrants, other equity interests or vesting of restricted stock units, including transfers deemed to occur upon the “net” or “cashless” exercise of options or (b) for the sole purpose of paying the exercise price of such warrants or options or other of our incentive awards or the vesting of restricted stock units, in each case on a “cashless” or “net exercise” basis, provided that (x) such options, restricted stock units or other incentive awards were granted under an incentive award plan described in this prospectus and were outstanding as of the date of this prospectus and such warrants are described in this prospectus and were outstanding as of the date of this prospectus and (y) such transfer or other disposition is not required to be reported with the SEC on Form 4 in accordance with Section 16 under the Exchange Act and no other public announcement will be voluntarily made during the lock-up period other than Schedule 13 filings filed with the SEC;
- (iv) transfers pursuant to any domestic or foreign, federal, state or local government, including any political subdivision thereof, any governmental or quasi-governmental authority, department, agency or official, any court or administrative body, and any national securities exchange or similar self-regulatory body or organization, in each case of competent jurisdiction, provided in each case that (x) the transferee, donee or distributee will agree in writing to be bound by the restrictions set forth in the lock-up agreement, and there will be no further transfer of such capital stock except in accordance with such lock-up agreement, and that any such transfer will not involve a disposition for value will not involve a disposition for value and (y) such transfer, disposition or distribution is not required to be reported with the SEC on Form 4 in accordance with Section 16 under the Exchange Act and no other public

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announcement will be voluntarily made during the lock-up period other than Schedule 13 filings filed with the SEC;

- (v) transfers pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction made to all holders of common stock involving a “change of control” approved by our board of directors, the result of which is that any “person” (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, other than us, becomes the beneficial owner (as defined in Rules 13d-3 and 13d-5 of the Exchange Act) of at least 51% of the total voting power of our voting capital stock, provided that (x) if such transaction is not consummated, such securities will remain subject to the restrictions set forth in the lock-up agreement and (y) such transfer or other disposition is not required to be reported with the SEC on Form 4 in accordance with Section 16 under the Exchange Act and no other public announcement will be voluntarily made during the lock-up period other than Schedule 13 filings filed with the SEC;
- (vi) establishment of a written plan meeting the requirements of Rule 10b5-1 of the Exchange Act, provided that (x) such plan does not provide for the sale or transfer of the holder’s common or such other securities during the lock-up period and (y) such transfer or other disposition is not required to be reported with the SEC on Form 4 in accordance with Section 16 under the Exchange Act and no other public announcement will be voluntarily made during the lock-up period other than Schedule 13 filings filed with the SEC; and
- (vii) disposition of common stock acquired by the holder or in open market transactions after this offering, provided that such transfer or other disposition is not required to be reported with the SEC on Form 4 in accordance with Section 16 under the Exchange Act and no other public announcement will be voluntarily made during the lock-up period other than Schedule 13 filings filed with the SEC.

The representatives may, in their sole discretion, release any of the securities subject to the lock-up agreements described above in whole or in part at any time.

This agreement does not apply to any existing employee benefit plans. See “Shares Available for Future Sale” for a discussion of certain transfer restrictions.

Prior to the offering, there has been no public market for the shares. The initial public offering price has been negotiated among the company and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be the company’s historical performance, estimates of the business potential and earnings prospects of the company, an assessment of the company’s management and the consideration of the above factors in relation to market valuation of companies in related businesses.

An application has been made to list the common stock on the Nasdaq Global Market under the symbol “FHTX.”

In connection with the offering, the underwriters may purchase and sell shares of common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A “covered short position” is a short position that is not greater than the amount of additional shares for which the underwriters’ option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. “Naked” short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions

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consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of the company's stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on the Nasdaq Global Market, in the over-the-counter market or otherwise.

The company estimates that its share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately \$3,800,000. The company has also agreed to reimburse the underwriters for certain of their expenses in an amount up to \$50,000.

The company has agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they received or will receive customary fees and expenses. Wedbush Securities Inc. is acting as our financial advisor in connection with the offering and we have agreed to pay Wedbush Securities Inc. a fee of up to 0.35% of the gross proceeds received by us from this offering for such services.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of the issuer (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with the issuer. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

### ***Directed Share Program***

At our request, the underwriters have reserved up to 5% of the shares of common stock offered hereby, at the initial public offering price, to offer to directors, officers, employees, business associates and related persons of Foghorn. Except for any shares acquired by our directors and officers, shares purchased pursuant to the directed share program will not be subject to lock-up agreements with the underwriters. The underwriters will receive the same underwriting discount on any shares purchased pursuant to this program as they will on any other shares sold to the public in this offering. The number of shares of common stock available for sale to the general public will be reduced to the extent these individuals purchase such reserved shares. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus.

### ***European Economic Area and the United Kingdom***

In relation to each Member State of the European Economic Area and the United Kingdom (each a “Member State”), no common shares (the “Shares”) have been offered or will be offered pursuant to the offering to the public in that Member State prior to the publication of a prospectus in relation to the Shares which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation), except that offers of Shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the Representatives for any such offer; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of Shares shall require the company or any Representative to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to any Shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase or subscribe for any Shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

In addition, in the United Kingdom, each Underwriter has represented and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (FSMA)) received by it in connection with the issue or sale of the shares in circumstances in which Section 21(1) of the FSMA does not apply to the company; and
- (b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

### ***Canada***

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this offering memorandum (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

### ***Hong Kong***

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) (“Companies (Winding Up and Miscellaneous Provisions) Ordinance”) or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (“Securities and Futures Ordinance”), or (ii) to “professional investors” as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

### ***Singapore***

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore (the “SFA”)) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation’s securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore (“Regulation 32”)

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries’ rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

***Japan***

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended), or the FIEA. The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

***Israel***

In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase shares of common stock under the Israeli Securities Law, 5728 – 1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728–1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions (the “Addressed Investors”); or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728 – 1968, subject to certain conditions (the “Qualified Investors”). The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728 – 1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our common stock to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728 – 1968. In particular, we may request, as a condition to be offered common stock, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728 – 1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728 – 1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728 – 1968 and the regulations promulgated thereunder in connection with the offer to be issued common stock; (iv) that the shares of common stock that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728 – 1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728 – 1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor’s name, address and passport number or Israeli identification number.

## LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Ropes & Gray, LLP, Boston, Massachusetts. Certain legal matters will be passed upon for the underwriters by Latham & Watkins LLP.

## EXPERTS

The consolidated financial statements of Foghorn Therapeutics Inc. and its subsidiary as of and for the years ended December 31, 2019 and 2018 included in this Prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein (which report expresses an unqualified opinion on the financial statements and includes explanatory paragraphs referring to substantial doubt that exists regarding the ability of the Company to continue as a going concern and the change in accounting principle resulting from the adoption of Financial Accounting Standards Board Accounting Standards Update No. 2016-02, Leases (Topic 842)). Such consolidated financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

## WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the shares of common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. The SEC also maintains an Internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the SEC. The address of that site is [www.sec.gov](http://www.sec.gov).

Upon the effectiveness of the registration statement, we will be subject to the informational requirements of the Exchange Act, and, in accordance with the Exchange Act, will file reports, proxy and information statements and other information with the SEC. Such annual, quarterly and special reports, proxy and information statements and other information can be inspected and copied at the locations set forth above. We intend to make this information available on the investor relations section of our website, which is located at <https://foghorntx.com>. Information on, or accessible through, our website is not part of this prospectus.

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## 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 financial statements of Foghorn Therapeutics Inc. and its subsidiary (the “Company”), as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders’ deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

### Emphasis of a Matter Regarding Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has recurring losses from operations and has stated that substantial doubt exists about its ability to continue as a going concern. Management’s evaluation of the events and conditions and management’s plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

### Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company has changed its method of accounting for leases in 2019 due to the adoption of the Financial Accounting Standards Board Accounting Standards Update No. 2016-02, Leases (Topic 842), as amended, using the modified retrospective transition approach.

### Basis for Opinion

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

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

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

*/s/ Deloitte & Touche LLP*

Boston, Massachusetts

August 28, 2020 (October 21, 2020 as to the effects of the reverse stock split discussed in Note 17)

We have served as the Company’s auditor since 2018

**Foghorn Therapeutics Inc.**  
**Consolidated Balance Sheets**  
(In thousands, except share and per share amounts)

	<u>December 31,</u>	
	<u>2018</u>	<u>2019</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 40,019	\$ 14,981
Restricted cash	—	541
Prepaid expenses and other current assets	383	1,363
Total current assets	<u>40,402</u>	<u>16,885</u>
Property and equipment, net	2,090	2,683
Restricted cash	566	1,733
Other assets	—	11
Operating lease right-of-use assets	—	1,030
Total assets	<u>\$ 43,058</u>	<u>\$ 22,342</u>
<b>Liabilities, Convertible Preferred Stock and Stockholders' Deficit</b>		
Current liabilities:		
Accounts payable	\$ 2,014	\$ 3,439
Accrued expenses	1,445	3,701
Operating lease liabilities	—	1,360
Notes payable, net of discount	—	4,152
Total current liabilities	3,459	12,652
Notes payable, net of discount and current portion	7,029	10,960
Deferred rent	547	—
Operating lease liabilities, net of current portion	—	157
Preferred stock warrant liability	46	45
Total liabilities	<u>11,081</u>	<u>23,814</u>
Commitments and contingencies (Note 14)		
Convertible preferred stock (Series A-1, A-2 and B), \$0.0001 par value; 28,589,622 and 28,629,622 shares authorized at December 31, 2018 and 2019, respectively; 26,575,544 and 28,615,546 shares issued and outstanding at December 31, 2018 and 2019, respectively; liquidation preference of \$86,782 at December 31, 2019	71,250	86,544
Stockholders' deficit:		
Common stock, \$0.0001 par value; 46,000,000 and 46,600,000 shares authorized at December 31, 2018 and 2019, respectively; 5,258,937 and 5,762,745 shares issued and 3,475,152 and 4,870,851 shares outstanding at December 31, 2018 and 2019, respectively	—	—
Additional paid-in capital	3,735	6,120
Accumulated deficit	<u>(43,008)</u>	<u>(94,136)</u>
Total stockholders' deficit	<u>(39,273)</u>	<u>(88,016)</u>
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 43,058</u>	<u>\$ 22,342</u>

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

**Foghorn Therapeutics Inc.**  
**Consolidated Statements of Operations and Comprehensive Loss**  
**(In thousands)**

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2019</b>
Operating expenses:		
Research and development	\$ 21,225	\$ 44,362
General and administrative	4,824	6,722
Total operating expenses	<u>26,049</u>	<u>51,084</u>
Loss from operations	<u>(26,049)</u>	<u>(51,084)</u>
Other income (expense):		
Interest expense	(371)	(540)
Interest income and other expense, net	113	495
Change in fair value of preferred stock warrant liability	(30)	1
Total other income (expense), net	<u>(288)</u>	<u>(44)</u>
Net loss and comprehensive loss	<u>\$ (26,337)</u>	<u>\$ (51,128)</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (8.94)</u>	<u>\$ (12.20)</u>
Weighted average common shares outstanding—basic and diluted	<u>2,947,093</u>	<u>4,191,793</u>
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited)		<u>\$ (2.60)</u>
Pro forma weighted average common shares outstanding—basic and diluted (unaudited)		<u>19,629,444</u>

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

**Foghorn Therapeutics Inc.**  
**Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit**  
(In thousands, except share amounts)

	Series A-1, A-2 and B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
<b>Balances at December 31, 2017</b>	20,497,915	\$25,788	2,185,718	\$ —	\$ 2,781	\$ (16,671)	\$ (13,890)
Issuance of Series B convertible preferred stock, net of issuance costs of \$120	5,408,004	40,440	—	—	—	—	—
Issuance of Series B convertible preferred stock upon conversion of convertible note and accrued interest	669,625	5,022	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	354,762	—	190	—	190
Vesting of restricted stock	—	—	891,891	—	—	—	—
Issuance of common stock for technology license	—	—	42,781	—	32	—	32
Stock-based compensation expense	—	—	—	—	732	—	732
Net loss	—	—	—	—	—	(26,337)	(26,337)
<b>Balances at December 31, 2018</b>	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)
<b>Balances at December 31, 2019</b>	28,615,546	\$86,544	4,870,851	\$ —	\$ 6,120	\$ (94,136)	\$ (88,016)

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

**Foghorn Therapeutics Inc.**  
**Consolidated Statements of Cash Flows**  
(In thousands)

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2019</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (26,337)	\$ (51,128)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	732	1,694
Depreciation and amortization expense	379	693
Loss on disposal of property and equipment	—	11
Change in fair value of preferred stock warrant liability	30	(1)
Noncash lease expense	—	1,100
Noncash interest expense	124	99
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	95	(991)
Accounts payable	1,276	1,211
Accrued expenses and other current liabilities	1,138	2,137
Operating lease liabilities	(85)	(1,160)
Net cash used in operating activities	<u>(22,648)</u>	<u>(46,335)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(1,541)	(968)
Proceeds from sale of property and equipment	—	4
Net cash used in investing activities	<u>(1,541)</u>	<u>(964)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of convertible preferred stock, net of issuance costs	40,440	15,294
Proceeds from issuance of common stock upon exercise of stock options	190	691
Proceeds from convertible notes	5,000	—
Proceeds from notes payable, net of issuance costs	6,963	7,984
Repayments of notes payable	(823)	—
Net cash provided by financing activities	<u>51,770</u>	<u>23,969</u>
<b>Net increase (decrease) in cash, cash equivalents and restricted cash</b>	<b>27,581</b>	<b>(23,330)</b>
Cash, cash equivalents and restricted cash at beginning of period	<u>13,004</u>	<u>40,585</u>
Cash, cash equivalents and restricted cash at end of period	<u>\$ 40,585</u>	<u>\$ 17,255</u>
<b>Supplemental cash flow information:</b>		
Cash paid for interest	\$ 211	\$ 420
<b>Supplemental disclosure of noncash investing and financing information:</b>		
Purchases of property and equipment included in accounts payable and accrued expenses	\$ 34	\$ 367
Common stock issued for license	\$ 32	\$ —
Conversion of convertible notes payable and accrued interest to preferred stock	\$ 5,022	\$ —
<b>Reconciliation of cash, cash equivalents and restricted cash:</b>		
Cash and cash equivalents	\$ 40,019	\$ 14,981
Restricted cash (current and non-current)	566	2,274
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	<u>\$ 40,585</u>	<u>\$ 17,255</u>

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 development-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 development-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 planned clinical trials. The impact of the COVID-19 coronavirus 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.

***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”).

***Going concern***

Since its inception, the Company has funded its operations primarily with proceeds from sales of preferred stock and debt financing. The Company has incurred losses since inception, including net losses of \$26.3 million and \$51.1 million for the years ended December 31, 2018 and 2019, respectively. In addition, as of December 31, 2019, the Company had an accumulated deficit of \$94.1 million. The Company expects to continue to generate operating losses for the foreseeable future. In April 2020, the Company received gross proceeds of \$48.1 million from the sale of 6,407,867 shares of Series B convertible preferred stock and in July and August 2020, the Company received gross proceeds of \$42.0 million from the sale of 5,600,000 shares of Series B convertible preferred stock. The Company also received a \$15.0 million upfront payment under a collaboration agreement entered into in July 2020 (see Note 17). The future viability of the Company is dependent on its ability to raise

**Foghorn Therapeutics Inc.**  
**Notes to Consolidated Financial Statements**

additional capital to finance its operations. Based on its losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and need to raise additional capital to finance its future operations, as of August 28, 2020, the issuance date of the consolidated financial statements for the year ended December 31, 2019, the Company has concluded that there is substantial doubt about its ability to continue as a going concern within one year after the date that these consolidated financial statements are issued.

The Company is seeking to complete an initial public offering (“IPO”) of its common stock. Upon the closing of a qualified public offering on specified terms, the Company’s outstanding convertible preferred stock will automatically convert into shares of common stock (see Note 7). In the event the Company does not complete an IPO, the Company expects to seek additional funding through private equity financings, debt financings, or other capital sources, including collaborations with other companies, government funding arrangements or other strategic transactions.

If the Company is unable to obtain additional funding, the Company will be required to delay, reduce or eliminate some or all of its research and development programs or the Company may be unable to continue operations. Although management continues to pursue these financing plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

## **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, the valuation of common stock, 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.

### ***Unaudited pro forma information***

In the accompanying consolidated statements of operations and comprehensive loss, the unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2019 has been prepared to give effect to the automatic conversion of all outstanding shares of convertible preferred stock as if the Company’s proposed initial public offering had occurred on the later of January 1, 2019 or the issuance date of the convertible preferred stock.

### ***Concentrations of credit risk and of significant suppliers***

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. As of December 31, 2019, the Company maintained cash balances in excess of

**Foghorn Therapeutics Inc.**  
**Notes to Consolidated Financial Statements**

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 discovery programs. These programs could be adversely affected by a significant interruption in these services or the availability of materials.

***Deferred financing costs***

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

***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.

***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:

	<u>Estimated Useful Life</u>
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 capitalized and 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

**Foghorn Therapeutics Inc.**  
**Notes to Consolidated Financial Statements**

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, 2018 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 preferred stock warrant liability 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.

***Classification of convertible preferred stock***

The Company's convertible preferred stock is classified outside of stockholders' deficit on the consolidated balance sheet because the holders of such shares have 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 and preclinical 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

**Foghorn Therapeutics Inc.**  
**Notes to Consolidated Financial Statements**

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***

Prior to January 1, 2019, the Company accounted for leases under ASC 840, *Leases* (“ASC 840”). The Company adopted ASC 842, *Leases* (“ASC 842”), effective January 1, 2019 using the modified retrospective transition method. Under this method, financial statements for reporting periods after adoption are presented in accordance with ASC 842 and prior-period financial statements continue to be presented in accordance with ASC 840, the accounting standard originally in effect for such periods.

In accordance with ASC 842, 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

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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***

The Company follows the two-class method when computing net income (loss) per share as the Company has 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 entitle the holders of such shares to participate in dividends but do not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports 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, 2018 and 2019.

***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' deficit that result from transactions and economic events other than those with stockholders. There was no difference between net loss and comprehensive loss for each of the periods presented in the accompanying consolidated financial statements.

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***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 adopted 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 adopts 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 February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which requires lessees to recognize most leases on their balance sheet as a right-of-use asset and a lease liability. In general, lease arrangements exceeding a twelve-month term must be recognized as assets and liabilities on the balance sheet. Under ASU 2016-02, a right of use asset and lease obligation is recorded for all leases, whether operating or financing, while the income statement reflects lease expense for operating leases and amortization and interest expense for financing leases. The FASB also issued ASU 2018-10, *Codification Improvements to Topic 842 Leases*, and ASU 2018-11, *Targeted Improvements to Topic 842 Leases*, which allows the new lease standard to be applied as of the adoption date with a cumulative-effect adjustment to the opening balance of retained earnings rather than retroactive restatement of all periods presented. The Company early-adopted the new leasing standards on January 1, 2019 using a modified retrospective approach applied at the beginning of the period of adoption.

The Company elected the "package of practical expedients," which permits the Company not to reassess under the new standards for prior conclusions about lease identification, lease classification and initial direct costs. The Company did not apply the hindsight practical expedient when determining the lease term for existing leases and assessing impairment of expired or existing leases. The Company elected to utilize its incremental borrowing rate based on the remaining lease term as of the date of adoption.

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In connection with the adoption of ASU 2016-02, the Company recognized right-of-use assets of \$8.4 million and lease liabilities of \$8.9 million on its consolidated balance sheet. The deferred rent balance of \$0.5 million as of January 1, 2019 was recorded as an offset to the Company's right-of-use asset. The adoption of the standard did not have a material impact on the Company's results of operations or cash flows.

**3. Fair Value Measurements**

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, 2018 Using:			Total
	Level 1	Level 2	Level 3	
<b>Assets:</b>				
Cash equivalents:				
Money market funds	\$ 2,994	\$ —	\$ —	\$ 2,994
<b>Liabilities:</b>				
Preferred stock warrant liability	\$ —	\$ —	\$ 46	\$ 46

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

During the year ended December 31, 2019, there were no transfers between Level 1, Level 2 and Level 3.

The preferred stock warrant liability in the tables above consisted of the fair value of warrants to purchase Series A-1 convertible preferred stock (see Note 8) and was based on significant inputs not observable in the market, which represent 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 incorporates assumptions and estimates to value the preferred stock warrants. The Company assesses these assumptions and estimates at the end of each reporting period. Changes in the fair value of the preferred stock warrants are recognized within other income (expense) in the consolidated statements of operations and comprehensive loss.

The quantitative elements associated with the Company's Level 3 inputs impacting the fair value measurement of the preferred stock warrant liability include the fair value per share of the underlying Series A-1 convertible preferred stock, the remaining contractual term of the warrants, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying preferred stock. The most significant assumption in the Black-Scholes option-pricing model impacting the fair value of the preferred stock warrants is the fair value of the Company's Series A-1 convertible preferred stock as of each remeasurement date. The Company determines the fair value per share of the underlying Series A-1 convertible preferred stock by taking into consideration its most recent sales of its convertible preferred stock as well as additional factors that the Company deems relevant. The change in the fair value of the preferred stock warrant liability was not material during the years ended December 31, 2018 or 2019.

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**4. Property and Equipment, Net**

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

	<b>December 31,</b>	
	<b>2018</b>	<b>2019</b>
Laboratory equipment	\$2,311	\$ 3,202
Furniture and fixtures	227	337
Computer equipment and software	81	81
Leasehold improvements	75	75
Assets not yet placed in service	12	280
	<u>2,706</u>	<u>3,975</u>
Less: Accumulated depreciation and amortization	(616)	(1,292)
	<u>\$2,090</u>	<u>\$ 2,683</u>

Depreciation and amortization expense was \$0.4 million and \$0.7 million for the years ended December 31, 2018 and 2019, respectively.

**5. Accrued Expenses**

Accrued expenses consisted of the following (in thousands):

	<b>December 31,</b>	
	<b>2018</b>	<b>2019</b>
Accrued employee compensation and benefits	\$1,274	\$1,867
Accrued external research and development expenses	75	1,384
Other	96	450
	<u>\$1,445</u>	<u>\$3,701</u>

**6. Notes Payable**

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

	<b>December 31,</b>	
	<b>2018</b>	<b>2019</b>
Principal amount of long-term debt	\$7,000	\$15,000
Less: Current portion of long-term debt	—	(4,152)
Long-term debt, net of current portion	7,000	10,848
Final payment fee	210	530
Debt discount, net of accretion	(181)	(418)
Long-term debt, net of discount and current portion	<u>\$7,029</u>	<u>\$10,960</u>

**Term loans**

The Company previously had a term loan facility agreement with Silicon Valley Bank (“SVB”) for up to \$2.0 million in available debt financing to be used toward the Company’s eligible equipment purchases made

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through June 30, 2017 (the “Term Loan”). In February 2018, the total remaining outstanding balance owed on the Term Loan of \$0.8 million and the final payment charge and the prepayment fee, which together were less than \$0.1 million were paid in full to SVB. No further borrowings are available on the Term Loan.

In conjunction with the drawdowns under the Term Loan agreement, the Company granted to SVB warrants to purchase 14,076 shares of Series A-1 convertible preferred stock at \$1.00 per share. The issued warrants are exercisable for 10 years from the date of execution of the warrant agreement. The fair value of the warrants as of the grant dates was less than \$0.1 million and was recorded as deferred financing cost and as a preferred stock warrant liability (see Note 8).

In February 2018, the Company entered a loan and security agreement with Comerica Bank (“Comerica”) for up to \$7.0 million in available debt financing to be used toward funding the Company’s operations (the “Loan”) and an option for an additional \$1.0 million pending receipt of a term sheet for a qualified financing as defined in the agreement. The borrowings under the Loan were repayable in monthly payments of interest-only at 0.75% plus the greater of 1) prime rate (as defined by Comerica) or 2) LIBOR plus 2.5%, through February 2020 to be followed by monthly payments of equal principal plus interest until the loan maturity date of February 23, 2022. A final payment fee of 3.0% of the amounts drawn under the Loan 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.

In March 2019, the Company amended the Loan to increase the maximum borrowing capacity available under the Loan to \$15.0 million. Under the amended Loan, \$7.0 million had been drawn down as of December 31, 2018 (“Term Loan A”) and an additional \$8.0 million was drawn down during the year ended December 31, 2019 (“Term Loan B”) so that the total amount outstanding under the amended Loan was \$15.0 million as of December 31, 2019.

Borrowings under both Term Loan A and Term Loan B were repayable in monthly payments of interest-only through February 2020 with the option to extend the interest-only period through August 2020 upon closure of a qualified financing, to be followed by monthly payments of equal principal plus interest until the loan maturity date of February 1, 2023. Interest for Term Loan A is 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 is 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 as of December 31, 2019 is being amortized to interest expense over the term of the debt using the effective interest method. Subsequent to December 31, 2019, the Company further amended the Loan to extend the interest-only period (see Note 17).

Borrowings under the amended Loan are collateralized by substantially all of the Company’s assets, other than its intellectual property. There are no financial covenants associated with the amended Loan; however, the Company is subject to certain affirmative and negative covenants restricting the Company’s activities, 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 amended 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, 2019, the Company believes an event of default would be remote.

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As of December 31, 2019, the weighted average stated interest rate applicable to outstanding borrowings under the amended Loan was 5.3%. During the year ended December 31, 2019, the weighted average effective interest rate on outstanding borrowings under the amended Loan was approximately 6.9%.

As of December 31, 2019, future principal payments due are as follows (in thousands):

<u>Year Ending December 31,</u>	
2020	\$ 4,167
2021	5,000
2022	5,000
2023	833
	<u>\$ 15,000</u>

***Convertible promissory notes***

In November 2018, the Company issued \$5.0 million of convertible promissory notes (the “Convertible Notes”) to one of the Company’s existing investors. The Convertible Notes accrued interest at 6.0% per annum, compounded annually, and had a maturity of one year from issuance unless previously converted. The Convertible Notes contained an automatic conversion feature in the event the Company was able to obtain financing through the issuance of a new class of equity securities (a “Qualified Financing”) prior to the maturity date. Under this automatic conversion feature, the Convertible Notes and accrued but unpaid interest converted into shares of preferred stock at a price equal to the weighted average per share price of all securities of the Company issued to investors in the Qualified Financing.

In December 2018, a Qualified Financing occurred with the Company’s issuance of Series B convertible preferred stock to investors (see Note 7). Accordingly, the full amount of the notes payable and accrued interest converted into 669,625 shares of Series B convertible preferred stock at \$7.50 per share.

**7. Convertible Preferred Stock**

The Company has 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 December 2018, the Company issued 5,408,004 shares of Series B preferred stock at a purchase price of \$7.50 per share, resulting in cash proceeds of \$40.4 million net of issuance costs of \$0.1 million. In December 2018, the Company also issued 669,625 shares of Series B preferred stock upon conversion of convertible notes payable of \$5.0 million and accrued interest of less than \$0.1 million at \$7.50 per share.

In January 2019, the Company sold an additional 2,040,002 shares of Series B preferred stock to new investors at a purchase price of \$7.50 per share resulting in net proceeds to the Company of \$15.3 million.

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Preferred Stock consisted of the following (in thousands, except share amounts):

	As of December 31, 2018				
	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	8,077,631	6,077,629	45,462	45,582	3,285,205
	<u>28,589,622</u>	<u>26,575,544</u>	<u>\$ 71,250</u>	<u>\$ 71,482</u>	<u>14,365,159</u>

	As of December 31, 2019				
	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
	<u>28,629,622</u>	<u>28,615,546</u>	<u>\$ 86,544</u>	<u>\$ 86,782</u>	<u>15,467,863</u>

As of December 31, 2019, the holders of Preferred Stock have the following rights and preferences:

**Voting**

The holders of Preferred Stock are entitled to vote, together with the holders of common stock as a single class, on matters submitted to stockholders for a vote. The holders of Preferred Stock are entitled to the number of votes equal to the number of shares of common stock into which each such share of Preferred Stock could convert.

**Conversion**

Each share of Preferred Stock is convertible into shares of common stock at the option of the holder at any time after the date of issuance. Each share of Preferred Stock will be automatically converted into shares of common stock, at the applicable conversion ratio then in effect, upon either (i) the closing of a firm commitment public offering with at least \$35.0 million of gross proceeds to the Company or (ii) the vote or written consent of the holders of at least a majority of the then-outstanding shares of Preferred Stock, voting together as a single class.

The conversion ratio of each series of Preferred Stock is determined by dividing the Original Issue Price of each series by the Conversion Price of each series. The Original Issue Price is defined as \$1.00 per share for Series A-1, \$1.50 per share for Series A-2 and \$7.50 per share for Series B. The Conversion Price is defined as \$1.85 per share for Series A-1, \$2.775 per share for Series A-2 and \$13.875 per share for Series B, subject to appropriate adjustment in the event of any stock split, stock dividend, combination or other similar recapitalization and other adjustments as set forth in the Company's certificate of incorporation, as amended and restated.

**Dividends**

The holders of Preferred Stock are entitled to receive noncumulative dividends if and when declared by the Company's board of directors. The Company may not declare, pay or set aside any dividends on shares of any

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other series of capital stock of the Company, other than dividends on common stock payable in common stock, unless the holders of the Preferred Stock first receive, or simultaneously receive, a dividend on each outstanding share of Preferred Stock. No dividends were declared or paid during the years ended December 31, 2018 or 2019.

***Liquidation***

In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Company or Deemed Liquidation Event (as described below), the holders of shares of Preferred Stock will receive, in preference to any distribution to the holders of common stock, an amount per share equal to the greater of (i) the Original Issue Price per share of the respective share of Preferred Stock, plus all dividends declared but unpaid on such shares, or (ii) the amount the holders would receive if the Preferred Stock were converted into common stock prior to such liquidation event. In the event that the assets available for distribution to the Company's stockholders are not sufficient to permit payment to the holders of Preferred Stock in the full amount to which they are entitled, the assets available for distribution will be distributed on a pro rata basis among the holders of the Preferred Stock. After the payment of all preferential amounts to the holders of the Preferred Stock, then, to the extent available, the remaining assets available for distribution shall be distributed among the holders of the common stock ratably based on the number of shares of common stock held by each holder.

Unless the holders of at least a majority of the then-outstanding shares of Preferred Stock, voting together as a single class on an as-converted basis, elect otherwise, a Deemed Liquidation Event shall include a merger or consolidation (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company. In the event of a Deemed Liquidation Event, if the Company does not effect a dissolution within 90 days after such Deemed Liquidation Event, each holder of Preferred Stock has the right to require the redemption of such shares, and if voting together as a majority, has the right to require redemption of all outstanding Preferred Stock in accordance with the liquidation preferences afforded to holders of the Preferred Stock.

**8. Warrants to Purchase Preferred Stock**

In connection with the Term Loan (see Note 6), the Company issued warrants to purchase 14,076 shares of Series A-1 preferred stock at an exercise price of \$1.00 per share. If unexercised, the warrants expire on November 28, 2026. As of December 31, 2018 and 2019, no warrants have been exercised.

**9. Common Stock**

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

***Restricted common stock***

The Company has outstanding shares of restricted common stock that vest over a five-year period (see Note 10). Shares of unvested restricted common stock may not be sold or transferred by the holder. Vesting may be accelerated upon a change in control, as defined. If the holders cease to have a business relationship with the Company, the Company may repurchase any unvested shares of common stock held by these individuals at their original purchase price (which was not significant). Restricted common stock is considered outstanding for accounting purposes only upon vesting.

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**10. Stock-Based Compensation****2016 Stock incentive plan**

The Company's 2016 Stock Incentive Plan (the "2016 Plan") provides for the Company to grant incentive stock options or nonqualified stock options and other equity awards to employees, directors and consultants of the Company. The 2016 Plan is 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 under the 2016 Plan with service-based vesting conditions generally vest over four years and expire after ten years. The total number of shares of common stock that may be issued under the 2016 Plan was 2,756,756 as of December 31, 2018 and was increased to 4,810,810 in 2019, of which 51,333 shares remain available for future issuance as of December 31, 2019. Shares that are expired, terminated, surrendered or canceled without having been fully exercised will be available for future awards under the 2016 Plan. In June 2020, the number of shares that may be issued under the 2016 Plan was increased to 5,027,026 and in August 2020, was increased to 6,513,512 (see Note 17).

The exercise price for stock options granted is not less than the fair value of common stock as determined by the board of directors as of the date of grant. The Company's board of directors values 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.

**Stock option valuation**

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. The Company is 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 2018 and 2019:

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2019</b>
Risk-free interest rate	2.7%	2.2%
Expected volatility	80.6%	78.2%
Expected dividend yield	—	—
Expected term (in years)	6.0	6.0

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The following table summarizes the Company's option activity during the year ended December 31, 2019:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Contractual Term</u> (in years)	<u>Aggregate Intrinsic Value</u> (in thousands)
Outstanding as of December 31, 2018	2,092,151	\$ 0.63	8.7	
Granted	2,328,720	3.72		
Exercised	(503,808)	1.37		
Forfeited	(30,574)	0.67		
Outstanding as of December 31, 2019	<u>3,886,489</u>	\$ 2.39	8.7	\$ 5,184
Vested and expected to vest as of December 31, 2019	3,886,489	\$ 2.39	8.7	\$ 5,184
Options exercisable as of December 31, 2019	853,152	\$ 0.87	7.8	\$ 2,432

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, 2018 and 2019 was \$0.1 million and \$1.2 million, respectively.

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2018 and 2019 was \$0.50 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 are 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. The following table summarizes the Company's restricted common stock activity during the year ended December 31, 2019:

	<u>Shares</u>
Unvested restricted common stock as of December 31, 2018	1,783,785
Issued	—
Vested	(891,891)
Unvested restricted common stock as of December 31, 2019	<u>891,894</u>

The aggregate fair value of restricted stock that vested during the years ended December 2018 and 2019 was \$1.3 million and \$3.3 million, respectively.

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**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):

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2019</b>
Research and development expenses	\$ 495	\$ 1,140
General and administrative expenses	237	554
	<u>\$ 732</u>	<u>\$ 1,694</u>

As of December 31, 2019, total unrecognized compensation cost related to unvested options and unvested restricted stock was \$5.2 million, which is expected to be recognized over a weighted average period of 3.0 years.

**11. Income Taxes**

During the years ended December 31, 2018 and 2019, the Company recorded no income tax benefits for the net operating losses incurred or for the research and development tax credits generated in each year, due to its uncertainty of realizing a benefit from those 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:

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2019</b>
Federal statutory income tax rate	(21.0)%	(21.0)%
State taxes, net of federal benefit	(6.1)	(7.1)
Federal and state research and development tax credits	0.4	(2.2)
Other	(0.3)	0.4
Change in deferred tax asset valuation allowance	27.0	29.9
Effective income tax rate	<u>0.0%</u>	<u>0.0%</u>

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**Notes to Consolidated Financial Statements**

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

	December 31,	
	2018	2019
Deferred tax assets:		
Net operating loss carryforwards	\$ 10,831	\$ 23,769
Research and development tax credit carryforwards	555	2,415
Capitalized start-up costs	194	190
Accrued expenses	218	596
Operating lease liabilities	—	414
Total deferred tax assets	<u>11,798</u>	<u>27,384</u>
Deferred tax liabilities:		
Depreciation	(472)	(482)
Operating lease right-of-use assets	—	(281)
Total deferred tax liabilities	<u>(472)</u>	<u>(763)</u>
Valuation allowance	(11,326)	(26,621)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2019, the Company had U.S. federal and state net operating loss carryforwards of \$87.6 million and \$84.9 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 \$75.1 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, 2019, the Company also had U.S. federal and state research and development tax credit carryforwards of \$1.5 million and \$1.2 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 presented 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.

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Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2018 and 2019. Management reevaluates the positive and negative evidence at each reporting period.

The valuation allowance increased by \$7.1 million and \$15.3 million during the years ended December 31, 2018 and 2019, respectively, primarily as a result of the increase in net operating loss carryforwards.

As of December 31, 2018 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. The Company is open to future tax examination under statute from 2016 to the present.

## 12. Net Loss per Share and Unaudited Pro Forma Net Loss per Share

### *Net loss per share*

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	<u>Year Ended December 31,</u>	
	<u>2018</u>	<u>2019</u>
<b>Numerator:</b>		
Net loss attributable to common stockholders	\$ (26,337)	\$ (51,128)
<b>Denominator:</b>		
Weighted average common shares outstanding basic and diluted	2,947,093	4,191,793
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (8.94)</u>	<u>\$ (12.20)</u>

### *Common stock equivalents*

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:

	<u>Year Ended December 31,</u>	
	<u>2018</u>	<u>2019</u>
Convertible preferred stock (as converted to common stock)	14,365,159	15,467,863
Warrants to purchase convertible preferred stock (as converted to common stock)	7,608	7,608
Unvested restricted common stock	1,783,785	891,894
Stock options to purchase common stock	2,092,151	3,886,489
	<u>18,248,703</u>	<u>20,253,854</u>

### *Unaudited pro forma net loss per share*

Unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2019 has been prepared to give effect to adjustments arising upon the completion of a qualified IPO. Unaudited pro forma net loss attributable to common stockholders used in the calculation of unaudited pro

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forma basic and diluted net loss per share attributable to common stockholders does not include the effects of the change in the fair value of the preferred stock warrant liability because the calculation gives effect to the automatic conversion of all shares of convertible preferred stock outstanding into shares of common stock as if the proposed IPO had occurred on January 1, 2019.

Unaudited pro forma basic and diluted weighted-average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2019 has been prepared to give effect, upon a qualified IPO, to the automatic conversion of all outstanding shares of convertible preferred stock into common stock as if the proposed IPO had occurred on January 1, 2019.

Unaudited pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	<b>Year Ended December 31, 2019 (unaudited)</b>
<b>Numerator:</b>	
Net loss attributable to common stockholders	\$ (51,128)
Add: Change in fair value of preferred stock warrant liability	(1)
Pro forma net loss attributable to common stockholders	<u>\$ (51,129)</u>
<b>Denominator:</b>	
Weighted average common shares outstanding, basic and diluted	4,191,793
Pro forma adjustment to reflect automatic conversion of convertible preferred stock to common stock upon the completion of the proposed initial public offering	<u>15,437,651</u>
Pro forma weighted average common shares outstanding, basic and diluted	<u>19,629,444</u>
Pro forma net loss per share attributable to common stockholders, basic and diluted	<u>\$ (2.60)</u>

### 13. Leases

#### ASC 842

The Company leases its office and laboratory facilities in Cambridge, Massachusetts under a noncancelable operating lease that began in August 2017 and expires in March 2025 with an option for an additional three-year term at fair-market rent at the time of the extension (the "Existing Lease"). The initial annual base rent was \$1.6 million, with such base rent increasing annually during the initial term by 3%. The extension was not included in the right-of-use assets and lease liabilities as it was not reasonably certain of being exercised. In October 2019, with the consent of the landlord, the Company entered into an agreement, with a related party, for the assignment and assumption of the Existing Lease effective the later of May 1, 2020 or when the Company has fully vacated the premises, which is expected to be in October 2020 (see Note 17). In accordance with the operating lease guidance under ASC 842, this assignment was accounted for as a lease reassessment and the right-of-use asset and lease liability were remeasured at the reassessment date of October 2019 resulting in a reduction of \$6.5 million to both the right-of-use asset and lease liabilities.

The Company is required to maintain a letter of credit, secured by restricted cash, for a security deposit of \$0.5 million in conjunction with this lease. This amount was classified as restricted cash (non-current) on the consolidated balance sheet as of December 31, 2018 and as restricted cash (current) on the consolidated balance sheet as of December 31, 2019.

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The Company also leases office space in Cambridge, Massachusetts for a period of less than one year, which was included in short-term lease cost.

The Company's real estate leases may require the Company to pay for certain operating expenses based on actual costs incurred, including costs of operations, maintenance, repair, replacement, and management of leased premises. As the amounts are variable in nature, these costs are expensed in the period incurred and included in variable lease costs in the table below.

In September 2019, the Company entered into a 36-month lease for laboratory equipment with fixed annual payments of \$0.1 million that was accounted for as an operating lease.

The components of lease expense under ASC 842 were as follows (in thousands):

	<b>Year Ended December 31, 2019</b>
Operating lease cost	\$ 1,671
Short-term lease cost	60
Variable lease cost	547
	<u>\$ 2,278</u>

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

	<b>Year Ended December 31, 2019</b>
Cash paid for amounts included in the measurement of operating lease liabilities	\$ 1,731
Operating lease liabilities arising from obtaining right-of-use assets	\$ 271
Reduction of operating lease liabilities and right-of-use assets due to lease remeasurement	\$ 6,513

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

	<b>December 31, 2019</b>
Weighted-average remaining lease term—operating leases (in years)	1.06
Weighted-average discount rate—operating leases	7.53%

Future annual minimum lease payments under operating leases as of December 31, 2019 were as follows (in thousands):

<b>Year Ending December 31,</b>	
2020	\$1,410
2021	100
2022	66
Total future minimum lease payments	1,576
Less: imputed interest	(59)
Total operating lease liabilities	<u>\$1,517</u>

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**Included on the consolidated balance sheet (in thousands):**

	<b>December 31, 2019</b>
Current operating lease liabilities	\$ 1,360
Operating lease liabilities, net of current portion	157
<b>Total operating lease liabilities</b>	<b>\$ 1,517</b>

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 is 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 total 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 will result in additional rent payments to the landlord. The Company will be obligated to pay its portion of real estate taxes and costs related to the premises, including costs of operations and management of the new leased premises. As of December 31, 2019, the lease commencement date under ASU 2016-02 had not occurred and therefore the Company did not record a right-of-use asset or the corresponding lease liabilities for its New Lease on its consolidated balance sheet.

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, 2019.

**ASC 840**

Under the previous lease accounting standard, *ASC 840, Leases*, the following table summarizes the future minimum lease payments due under the operating leases as of December 31, 2018 (in thousands):

<b>Year Ending December 31,</b>	
2019	\$ 1,665
2020	1,715
2021	1,766
2022	1,819
2023	1,874
Thereafter	2,253
	<b>\$ 11,092</b>

The Company incurred rent expense of \$1.8 million for the year ended December 31, 2018.

**14. Commitments and Contingencies****Leases**

The Company's commitments under its leases are described in Note 13.

**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

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**Notes to Consolidated Financial Statements**

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 agreed to issue 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.

In April 2018, the Company issued the 42,781 shares of common stock upon the execution of a share purchase agreement.

***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.

**15. 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, 2018 and 2019.

**16. 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 Flagship Venture Funds, to provide general and administrative services to

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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 \$0.5 million and \$0.9 million during the years ended December 31, 2018 and 2019, respectively. As of December 31, 2018 and 2019, the Company had no accounts payable to Flagship for costs related to the service agreement.

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. During the years ended December 31, 2018 and 2019, the Company paid the scientific founder \$0.2 million and \$0.2 million, respectively. As of December 31, 2018 and 2019, the Company had no accounts payable to this scientific founder.

**17. Subsequent Events**

The Company has evaluated subsequent events for financial statement purposes occurring through August 28, 2020, the date the consolidated financial statements were issued and October 21, 2020 for the reverse stock split described below. The Company determined that no subsequent events have occurred that require disclosure, except for those described below.

***Series B preferred stock***

In April 2020, in two separate closings, the Company sold an additional 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.

In July and August 2020, in two separate closings, the Company sold an additional 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.

***Loan and security agreement***

In April 2020, the Company amended its Loan and Security Agreement with Comerica to waive the requirement to begin making principal payments on March 1, 2020 and to extend the interest-only period through May 31, 2020 upon the closure of a certain qualified financing by a determinable date as defined in the agreement. In addition, the amendment further extended the interest-only period through August 1, 2020 upon the achievement of certain specified operational milestones or a qualified financing as defined in the agreement. In April 2020, upon closing of the Company's sale of Series B preferred stock, a qualified financing, the interest-only portion was extended through May 31, 2020 to be followed by monthly payments of equal principal plus interest until the loan maturity date of February 1, 2023. In June 2020, the Loan and Security Agreement was amended to extend the interest-only period through August 31, 2020 effective upon confirmation of receipt by the Company of at least a \$15.0 million payment from a strategic partner, which condition was satisfied in July 2020.

***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, for which it will receive \$3.4 million of base rent payments over the sublease term. In accordance with the terms of the sublease, rent payments commenced in July 2020.

***New Lease amendment***

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.

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***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 against a transcription factor target believed to be relevant to a broad range of cancer patients. 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 agreement, Foghorn received an upfront payment of \$15.0 million from Merck, and is eligible to receive up to \$245.0 million upon first 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 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.

***Increase in shares available for issuance under the 2016 Plan and Grant of Options***

In June 2020, the number of common shares that may be issued under the 2016 plan was increased from 4,810,810 shares to 5,027,026 shares. In August 2020, the number of shares of common stock authorized for issuance under the 2016 Plan was increased from 5,027,026 shares to 6,513,512 shares. In August 2020, the Company granted options with service-based vesting criteria for the purchase of an aggregate of 1,243,740 shares of common stock, at an exercise price of \$8.77 per share. The aggregate grant-date fair value of these options is approximately \$7.3 million, which is expected to be recognized over approximately four years.

***Stock split***

On October 18, 2020, the board of directors of the Company approved a 1-for-1.85 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company’s Preferred Stock. The reverse stock split will legally occur upon the effectiveness of the Company’s amended and restated certification of incorporation, which will be effective prior to the completion of this initial public offering. All share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

**Foghorn Therapeutics Inc.**  
**Condensed Consolidated Balance Sheets**  
(In thousands, except share and per share amounts)  
(Unaudited)

	December 31, 2019	June 30, 2020	Pro Forma June 30, 2020
<b>Assets</b>			
Current assets:			
Cash and cash equivalents	\$ 14,981	\$ 36,563	\$ 36,563
Restricted cash	541	541	541
Prepaid expenses and other current assets	1,363	1,863	1,863
Total current assets	16,885	38,967	38,967
Property and equipment, net	2,683	8,191	8,191
Restricted cash	1,733	1,735	1,735
Deferred offering costs	—	75	75
Other assets	11	—	—
Operating lease right-of-use assets	1,030	45,346	45,346
Total assets	<u>\$ 22,342</u>	<u>\$ 94,314</u>	<u>\$ 94,314</u>
<b>Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)</b>			
Current liabilities:			
Accounts payable	\$ 3,439	\$ 2,981	\$ 2,981
Accrued expenses	3,701	7,516	7,516
Operating lease liabilities	1,360	380	380
Notes payable, net of discount	4,152	4,988	4,988
Total current liabilities	12,652	15,865	15,865
Notes payable, net of discount and current portion	10,960	10,250	10,250
Operating lease liabilities, net of current portion	157	50,086	50,086
Preferred stock warrant liability	45	44	—
Total liabilities	<u>23,814</u>	<u>76,245</u>	<u>76,201</u>
Commitments and contingencies (Note 10)			
Convertible preferred stock (Series A-1, A-2 and B), \$0.0001 par value; 28,629,622 and 36,629,622 shares authorized at December 31, 2019 and June 30, 2020, respectively; 28,615,546 and 35,023,413 shares issued and outstanding at December 31, 2019 and June 30, 2020, respectively; liquidation preference of \$134,841 at June 30, 2020; no shares authorized, issued or outstanding, pro forma as of June 30, 2020	86,544	134,480	—
Stockholders' equity (deficit):			
Common stock, \$0.0001 par value; 46,600,000 and 55,000,000 shares authorized at December 31, 2019 and June 30, 2020, respectively; 5,762,745 and 5,880,598 shares issued and 4,870,851 and 5,434,649 shares outstanding at December 31, 2019 and June 30, 2020, respectively; 24,812,173 shares issued and 24,366,224 shares outstanding, pro forma at June 30, 2020	—	1	2
Additional paid-in capital	6,120	7,399	141,922
Accumulated deficit	(94,136)	(123,811)	(123,811)
Total stockholders' equity (deficit)	(88,016)	(116,411)	18,113
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 22,342</u>	<u>\$ 94,314</u>	<u>\$ 94,314</u>

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

**Foghorn Therapeutics Inc.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
**(In thousands, except share and per share amounts)**  
**(Unaudited)**

	<u>Six Months Ended June 30,</u>	
	<u>2019</u>	<u>2020</u>
Operating expenses:		
Research and development	\$ 19,550	\$ 25,131
General and administrative	3,248	4,132
Total operating expenses	<u>22,798</u>	<u>29,263</u>
Loss from operations	<u>(22,798)</u>	<u>(29,263)</u>
Other income (expense):		
Interest expense	(249)	(456)
Interest income and other expense, net	303	43
Change in fair value of preferred stock warrant liability	—	1
Total other income (expense), net	<u>54</u>	<u>(412)</u>
Net loss and comprehensive loss	<u>\$ (22,744)</u>	<u>\$ (29,675)</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (5.91)</u>	<u>\$ (5.61)</u>
Weighted average common shares outstanding—basic and diluted	<u>3,851,643</u>	<u>5,286,537</u>
Pro forma net loss per share attributable to common stockholders—basic and diluted		<u>\$ (1.34)</u>
Pro forma weighted average common shares outstanding—basic and diluted		<u>22,127,383</u>

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

**Foghorn Therapeutics Inc.**
**Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit**

(In thousands)  
(Unaudited)

	Series A-1, A-2 and B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
<b>Balances at December 31, 2018</b>	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	—	—	93,530	—	53	—	53
Vesting of restricted stock	—	—	445,945	—	—	—	—
Stock-based compensation expense	—	—	—	—	681	—	681
Net loss	—	—	—	—	—	(22,744)	(22,744)
<b>Balances at June 30, 2019</b>	<u>28,615,546</u>	<u>\$ 86,544</u>	<u>4,014,627</u>	<u>\$ —</u>	<u>\$ 4,469</u>	<u>\$ (65,752)</u>	<u>\$ (61,283)</u>
	Series A-1, A-2 and B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
<b>Balances at December 31, 2019</b>	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 \$123	6,407,867	47,936	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	117,853	—	274	—	274
Vesting of restricted stock	—	—	445,945	1	(1)	—	—
Stock-based compensation expense	—	—	—	—	1,006	—	1,006
Net loss	—	—	—	—	—	(29,675)	(29,675)
<b>Balances at June 30, 2020</b>	<u>35,023,413</u>	<u>\$134,480</u>	<u>5,434,649</u>	<u>\$ 1</u>	<u>\$ 7,399</u>	<u>\$ (123,811)</u>	<u>\$ (116,411)</u>

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

**Foghorn Therapeutics Inc.**  
**Condensed Consolidated Statements of Cash Flows**  
(In thousands)  
(Unaudited)

	<u>Six Months Ended June 30,</u>	
	<u>2019</u>	<u>2020</u>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (22,744)	\$ (29,675)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	681	1,006
Depreciation and amortization expense	290	509
Loss on disposal of property and equipment	1	—
Change in fair value of preferred stock warrant liability	—	(1)
Noncash lease expense	537	1,659
Noncash interest expense	39	126
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(98)	(774)
Accounts payable	1,097	(285)
Accrued expenses and other current liabilities	(155)	819
Operating lease liabilities	(509)	3,259
Net cash used in operating activities	<u>(20,861)</u>	<u>(23,357)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(794)	(3,269)
Net cash used in investing activities	<u>(794)</u>	<u>(3,269)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of convertible preferred stock, net of issuance costs	15,294	47,936
Proceeds from issuance of common stock upon exercise of stock options	53	274
Payment of notes payable issuance costs	(16)	—
Net cash provided by financing activities	<u>15,331</u>	<u>48,210</u>
<b>Net increase (decrease) in cash, cash equivalents and restricted cash</b>	<u>(6,324)</u>	<u>21,584</u>
Cash, cash equivalents and restricted cash at beginning of period	40,585	17,255
Cash, cash equivalents and restricted cash at end of period	<u>\$ 34,261</u>	<u>\$ 38,839</u>
<b>Supplemental cash flow information:</b>		
Cash paid for interest	\$ 216	\$ 341
<b>Supplemental disclosure of noncash investing and financing information:</b>		
Purchases of property and equipment included in accounts payable and accrued expenses	\$ —	\$ 3,115
Deferred offering costs included in accounts payable and accrued expenses	\$ —	\$ 75
<b>Reconciliation of cash, cash equivalents and restricted cash:</b>		
Cash and cash equivalents	\$ 33,695	\$ 36,563
Restricted cash (current and non-current)	566	2,276
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	<u>\$ 34,261</u>	<u>\$ 38,839</u>

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

**Foghorn Therapeutics Inc.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**1. Nature of Business and Basis of Presentation**

Foghorn Therapeutics Inc. (the “Company”) is a development-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 development-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 planned clinical trials. The impact of the COVID-19 coronavirus 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.

***Basis of presentation***

The Company’s condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”). The accompanying condensed 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”).

***Going concern***

Since its inception, the Company has funded its operations primarily with proceeds from sales of preferred stock and debt financing. The Company has incurred losses since inception, including net losses of \$51.1 million for the year ended December 31, 2019 and \$29.7 million for the six months ended June 30, 2020. In addition, as of June 30, 2020, the Company had an accumulated deficit of \$123.8 million. The Company expects to continue to generate operating losses for the foreseeable future. In July 2020, the Company received a \$15.0 million upfront payment under a collaboration agreement and in July and August 2020, the Company received gross proceeds of \$42.0 million from the sale of 5,600,000 shares of Series B convertible preferred stock (see Note 13). The future viability of the Company is dependent on its ability to raise additional capital to finance its operations.

**Foghorn Therapeutics Inc.**  
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The Company is seeking to complete an initial public offering (“IPO”) of its common stock. Upon the closing of a qualified public offering on specified terms, the Company’s outstanding convertible preferred stock will automatically convert into shares of common stock (see Note 6). In the event the Company does not complete an IPO, the Company expects to seek additional funding through private equity financings, debt financings, or other capital sources, including collaborations with other companies, government funding arrangements or other strategic transactions.

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, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Based on its recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and need to raise additional capital to finance its future operations, the Company has concluded that there is substantial doubt about its ability to continue as a going concern within one year after the date that the condensed consolidated interim financial statements are issued.

The accompanying condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the condensed consolidated interim financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

## **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, the valuation of common stock, 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.

### ***Unaudited interim financial information***

The accompanying condensed consolidated balance sheet as of June 30, 2020, the condensed consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders’ deficit and cash flows for the six months ended June 30, 2019 and 2020 are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company’s financial position as of June 30, 2020 and the results of its operations and its cash flows for the six months ended June 30, 2019 and 2020. The financial data and other information disclosed in these consolidated notes related to the six months ended

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June 30, 2019 and 2020 are also unaudited. The results for the six months ended June 30, 2020 are not necessarily indicative of results to be expected for the year ending December 31, 2020, any other interim periods, or any future year or period.

***Unaudited pro forma information***

The accompanying unaudited pro forma balance sheet as of June 30, 2020 has been prepared to give effect to the automatic conversion of all outstanding shares of convertible preferred stock into shares of common stock as if the Company's proposed initial public offering had occurred on June 30, 2020.

In the accompanying consolidated statements of operations and comprehensive loss, the unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the six months ended June 30, 2020 has been prepared to give effect to the automatic conversion of all outstanding shares of convertible preferred stock as if the Company's proposed initial public offering had occurred on the later of January 1, 2019 or the issuance date of the convertible preferred stock.

***Concentrations of credit risk and of significant suppliers***

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. As of June 30, 2020, the Company maintained cash balances 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 discovery programs. These programs could be adversely affected by a significant interruption in these services or the availability of materials.

***Deferred offering costs***

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the carrying value of the preferred stock or, for issuances of common stock, in stockholder's equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should the planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statement of operations and comprehensive loss. As of December 31, 2019, the Company had no deferred offering costs. As of June 30, 2020, the Company had \$0.1 million of deferred offering costs on its consolidated balance sheet.

**Foghorn Therapeutics Inc.**  
**Notes to Condensed Consolidated Financial Statements**  
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**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 capitalized and depreciated once placed into service. As of June 30, 2020, the Company had \$6.1 million of capitalized costs not yet placed in service related to leasehold improvements for its new lease.

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.

**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 preferred stock warrant liability 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.

**Net loss per share**

The Company follows the two-class method when computing net income (loss) per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income

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(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 entitle the holders of such shares to participate in dividends but do not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports 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 six months ended June 30, 2019 and 2020.

***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.

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**3. Fair Value Measurements**

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

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

	Fair Value Measurements at June 30, 2020 Using:			Total
	Level 1	Level 2	Level 3	
<b>Assets:</b>				
Cash equivalents:				
Money market funds	\$ 36,443	\$ —	\$ —	\$ 36,443
<b>Liabilities:</b>				
Preferred stock warrant liability	\$ —	\$ —	\$ 44	\$ 44

During the six months ended June 30, 2020, there were no transfers between Level 1, Level 2 and Level 3.

The preferred stock warrant liability in the tables above 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 represent 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 incorporates assumptions and estimates to value the preferred stock warrants. The Company assesses these assumptions and estimates at the end of each reporting period. Changes in the fair value of the preferred stock warrants are recognized within other income (expense) in the consolidated statements of operations and comprehensive loss.

The quantitative elements associated with the Company's Level 3 inputs impacting the fair value measurement of the preferred stock warrant liability include the fair value per share of the underlying Series A-1 convertible preferred stock, the remaining contractual term of the warrants, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying preferred stock. The most significant assumption in the Black-Scholes option-pricing model impacting the fair value of the preferred stock warrants is the fair value of the Company's Series A-1 convertible preferred stock as of each remeasurement date. The Company determines the fair value per share of the underlying Series A-1 convertible preferred stock by taking into consideration its most recent sales of its convertible preferred stock as well as additional factors that the Company deems relevant. The change in the fair value of the preferred stock warrant liability was not material during the six months ended June 30, 2019 and 2020.

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**4. Accrued Expenses**

Accrued expenses consisted of the following (in thousands):

	December 31, 2019	June 30, 2020
Accrued employee compensation and benefits	\$ 1,867	\$3,304
Accrued construction in progress	119	3,115
Accrued external research and development expenses	1,384	706
Other	331	391
	<u>\$ 3,701</u>	<u>\$7,516</u>

**5. Notes Payable**

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

	December 31, 2019	June 30, 2020
Principal amount of long-term debt	\$ 15,000	\$15,000
Less: Current portion of long-term debt	(4,152)	(4,988)
Long-term debt, net of current portion	10,848	10,012
Final payment fee	530	530
Debt discount, net of accretion	(418)	(292)
Long-term debt, net of discount and current portion	<u>\$ 10,960</u>	<u>\$10,250</u>

The Company has outstanding loans under its amended loan and security agreement (the "Loan") of \$7.0 million ("Term Loan A") and \$8.0 million ("Term Loan B") so that the total amount outstanding under the Loan was \$15.0 million as of June 30, 2020.

Borrowings under both Term Loan A and Term Loan B were repayable in monthly payments of interest-only through February 2020 with the option to extend the interest-only period through August 2020 upon closure of a qualified financing, to be followed by monthly payments of equal principal plus interest until the loan maturity date of February 1, 2023. Interest for Term Loan A is 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 is 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 is being amortized to interest expense over the term of the debt using the effective interest method.

In April 2020, the Company amended the Loan to extend the interest only period through May 31, 2020 upon the closure of a certain qualified financing by a determinable date as defined in the agreement, and to further extend the interest-only period through August 1, 2020 upon the achievement of certain specified operational milestones or a qualified financing as defined in the agreement. In April 2020, upon closing of the Company's sale of Series B preferred stock, a qualified financing, the interest-only portion was extended through May 31, 2020 to be

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followed by monthly payments of equal principal plus interest until the loan maturity date of February 1, 2023. In June 2020, the Loan was further amended to extend the interest-only period through August 31, 2020 effective upon confirmation of receipt by the Company of at least a \$15.0 million payment from a strategic partner, which condition was satisfied in July 2020 (see Note 13).

Borrowings under the Loan are collateralized by substantially all of the Company's assets, other than its intellectual property. There are no financial covenants associated with the Loan; however, the Company is subject to certain affirmative and negative covenants restricting the Company's activities, 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, 2019 and June 30, 2020, the Company believes an event of default would be remote.

As of June 30, 2020, the interest rate applicable to outstanding borrowings under the Loan was 3.8%. During the six months ended June 30, 2020, the weighted average effective interest rate on outstanding borrowings under the Loan was approximately 6.1%.

As of June 30, 2020, future principal payments due are as follows (in thousands):

Remainder of 2020 (six months)	\$ 2,000
2021	6,000
2022	6,000
2023	1,000
	<u>\$ 15,000</u>

**6. Convertible Preferred Stock**

As of each balance sheet date, the Preferred Stock consisted of the following (in thousands, except share amounts):

	As of December 31, 2019				
	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
	<u>28,629,622</u>	<u>28,615,546</u>	<u>\$ 86,544</u>	<u>\$ 86,782</u>	<u>15,467,863</u>

	As of June 30, 2020				
	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	16,117,631	14,525,498	108,692	108,941	7,851,621
	<u>36,629,622</u>	<u>35,023,413</u>	<u>\$ 134,480</u>	<u>\$ 134,841</u>	<u>18,931,575</u>

**Foghorn Therapeutics Inc.**  
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**7. Stock-Based Compensation**

**2016 Stock incentive plan**

The Company grants stock-based awards under its 2016 Stock Incentive Plan, (the “2016 Plan”). The total number of shares of common stock that may be issued under the 2016 Plan was 5,027,026 shares as of June 30, 2020, of which 45,710 shares remained available for future grant as of June 30, 2020. In August 2020, the number of shares that may be issued under the 2016 Plan was increased to 6,513,512 (see Note 13).

**Common stock option valuation**

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 the six months ended June 30, 2019 and 2020:

	Six Months Ended June 30,	
	2019	2020
Risk-free interest rate	2.5%	0.5%
Expected volatility	78.3%	75.3%
Expected dividend yield	—	—
Expected term (in years)	6.0	5.8

**Common stock option activity**

The following table summarizes the Company’s option activity during the six months ended June 30, 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	351,073	3.93		
Exercised	(117,853)	2.34		
Forfeited	(129,234)	1.95		
Outstanding as of June 30, 2020	<u>3,990,475</u>	\$ 2.54	8.3	\$ 5,531
Vested and expected to vest as of June 30, 2020	3,990,475	\$ 2.54	8.3	\$ 5,531
Options exercisable as of June 30, 2020	1,333,136	\$ 1.41	7.5	\$ 3,346

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 six months ended June 30, 2019 and 2020 was \$0.3 million and \$0.2 million, respectively.

The weighted average grant-date fair value per share of options granted during the six months ended June 30, 2019 and 2020 was \$2.56 and \$2.52, 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 are subject to vesting over a period of five years and began

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vesting upon the closing of the Series A-1 Preferred Stock in April 2016. The following table summarizes the Company's restricted common stock activity during the six months ended June 30, 2020:

	<u>Shares</u>
Unvested restricted common stock as of December 31, 2019	891,894
Issued	—
Vested	(445,945)
Unvested restricted common stock as of June 30, 2020	<u>445,949</u>

The total fair value of restricted stock vested during each of the six months ended June 30, 2019 and 2020 was \$1.7 million.

***Stock-based compensation***

Stock-based compensation expense was classified in the statements of operations and comprehensive loss as follows (in thousands):

	<u>Six Months Ended June 30,</u>	
	<u>2019</u>	<u>2020</u>
Research and development expenses	\$ 455	\$ 625
General and administrative expenses	226	381
	<u>\$ 681</u>	<u>\$ 1,006</u>

As of June 30, 2020, total unrecognized compensation cost related to unvested options and unvested restricted stock was \$4.9 million, which is expected to be recognized over a weighted average period of 2.7 years.

**8. Net Loss per Share and Unaudited Pro Forma Net Loss per Share**

***Net loss per share***

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	<u>Six Months Ended June 30,</u>	
	<u>2019</u>	<u>2020</u>
Numerator:		
Net loss attributable to common stockholders	\$ (22,744)	\$ (29,675)
Denominator:		
Weighted average common shares outstanding basic and diluted	<u>3,851,643</u>	<u>5,286,537</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (5.91)</u>	<u>\$ (5.61)</u>

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**Common stock equivalents**

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:

	June 30,	
	2019	2020
Convertible preferred stock (as converted to common stock)	15,467,863	18,931,575
Warrants to purchase convertible preferred stock (as converted to common stock)	7,608	7,608
Unvested restricted common stock	1,337,840	445,949
Stock options to purchase common stock	3,441,268	3,990,475
	<u>20,254,579</u>	<u>23,375,607</u>

**Unaudited pro forma net loss per share**

Unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the six months ended June 30, 2020 has been prepared to give effect to adjustments arising upon the completion of a qualified IPO. Unaudited pro forma net loss attributable to common stockholders used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders does not include the effects of the change in the fair value of the preferred stock warrant liability because the calculation gives effect to the automatic conversion of all shares of convertible preferred stock outstanding into shares of common stock as if the proposed IPO had occurred on January 1, 2019.

Unaudited pro forma basic and diluted weighted-average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the six months ended June 30, 2020 has been prepared to give effect, upon a qualified IPO, to the automatic conversion of all outstanding shares of convertible preferred stock into common stock as if the proposed IPO had occurred on the later of January 1, 2019 or the issuance date of the convertible preferred stock.

Unaudited pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Six Months Ended June 30, 2020
<b>Numerator:</b>	
Net loss attributable to common stockholders	\$ (29,675)
Add: Change in fair value of preferred stock warrant liability	(1)
Pro forma net loss attributable to common stockholders	<u>\$ (29,676)</u>
<b>Denominator:</b>	
Weighted average common shares outstanding, basic and diluted	5,286,537
Pro forma adjustment to reflect automatic conversion of convertible preferred stock to common stock upon the completion of the proposed initial public offering	16,840,846
Pro forma weighted average common shares outstanding, basic and diluted	<u>22,127,383</u>
Pro forma net loss per share attributable to common stockholders, basic and diluted	<u>\$ (1.34)</u>

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**9. Leases**

The Company has a lease for office and laboratory facilities in Cambridge, Massachusetts (the “Existing Lease”) under a noncancelable operating lease that began in August 2017 and expires in March 2025. The Company has an agreement, with a related party, for the assignment and assumption of the Existing Lease effective when the Company has fully vacated the premises, which is expected to be in October 2020.

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 will result in additional rent payments to the landlord. During the six months ended June 30, 2020, \$3.0 million of leasehold improvements were reimbursed by the landlord, which resulted in an increase to operating lease liabilities. The Company will be 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. 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 components of lease expense were as follows (in thousands):

	<b>Six Months Ended June 30,</b>	
	<b>2019</b>	<b>2020</b>
Operating lease cost	\$ 873	\$ 2,983
Short-term lease cost	15	46
Variable lease cost	238	392
	<u>\$ 1,126</u>	<u>\$ 3,421</u>

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

	<b>Six Months Ended June 30,</b>	
	<b>2019</b>	<b>2020</b>
Cash paid for amounts included in the measurement of operating lease liabilities	\$ 845	\$ 1,064
Operating lease liabilities arising from obtaining right-of-use assets	\$ —	\$ 38,306
Increase in operating lease liabilities and right-of-use assets due to lease remeasurement	\$ —	\$ 7,384

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

	<b>December 31, 2019</b>	<b>June 30, 2020</b>
Weighted-average remaining lease term—operating leases (in years)	1.06	8.11
Weighted-average discount rate—operating leases	7.53%	5.36%

**Foghorn Therapeutics Inc.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

Future annual minimum lease payments under the Company's operating leases as of June 30, 2020 were as follows (in thousands):

Remainder of 2020 (six months)	\$ 1,982
2021	9,766
2022	10,011
2023	10,116
2024	10,356
Thereafter	41,130
Total future minimum lease payments	83,361
Less: imputed interest	(16,569)
Less: estimated lease incentives	(16,326)
Total operating lease liabilities	<u>\$ 50,466</u>

**Included in the consolidated balance sheet (in thousands):**

	<b>June 30, 2020</b>
Current operating lease liabilities	\$ 380
Operating lease liabilities, net of current portion	50,086
Total operating lease liabilities	<u>\$ 50,466</u>

***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, for which it will receive \$3.4 million of base rent payments over the sublease term which began in July 2020.

**10. Commitments and Contingencies**

***Leases***

The Company's commitments under its leases are described in Note 9.

***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.

**Foghorn Therapeutics Inc.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**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.

**11. 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 has been no discretionary match made under the 401(k) Plan as of June 30, 2020.

**12. 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 Flagship Venture Funds, 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 \$0.4 million and \$0.6 million during the six months ended June 30, 2019 and 2020, respectively. As of December 31, 2019, the Company had no accounts payable to Flagship related to this service agreement. At June 30, 2020, the Company had less than \$0.1 million in accounts payable to Flagship for costs related to the service agreement.

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. During each of the six months ended June 30, 2019 and

**Foghorn Therapeutics Inc.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

2020, the Company paid the scientific founder \$0.1 million. As of December 31, 2019 and June 30, 2020, the Company had no accounts payable to this scientific founder.

**13. Subsequent Events**

For its interim consolidated financial statements as of June 30, 2020 and for the six months then ended, the Company evaluated subsequent events through August 28, 2020, the date on which those consolidated financial statements were issued and October 21, 2020 for the reverse stock split described below.

***Series B preferred stock***

In July and August 2020, in two separate closings, the Company sold an additional 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.

***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 against a transcription factor target believed to be relevant to a broad range of cancer patients. 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 agreement, Foghorn received an upfront payment of \$15.0 million from Merck, and is eligible to receive up to \$245.0 million upon first 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 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.

***Increase in shares available for issuance under the 2016 Plan and Grant of Options***

In August 2020, the number of shares of common stock authorized for issuance under the 2016 Plan was increased from 5,027,026 shares to 6,513,512 shares. In August 2020, the Company granted options with service-based vesting criteria for the purchase of an aggregate of 1,243,740 shares of common stock, at an exercise price of \$8.77 per share. The aggregate grant-date fair value of these options was approximately \$7.3 million, which is expected to be recognized over approximately four years.

***Stock split***

On October 18, 2020, the board of directors of the Company approved a 1-for-1.85 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company’s Preferred Stock. The reverse stock split will legally occur upon the effectiveness of the Company’s amended and restated certification of incorporation, which will be effective prior to the completion of this initial public offering. All share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

# Foghorn Therapeutics Inc.



**7,500,000 shares of common stock**

**Goldman Sachs & Co. LLC**

**Morgan Stanley  
Wedbush PacGrow**

**Cowen**

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, 2020

Through and including \_\_\_\_\_, 2020 (the 25th day after the date of this prospectus), all dealers effecting transactions in the Common Stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

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**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. other expenses of issuance and distribution.**

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of common stock being registered. All amounts are estimates except for the SEC registration fee, the FINRA filing fee and the exchange listing fee:

<u>Item</u>	<u>Amount to be paid</u>
SEC registration fee	\$ 15,997
FINRA filing fee	22,494
Exchange listing fee	175,000
Printing and engraving expenses	265,000
Legal fees and expenses	1,538,000
Accounting fees and expenses	1,111,000
Financial and business advisory fee	503,000
Transfer Agent fees and expenses	15,000
Miscellaneous expenses	154,509
Total	<u>\$ 3,800,000</u>

**Item 14. indemnification of directors and officers.**

As permitted by Section 102(b)(7) of the DGCL, we plan to include in our amended and restated certificate of incorporation a provision to eliminate the personal liability of our directors for monetary damages for breach of their fiduciary duties as directors, subject to certain exceptions. In addition, our amended and restated certificate of incorporation and by-laws will provide that we are required to indemnify our officers and directors under certain circumstances, including those circumstances in which indemnification would otherwise be discretionary, and we are required to advance expenses to our officers and directors as incurred in connection with proceedings against them for which they may be indemnified, in each case except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145(a) of the DGCL provides that a corporation shall have the power to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interest of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent shall not, of itself, create a presumption that the person did not act in good faith and in a manner which the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his conduct was unlawful.

Section 145(b) of the DGCL provides that a corporation shall have the power to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the

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right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by him in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

We expect to enter into indemnification agreements with our directors and officers prior to the completion of this offering. These indemnification agreements will provide broader indemnity rights than those provided under the DGCL and our amended and restated certificate of incorporation. These indemnification agreements are not intended to deny or otherwise limit third-party or derivative suits against us or our directors or officers, but to the extent a director or officer were entitled to indemnity or contribution under the indemnification agreement, the financial burden of a third-party suit would be borne by us, and we would not benefit from derivative recoveries against the director or officer. Such recoveries would accrue to our benefit but would be offset by our obligations to the director or officer under the indemnification agreement.

The underwriting agreement will provide that the underwriters are obligated, under certain circumstances, to indemnify our directors, officers and controlling persons against certain liabilities, including liabilities under the Securities Act.

We maintain directors' and officers' liability insurance for the benefit of our directors and officers.

### **Item 15. Recent sales of unregistered securities.**

The following list sets forth information regarding all unregistered securities sold by us since August 28, 2017. No underwriters were involved in the sales and the certificates representing the securities sold and issued contain legends restricting transfer of the securities without registration under the Securities Act or an applicable exemption from registration.

#### ***Issuances of capital stock***

In 2018, we issued an aggregate of 6,077,629 shares of our Series B convertible preferred stock for aggregate consideration of \$45,582,217.50 to 10 investors; and 42,781 shares of our common stock for partial consideration of a license with the Leland Stanford Junior University and six inventors. Of the shares of Series B convertible preferred stock issued, 669,625 shares were issued upon the conversion of a convertible promissory note held by one investor.

In 2019, we issued an aggregate of 2,040,002 shares of our Series B convertible preferred stock for aggregate consideration of \$15,300,015 to two investors.

In 2020, we issued an aggregate of 12,007,867 shares of our Series B convertible preferred stock for aggregate consideration of \$90,059,002.50 to 22 investors.

All sales of securities described above were made in reliance upon the exemption from registration provided by Section 4(a)(2) of the Securities Act for transactions by an issuer not involving a public offering.

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***Grants of stock options and restricted stock***

Since August 28, 2017, we have granted stock options to purchase an aggregate of 5,099,479 shares of our common stock at a weighted-average exercise price of \$4.50 to employees, directors and consultants.

The issuances of the above securities were exempt either pursuant to Rule 701, as transactions pursuant to a compensatory benefit plan, or pursuant to Section 4(a)(2), as transactions by an issuer not involving a public offering.

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### **Item 16. exhibits and consolidated financial statement schedules.**

#### (a) Exhibits

<u>Exhibit number</u>	<u>Description of document</u>
1.1*	<a href="#"><u>Form of Underwriting Agreement</u></a>
3.1*	<a href="#"><u>Second Amended and Restated Certificate of Incorporation of Foghorn Therapeutics Inc., as amended through July 17, 2020.</u></a>
3.2	<a href="#"><u>Certificate of Amendment to Second Amended and Restated Certificate of Incorporation of Foghorn Therapeutics Inc.</u></a>
3.3*	<a href="#"><u>Form of Third Amended and Restated Certificate of Incorporation of Foghorn Therapeutics Inc. (to be effective upon the closing of this offering)</u></a>
3.4*	<a href="#"><u>Amended and Restated By-laws of Foghorn Therapeutics Inc.</u></a>
3.5*	<a href="#"><u>Form of Second Amended and Restated By-laws of Foghorn Therapeutics Inc. (to be effective upon the closing of this offering)</u></a>
4.1*	<a href="#"><u>Specimen stock certificate evidencing shares of common stock</u></a>
4.2*	<a href="#"><u>Amended and Restated Investors' Rights Agreement, by and among Foghorn Therapeutics Inc. and the investors party thereto, dated as of December 18, 2018</u></a>
4.3*	<a href="#"><u>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</u></a>
4.4*	<a href="#"><u>Form of Warrant to Purchase Series A-2 Preferred Stock of the Registrant issued to Silicon Valley Bank, dated November 29, 2016</u></a>
5.1	<a href="#"><u>Opinion of Ropes &amp; Gray LLP</u></a>
10.1*	<a href="#"><u>Lease Agreement by and between ARE-MA Region No. 45, LLC and Foghorn Therapeutics Inc., dated August 24, 2017</u></a>
10.2*	<a href="#"><u>Lease Agreement by and between ARE-Tech Square, LLC and Foghorn Therapeutics Inc., dated October 23, 2019</u></a>
10.3++*	<a href="#"><u>Exclusive Collaboration and License Agreement, by and between Merck Sharp &amp; Dohme Corp. and Foghorn Therapeutics Inc., dated as of July 2, 2020</u></a>
10.4*	<a href="#"><u>Foghorn Therapeutics Inc. 2016 Stock Incentive Plan, as amended</u></a>
10.5*	<a href="#"><u>Form of Stock Restriction Agreement under the Foghorn Therapeutics Inc. 2016 Stock Incentive Plan</u></a>
10.6*	<a href="#"><u>Form of Incentive Stock Option Grant Notice under the Foghorn Therapeutics Inc. 2016 Stock Incentive Plan</u></a>
10.7*	<a href="#"><u>Form of Non-Qualified Stock Option Grant Notice under the Foghorn Therapeutics Inc. 2016 Stock Incentive Plan</u></a>
10.8*	<a href="#"><u>Form of Indemnification Agreement between Foghorn Therapeutics Inc. and its directors and officers</u></a>
10.9*	<a href="#"><u>Amended and Restated Letter Agreement between Foghorn Therapeutics Inc. and Adrian Gottschalk, dated October 14, 2020</u></a>
10.10*	<a href="#"><u>Amended and Restated Letter Agreement between Foghorn Therapeutics Inc. and Samuel Agresta, M.D., M.P.H. &amp; T.M., dated October 14, 2020</u></a>
10.11*	<a href="#"><u>Amended and Restated Letter Agreement between Foghorn Therapeutics Inc. and Carl P. Decicco, Ph.D., dated October 14, 2020</u></a>

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<u>Exhibit number</u>	<u>Description of document</u>
10.12*	<a href="#">Foghorn Therapeutics Inc. 2020 Equity Incentive Plan</a>
10.13*	<a href="#">Form of Incentive Stock Option Agreement under the Foghorn Therapeutics Inc. 2020 Equity Incentive Plan</a>
10.14*	<a href="#">Form of Non-Statutory Stock Option Agreement (Employees) under the Foghorn Therapeutics Inc. 2020 Equity Incentive Plan</a>
10.15*	<a href="#">Form of Non-Statutory Stock Option Agreement (Non-Employee Directors) under the Foghorn Therapeutics Inc. 2020 Equity Incentive Plan</a>
10.16*	<a href="#">Foghorn Therapeutics Inc. 2020 Employee Stock Purchase Plan</a>
10.17*	<a href="#">Foghorn Therapeutics Inc. 2020 Cash Incentive Plan</a>
10.18*	<a href="#">Consulting Agreement between Foghorn Therapeutics Inc. and Cigall Kadoch, dated October 1, 2015</a>
21.1*	<a href="#">List of Subsidiaries of Foghorn Therapeutics Inc.</a>
23.1	<a href="#">Consent of Deloitte &amp; Touche LLP</a>
23.2	<a href="#">Consent of Ropes &amp; Gray LLP (included in Exhibit 5.1)</a>
24.1*	<a href="#">Power of Attorney (included on signature page)</a>

\* Previously filed

++ 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.

### (b) Consolidated Financial Statement Schedules

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the consolidated financial statements or notes thereto.

### **Item 17. Undertakings.**

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer, or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

1. For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.
2. For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cambridge, Commonwealth of Massachusetts, on October 22, 2020.

**FOGHORN THERAPEUTICS INC.**

By: /s/ Adrian Gottschalk  
Adrian Gottschalk  
President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Adrian Gottschalk</u> Adrian Gottschalk	President, Chief Executive Officer and Director (Principal Executive Officer)	October 22, 2020
<u>/s/ Allan Reine</u> Allan Reine, M.D.	Chief Financial Officer (Principal Accounting and Financial Officer)	October 22, 2020
<u>*</u> José Baselga, M.D., Ph.D.	Director	October 22, 2020
<u>*</u> Scott Biller, Ph.D.	Director	October 22, 2020
<u>*</u> Douglas Cole, M.D.	Director	October 22, 2020
<u>*</u> Simba Gill, Ph.D.	Director	October 22, 2020
<u>*</u> Cigall Kadoch, Ph.D.	Director	October 22, 2020
<u>*</u> Adam Koppel, M.D., Ph.D.	Director	October 22, 2020
<u>*</u> Michael Mendelsohn, M.D.	Director	October 22, 2020

\*By: /s/ Adrian Gottschalk  
Adrian Gottschalk  
Attorney-in-fact

**CERTIFICATE OF AMENDMENT  
TO THE  
SECOND AMENDED AND RESTATED CERTIFICATE OF INCORPORATION  
OF  
FOGHORN THERAPEUTICS INC.**

Foghorn Therapeutics Inc. (the "Corporation"), a corporation organized and existing under the laws of the State of Delaware, does hereby certify:

FIRST: The Second Amended and Restated Certificate of Incorporation of the Corporation (the "Certificate") was filed with the Secretary of State of Delaware on December 18, 2018.

SECOND: The Certificate is hereby amended by adding the following paragraph immediately before the second sentence in Article FOURTH:

Reverse Common Stock Split. Effective upon the filing of this Certificate of Amendment with the Secretary of State of the State of Delaware (the "**Effective Time**"), each share of this Common Stock issued and outstanding immediately prior to the Effective Time (collectively, the "**Pre-Split Common Stock**") shall automatically and without any action on the part of the holder thereof be reclassified such that each 1.85 shares of the Common Stock shall become one share of the Common Stock (such reduction and resulting combination of shares is designated as the "**Reverse Common Stock Split**"). The par value of the Common Stock following the Reverse Common Stock Split shall remain \$0.0001 per share. Each holder of a certificate or certificates of Pre-Split Common Stock shall be entitled to receive a number of shares equal to the number of shares represented by such certificate or certificates of such holder's Pre-Split Common Stock divided by 1.85 and then rounded down to the nearest whole number. No fractional shares will be issued in connection with or following the Reverse Common Stock Split. Each holder of Pre-Split Common Stock at the Effective Time who would otherwise be entitled to a fraction of a share shall, in lieu thereof and in accordance with Section 155 of the General Corporation Law, be entitled to receive an amount in cash to be determined in good faith by the Board of Directors of the Corporation equal to such fraction of a share multiplied by the fair value of a share of the Common Stock."

THIRD: That the remaining provisions of the Certificate not affected by the aforementioned amendments shall remain in full force and not be affected by this Certificate of Amendment.

FOURTH: That the amendment of the Second Amended and Restated Certificate of Incorporation of the Corporation effected by this Certificate was duly authorized by the stockholders of the Corporation, after first having been declared advisable by the Board of Directors of the Corporation, all in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

*[The remainder of this page is intentionally left blank]*

IN WITNESS WHEREOF, the undersigned has caused this Certificate of Amendment to the Second Amended and Restated Certificate of Incorporation be signed as of the 21st day of October, 2020.

FOGHORN THERAPEUTICS INC.

By: /s/ Allan Reine

Name: Allan Reine, M.D.

Title: Chief Financial Officer

[Signature to Certificate of Amendment to Second Amended and Restated Certificate of Incorporation]



ROPES & GRAY LLP  
PRUDENTIAL TOWER  
800 BOYLSTON STREET  
BOSTON, MA 02199-3600  
WWW.ROPESGRAY.COM

October 22, 2020

Foghorn Therapeutics Inc.  
500 Technology Square, Ste 700  
Cambridge, MA 02139

Ladies and Gentlemen:

We have acted as counsel to Foghorn Therapeutics Inc., a Delaware corporation (the "Company"), in connection with the Registration Statement on Form S-1 (File No. 333-249264) (as amended through the date hereof, the "Registration Statement") filed by the Company with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Securities Act"), for the registration of 8,625,000 shares of the common stock, \$0.0001 par value per share, of the Company (the "Securities").

In connection with this opinion letter, we have examined such certificates, documents and records and have made such investigation of fact and such examination of law as we have deemed appropriate in order to enable us to render the opinions set forth herein. In conducting such investigation, we have relied, without independent verification, upon certificates of officers of the Company, public officials and other appropriate persons.

The opinions expressed below are limited to the Delaware General Corporation Law.

Based upon and subject to the foregoing, we are of the opinion that the Securities have been duly authorized and, when issued and delivered pursuant to the Underwriting Agreement and against payment of the consideration set forth therein, will be, validly issued, fully paid and non-assessable.

We hereby consent to your filing this opinion as an exhibit to the Registration Statement and to the use of our name therein and in the related prospectus under the caption "Legal Matters." In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder.

Very truly yours,

/s/ Ropes & Gray LLP

Ropes & Gray LLP

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use in this Registration Statement No. 333-249264 on Form S-1 of our report dated August 28, 2020 (October 21, 2020, as to the effects of the reverse stock split described in Note 17) relating to the financial statements of Foghorn Therapeutics Inc. We also consent to the reference to us under the heading “Experts” in such Registration Statement.

*/s/ Deloitte & Touche LLP*

Boston, Massachusetts  
October 21, 2020