UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025
OR

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

For the transition period from _____ to _____

Commission file number: 001-39634

Foghorn Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware	**47-5271393**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
99 Coolidge Avenue, Suite 500 Watertown, Massachusetts	**02472**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: 617-586-3100
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 Par Value	**FHTX**	**The Nasdaq Global Market**

Securities registered pursuant to Section 12(g) of the Act:
None

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of common stock held by non-affiliates of the registrant computed by reference to the price of the registrant's common stock as of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, was approximately (based on the last reported sale price on the NASDAQ Global Market as of such date) $172.3 million.

As of February 27, 2026 there were 58,700,246 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2026 Annual Meeting of Stockholders, which the registrant intends to file with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the initiation, timing, progress, enrollment, results, and timing of results and regulatory filings of our research and development programs and our preclinical and clinical studies, including those included in our collaboration with Eli Lilly and Company ("Lilly");
- our ability to advance any product candidates that we may develop and to successfully complete preclinical and clinical studies;
- our ability to leverage our initial programs to develop additional product candidates using our Gene Traffic Control® platform;
- 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-909 and any future product candidates from the U.S. Food and Drug Administration (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 contract development and manufacturing organizations ("CDMOs") or contract research organizations ("CROs"), including those located outside the United States, such as those located in China, for our manufacturing and research needs;
- regulatory developments in the United States and foreign countries;
- general economic conditions, including recessionary conditions, interest rates, monetary fluctuations and supply chain constraints;
- ongoing and potential geopolitical instability and armed conflicts;
- our ability to attract and retain key scientific and management personnel; and
- the scope of protection we are able to establish, maintain and enforce for intellectual property rights covering our current and future product candidates, and our Gene Traffic Control platform.

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

SUMMARY OF RISK FACTORS

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

- We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- We have incurred significant losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- We will need substantial additional funding. If we are unable to raise capital when needed or under acceptable terms, we could be forced to delay, reduce or eliminate our research and product development programs or future commercialization efforts.
- We are heavily dependent on the success of our product candidates, which are in preclinical and Phase 1 clinical development. We may not be successful in our efforts to identify and develop potential product candidates. If these efforts are unsuccessful, or if we experience significant delays, we may never become a commercial stage company or generate any revenues, and our business could be materially harmed.
- 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 their commercial potential or result in significant negative consequences following any potential marketing approval.
- We or our collaboration partner may not be able to file Investigational New Drug Applications ("INDs") or IND amendments to commence clinical trials of our product candidates on the timelines we expect, and even if we or they are able to, the FDA may not permit us to proceed. For our partnered programs, we may not be able to exert unilateral control over the development of such product candidates.
- We are not able to exert unilateral control over the development of FHD-909 through our collaboration with Lilly and may not be able to exert unilateral control over future product candidates as part of that collaboration or other future collaborations.
- There is substantial competition in our field, which may result in others developing or commercializing products that may be competitors of ours before we do.
- 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.
- 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.
- Unfavorable global macroeconomic conditions, geopolitical trends, and armed conflict, together with legislative, executive, and administrative actions meant to address these and other conditions, could adversely affect our business, financial condition or results of operations.

PART I

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

ITEM 1. BUSINESS

Overview

Foghorn is a clinical stage, precision therapeutics biotechnology company pioneering a new class of medicines that treat serious diseases by correcting abnormal gene expression through selectively targeting the chromatin regulatory system, an untapped opportunity for therapeutic intervention in oncology and with potential in a wide spectrum of other diseases, including immunology and inflammation.

The chromatin regulatory system orchestrates gene expression—the turning on and off of genes—which is fundamental to how all our cells function. The chromatin regulatory system is implicated in approximately 50 percent of all cancers, and understanding how this system works could lead to an entirely new class of precision medicines. To our knowledge, we are the only company with the ability to study and target the chromatin regulatory system at scale, in context, and in an integrated way.

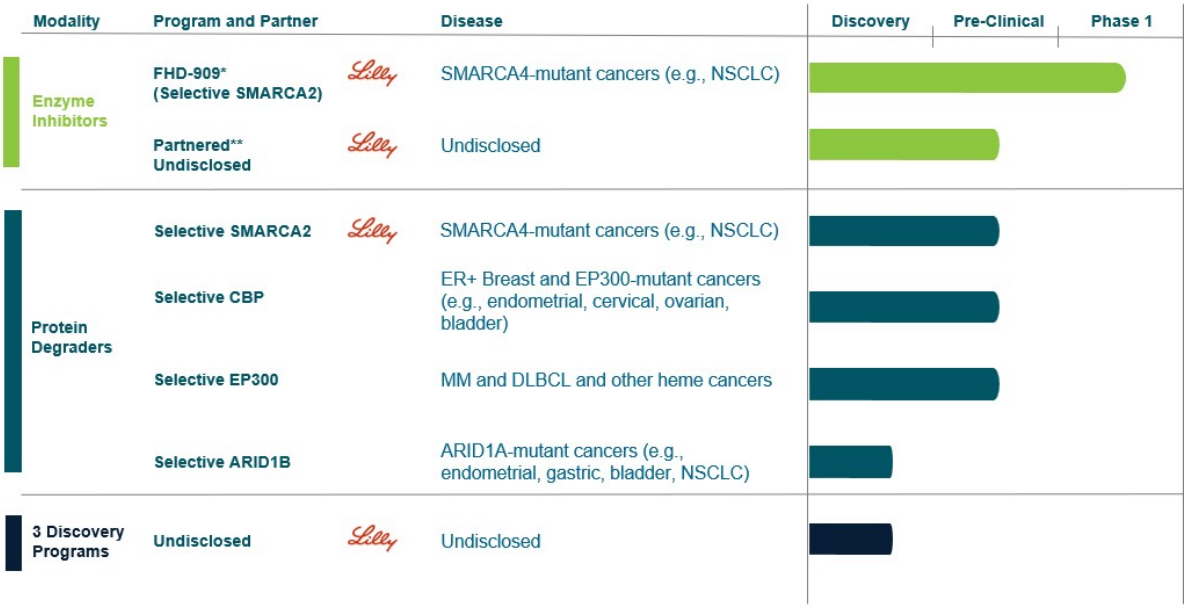
Our proprietary Gene Traffic Control® platform provides an integrated and mechanistic understanding of how the various components of the chromatin regulatory system interact, allowing us to identify, validate and potentially drug targets within this system. We have developed unique capabilities that have yielded new insights and scalability in drugging this new, previously untapped and promising area.

At present, we are working on more than seven programs with one clinical-stage drug candidate currently in Phase 1 development. We have discovered highly selective chemical matter for some of the most challenging targets in oncology including SMARCA2 (BRM), CBP, EP300 and ARID1B, as well as other undisclosed targets. We believe our current pipeline has the potential to help more than 500,000 cancer patients. We take a small molecule modality agnostic approach to drugging targets which includes protein degraders, allosteric enzymatic inhibitors, and transcription factor disruptors. We are a biology first company, which means we focus first on the underlying genetics and biology of a disease relevant target and then leverage the most appropriate drugging approach to impact the disease biology.

As part of our collaboration with Eli Lilly and Company ("Lilly"), Lilly has initiated a Phase 1 dose escalation trial with FHD-909 (LY4050784), a selective ATPase inhibitor of SMARCA2, with first patient dosed in October 2024.

We believe Foghorn has the potential to be a major biopharmaceutical company with our current pipeline addressing more than 20 tumor types impacting more than 500,000 patients annually. We believe that we have the potential to file four Investigational New Drug Applications ("INDs") over the next two years.

Our current pipeline of product candidates and discovery programs are shown below:



*LY4050784, 50/50 U.S. economic split, ex-U.S. royalties. **Pending Lilly decision to proceed, 50/50 U.S. economic split, ex-U.S. royalties.
SMARCA2 = BRM
DLBCL: Diffuse Large B-Cell Lymphoma; ER+: Estrogen Receptor-positive; MM: Multiple Myeloma; NSCLC: Non-Small Cell Lung Cancer

In December 2021, we entered into a strategic collaboration agreement with Lilly (the "Lilly Collaboration Agreement"). Under the terms of the Lilly Collaboration Agreement, we are leveraging our platform technology to discover and develop therapeutic molecules directed to the SMARCA2 target and an additional undisclosed oncology target, and up to three additional discovery programs. FHD-909 is a first-in-class oral SMARCA2 selective inhibitor that has demonstrated in preclinical studies to have high selectivity over its closely related paralog SMARCA4 (BRG1), two proteins that are the catalytic engines across all forms of the BAF complex. Selectively blocking SMARCA2 activity is a promising synthetic lethal strategy intended to induce tumor death while sparing healthy cells. SMARCA4 is mutated in up to 10 percent of non-small cell lung cancer ("NSCLC") and implicated in a significant number of solid tumors. In October 2024, we announced that the first patient had been dosed in the Phase 1 trial for FHD-909 in SMARCA4 mutated cancers, with NSCLC as the primary patient population.

We believe this strategic collaboration confirms the rigor of our science, highlights the importance of the targets we are tackling and underscores the relevance of the biology on which we are focused.

How the Chromatin Regulatory System Orchestrates Gene Expression

The major components of the chromatin regulatory system are chromatin remodeling complexes, transcription factors, helicases and other chromatin related factors which work in concert to orchestrate gene expression. One important role for this system is to control the accessibility of chromatin which in turn determines if other factors necessary for gene expression can access the genetic material. In addition, the system controls the structure, modification, and repair of chromatin which are all necessary for the proper control of gene expression. Because of the central role this system plays in orchestrating normal gene expression, aberrations in the system may result in disease. We believe our platform is uniquely suited to address these aberrations and treat these diseases.

Our Gene Traffic Control Platform

Our proprietary Gene Traffic Control platform gives us an integrated and mechanistic understanding of how the various components of the chromatin regulatory system interact, allowing us to identify, validate and drug targets within the system. 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. Our platform enables us 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 epigenomic 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 epigenome sequencing and computational tools, including aspects of artificial intelligence and machine learning, to characterize, identify, and validate targets within the chromatin regulatory system. Our epigenome 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, transcription factors, helicases, and other chromatin related 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 regulatory system component activity, for binders that we can turn into protein degraders, and for disruptors of transcription factor-chromatin remodeling complex interactions. Once we identify 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—**We have built extensive targeted protein degrader capabilities encompassing proprietary chemistry, high-throughput cellular screening capabilities, mechanistic assays to triage and rank compounds against multiple parameters including kinetics of degradation, and ternary complex formation understanding through both biophysical structural determination and computational modeling. We develop both heterobifunctional degraders and molecular glues that serve to bridge an interaction between an E3 ligase and target protein of interest. This induced proximity results in driving the target protein of interest for degradation via the ubiquitin-proteasome pathway. A demonstrated strength of our platform is leveraging degradation to enable selectivity, which we have done for several programs including SMARCA2, CBP, EP300 and ARID1B. We have developed capabilities with long-acting formulation of our protein degraders, which we believe have the potential to enable enhanced convenience and route of administration.
- **Translation to Clinic and Identification of Biomarkers**—Early in the drug discovery process, we use various genome and epigenome 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 Leadership

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 20 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, Alfonso Quintas-Cardama, M.D., previously served as Chief Medical Officer at TCR^2 and led the development of their cell therapy platform. Our Chief Scientific Officer, Steven Bellon, PhD., has more than 25 years of drug discovery experience from multiple drug classes with prior roles at Vertex Pharmaceuticals, Amgen, and Constellation Therapeutics. We have assembled an exceptional team of 106 employees as of December 31, 2025.

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 have pursued to date 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 candidate, FHD-909, through clinical development in patients with NSCLC and with select solid tumors with partner Lilly.** FHD-909 is a first-in-class oral SMARCA2 selective inhibitor that has demonstrated in preclinical studies to have high selectivity over its closely related paralog SMARCA4, two proteins that are the catalytic engines across all forms of the BAF complex. Selectively blocking SMARCA2 activity is a promising synthetic lethal strategy intended to induce tumor death while sparing healthy cells. SMARCA4 is mutated in up to 10 percent of NSCLC and implicated in a significant number of solid tumors.
- **Expand our precision oncology pipeline by developing proprietary enzymatic inhibitors, degraders and disruptors that target genetically defined dependencies.** 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 various components of the chromatin regulatory system. For example, using our proprietary platform, we have disclosed four distinct targets: SMARCA2, CBP, EP300 and ARID1B , that have genetically determined dependencies within the chromatin regulatory system. We intend to use our platform to develop novel product candidates to further deepen our precision therapeutics approach in oncology and beyond and believe we have the potential to file four INDs over the next two years.
- **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 over time. 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 in oncology and other therapeutic areas.
- **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 December 2021, we entered into a strategic collaboration with Lilly to create novel oncology medicines. The Lilly collaboration includes a U.S. co-development and co-commercialization agreement for the selective SMARCA2 oncology program and an additional undisclosed oncology target. In addition, the collaboration includes three additional discovery programs using Foghorn's proprietary Gene Traffic Control platform.

Chromatin Regulatory System: An Untapped Opportunity for Therapeutic Intervention

The major components of the chromatin regulatory system are chromatin remodeling complexes, transcription factors, helicases and other chromatin related factors which work in concert to orchestrate gene expression. One important role for this system is to control the accessibility of chromatin which in turn determines if other factors necessary for gene expression can access the genetic material. In addition, the system controls the structure, modification, and repair of chromatin which are all necessary for proper control of gene expression. Because of the central role this system plays in orchestrating normal gene expression, aberrations in the system may result in disease. Our platform is uniquely suited to correct these aberrations and treat these diseases.

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, helicases and other chromatin related 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 historically lacked a systematic approach to doing so. 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 has highlighted the association of this system in other

therapeutic areas, including virology, autoimmune disease and neurology, implying even greater potential for therapeutic intervention.

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

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

Genetically determined dependencies may arise from mutations in various components of the chromatin regulatory system (e.g., chromatin remodeling complexes, helicases, transcription factors, chromatin related factors) or through mutations elsewhere in the cell that create dependencies on the system.

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

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 and protein degraders .

- **Enzyme inhibitors**. These candidates have the potential to act on targets such as the ATPase SMARCA2 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 either heterobifunctional or molecular glue degraders which serve to specifically recruit a target to an E3 ligase component, resulting in the removal of the target protein by the cell's native protein degradation system.

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.

For components of the chromatin regulatory system that have an enzymatic function (e.g., chromatin remodeling complexes and helicases), we may leverage enzymatic inhibitors. For components of the system that are not amenable to enzymatic inhibition or where selectivity through inhibition may not be possible, we may leverage targeted protein degradation.

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 its various components. Building upon the groundbreaking discoveries of our academic co-founders, we have developed our proprietary Gene Traffic Control platform which allows us to identify and validate targets within the chromatin regulatory system. We have unique capabilities to isolate, synthesize, characterize, and interrogate components of the system at a level of scale, precision, and efficiency, that to our knowledge, no others have achieved.

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

Our Gene Traffic Control platform encompasses the following:

- Target Identification and Validation
- Production of Chromatin Regulatory System Components at Scale and Proprietary Assays
- Discovery and Optimization of Chemical Matter
- Development of Targeted Protein Degraders

- 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 epigenome sequencing and computational tools to characterize, identify and validate targets within the chromatin regulatory system. Our epigenome 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 to understand relationships and synthetic lethality across and within a range of cancer cell lines.
- **Perform broad epigenome sequencing to validate dependencies *in vitro*.** We apply cutting edge epigenome sequencing tools in combination with proprietary tool compounds to further validate targets and enhance our understanding of the impact of drugging the chromatin regulatory system. These tools allow us to rapidly understand the gene expression profiles of specific cancer cell lines, the open / closed state of chromatin, and give us mechanistic understanding of how components of the system work together.
- **Apply machine learning and artificial intelligence ("AI") to enhance discovery efforts.** We use AI systems, such as AlphaFold and ColabFold, to predict protein structures where experimentally solved crystal structures are not available in the Protein Data Bank. These predicted models inform the design of protein constructs for discovery targets and serve as references for our internal crystal structures. Additionally, we use AI systems to predict patient tumor burden when direct measurements are not available and predict potential patient response to treatment using novel biomarkers. Additionally, we use large-language models to summarize collections of related biological pathways and processes and to enable non-computational scientists to aid our discovery efforts.
- **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 (short hairpin RNA) to validate that knockdown of our target of interest results in tumor growth inhibition. We also apply epigenome sequencing tools in the animal model setting to identify potential biomarkers.

Production of Chromatin Regulatory System Components at Scale and Proprietary Assays

We have built unique capabilities to purify and synthesize components of the chromatin regulatory system (chromatin remodeling complexes, transcription factors helicases, chromatin related 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 chromatin remodeling complexes such as the BAF complex, as well as mutant forms of these complexes. We also produce and screen full length versions of transcription factors and other chromatin regulatory system components.
- **Structural Biology.** We believe that the three-dimensional structure of chromatin regulatory system components provides a mechanistic understanding of the targets and thus enables drug discovery. We have repeatably been able to determine three dimensional structures for various chromatin regulatory system targets, including x-ray structures of the enzymes targets, ternary structures of protein degrader targets, and mass spectrometry mapping of transcription factor - chromatin remodeling complex interactions.

Discovery and Optimization of Chemical Matter

We perform proprietary high throughput screens that leverage our ability to produce 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 SMARCA2 form of BAF which corresponds to SMARCA4 mutated cancer). 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 biophysical 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.

Development of Targeted Protein Degraders

For targets in the portfolio whose biology demonstrates that degradation could offer a therapeutic advantage, we develop small molecule heterobifunctional or molecular glue degraders. Many of our targets play important scaffolding roles in chromatin remodeling complexes and/or are not enzymes. Therefore, inhibition would not be effective or possible. Protein degraders recruit target proteins to specific E3 ligase complexes and by doing so, promote the removal of the target protein by harnessing the cell's native ubiquitin and proteasome-based degradation system. This approach results in rapid loss and clearance from the cell of disease driving proteins and is a powerful complement to our inhibitor capabilities.

We have a broad and highly efficient degradation development, screening, and triaging platform. This know-how and capabilities include:

- Proprietary library of linkers and E3 ligase binders for heterobifunctional degrader development;
- Proprietary screening strategy for novel molecular glue discovery;
- Biochemical, biophysical, and cellular assays that characterize protein degrader mechanism of action and guide optimization, including degradation kinetics, ubiquitination, and permeability;
- Biochemical and cellular ternary complex assays, ternary complex structural determination;
- Molecular and protein:protein interaction interface prediction modeling and compound docking programs;
- Global proteomics and mass spectrometry to measure selectivity in an unbiased fashion;
- Induced proximity and proximity labeling capabilities for exploration of novel approaches;
- Oral and long-acting formulation of protein degraders which enhances route of administration and/or decrease frequency of delivery;
- Degraders compatible with antibody conjugation and delivery as degrader antibody conjugates; and
- Development of a new ligases and effector proteins, which have potential to degrade transcription factors and other important factors.

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 epigenome 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 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. Our most advanced product candidate is FHD-909. In February 2024, Lilly selected FHD-909 for clinical development pursuant to the Lilly Collaboration Agreement, and in May 2024, the IND was cleared. The first patient was dosed in the Phase 1 dose escalation trial for FHD-909 in October 2024, with NSCLC as the primary patient population.

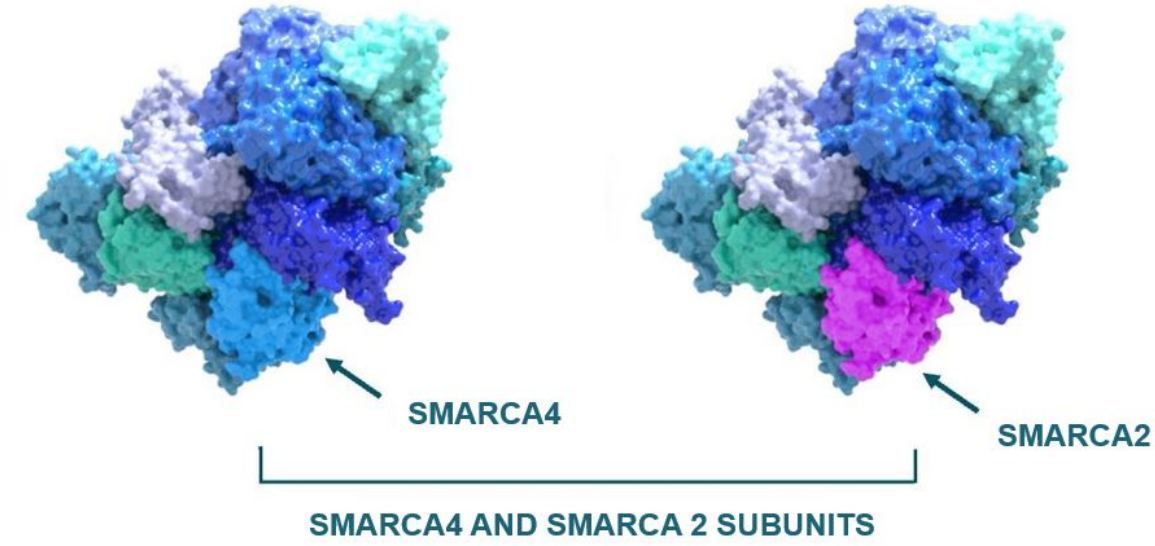


Figure 1. The enzymatic activity of the BAF complex is provided by the SMARCA2 or SMARCA4 subunits.

Selective SMARCA2 Inhibitor and Degrader

Overview

Broad cancer sequencing initiatives have shown that SMARCA4 is one of the most highly mutated subunits of the BAF complex. SMARCA4 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 10 percent of NSCLC tumors. Beyond NSCLC, the MSK-IMPACT study highlighted SMARCA4 mutations in over 30 different types of tumors. In many cases, these mutations lead to a loss of enzymatic activity in the SMARCA4 subunit, creating a genetically determined dependency on SMARCA2. This loss of SMARCA4 and subsequent dependency on SMARCA2 leads to a drugging opportunity. We are currently developing selective modulators of SMARCA2 to target this genetic dependency in SMARCA4 mutated cancers. In December 2021, we entered into a strategic collaboration with Lilly to create novel oncology medicines. The Lilly collaboration includes a U.S. co-development and co-commercialization agreement for the selective SMARCA2 oncology program. In February 2024, Lilly declared FHD-909, a first-in-class SMARCA2 inhibitor, a development candidate pursuant to the Lilly Collaboration Agreement and in May 2024, the IND was cleared. The first patient was dosed in the Phase 1 dose escalation trial for FHD-909 in October 2024 with NSCLC as the primary patient population.

12 Tumor Types with Highest Prevalence of SMARCA4 Mutations

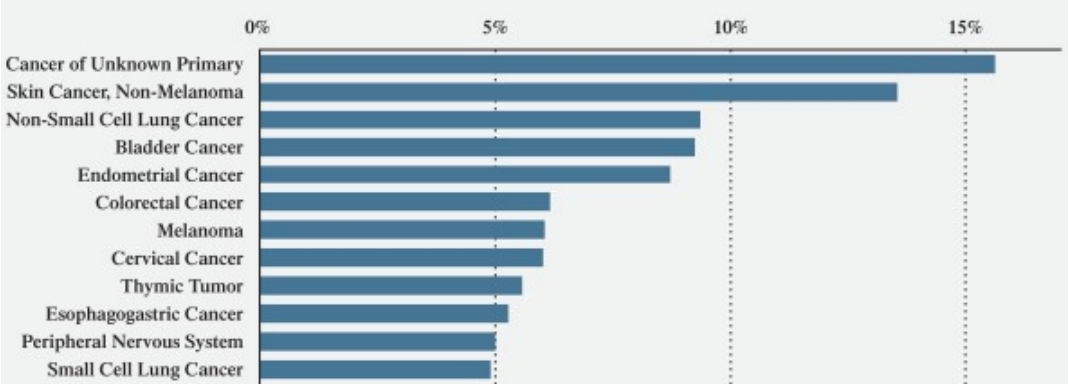


Figure 2. The above chart highlights the cancers with the highest prevalence of SMARCA4 mutations from the MSK-IMPACT study.

Non-Small Cell Lung Cancer Overview

Lung cancer is the leading cause of cancer-related death globally, accounting for approximately 1.8 million deaths per year. According to data from the National Cancer Institute Surveillance, Epidemiology, and End Results Program ("SEER"), in the United States, cancer of the lung and bronchus is the third leading cancer by estimated cases and deaths annually, with an estimated 227,000 new cases diagnosed and 125,000 deaths in the United States each year. 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. Targeted therapies developed for the proteins encoded by some of these genes such as the epidermal growth factor receptor ("EGFR") and anaplastic lymphoma kinase gene ("ALK") are standard of care for patients with NSCLC harboring such actionable mutations. 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 targeted therapies such as EGFR or ALK have tumors that express PD-L1 and are candidates for immunotherapies with or without conventional chemotherapy. Despite the availability of both targeted and immunotherapies, the prognosis in NSCLC remains poor, with an overall relative five-year survival for all patients diagnosed with lung cancer of 28.1 percent, according to SEER.

An analysis of genomic data in NSCLC cancer patients, collected as part of MSK-IMPACT, revealed that gene alterations in SMARCA4 were found in 10 percent of NSCLC samples. In a retrospective analysis conducted by MSKCC it was observed that among patients with SMARCA4-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 SMARCA4-deficient NSCLC, highlighting the importance of developing novel therapeutics that address this unmet need.

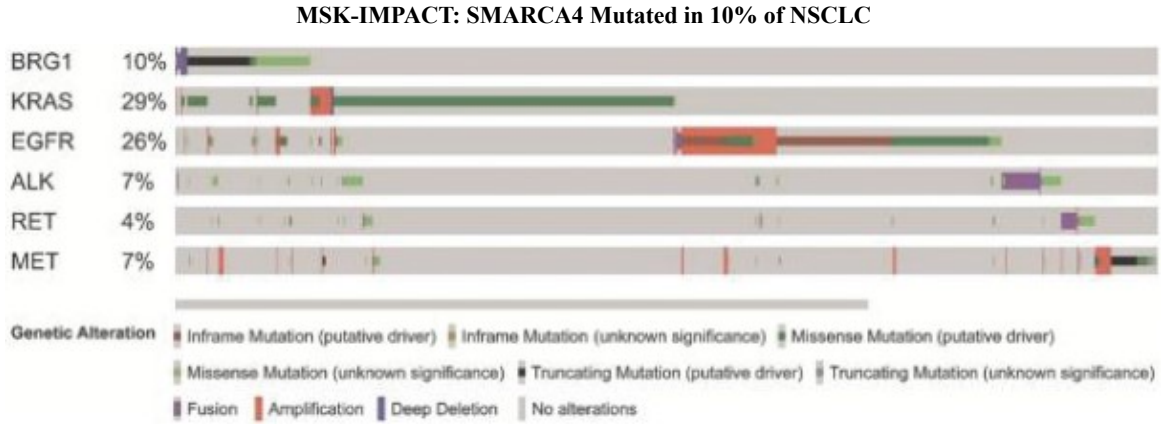


Figure 3. SMARCA4 gene alterations are found in 10 percent of NSCLC tumors and have minimal overlap with other actionable mutations present in NSCLC, such as EGFR and ALK.

Genomic screening of over 400 cancer cell lines that remove SMARCA2 via CRISPR revealed a genetic dependency of certain SMARCA4-mutated cancers on SMARCA2. This finding suggests that selective inhibition or selective degradation of SMARCA2 has the potential to be therapeutically meaningful in certain cancers with SMARCA4 mutations.

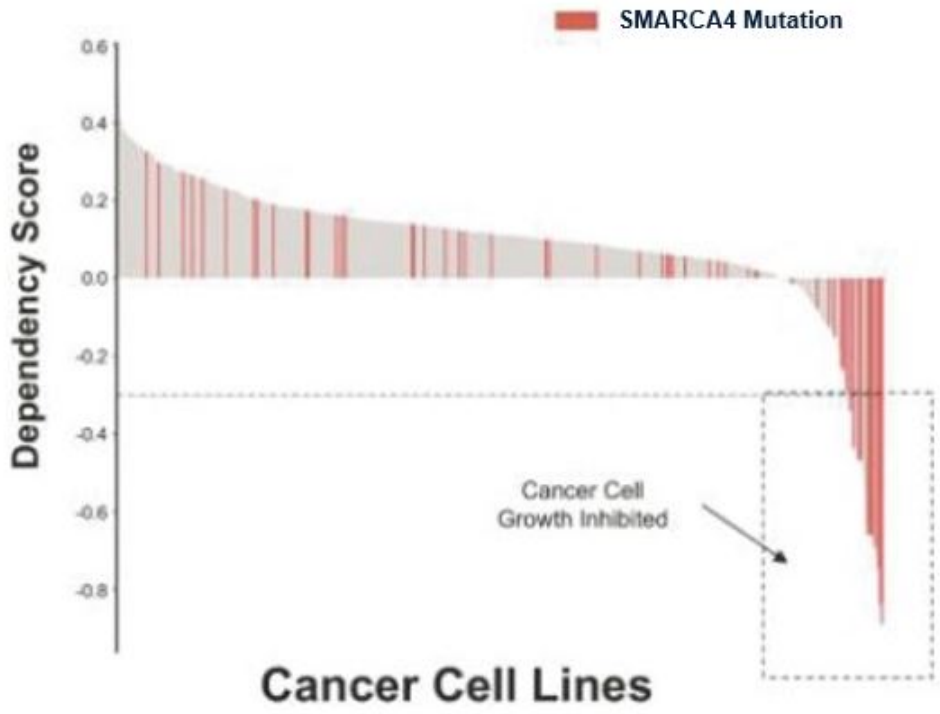


Figure 4. In a screen of over 400 cancer cell lines, inactivation of the SMARCA2 gene resulted in selective inhibition of cell lines containing mutations in SMARCA4.

Our Solution: Selective SMARCA2 Inhibitor, FHD-909, and Selective SMARCA2 Degrader

With our collaboration partner, Lilly, we are advancing two classes of molecules, an enzymatic inhibitor, FHD-909, and a protein degrader, as selective modulators of SMARCA2.

FHD-909 is a first-in-class oral selective SMARCA2 inhibitor that has demonstrated in preclinical studies to have high selectivity over its paralog SMARCA4, two proteins that are the catalytic engines across all forms of the BAF complex. FHD-909 is currently being studied in a Phase 1 open label multi-center clinical trial.

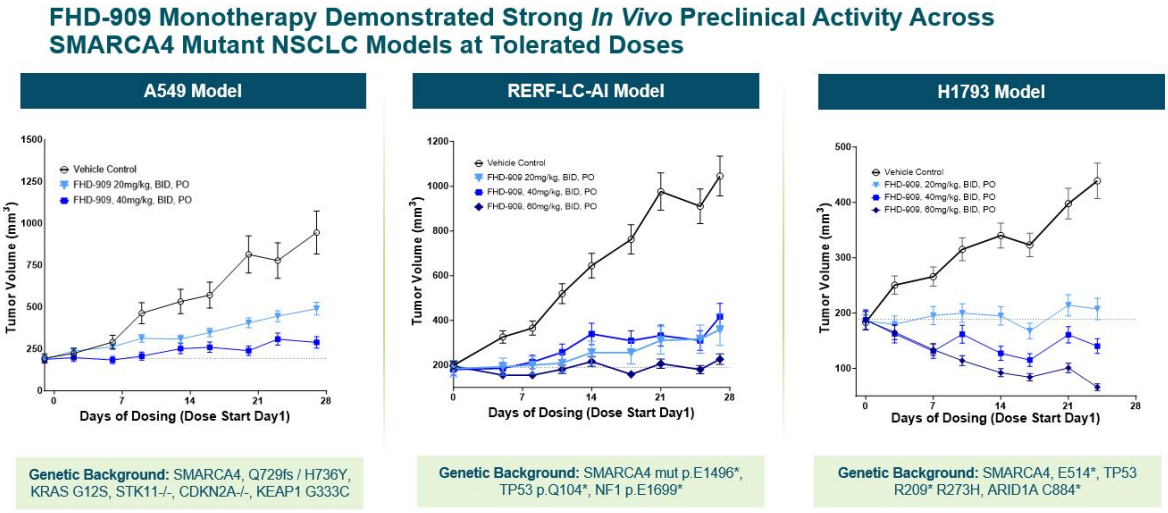


Figure 5. FHD-909 Monotherapy Demonstrated Strong In Vivo Preclinical Activity Across SMARCA4 Mutant NSCLC Models at Tolerated Doses.

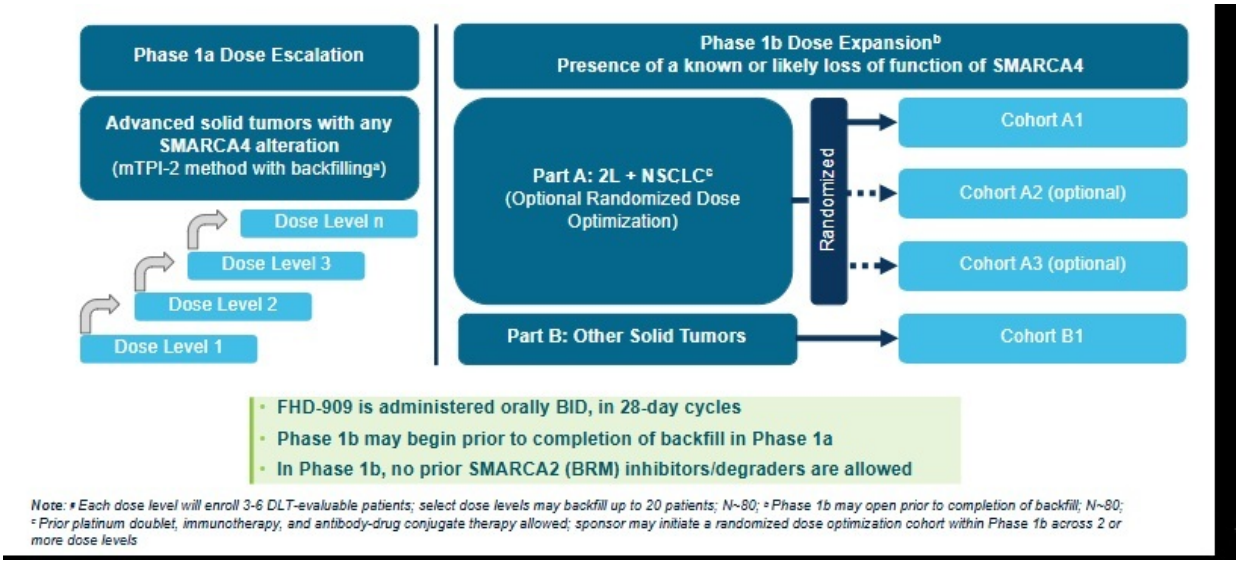


Figure 6. A First-in-Human Phase 1 Trial of FHD-909 in Advanced Solid Tumor Patients with SMARCA4 Mutations

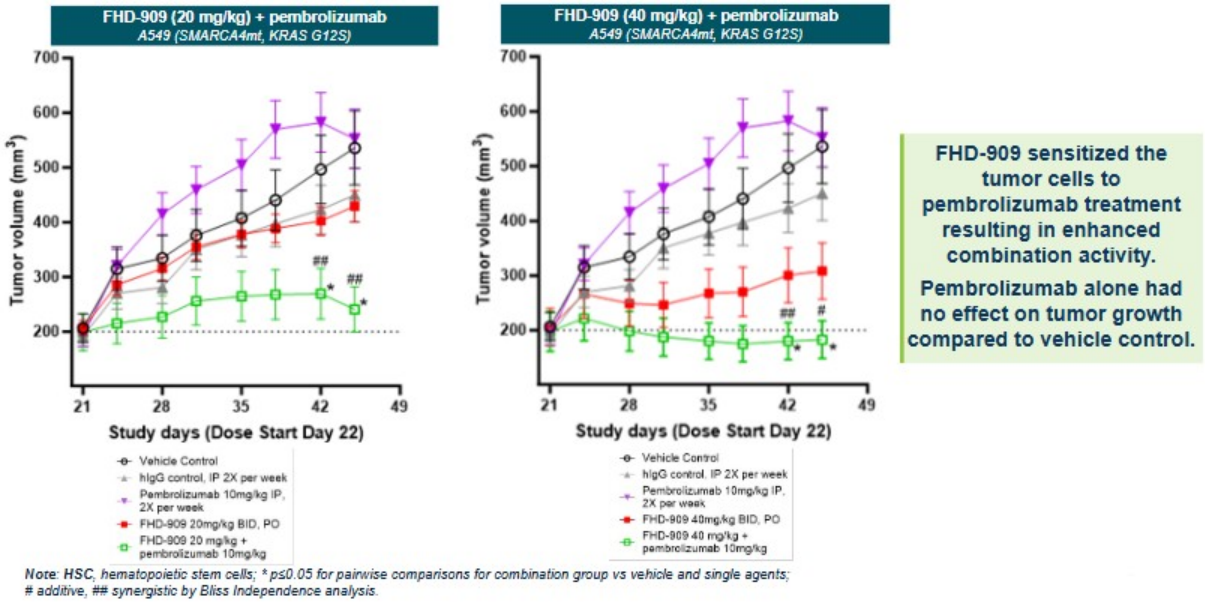


Figure 7. FHD-909 in Combination with Pembrolizumab Shows Significantly Enhanced Anti-Tumor Activity in A549 CD34 + HSC Humanized Xenograft NSCLC Model

Selective SMARCA2 Degrader

Our other approach to selective SMARCA2 modulation consists of protein degrader molecules that activate the cell's ubiquitin proteasome degradation system to selectively destroy SMARCA2. One domain of the SMARCA2 degrader molecule is a potent and selective binder of SMARCA2. 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 ubiquitin proteasome degradation system. We have shown that it is possible to identify protein degraders that lead to the destruction of SMARCA2 while leaving SMARCA4 virtually untouched.

Selective Degradation of SMARCA2

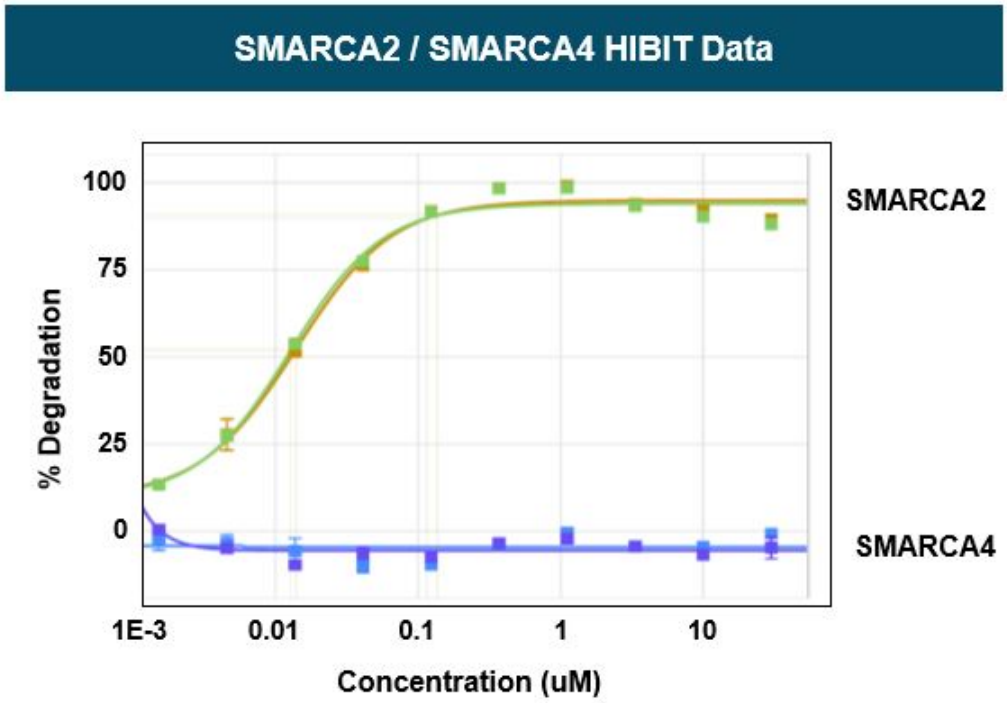


Figure 8. Selective SMARCA2 degrading molecules led to the degradation of over 75 percent of SMARCA2 while leaving the levels of SMARCA4 virtually unchanged.

Selective CBP Degrader for EP300 Mutated and CBP Dependent Cancers

CREB binding protein (CBP) serves as a critical co-activator for transcription factors involved in signaling pathways in a subset of cancers including bladder, endometrial, colorectal, breast, gastric and lung.

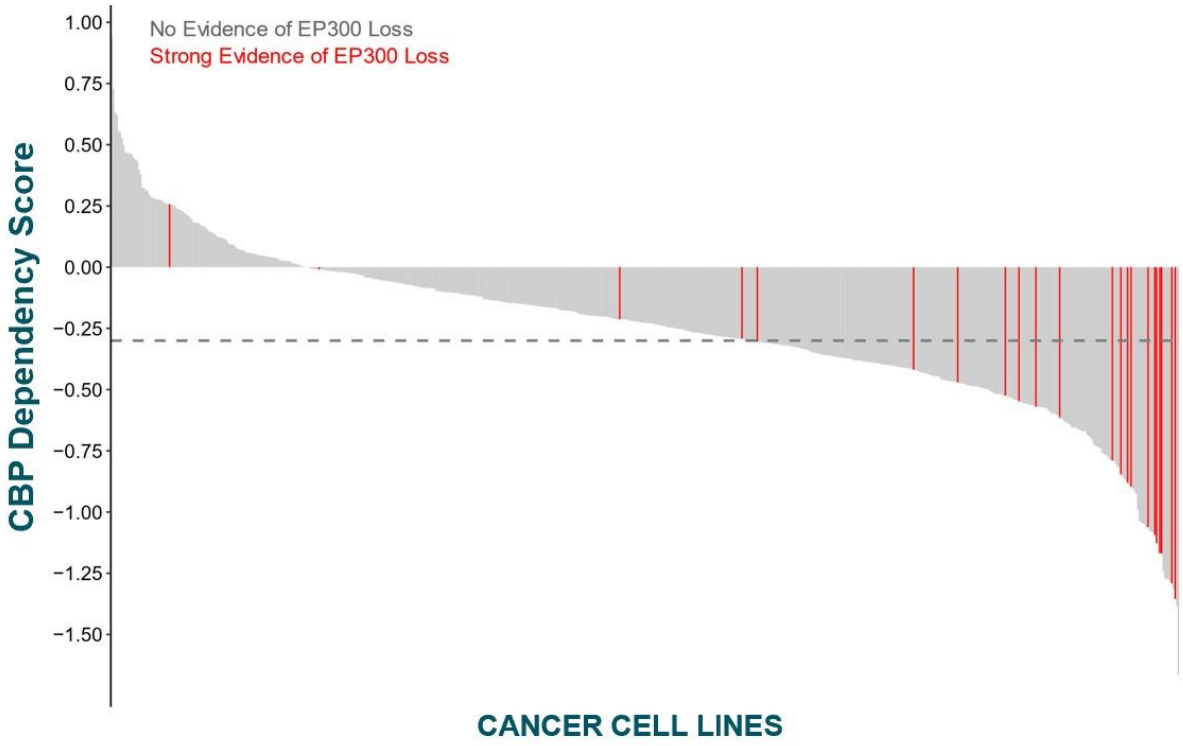


Figure 9. In a screen of over 1,000 cancer cell lines, CRISPR knockout of the CBP gene resulted in selective growth inhibition of cell lines containing mutations in EP300, establishing the dependency on CBP in these cell lines.

CBP and E1A-binding protein (EP300) are paralog chromatin regulators and histone acetyltransferases with highly homologous domain structure and architecture. Functional genomics screens have shown that CBP and EP300 share a bi-directional synthetic lethal relationship. As a result, loss of function of one of these proteins leads to dependency on the other. Selectively targeting CBP has applications in tumors with EP300 mutations and in CBP-dependent cancers including but not limited to endometrial, cervical, ovarian, bladder, colorectal and ER+ breast cancer. According to Clarivate, the annual U.S. incidence of these cancers exceeds 500,000.

We are developing a selective CBP degrader and plan to exploit the bi-directional synthetic lethal relationship it shares with its paralog acetyltransferase, EP300, to identify and treat those patients with EP300 mutated cancers. We believe selectively targeting and degrading CBP will potentially offer increased anti-tumor activity resulting from the tolerability advantage compared with non-selectively degrading both targets.

With more advanced degraders of CBP, we have generated data in several cell derived xenograft (“CDX”) mouse models which include gastric, colorectal, and bladder models. As seen in Figure 10 below, the degrader denoted as FHT-CBPd-9 appears well-tolerated based on the limited mouse body weight percentage changes and achieves tumor growth inhibition in the bladder model and tumor regression in the gastric model.

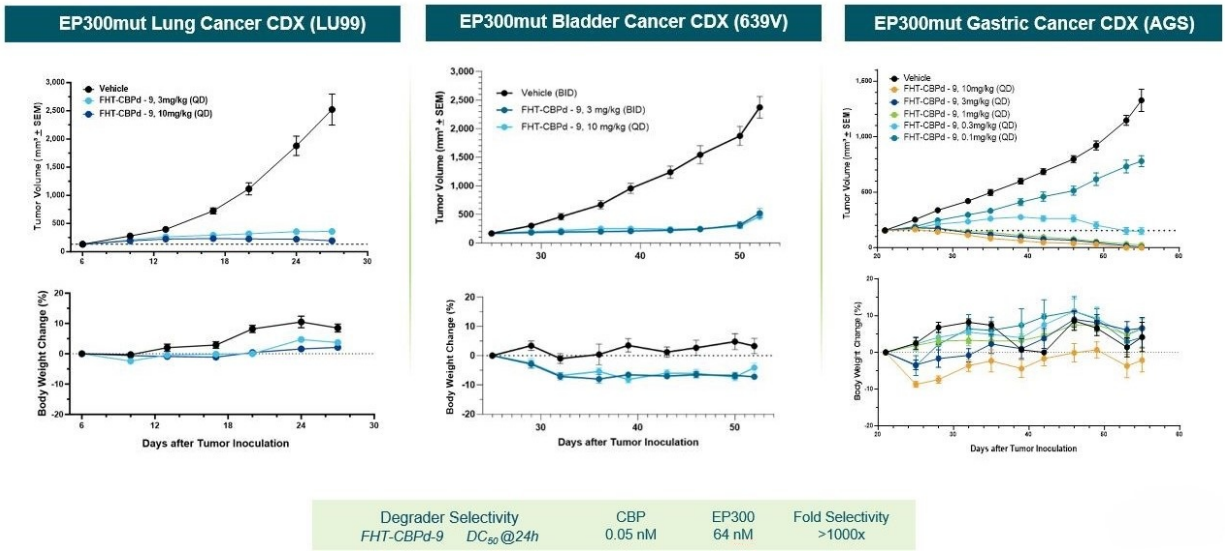


Figure 10. Selective CBP Degradation Results in Significant Anti-Tumor Activity in EP300mut Solid Tumor Models.

Historically, targeting CBP and EP300 has been attempted with dual inhibitors – therapeutics that simultaneously inhibit both the function of CBP and EP300. It has been reported in the literature that these compounds in both pre-clinical as well as the clinical setting can cause thrombocytopenia, low counts of platelet cells that are important in the clotting of blood. We have demonstrated that selective degradation of either CBP alone or EP300 alone in animal models does not cause thrombocytopenia as shown in Figure 11 below. In the figure, we show that a dual bromodomain inhibitor which inhibits both CBP and EP300 causes a meaningful drop in platelets. In contrast, our selective degraders of EP300 and CBP, FHT-EP300d and FHT-CBPd respectively, do not cause a drop in platelets at doses that are relevant and achieve efficacy in the animal models shown in Figure 10 (FHT-CBPd) and Figure 12 (FHT-EP300d).

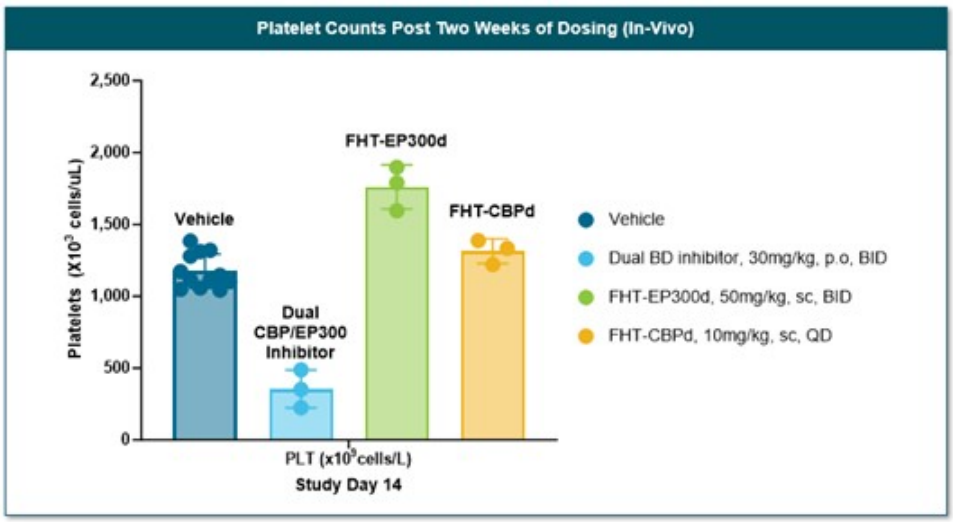


Figure 11. Selective degraders of CBP and EP300 demonstrate that they do not reduce platelet counts as compared to a dual inhibitor of both CBP and EP300.

Selective EP300 Degrader for EP300 Dependent Cancers and CBP Mutated Cancers

We are developing a selective EP300 degrader targeting EP300 dependent cancers and CBP mutant cancers, including multiple myeloma, diffuse large B-cell lymphoma (“DLBCL”), acute myeloid leukemia and myelodysplastic syndrome. According to

Clarivate, the annual U.S. incidence of multiple myeloma, DLBCL, acute myeloid leukemia and myelodysplastic syndrome in the U.S. exceeds 100,000.

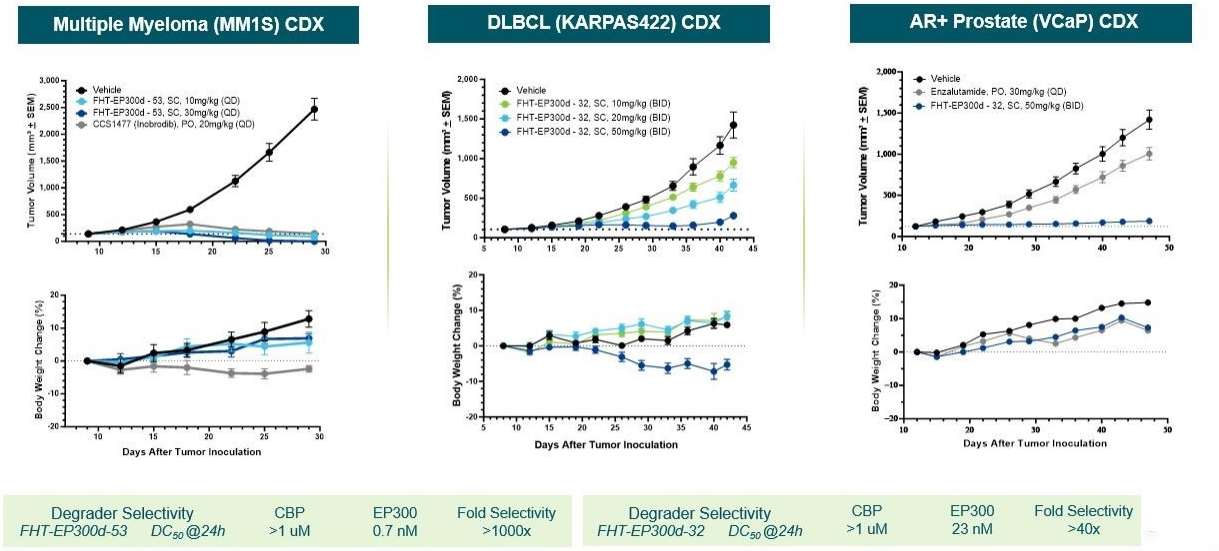


Figure 12. EP300 Degradation Results in Significant Tumor Growth Inhibition in Multiple Myeloma, DLBCL and Prostate Models.

As seen in Figure 12, the degrader denoted as FHT-EP300d-32 appears well-tolerated based on the limited mouse body weight percentage changes and achieves tumor growth inhibition in the multiple myeloma, DLBCL, and AR+ prostate models. In the AR+ prostate model, FHD-EP300d achieves better tumor growth inhibition than enzalutamide, an androgen receptor inhibitor that is presently used to treat patients with prostate cancer.

Selective ARID1B Degrader for ARID1A Mutated Cancers

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 endometrial, gastric, gastroesophageal junction, bladder and NSCLC. According to Clarivate the annual U.S. incidence of endometrial, gastric, gastroesophageal junction, bladder and non small cell lung cancer exceeds 300,000.

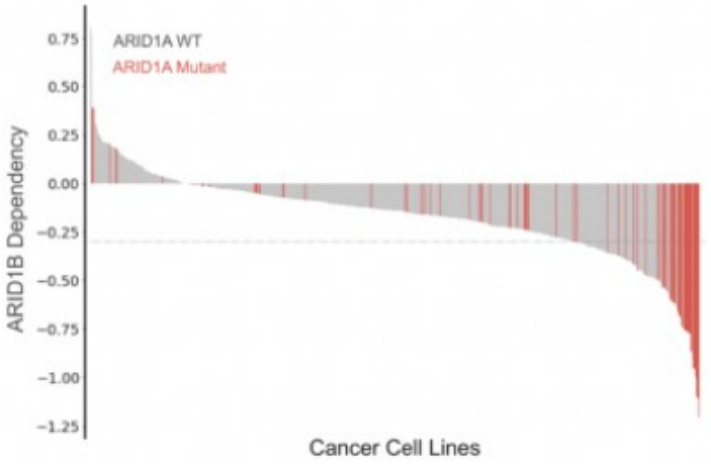


Figure 13. In a screen of over 1,000 cancer cell lines, CRISPR knockout of the ARID1B gene resulted in selective growth inhibition of cell lines containing mutations in ARID1A, establishing the dependency on ARID1B in these cell lines.

Since ARID1B is a scaffolding protein with no known enzymatic domains or function, our strategy is to utilize protein degradation to selectively target and remove ARID1B from BAF complexes. 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 identified and validated selective small molecule binders to the ARID1B protein and use these binders as starting points for generating heterobifunctional protein degraders. We have used a structure-based hypothesis to drive optimization of multiple ARID1B binders toward nM affinity with selectivity over ARID1A.

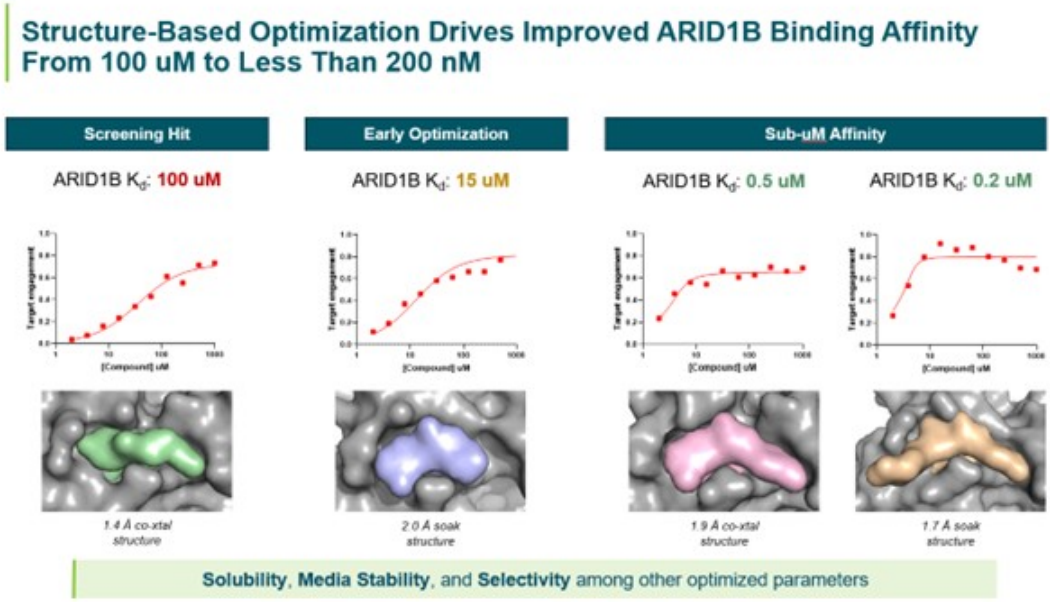


Figure 14. Structure-based optimization improves ARID1B binding affinity of ligands from 100uM to less than 200nM

The identified ARID1B binders have been successfully incorporated into bifunctional molecules to achieve selective degradation of ARID1B. The degradation was validated to operate through the ubiquitin-proteasome system via experiments with both ligase-inactive versions of the degrader as well as co-treatment with proteasome and neddylation inhibitors.

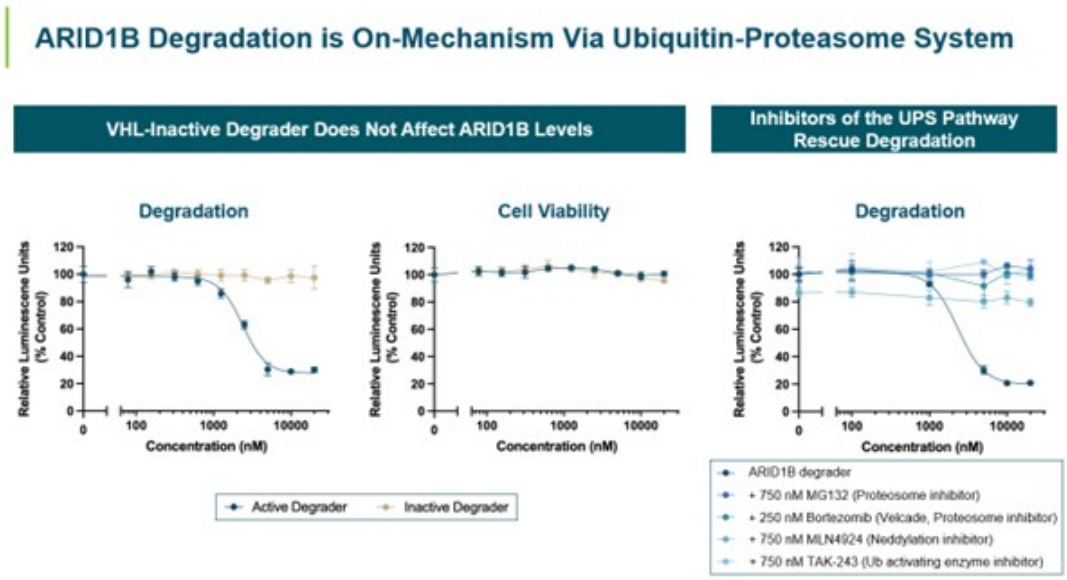


Figure 15. ARID1B degradation is on-mechanism via ubiquitin-proteasome system

A high level of selectivity is achieved with the ARD1B degrader as evidenced by both discrete HiBiT assay readouts against key off-targets (ARID1A, SMARCA2, SMARCA4) as well as global proteomics.

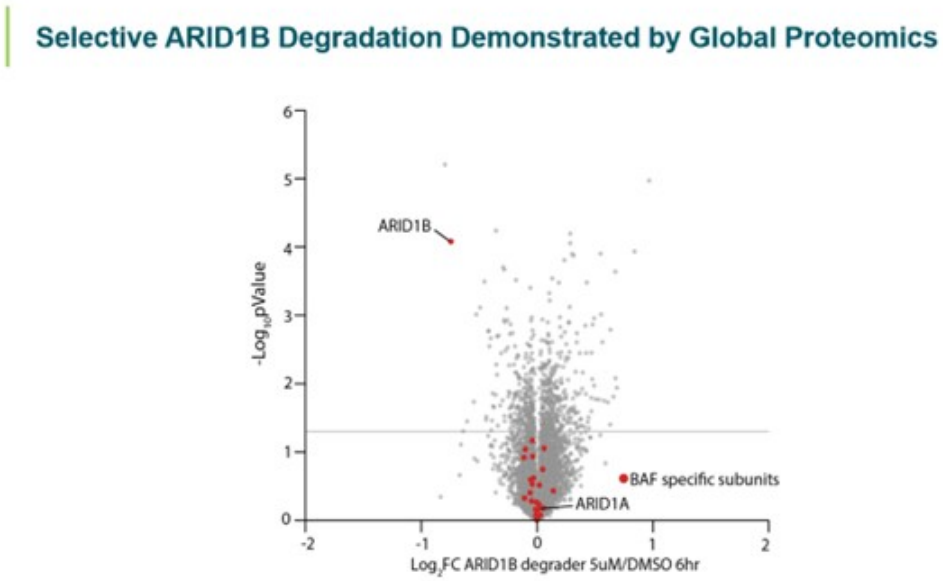


Figure 16. ARID1B degrader exhibits selective degradation as evidenced by global proteomics

Induced Proximity Platform: Extension of Protein Degrader Platform

We are expanding our platform beyond heterobifunctional degraders into induced proximity. Heterobifunctional degraders involve recruiting a ubiquitin ligase to a protein target where it can conjugate ubiquitin proteins onto the target thereby targeting it for degradation. This process can be thought of as a specific example of a more general concept of induced proximity which represents the recruitment of a biological activity to a specific target site. We are exploring different possibilities for implementing this approach including: recruiting a de-ubiquitinase to a target in order to stabilize that target, and recruiting an activator such as BAF to a site on chromatin in order to activate a repressed gene and thereby 'turn on that gene'.

We believe that our platform is well suited to expand into induced proximity because of several factors, including:

- our extensive knowledge of chromatin biology;
- our existing chemical library specifically designed to link two binders and create heterobifuctional molecules;
- our suite of assays designed to characterize ternary complexes; and
- our collection of binders to BAF and other chromatin factors.

Currently we are evaluating the best opportunity for proof of concept in induced proximity.

Competition

The biotechnology and pharmaceutical industries are characterized by the rapid evolution of technologies and understanding of disease etiology, intense competition and a strong emphasis on intellectual property. We believe that our approach, strategy, scientific capabilities, know-how and experience provide us with competitive advantages, including, to our knowledge, our being the only company with the ability to study the chromatin regulatory system at scale, in context, and in an integrated way. However, we expect substantial competition from multiple sources, including major pharmaceutical, specialty pharmaceutical, and existing or emerging biotechnology companies, academic research institutions and governmental agencies and public and private research institutions worldwide. Many of our competitors, either alone or through collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also

prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies may be or may become interested in the chromatin regulatory system and rapidly develop programs that may compete with ours by studying the chromatin regulatory system at scale, in context and in an integrated way. Even if they do not advance programs with the same mechanism of action as ours, these companies could develop products or product candidates that are competitive with ours or that have a superior product profile and may do so at a rapid pace. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

We face competition from segments of the pharmaceutical, biotechnology and other related markets that pursue the development of therapies that target broad genetic expression mechanisms, including the chromatin regulatory system. In addition, we may face competition from companies developing product candidates that utilize protein degradation approaches, including Arvinas, Inc., C4 Therapeutics, Inc., Kymera Therapeutics, Inc., and Nurix 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 including Amphista, CellCentric Limited, IDEAYA Biosciences Inc., Novartis AG, Plexium, Inc., Opna Bio, Relay Therapeutics, Inc, SK Bio, and Tolremo Therapeutics AG. In addition to these competitors, recent news and publications suggest multiple assets in earlier stages of development from Chinese companies.

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 Patent Cooperation Treaty (“PCT”) patent applications, and any patent applications that we may in the future file or license from third parties, may not result in the issuance of patents and any issued patents we may obtain do not guarantee us the right to practice our technology or commercialize our product candidates. We also cannot predict the breadth of claims that may be allowed or enforced in any patents we may own or in-license in the future. Any issued patents that we may own or in-license in the future may be challenged, invalidated, circumvented or have the scope of their claims narrowed. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting the protection such patent would afford the respective product and any competitive advantage such patent may provide.

The term of individual patents depends upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office (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 USPTO 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 March 1, 2026, we owned more than 25 pending U.S. non-provisional patent applications and more than 100 pending ex-U.S. patent applications and granted patents. We currently do not in-license any issued patents with respect to any of our product candidates or our platform technology.

FHD-909

As of March 1, 2026, we owned one U.S. patent and more than 50 pending U.S. and ex-U.S. non-provisional patent applications that relate to FHD-909, 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 2041-2043, excluding any additional term for patent term adjustment or patent term extension, if applicable.

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.”

Strategic Collaboration with Lilly

On December 10, 2021, we entered into a strategic collaboration with Lilly. Under the terms of the Lilly Collaboration Agreement, the parties will seek to leverage our platform technology to research, discover and develop therapeutic molecules directed to the SMARCA2 target and an additional undisclosed oncology target, and to three additional discovery programs. Lilly will pursue the clinical development, manufacture and commercialization of products derived from or containing certain compounds developed and Foghorn will have the right to participate in the development and commercialization of these products for the U.S. market.

Under the Lilly Collaboration Agreement, Lilly made an upfront payment of $300.0 million, and a concurrent $80.0 million equity investment in Foghorn. We are eligible to receive a share of U.S. profits for co-commercialized products. Lilly and Foghorn will share 50/50 in the U.S. economics for products directed to the SMARCA2-selective program and one other undisclosed target. For the three Discovery Programs, Foghorn will have an option to participate in a percentage of the U.S. economics following the successful completion of dose-finding toxicity studies. For these programs, Foghorn is eligible to receive development and commercialization milestones of up to an aggregate of approximately $1.3 billion if Foghorn does not exercise its option to participate in the U.S. economics for any discovery program. In addition, Lilly will pay the Company

tiered royalties on product sales on a country-by-country and product-by-product basis (1) at royalty rates ranging from low-double digits to the twenties on ex-U.S. sales for products directed to the SMARCA2-selective program and one other undisclosed target and (2) at royalty rates ranging from mid-single digits to low-double digits on sales outside the U.S. for products directed to the Discovery Programs, during the applicable royalty term and subject to certain royalty step-down provisions.

Manufacturing

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

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

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

Commercialization

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

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

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in ex-United States countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, recordkeeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs. We, along with our vendors, contract research organizations and contract manufacturers, will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidates. The process of obtaining regulatory approvals of drugs and ensuring subsequent compliance with appropriate federal, state, local and ex-United States statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, where we are initially focusing our drug development, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act (the "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 ("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 ("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 ("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 ("NDA");
- a determination by the FDA within 60 days of its receipt of an NDA, to accept the filing for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potentially, satisfactory completion of FDA audit of the clinical trial sites that generated the data in support of the NDA;
- payment of user fees for FDA review of the NDA; and
- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States.

Preclinical Studies and Clinical Trials for Drugs

Before testing any drug in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of drug chemistry, formulation and stability, as well as *in vitro* and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to United States federal and state regulation, including GLP requirements for safety/toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data, must be submitted to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before clinical trials may begin. Some long-term preclinical testing may continue after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and imposes a full or partial clinical hold. FDA must notify the sponsor of the grounds for the hold and any identified deficiencies must be resolved before the clinical trial can begin. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing clinical trials to commence on the terms originally specified in the IND. A clinical hold can also be imposed once a trial has already begun, thereby halting the trial until the deficiencies articulated by FDA are corrected.

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

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, FDA will nevertheless accept

the results of the study in support of an NDA if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

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

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

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

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

With the passage of the Food and Drug Omnibus Reform Act of 2022 ("FDORA") signed by President Biden on December 29, 2022 as part of the Consolidated Appropriations Act, 2023 (H.R. 2617), Congress added a requirement for sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. Action plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. This requirement will apply with respect to clinical investigations for which enrollment commences 180 days after the publication of a final guidance by the FDA on diversity action plans. The statute directs FDA to issue new or revised draft guidance on diversity action plans by the end of 2023, and final guidance within 9 months of closing the comment period on such draft guidance. FDA has not yet published new or revised draft guidance.

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

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

U.S. Marketing Approval for Drugs

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA package requesting approval to market the product for one or more indications. An NDA is a request for approval to market a new drug for one or more specified indications and must contain proof of the drug's safety and efficacy for the requested indications. The marketing application is required to include both negative and ambiguous

results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA must approve an NDA before a drug may be marketed in the United States.

The FDA reviews all submitted NDAs before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective for the indications sought and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. Under the goals and polices agreed to by the FDA under the Prescription Drug User Fee Act ("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 ("REMS") if it believes that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh its risks. A REMS can include use of risk evaluation and mitigation strategies like medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk-minimization tools.

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

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

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

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

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or that affects more than 200,000 individuals in the United States where 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 drug 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 drug 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 drug exclusivity. Further, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Development and Review Programs for Drugs

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

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

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review designation and Accelerated Approval. A product is eligible for Priority Review, once an NDA or BLA is submitted, if the drug that is the subject of the marketing application has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under priority review, the FDA's goal date to take action on the marketing application is six months compared to ten months for a standard review. Products are eligible for Accelerated Approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

Accelerated Approval is usually contingent on a sponsor's agreement to conduct additional post-approval studies to verify and describe the product's clinical benefit. The FDA may withdraw approval of a drug or an indication approved under Accelerated Approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA generally requires, as a condition for Accelerated Approval, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period. After the 120-day period has passed, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication. FDORA signed by President Biden on December 29, 2022 as part of the Consolidated Appropriations Act, 2023 (H.R. 2617) includes numerous reforms to the Accelerated Approval process for drugs and biologics and enables the FDA to require, as appropriate, that a post-approval study be underway prior to granting accelerated approval. FDORA also expands the expedited withdrawal procedures already available to the FDA to allow the agency to use expedited procedures if a sponsor fails to conduct any required post-approval study of the

product with due diligence including with respect to "conditions specified by the Secretary [of HHS]." FDORA also adds the failure of a sponsor of a product approved under Accelerated Approval to conduct with due diligence any required post-approval study with respect to such product or to submit timely reports with respect to such product to the list of prohibited acts in the FD&C Act.

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 ("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 ("PSP") within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

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

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;
- 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 ("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 management system regulation, or QMSR, 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 QMSR, 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 ("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 ("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, federal and state fraud and abuse laws, transparency laws, and patient data privacy and security laws, including but not limited to those described below, some of which will not apply to us unless or until we have a marketed product.

- The 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 for, or the purchase 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 statement and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payments of government funds or knowingly making, or causing to be made, a false statement material to a false claim;
- The Health Insurance Portability and Accountability Act of 1996 ("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;
- So-called federal "sunshine" law, or Open Payments, which requires pharmaceutical and medical device companies to report information related to certain payments and transfers of value provided to certain healthcare providers to CMS, as well as ownership and investment interests held by physicians and their immediate family members;
- Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.
- The Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products prior to approval or for unapproved indications and regulates the distribution of samples;
- Federal laws, including the Medicaid Drug Rebate Program, that require pharmaceutical manufacturers to calculate, certify and report certain complex calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs; 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, require companies to report information related to payments to healthcare providers, marketing expenditures or pricing, require the licensing or registration of sales representatives or regulate the manufacture and distribution of drugs and biological products, imposing extensive record-keeping, licensing, storage and security requirements.

Given the breadth of the laws and regulations, narrowness of exceptions, limited guidance for certain laws and regulations, and evolving government interpretations of the laws and regulations, ensuring compliance is challenging. Federal and state enforcement agencies scrutinize 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. 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. Sales of an approved drug product will depend, in part, on the extent to which third-party payors, including government health programs such as Medicare and Medicaid, and private health insurance such as managed care plans, provide coverage, and establish adequate reimbursement levels for the product. No uniform policy of coverage and reimbursement for drug products exists 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. A third-party payor's decision to provide coverage for a product therefore does not imply that an adequate

reimbursement rate will be 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 seek to control costs and manage utilization by, for example, excluding products from lists of approved covered products (known as "formularies"), imposing step edits that require patients to try alternative treatments before authorizing payment for products, limiting the types of diagnoses for which coverage will be provided, requiring pre-approval (known as "prior authorization") for coverage of a prescription for each patient (to allow the payor to assess medical necessity) or imposing a moratorium on coverage for products while the payor makes a coverage decision.

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. Nonetheless, product candidates may not be considered medically necessary or cost effective. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs. A decision by a third-party payor not to cover a product could reduce utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition.

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 Patient Protection and Affordable Care Act, as amended, the Health Care and Education Reconciliation Act (the "Affordable Care Act"), which, among other things, expanded health care coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and which included a number of changes to the coverage and reimbursement of drug products under government healthcare programs.

Beyond the Affordable Care Act, there have been ongoing healthcare reform efforts, including efforts focused on drug pricing and payment. For example, the Inflation Reduction Act ("IRA") of 2022 includes a number of changes intended to address rising prescription drug prices in Medicare Parts B and D. These changes include caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program (replacing the ACA Medicare Part D coverage gap discount program) and a drug price negotiation program for certain high spend Medicare Part B and D drugs (with negotiated prices for the first set of drugs taking effect in 2026). The IRA has had and will likely continue to have a significant impact on the pharmaceutical industry. Additionally, changes to Medicaid effective in 2024 eliminated the Medicaid rebate cap. And changes to certain Medicare price reporting requirements for drugs beginning in 2026 will likely increase the administrative and compliance burden for manufacturers.

Recently, drug pricing and payment has been subject to a number of reform initiatives. For example, President Trump issued an Executive Order in April 2025 with multiple directives aimed at lowering drug prices, including refining the Medicare drug price negotiation program established by the IRA; accelerating competition for high-cost prescription drugs by accelerating approval of generics and biosimilars and facilitating the process for re-classifying prescription drugs as over-the-counter drugs; and increasing drug importation. In May 2025, President Trump issued another Executive Order that directed government agencies and officials to identify most-favored nation pricing targets for prescription drugs (and looked to pharmaceutical manufacturers to make significant progress towards delivering target prices to patients); prevent foreign countries from disproportionately shifting the cost of global pharmaceutical research and development to the United States; and facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers to sell their products to patients at the most-favored-nation price. In the wake of the Executive Orders and related executive initiatives, a number of pharmaceutical manufacturers have announced direct-to-consumer offerings with discounted prices and/or reached agreement with the federal government regarding pricing for drugs, including prices for Medicaid drugs and newly launched products. A website sponsored by the federal government that is anticipated to offer pharmaceutical direct-to-consumer channels in the future has also been launched. Federal agencies are developing new drug pricing pilot programs, such as a voluntary Medicaid initiative which would authorize the federal government to negotiate Medicaid supplemental rebates with participating manufacturers on behalf of state Medicaid programs, in exchange for standardized coverage criteria for participating manufacturer drugs, and proposed

Medicare Part B and Part D pilot models that, if finalized as proposed, would replace existing inflation-based Medicare rebates with rebates determined on the basis of international prices, for drugs and patients subject to the model. Many of these reform initiatives would require additional legal and/or administrative action to implement and may be subject to legal challenge.

Other federal healthcare reform efforts or actions may affect access to healthcare coverage or the funding of health care benefits, although the full impact of such efforts or actions cannot be predicted. For example, the Congressional Budget Office has estimated that Medicaid provisions in the 2025 budget reconciliation legislation, including restrictions in eligibility and funding for Medicaid, as well as changes to the healthcare marketplace such as the elimination of certain subsidies, will increase the number of uninsured.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.

Healthcare reform efforts have been and may continue to be subject to scrutiny, legal challenge and subsequent amendment, creating further uncertainty. Other recent government actions may also affect prices or payments for prescription drugs. For example, the Trump Administration's recently announced tariff on branded or patented drugs may increase the cost of drug products that are imported from abroad or manufactured using products or materials imported from abroad. The timeline for implementation of this tariff has not yet been finalized. As another example, the Budget Control Act, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

Healthcare reform initiatives at the federal or state level could affect demand for, or pricing of, our current or future products if approved for sale. We cannot, however, predict the ultimate content, timing or effect of any federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government authorities can extend well beyond the receipt of regulatory approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

Other U.S. Environmental, Health and Safety Laws and Regulations

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

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

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

Government Regulation of Drugs Outside of the United States

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than

that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution would apply to any product that is approved outside the United States.

Data Privacy Regulations

The conduct of our clinical trials may be subject to privacy restrictions based on U.S. and non-U.S. regulations. For example, the collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU and the UK, including personal health data, is subject to the EU General Data Protection Regulation ("GDPR") including as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (SI 2019/419), known as UK GDPR. Compliance with the GDPR and the UK 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. The UK's data protection authority, the Information Commissioner's Office, has indicated that following Brexit it will continue to enforce the UK GDPR in line with the enforcement of the GDPR in the EU. However, the UK government recently announced its intention to adopt a more flexible approach to the regulation of data, and as a result, there remains a risk of future divergence between the EU and UK data protection regimes. In addition, we may be subject to the California Consumer Privacy Act ("CCPA") and other U.S. privacy laws. Although the CCPA does not apply directly to our clinical trials, it does impact our collection of information regarding investigators, business contacts, website users and other data subjects. 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.

Human Capital Resources

As of December 31, 2025, we had 106 full-time employees. We consider our employees to be our greatest asset and have assembled a team with deep scientific, clinical, manufacturing, business, and leadership expertise in biotechnology, platform research, drug discovery, and development. 55 of our employees have M.D. or Ph.D. degrees. Within our workforce, 78 employees are engaged in research and development and 28 are engaged in business development, finance, legal, and general management and administration. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our Corporate Information

We were formed as a Delaware corporation in October 2015 under the name Foghorn Therapeutics Inc. Our principal executive office is located at 99 Coolidge Avenue, Suite 500, Watertown, Massachusetts, 02472, and our phone number is 617-586-3100. Our website address is https://foghorntx.com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K.

We are a "smaller reporting company" as defined in the Securities and Exchange Act of 1934, as amended (the "Exchange Act"). We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

Available Information

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

We have adopted 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. A current copy of the code is posted to the "Investors" portion 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.

ITEM 1A. RISK FACTORS

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

Risks Related to Our Financial Position and Need for Additional Capital

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

We are a clinical-stage biopharmaceutical company with a limited operating history. We were incorporated in October 2015, and our operations to date have been focused on building our proprietary Gene Traffic Control platform, organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, conducting early stage clinical trials, 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. As part of our collaboration with Lilly, we are currently in a Phase 1 dose escalation trial for FHD-909. Our other product candidates are in preclinical development. We have not yet demonstrated an ability to successfully 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, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

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

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

Since inception, we have incurred significant operating losses. As of December 31, 2025, we had an accumulated deficit of $632.5 million. We have financed our operations primarily through our strategic collaboration with Lilly and Lilly's concurrent investment in our equity; proceeds from the January 2026 Offering and May 2024 Offering; our IPO and private placements of our preferred stock; and our former collaboration agreement with Merck Sharp & Dohme Corp. For further information about our collaborations and Lilly's equity investment, see "Business—Strategic Collaboration with Lilly." 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:

- continue our preclinical and clinical development of product candidates from our current research programs, including those partnered with Lilly;
- identify additional research programs and additional product candidates;
- initiate preclinical testing for any new product candidates we identify and develop;
- obtain, maintain, expand, enforce, defend and protect our trade secrets and intellectual property portfolio and provide reimbursement of third-party expenses related to our patent portfolio;
- hire additional research and development personnel;

- add operational, legal, compliance, financial and management information systems and personnel to support our research, product development and operations as a public company;
- expand the capabilities of our platform;
- acquire or in-license product candidates, intellectual property and technologies;
- operate as a public company;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials; and
- ultimately establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval.

Currently, we have one Lilly-partnered product candidate, FHD-909, in Phase 1 clinical development. We have not initiated clinical development of our other current product candidates 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, including FHD-909, which is in Phase 1 clinical development. 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.

Additional capital raising efforts, when needed, may divert our management's attention from their day-to-day activities, which may adversely affect our ability to advance our product candidates or develop new product candidates. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives.

If we are unable to obtain funding on a reasonable and timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs, clinical research, or the commercialization of any product candidate. We may be unable to expand our operations or otherwise capitalize on our business opportunities as desired. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

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

We are currently in the Phase 1 clinical development for FHD-909 as part of our collaboration with Lilly. We are in the preclinical development stage for our other lead research programs. 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.

Unfavorable global macroeconomic conditions, geopolitical trends, and armed conflict 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 financial markets, including inflation, rising interest rates, economic sanctions or other restrictions on international commerce, natural disasters,

pandemics, political instability, ongoing and potential global armed conflicts and wars. A severe or prolonged economic downturn, or additional global financial or political 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. 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.

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. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

Our future ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

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

Risks Related to Discovery and Development

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

The success of our business depends primarily upon our ability to identify, develop, and commercialize product candidates based on our platform. All of our product development programs are still in the research or preclinical or early clinical stage of development. Our research programs may fail to identify potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates, our potential product candidates may be shown to have harmful side effects in preclinical *in vitro* experiments or animal model studies, they may not show promising signals of therapeutic effect in such experiments or studies or they may have other characteristics that may make the product candidates impractical to administer or market.

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

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

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. 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 approval is secured for a product candidate, the terms of such approval may also limit its commercial potential.

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

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

Further, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that even once clinical trials have begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if the FDA agrees with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that the FDA will not change its requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory authorizations for our trials to proceed may prevent us from completing our clinical trials or commercializing our product candidates on a timely basis, if at all.

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

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

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

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

We have one product candidate, FHD-909, which is partnered with Lilly, in Phase 1 clinical development; our other product candidates are in preclinical development, and, as a result, 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;
- 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 ("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; 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 is recommended for suspension or termination by the data monitoring committee for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the

imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or comparable foreign regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

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

We are not able to exert unilateral control over the development of product candidates when part of a collaboration.

Under the Lilly Collaboration Agreement, we influence, but do not control, the development activity of any of the product candidates covered by the Lilly Collaboration Agreement, including FHD-909. This may result in delayed and/or diminished visibility and predictability of certain aspects of development strategy, which may impact timelines, costs, and ultimate success of the product candidate.

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

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

Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- size of the patient population and process for identifying patients;
- design of the trial protocol;
- availability and efficacy of approved medications for the disease under investigation;
- convenience and ease of administration compared to approved or other investigational medications for the disease under investigation and the willingness of patients to undergo the surgical procedures necessary to administer our product candidates, such as biopsy;
- ability to obtain and maintain patient informed consent;
- risk that enrolled patients will drop out before completion of the trial;
- eligibility and exclusion criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and

- factors we may not be able to control, such as potential pandemics that may limit patients, principal investigators or staff or clinical site availability.

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

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

Data obtained from preclinical activities are subject to varying interpretations and analyses, which may delay, limit or prevent regulatory approval. Many companies that have believed their product candidates performed satisfactorily in preclinical studies have nonetheless failed to demonstrate results in clinical studies. As we generate preclinical results, such results will not ensure that later preclinical studies or clinical trials will demonstrate similar results. There is a high failure rate for drugs and biologics proceeding through clinical trials. Even product candidates that reach the clinical trial stage may fail to show the desired safety and efficacy in a 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 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. Our research and development efforts to date have resulted in our discovery and preclinical development of FHD- 909 for the treatment of cancer. However, FHD-909 and any other cancer product candidates we may advance into the clinic may not be safe or effective as cancer treatments, and we may not be able to develop any other product candidates. We may not be successful in identifying further targets in the chromatin regulatory system that are relevant in cancer, or other diseases, and which can be “basketed” into a group that is large enough to present a sufficient commercial opportunity or that is druggable with one chemical compound. Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future, which likely would result in significant harm to our financial position and adversely affect our stock price.

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

We currently rely on third parties to perform certain pre-clinical experiments, manufacture preclinical and clinical product supplies and to manufacture clinical supplies of our product candidates, and certain of these third parties are located outside the United States, including in China. We need to negotiate and maintain contractual arrangements with these outside vendors for the supply of our product candidates and we may not be able to do so on favorable terms. We have not yet caused any product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other foreign regulatory authorities following inspections that will be conducted after we submit an application to the FDA or other foreign regulatory authorities. We will be completely dependent on our contract manufacturing partners for compliance with cGMP and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates, if it withdraws any approval in the future, or if it otherwise identifies noncompliance with cGMPs at these facilities, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Similarly, if any third-party manufacturers on which we will rely fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition, results of operations, and prospects could be materially and adversely affected.

In addition, we have relied upon and plan to continue to rely upon 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, including delays and restrictions that may be imposed by legislation or executive order or other administrative action. We may be unable to identify and contract with a sufficient number of investigators, CROs and consultants on a timely basis or at all. There can be no assurance that we will be able to negotiate and enter into any additional master services agreement with other CROs, as necessary, on terms that are acceptable to us on a timely basis or at all.

Disruptions at the FDA and other government agencies caused by funding shortages or personnel cuts 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, make decisions relating to development, 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.

The current presidential administration and federal government could adopt legislation, regulation, orders or policies that adversely affect our business, including by creating a more challenging and costly environment to pursue the development and commercialization of our current or future product candidates. The impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates.

The current administration has also undertaken significant efforts to reduce the size and spending of the federal government, including at the FDA. A significant reduction in the FDA's workforce or the FDA's budget, or other disruptions at the FDA, could materially impact the FDA's ability to engage in a variety of activities that may affect our business, including routine regulatory and oversight activities. The current administration has substantially reduced the FDA's workforce and may make further reductions, which may lead to disruptions and delays in the FDA's review and oversight of our product candidates and impact the FDA's ability to provide timely feedback on our development programs. Further, reductions in workforce in divisions of the FDA responsible for overseeing the importation of pharmaceutical and biological goods may delay our manufacturing timelines. Additionally, reductions in the FDA's review or inspection divisions could extend review timelines, delay or prevent pre-approval inspections and limit opportunities for FDA feedback on pending applications. Further, FDA may pursue legislative, regulatory or policy changes regarding the standards or processes for approving drug and biological products that we may be unable to satisfy. Any of these actions may delay or limit our ability to obtain FDA approval and commercialize our product candidates.

Additionally, the current administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs.

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 may need to grow the size of our organization, and we may experience difficulties in managing this growth and other issues relating to our employees.

As of December 31, 2025, we had 106 full-time employees. 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 Watertown, 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. Additionally, 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.

In the future, we may hire new employees to assume activities and responsibilities within the company, including conducting our research and performing development activities. 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 service providers, including our CROs and other contractors and consultants are vulnerable to damage from computer viruses, ransomware, unauthorized access, denial of service attacks, internal or external hacking, among other cyber attacks. Other events like natural disasters, and telecommunication and electrical failures could also impact the availability of our or our service providers networks. While to our knowledge, we have not experienced a material system failure or security breach to date, like other companies we are subject to attacks and 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. Such an attack could also have reputational impact, result in regulatory investigations, fines, litigation, remediation costs, increased insurance premiums or impact the availability of insurance, and other costs. 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 adverse legislation or administrative restrictions, 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.

Our use of artificial intelligence and machine learning exposes us to operational, regulatory, legal, and ethical risks that could adversely affect our business, reputation, financial condition, and results of operations.

We procure and deploy certain AI and machine learning technologies across our operations. For example, we use AI systems such as AlphaFold and ColabFold, to predict protein structures where experimentally solved crystal structures are not available in the Protein Data Bank. While these tools may create efficiencies, they also introduce risks related to data quality, transparency, model reliability, cybersecurity, intellectual property, privacy, discrimination, liability, and vendor/supply chain dependencies. Errors or bias in AI outputs, inadequate monitoring, or insufficient documentation could impair clinical development, manufacturing quality, or commercial activities, resulting in delays, higher costs or reputational harm.
Additionally, the emergence of AI and other technologies may contribute to other risks, including those related to regulation, litigation, compliance issues, ethical concerns, confidentiality, and data privacy or security. For example, regulatory uncertainty related to AI or other emerging technologies may require additional resources to adjust business practices to comply with developing laws.

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 primarily consists of provisional patent applications and patent applications filed pursuant to the Patent Cooperation Treaty (the "PCT"), both of which do not themselves issue as patents. We have one issued U.S. patent related to FHD-909. 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-909 or our other current or future product candidates. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar or identical to our product candidates, including generic versions of such products.

Other parties have developed technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications, in either case that they may rely upon to dominate our patent position in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty.

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

Even if we acquire patent protection that we expect should enable us to maintain such competitive advantage, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party submission of prior art to the USPTO challenging the priority of an invention claimed within one of our

patents, which submissions may also be made prior to a patent's issuance, precluding the granting of any of our pending patent applications. We may become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others from whom we have obtained licenses to such rights. Competitors may claim that they invented the inventions claimed in our issued patents or patent applications prior to us, or may file patent applications before we do. Competitors may also claim that we are infringing on their patents and that we therefore cannot practice our technology as claimed under our patents, if issued. Competitors may also contest our patents, if issued, by showing the patent examiner that the invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our product candidates and technology. We may choose to obtain a license, even in the absence of an action or finding of infringement. In either case, we may not be able to obtain any required license on

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

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

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

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

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

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

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

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time-consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their

greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights, or we may be unable to successfully defend ourselves from allegations of infringement or misappropriation. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

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

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

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in any patents we may own or in-license in the future, trade secrets, or other intellectual property as an inventor or co-inventor. We may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates or other technologies. We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to an inventorship dispute, such dispute may lead to litigation which could be expensive and time-consuming. If we are unsuccessful, in addition to paying monetary damages, we could lose valuable rights in intellectual property that we regard as our own, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and our Gene Traffic Control platform. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents, if obtained, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable

time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our business, financial condition, results of operations and prospects could be materially harmed.

Intellectual property rights do not necessarily address all potential threats.

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

- aspects of our Gene Traffic Control platform are protected by trade secrets, which may be inadequate to safeguard our competitive advantage, and some aspects of our platform may not be protectable by intellectual property rights at all;
- others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of any patents that may issue to us, our licensors or our collaborator;
- we or our licensors or collaborators, might not have been the first to make the inventions covered by our pending patent applications, or any patents that may issue in the future;
- we or our licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing or misappropriating our intellectual property rights;
- it is possible that our present or future pending patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates;
- the patents of others may harm our business; and
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the "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 pre-clinical studies and development, and our 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, pre-clinical 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 are not 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.

In addition, certain of our CDMOs and CROs located in China may experience adverse legal and regulatory restrictions, which could adversely affect their ability to provide services to us and, thereby, harm our business.

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 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 instead 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.

Our business is exposed to risks from operating with third parties, particularly those outside the United States.

There is currently significant uncertainty about the future relationship between the U.S. and various other countries, including China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been passed in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business could be materially and adversely affected.

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-909, and any other future product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective in humans.

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

Even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or other comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA or other comparable foreign regulatory authorities will view our product candidates as having sufficient efficacy to support the

indication studied in the clinical trial even if positive results are observed in early clinical trials. To the extent that the results of the trials are not satisfactory to the FDA or other comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Additionally, any safety or efficacy concerns observed in any tumor-specific subgroup of our clinical trials could limit the prospects for regulatory approval of our product candidates for a tumor-agnostic indication, which could have a material adverse effect on our business, financial condition and results of operations.

We may in the future seek orphan drug status for our 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 drug 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 drug exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. The FDA has historically taken the position that the scope of orphan exclusivity aligns with the approved indication or use of a product, rather than the disease or condition for which the product received orphan designation. However, on September 30, 2021, the U.S. Court of Appeals for the 11th Circuit issued a decision in *Catalyst Pharms., Inc. v. Becerra* holding that the scope of orphan drug exclusivity must align with the disease or condition for which the product received orphan designation, even if the product's approval was for a narrower use or indication. It remains to be seen how this decision affects orphan drug exclusivity going forward. The FDA announced on January 24, 2023 that despite the *Catalyst* decision, it will continue to apply its longstanding regulations, which tie the scope of orphan exclusivity to the uses or indications for which the drug is approved, rather than to the designation. The FDA's application of its orphan drug regulations post-*Catalyst* could be the subject of future legislation or to further challenges in court, which could impact our ability to obtain or seek to work around orphan exclusivity, and might affect our ability to retain orphan exclusivity that the FDA previously has recognized for our products. Furthermore, the FDA can waive orphan drug 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 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 some or all of our 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 current and future activities, including our relationships with healthcare providers, physicians, and third-party payors, may be subject to applicable anti-kickback, fraud and abuse, anti-bribery, 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 current and future activities, including 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 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, some of which will not apply unless or until we have a marketed product:

- 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 for, 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;
- 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 so-called federal “sunshine” law, or Open Payments, 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;
- federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers;
- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products prior to approval or for unapproved indications and regulates the distribution of samples;
- federal laws, including the Medicaid Drug Rebate Program, that require pharmaceutical manufacturers to calculate, certify and report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs; 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, require companies to report information related to payments to health care providers, marketing expenditures or pricing, or require the

licensing or registration of sales representatives or regulate the manufacture and distribution of drugs and biological products, imposing extensive record-keeping, licensing, storage and security requirements.

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. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Additionally, in its 2024 decision in *Loper Bright Enterprises v. Raimondo*, the U.S. Supreme Court overruled the "Chevron doctrine," which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, the Centers for Medicare & Medicaid Services ("CMS") and other federal agencies where the law is ambiguous. The *Loper* decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA and the CMS, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed.

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 reform initiatives at the federal and state level to contain healthcare costs, including specifically the cost of drugs. For example, the implementation of the IRA was intended in part to address the high cost of prescription drugs. The IRA includes caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program and a drug price negotiation program for certain high spend Medicare Part B and D drugs. The IRA has had and will have an ongoing significant effect on the healthcare industry and prescription drug pricing overall. As another example, under the current presidential administration, there has also been executive and administrative action taken that is intended to reduce the cost of prescription drugs to third party payors and to consumers. *See* "*Business Section—Government Regulation—Current and Future Healthcare Reform Legislation.*"

Changes in law, regulation or policy 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, reductions in Medicare and other healthcare funding or restrictions on access to covered healthcare services. If any such changes were to be imposed, they could adversely affect the operation of our business.

Executive, legislative or regulatory health care reform initiatives at the federal or state level could affect demand for, or pricing of, our current or future products if approved for sale. We cannot, however, predict the ultimate content, timing or effect of any such reform efforts. There is no assurance that such reform will not adversely affect our future business and financial results.

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 future product candidate 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. To obtain coverage and reimbursement, we may have to offer discounts on our products. Even if we obtain coverage and reimbursement, third party payors may implement mechanisms to control utilization. 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 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 and the UK, including personal health data, is subject to the GDPR including as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (SI 2019/419), known as UK GDPR. See "Business—Government Regulation." Compliance with the GDPR and the UK 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. The UK's data protection authority, the Information Commissioner's Office, has indicated that following Brexit it will continue to enforce the UK GDPR in line with the enforcement of the GDPR in the EU. However, the UK government recently announced its intention to adopt a more flexible approach to the regulation of data, and as a result there remains a risk of future divergence between the EU and UK data protection regimes.

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

General Risk Factors

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

Our stock price has been and may continue to be volatile. Since our IPO in October 2020, the closing price of our common stock as reported on the Nasdaq Global Market has ranged from a low of $2.82 on February 5, 2024 to a high of $25.88 on December 18, 2020. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the success of existing or new competitive product candidates or technologies;
- the timing and results of preclinical studies and clinical trials for any product candidates that we may develop;
- the 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;
- the 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 agreements;
- the effects of geopolitical crises and the outbreak or worsening of wars or other armed conflicts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

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

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

If securities analysts cease to publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

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

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Certain holders of shares of our common stock have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Securities Act Rule 144 or until the rights terminate pursuant to the terms of the investors' rights agreement between us and such holders. If additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

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

Our directors and executive officers and their affiliates beneficially own shares representing approximately 30% 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 adversely affect the market price of our common stock.

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

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

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

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

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware (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 (i) any derivative action or proceeding brought on our behalf, (ii) 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, (iii) 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, (iv) 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 (v) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

We have established an enterprise risk management program, with cybersecurity representing a relevant component of our overall approach to risk management. The cybersecurity portion of our risk management program shares common methodologies, reporting channels and governance processes that apply across the program to other legal, compliance, strategic, operational, and financial risk areas. In general, we seek to address cybersecurity risks through a data security framework that is focused on information classification and location, access and acceptable use controls, alerts and protections, vendor risk assessment, and backup and recovery. We engage third parties to perform assessments of our cybersecurity measures, including tabletop exercises, penetration testing, and other cybersecurity audits. As part of our cybersecurity risk management procedures, we also have a third-party cyber risk management process for service providers, suppliers, and vendors. Additionally, we provide regular, mandatory training for all employees regarding cybersecurity threats.

As of the date of this Annual Report on Form 10-K, we have not experienced a cybersecurity incident or other threats that resulted in a material effect on our business strategy, results of operations, or financial condition, but we cannot provide assurance that we will not be materially affected in the future by such risks or any future material incidents. For more information on our cybersecurity related risks, see Item 1A Risk Factors of this Annual Report on Form 10-K.

Governance

Our Board of Directors and Audit Committee oversee our enterprise risk management process, including the management of risks arising from cybersecurity threats. On at least an annual basis, the Board of Directors and Audit Committee receive presentations and reports on cybersecurity risks from our Vice President of Information Technology, which may address topics including our overall assessment of cybersecurity risks, compliance with cybersecurity policies and procedures, third-party test results, the current threat environment, and technological trends and information security considerations arising with respect to our peers in the biotechnology space. The Board and Audit Committee also receive ad hoc reporting as appropriate. Our Vice President of Information Technology, who reports to our Chief Legal Officer, is primarily responsible for assessing such risks. This individual has over 20 years of information technology and cybersecurity experience in the biotechnology industry.

ITEM 2. PROPERTIES

Our corporate headquarters is located at 99 Coolidge Avenue, Suite 500, Watertown, MA 02472, where we lease and occupy approximately 72,846 square feet of office and laboratory space. The current term of our 99 Coolidge Avenue lease expires in September 2035, with two consecutive options to extend the term five additional years with 12 months' notice at an agreed upon market rate.

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

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Certain Information Regarding the Trading of Our Common Stock

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

Holders of Our Common Stock

As of February 27, 2026, there were approximately 21 holders of record of shares of our common stock. This number does not include stockholders for whom shares are held in "nominee" or "street" name.

Securities Authorized for Issuance Under Equity Compensation Plans

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

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes to those statements included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Some of the numbers included herein have been rounded for the convenience of presentation. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Overview

Foghorn is a clinical stage, precision therapeutics biotechnology company pioneering a new class of medicines that treat serious diseases by correcting abnormal gene expression through selectively targeting the chromatin regulatory system, an untapped opportunity for therapeutic intervention in oncology and with potential in a wide spectrum of other diseases including immunology and inflammation.

The chromatin regulatory system orchestrates gene expression—the turning on and off of genes—which is fundamental to how all our cells function. The chromatin regulatory system is implicated in approximately 50 percent of all cancers, and understanding how this system works could lead to an entirely new class of precision medicines. To our knowledge, we are the only company with the ability to study and target the chromatin regulatory system at scale, in context, and in an integrated way.

Our proprietary Gene Traffic Control platform provides 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 this system. We have developed unique capabilities that have yielded new insights and scalability in drugging this new, previously untapped and promising area.

At present, we are working on more than seven programs with one clinical-stage drug candidate currently in Phase 1 development. We have discovered highly selective chemical matter for some of the most challenging targets in oncology including SMARCA2 (BRM), CBP, EP300, and ARID1B as well as other undisclosed targets. We believe our current pipeline has the potential to help more than 500,000 cancer patients. We take a small molecule modality agnostic approach to drugging

targets which includes protein degraders, allosteric enzymatic inhibitors, and transcription factor disruptors. We are a biology first company, which means we focus first on the underlying genetics and biology of a disease relevant target and then leverage the most appropriate drugging approach to impact the disease biology.

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

On December 10, 2021, we entered into a collaboration agreement (the "Lilly Collaboration Agreement") with Eli Lilly and Company ("Lilly"), for which we received an upfront payment of $300.0 million in January 2022 (see Note 8 to our notes to consolidated financial statements included elsewhere in this Annual Report on Form 10-K). Concurrent with the Lilly Collaboration Agreement, we also entered into a stock purchase agreement (the "Lilly SPA") with Lilly whereby we issued and sold Lilly 4,000,000 shares of our common stock, par value $0.0001 per share ("Common Stock"), at a price of $20.00 per share, resulting in net proceeds of $80.0 million, of which $42.2 million was allocated to equity upon the issuance of our common stock.

The Lilly Collaboration Agreement generally provides that Lilly and Foghorn will co-develop and co-commercialize certain "joint" programs for the U.S., and these joint programs will be subject to a U.S. profit and expense share. Outside the U.S., the joint programs are subject to a world-wide research and development expense share and ex-U.S. royalties. The joint programs include the selective SMARCA2 oncology program that includes both a selective inhibitor (FHD-909) and a selective degrader, as well as an additional undisclosed oncology target. The collaboration also includes three discovery programs that will leverage Foghorn's proprietary Gene Traffic Control platform which are subject to customary royalties and milestones and are not subject to co-development, co-commercialization rights.

FHD-909 was transitioned to Lilly during the third quarter of 2023, which triggered the 50/50 cost share for the SMARCA2 programs. Costs related to the cost-share are included in research and development expenses on the consolidated statements of operations and comprehensive loss.

In October 2024, the first patient was dosed in a Phase 1 dose escalation study of FHD-909, a selective allosteric ATPase inhibitor of SMARCA2, developed in collaboration with Lilly.

In December 2024, we announced our decision to discontinue the independent development of FHD-286 in combination with decitabine in patients with relapsed and/or refractory acute myeloid leukemia.

In May 2024, the Company entered into an underwriting agreement with Jefferies LLC, TD Securities (USA) LLC and Evercore Group LLC relating to the issuance and sale of an aggregate of 12,743,039 shares of its Common Stock at a public offering price of $5.51 per share to certain investors. In addition, the Company issued and sold to certain investors in lieu of Common Stock pre-funded warrants to purchase 7,220,794 shares of its Common Stock (the "Pre-funded Warrants") at a public offering price of $5.5099 per pre-funded warrant, which represents the public offering price per share of the Common Stock less the $0.0001 exercise price per share of each pre-funded warrant. The offering (the "May 2024 Offering") closed on May 22, 2024, resulting in net proceeds of $102.8 million, after deducting underwriting discounts, commissions and other offering expenses.

In the fourth quarter of 2025, the Company utilized its at-the-market facility (the "ATM Facility") to sell 101,174 shares of its Common Stock for proceeds of $0.5 million.

On January 9, 2026, the Company entered into securities purchase agreements (the "Purchase Agreements") with certain leading life sciences investors (the "Investors"), relating to the issuance and sale of 2,030,314 shares of its Common Stock and, in lieu of Common Stock, pre-funded warrants to purchase 5,421,250 shares of Common Stock (the "Pre-Funded Warrants"). The Company sold the shares of Common Stock and Pre-Funded Warrants together with two series of warrants, Series 1 Warrants and Series 2 Warrants, to purchase an aggregate of 7,451,564 shares of the Common Stock (the "Series Warrants"). The Pre-Funded Warrants were exercisable immediately upon issuance at an initial exercise price of $0.0001 per share and have a term of 20 years. The shares of Common Stock, or Pre-Funded Warrants, as applicable, and the accompanying Series Warrants were immediately separable and were issued separately, but they were purchased together in the offering.

The Series Warrants were immediately exercisable. Each Series 1 Warrant has an initial exercise price of $13.42 per share of Common Stock, subject to certain adjustments, and expires on June 30, 2027. Each Series 2 Warrant has an initial exercise price of $20.13 per share of Common Stock, subject to certain adjustments, and expires on December 31, 2030. For the Series Warrants, the Investor may elect to receive, in lieu of shares of Common Stock, pre-funded warrants to purchase an equivalent number of shares of Common Stock. The offering (the "January 2026 Offering") closed on January 13, 2026, resulting in gross

proceeds of approximately $50 million before offering expenses, and excluding any proceeds the Company may receive upon exercise of the Pre-Funded Warrants and Series Warrants.

We have incurred significant operating losses since our inception. For the years ended December 31, 2025 and 2024, we reported net losses of $74.3 million and $86.6 million, respectively. As of December 31, 2025, we had an accumulated deficit of $632.5 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 are developing or 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 FHD-909 and other product candidates partnered with Lilly, and continue preclinical and clinical development of product candidates from our current portfolio;
- identify and advance additional research programs and additional product candidates;
- initiate preclinical testing for any new product candidates we identify and develop;
- obtain, maintain, expand, enforce, defend and protect our trade secrets and intellectual property portfolio and provide reimbursement of third-party expenses related to our patent portfolio;
- hire additional research and development personnel;
- add operational, legal, compliance, financial and management information systems and personnel to support our research, product development and operations;
- expand the capabilities of our platform;
- acquire or in-license product candidates, intellectual property and technologies;
- experience significant operating cost increases as a result of increased inflation or increased tariffs;
- 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, manufacturing and distribution. Further, we expect to incur additional costs associated with operating as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until 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 and the Lilly Collaboration Agreement. 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 and the current geopolitical and economic and trade environment, 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.

Components of Our Results of Operations

Collaboration Revenue

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

In December of 2021, we entered into a strategic collaboration with Lilly to create novel oncology medicines by applying Foghorn's proprietary Gene Traffic Control platform. The collaboration includes a U.S. co-development and co-commercialization agreement for the aforementioned selective SMARCA2 (BRM) oncology program and an additional undisclosed oncology target. In addition, the collaboration includes three additional discovery programs using Foghorn's proprietary Gene Traffic Control platform. Under the terms of the collaboration, Foghorn received upfront consideration of $300.0 million in cash pursuant to the Lilly Collaboration Agreement, together with an equity investment by Lilly of $80.0 million in shares of Foghorn Common Stock pursuant to the Lilly SPA.

For the SMARCA2 selective program and the additional undisclosed target program, Foghorn will lead discovery and early research activities, while Lilly will lead development and commercialization activities with participation from Foghorn in operational activities and cost sharing. Foghorn and Lilly will share 50/50 in the U.S. economics, and Foghorn is eligible to receive royalties on ex-U.S. sales starting in the low double-digit range and escalating into the twenties based on revenue levels.

For the additional discovery programs, Foghorn will lead discovery and early research activities. Foghorn may receive up to a total of $1.3 billion in potential development and commercialization milestones. Additionally, Foghorn will have an option to participate in a percentage of the U.S. economics and is eligible to receive tiered royalties from the mid-single digit to low-double digit range on sales outside the U.S. that may be exercised after the successful completion of the dose-finding toxicity studies.

We cannot provide assurances as to the timing of future milestones, royalty payments and economics associated with the strategic collaboration with Lilly, if any.

In the third quarter of 2023, we transitioned the Selective SMARCA2 inhibitor, FHD-909, to Lilly, for which Lilly will lead and we will participate and share in 50% of the costs until at least registrational trials. Costs incurred will continue to be included in research and development expenses on the consolidated statements of operations and comprehensive loss.

We recognized total deferred revenue of $337.8 million related to the Lilly Collaboration Agreement and the Lilly SPA, which included the $300.0 million upfront payment under the Lilly Collaboration Agreement as well as $37.8 million allocated to deferred revenue from the gross proceeds of the Lilly SPA to be recognized over the performance period. For the years ended December 31, 2025 and 2024, we recognized $30.9 million and $22.6 million, respectively, of revenue under the Lilly Collaboration Agreement and, as of December 31, 2025, we had $249.2 million of deferred revenue related to the above mentioned upfront payment and revenue allocation remaining on our consolidated balance sheets.

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 to progress our proprietary and partnered pipeline, including our discovery efforts, which include:

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

We track our direct external research and development expenses on a program-by-program basis. These consist of costs that include fees, reimbursed materials, and other costs paid to consultants, contractors, CDMOs, and CROs in connection with our preclinical, clinical and manufacturing activities. We do not allocate employee costs, costs associated with our discovery efforts, laboratory supplies, and facilities expenses, including depreciation or other indirect costs, to specific product

development programs because these costs are deployed across multiple programs and our platform and, as such, are not separately classified.

We expect that our research and development expenses may increase in the future as we advance our programs into clinical development and continue 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. In addition, given the uncertainties associated with the current geopolitical and economic and trade environment, our research and development expenses may increase in an unpredictable manner.

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, finance and accounting, legal, and other administrative functions. General and administrative expenses also include professional fees for legal, patent, consulting, investor and public relations, human resources, and accounting and audit services as well as direct and allocated facility-related costs.

We anticipate that our general and administrative expenses may increase in the future as we continue to support our continued research activities and development of our programs and platform. We also anticipate that we will continue to incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance costs and investor and public relations expenses associated with operating as a public company.

Other Income, Net

Interest Income

Interest income consists of interest earned on our invested cash balances.

Other Income, Net

Other income, net consists of sublease income and miscellaneous expense unrelated to our core operations.

Provision for Income Taxes

Since our inception, we have not recorded any federal or state income tax benefits for the net losses we have incurred in any year or for our federal or state earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. During the years ended December 31, 2025 and 2024, we recorded no provision for income taxes. As of December 31, 2025, we had federal net operating loss carryforwards of $198.5 million, which may be available to offset future taxable income. The federal net operating loss can be carried forward indefinitely but are limited to offset 80% of annual taxable income. As of December 31, 2025, we also had U.S. federal and state research and development tax credit carryforwards of $9.4 million and $3.7 million, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2043 and 2037, 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. We do not expect to have taxable income in the current year.

On July 4, 2025, the One Big Beautiful Bill Act (“OBBBA”) was enacted in the U.S. The OBBBA provides for, among other things, the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, modifications to the international tax framework and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. The Company has evaluated the impact of the OBBBA and determined that it does not have a material impact on the Company’s consolidated financial statements. The most significant impact is the provision allowing for immediate expensing of certain research and development expenses. The Company has implemented the two-year accelerated expensing under the OBBBA causing the previously capitalized US R&D expenses, amortized over 5 years, to be accelerated over two years. Note that the Company will continue to assess its overall business up until the filing of the 2025 federal tax return and may change its election under IRC Section 174A if it determines there is a more beneficial position.

Critical Accounting Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States, (“GAAP”). The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses and the disclosure of

contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

We received significant non-refundable upfront payments under our collaboration agreements with Lilly, from which we recognize revenue over time using the cost-to-cost method. Under the cost-to-cost method, the extent of progress towards completion is measured based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the identified single performance obligation. In estimating the total costs to satisfy our performance obligation, we are required to make significant estimates including an estimate of the expected time and expected internal and external costs to fulfill the performance obligation. In developing these estimates we consider historical experience, relevant entity-specific factors, known market trends and conditions, and a variety of other factors we believe are relevant to estimating the total cost to fulfill the performance obligation. We periodically evaluate estimates against the actual time and costs incurred as well as any anticipated changes to the timing or estimated costs. Any cumulative effect of revisions to the total estimated costs to complete our performance obligation will be recorded in the period in which the changes are identified, and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods and the classification of deferred revenue between short-term and long-term.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate certain accrued research and development expenses. This process involves estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include those related to fees paid to:

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

We base the expense recorded related to contract research and manufacturing on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs and CDMOs that conduct services and produce and supply materials. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. While the majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met, some require advance payments. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. We record these as prepaid expenses on our consolidated balance sheets.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024:

	Year Ended December 31,		
	2025	2024	Change
	(in thousands)		
Collaboration revenue	$ 30,909	$ 22,602	$ 8,307
Operating expenses:			
Research and development	85,466	94,528	(9,062)
General and administrative	27,550	28,359	(809)
Gain on lease modification	(1,632)	—	(1,632)
Impairment of long-lived assets	5,914	2,398	3,516
Total operating expenses	117,298	125,285	(7,987)
Loss from operations	(86,389)	(102,683)	16,294
Other income, net:			
Interest income	8,745	11,900	(3,155)
Other income, net	3,361	4,163	(802)
Total other income, net	12,106	16,063	(3,957)
Net loss	$ (74,283)	$ (86,620)	$ 12,337

Collaboration Revenue

Under the Lilly Collaboration Agreement, revenue is recognized based on the work performed during the period. Collaboration revenue was $30.9 million for the year ended December 31, 2025, compared to $22.6 million for the year ended December 31, 2024. The increase in collaboration revenue is attributed to continued advancement of programs under the Lilly Collaboration Agreement.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2025 and 2024:

	Year Ended December 31,		
	2025	2024	Change
	(in thousands)		
Research and development program expenses:			
FHD-286	$ 916	$ 11,136	$ (10,220)
Lilly partnered programs	22,509	17,335	5,174
Platform, research and discovery, and unallocated expenses:			
Early development and other research external costs	16,658	18,407	(1,749)
Personnel related (including stock-based compensation)	27,266	27,718	(452)
Facilities and IT related expenses and other	18,117	19,932	(1,815)
Total research and development expenses	$ 85,466	$ 94,528	$ (9,062)

Research and development expenses were $85.5 million for the year ended December 31, 2025, compared to $94.5 million for the year ended December 31, 2024. The decrease is attributed to the following:

- a decrease in FHD-286 costs of $10.2 million due to the discontinuation of both the independent development of FHD-286 in combination with decitabine in patients with relapsed and/or refractory AML, resulting in the shutdown of the Phase 1 clinical trial, and termination of the independent development of FHD-286 in patients with uveal melanoma; and
- a decrease in facilities and IT related expenses and other costs of $1.8 million primarily due to the June 2025 lease modification (see Note 10 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K) and decreased headcount in our research and development function compared to prior year; and

- a decrease in early development and other research external costs of $1.7 million which was driven by decreased FHD-609 spend due to the shutdown of the Phase 1 clinical trial in synovial sarcoma and SMARCAB1-loss tumors and a decrease in preclinical research costs due to program progression; and
- a decrease in personnel-related costs of $0.5 million, primarily driven by a $0.6 million decrease in stock-based compensation expense due to a lower weighted average expense per award compared to prior year, partially offset by increased payroll taxes period over period; and
- an increase in Lilly partnered programs of $5.2 million primarily driven by initiation of the Phase 1 dose escalation study of FHD-909. We expect these costs to continue to increase with increasing enrollment of FHD-909.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2025 and 2024:

	Year Ended December 31,		
	2025	2024	Change
	(in thousands)		
Personnel related (including stock-based compensation)	$ 17,415	$ 17,125	$ 290
Professional and consulting	6,094	6,250	(156)
Facilities and IT related expenses and other	4,041	4,984	(943)
Total general and administrative expenses	$ 27,550	$ 28,359	$ (809)

General and administrative expenses were $27.6 million for the year ended December 31, 2025, compared to $28.4 million for the year ended December 31, 2024. The decrease is attributed to the following:

- a decrease in facilities and IT related expenses and other costs of $0.9 million primarily due to the June 2025 lease modification (see Note 10 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K).

Gain on Lease Modification

For the year ended December 31, 2025, we recorded a gain on lease modification of $1.6 million resulting from the remeasurement of the right-of-use asset and lease liabilities in connection with the Company's main office lease and relocation to Watertown, MA, in December 2025 (See Note 10 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K). For the year ended December 31, 2024, the Company recorded no gain on lease modification.

Impairment of Long-Lived Assets

For the year ended December 31, 2025, we recorded a non-cash impairment of long-lived assets charge of $5.9 million for the abandonment of leasehold improvements in connection with the Company's main office lease and relocation to Watertown, MA, in December 2025 (See Note 10 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K). For the year ended December 31, 2024, we recorded a non-cash impairment of long-lived assets charge of $2.4 million related to the sublease of office space at the Company's prior headquarters in Cambridge, MA.

Other Income, Net

Total other income, net was $12.1 million for the year ended December 31, 2025, compared to $16.1 million for the year ended December 31, 2024. The decrease was due to decreased interest income due to a lower average balance of marketable securities during the period and decreased sublease income due to the conclusion of both subleases during 2025 (see Note 10 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K).

Liquidity and Capital Resources

Since our inception in October 2015, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we support our continued research activities and development of our programs and platform. Through December 31, 2025, we have funded our operations with proceeds from our initial public offering ("IPO") in October 2020, sales of preferred stock, term loans, an upfront payment of $15.0 million we received in July 2020 under the Research Collaboration and Exclusive License Agreement (the "Merck Collaboration Agreement") with Merck Sharp & Dohme Corp. ("Merck"), proceeds we received in December 2021 under the Lilly SPA of $80.0 million; an upfront payment of $300.0 million received in January 2022 under the Lilly Collaboration Agreement; a payment of $5.0 million received from Merck under the Merck Collaboration Agreement in the third quarter of 2022 for the achievement of a research milestone; net

proceeds of $102.8 million, after deducting underwriting discounts, commissions and other offering expenses, from the May 2024 Offering; and net proceeds from our ATM Facility of $0.5 million. As of December 31, 2025, we had cash, cash equivalents and marketable securities of $158.9 million.

January 2026 Offering

On January 9, 2026, the Company entered into the Purchase Agreements with the Investors, relating to the issuance and sale of 2,030,314 shares of its Common Stock and, in lieu of Common Stock, Pre-Funded Warrants to purchase 5,421,250 shares of Common Stock. The Company sold the shares of Common Stock and Pre-Funded Warrants together with Series Warrants, consisting of Series 1 Warrants and Series 2 Warrants to purchase an aggregate of 7,451,564 shares of the Common Stock. The Pre-Funded Warrants were exercisable immediately upon issuance at an initial exercise price of $0.0001 per share and have a term of 20 years. The shares of Common Stock, or Pre-Funded Warrants, as applicable, and the accompanying Series Warrants were immediately separable and were issued separately, but they were purchased together in the offering.

The Series Warrants were immediately exercisable. Each Series 1 Warrant has an initial exercise price of $13.42 per share of Common Stock, subject to certain adjustments, and expires on June 30, 2027. Each Series 2 Warrant has an initial exercise price of $20.13 per share of Common Stock, subject to certain adjustments, and expires on December 31, 2030. For the Series Warrants, the Investor may elect to receive, in lieu of shares of Common Stock, pre-funded warrants to purchase an equivalent number of shares of Common Stock.

The offering price for the shares of Common Stock is $6.71 per share (or $6.7099 for each Pre-Funded Warrant, which equals the price per share of the Common Stock less the exercise price of the Pre-Funded Warrants). The aggregate gross proceeds to the Company from this offering were approximately $50.0 million before any offering expenses, and excluding any proceeds the Company may receive upon exercise of the Pre-Funded Warrants and Series Warrants. No underwriter or placement agent participated in the offering.

Cash Flows

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

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Net cash used in operating activities	$ (86,099)	$ (100,406)
Net cash provided by (used in) investing activities	112,040	(29,904)
Net cash provided by financing activities	1,023	105,428
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 26,964	$ (24,882)

Operating Activities

For the year ended December 31, 2025, operating activities used $86.1 million of cash, resulting from our net loss of $74.3 million to fund our operations and by changes in our operating assets and liabilities of $32.1 million partially offset by net non-cash charges of $20.3 million. Net cash used in changes in our operating assets and liabilities for the year ended December 31, 2025 consisted primarily of a decrease of $30.9 million in deferred revenue resulting from the recognition of revenue on the upfront payments received in connection with our collaboration agreements and a $6.7 million decrease in operating lease liabilities, partially offset by a $5.5 million net increase in working capital.

For the year ended December 31, 2024, operating activities used $100.4 million of cash, resulting from our net loss of $86.6 million to fund our operations and by changes in our operating assets and liabilities of $32.3 million partially offset by net non-cash charges of $18.5 million. Net cash provided by changes in our operating assets and liabilities for the year ended December 31, 2024 consisted primarily of a decrease of $22.6 million in deferred revenue resulting from the recognition of revenue on the upfront payments received in connection with our collaboration agreements, a $7.9 million decrease in operating lease liabilities and a $1.7 million net decrease in working capital.

Investing Activities

For the year ended December 31, 2025, net cash provided by investing activities was $112.0 million consisting of $243.3 million of marketable securities maturing partially offset by $131.2 million of purchases of marketable securities and $0.1 million in purchases of property and equipment.

For the year ended December 31, 2024, net cash used in investing activities was $29.9 million primarily due to $261.5 million of purchases of marketable securities and $0.9 million in purchases of property and equipment offset by $232.5 million of marketable securities maturing.

Financing Activities

For the year ended December 31, 2025, net cash provided by financing activities was $1.0 million, consisting of $0.5 million net proceeds from the sale of common stock under our ATM Facility and $0.5 million net proceeds from the exercise of common stock options and the employee stock purchase plan.

For the year ended December 31, 2024, net cash provided by financing activities was $105.4 million, consisting of net proceeds from the offering of our common stock and pre-funded warrants of $102.8 million, after deducting underwriting discounts, commissions and other offering expenses that had been paid in during the twelve months ended December 31, 2024 and $2.6 million net proceeds from the exercise of common stock options and the employee stock purchase plan.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we continue to fund on-going and potential future clinical activities, including the Phase 1 clinical trial of FHD-909 partnered with Lilly, advance preclinical activities, and initiate clinical trials for our product candidates in development, including those partnered with Lilly. As of the issuance date of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we expect that our cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements for at least twelve months. We have based this estimate on assumptions that may prove to be inaccurate. We could use our available capital resources sooner than we currently expect, in which case we would be required to obtain additional financing sooner than planned, which may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our long-term business strategy. We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources.

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

Off-balance Sheet Arrangements

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

Recently Issued Accounting Pronouncements

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

FOGHORN THERAPEUTICS INC.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Foghorn Therapeutics, Inc. and its subsidiary (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, shareholders' 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, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Collaboration Revenue - Refer to Notes 2 and 8 to the financial statements

Critical Audit Matter Description

During the year ended December 31, 2025, the Company recognized revenue of $30.9 million. As discussed in Note 2 to the consolidated financial statements, at inception, the Company determines whether contracts are within the scope of ASC 606, Revenue from Contracts with Customers, or ASC 606, or other topics. Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration that the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. For performance obligations where revenue is recognized over time, the Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The Company recognizes revenue using the cost-to-cost method, where the extent of progress towards completion is measured based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the identified performance obligation. The impacts on revenue from changes in total estimated costs are recognized on a cumulative basis in the period when the changes occur. If estimates of the total cost change, or if contract amendments change the scope of the performance obligation, the required adjustments to revenue could be material.

We identified revenue recognition as a critical audit matter because of the judgments necessary for management to estimate total costs to satisfy the applicable performance obligation under the contract. This required a high degree of auditor judgment when performing audit procedures to audit management's estimates of total costs and evaluating the results of those procedures.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to collaboration revenue included the following, among others:

- We obtained and read the relevant contracts and other documents related to the collaboration agreement.
- We evaluated the Company's accounting analysis for the applicable contract, including the application to the relevant authoritative guidance.
- We tested the amount of revenue recognized, including the measurement of progress for revenue that is recognized over time.
- We tested management's estimate of the total cost of fulfilling the performance obligation, including retrospective reviews of the changes in such estimates over time.
- We also discussed the basis for key assumptions with the Company's research and development personnel, who oversee the completion of the collaboration arrangement.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 11, 2026

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

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

	December 31,	
	2025	2024
Assets		
Current assets:		
Cash and cash equivalents	$ 80,876	$ 55,454
Marketable securities	78,018	188,293
Restricted cash	1,250	—
Prepaid expenses and other current assets	3,091	5,854
Total current assets	163,235	249,601
Property and equipment, net	1,915	9,964
Restricted cash	2,000	1,708
Other assets	4	68
Operating lease right-of-use assets	30,949	22,641
Total assets	$ 198,103	$ 283,982
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 4,266	$ 3,785
Accrued expenses and other current liabilities	11,357	8,531
Operating lease liabilities	923	9,067
Deferred revenue	43,192	45,606
Total current liabilities	59,738	66,989
Operating lease liabilities, net of current portion	40,347	28,064
Deferred revenue, net of current portion	205,962	234,457
Other liabilities	556	—
Total liabilities	306,603	329,510
Commitments and contingencies (Note 11)		
Stockholders' deficit:		
Preferred stock, $0.0001 par value; 25,000,000 shares authorized as of December 31, 2025 and 2024; no shares issued and outstanding as of December 31, 2025 and 2024	—	—
Common stock, $0.0001 par value; 175,000,000 shares authorized at December 31, 2025 and 2024; 56,657,329 shares issued and outstanding at December 31, 2025 and 55,594,131 shares issued and outstanding at December 31, 2024	6	6
Additional paid-in capital	523,937	512,515
Accumulated other comprehensive gain	24	135
Accumulated deficit	(632,467)	(558,184)
Total stockholders' deficit	(108,500)	(45,528)
Total liabilities and stockholders' deficit	$ 198,103	$ 283,982

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

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

	Year Ended December 31,	
	2025	2024
Collaboration revenue	$ 30,909	$ 22,602
Operating expenses:		
Research and development	85,466	94,528
General and administrative	27,550	28,359
Gain on lease modification	(1,632)	—
Impairment of long-lived assets	5,914	2,398
Total operating expenses	117,298	125,285
Loss from operations	(86,389)	(102,683)
Other income, net:		
Interest income	8,745	11,900
Other income, net	3,361	4,163
Total other income, net	12,106	16,063
Net loss	$ (74,283)	$ (86,620)
Net loss per share attributable to common stockholders—basic and diluted	$ (1.18)	$ (1.58)
Weighted average common shares outstanding—basic and diluted	62,980,959	54,899,432
Comprehensive loss:		
Net loss	$ (74,283)	$ (86,620)
Other comprehensive gain (loss):		
Unrealized gains (losses) on marketable securities	(111)	961
Total other comprehensive gain (loss)	(111)	961
Total comprehensive loss	$ (74,394)	$ (85,659)

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

Foghorn Therapeutics Inc.
Consolidated Statements of Stockholders' Deficit
(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount				
Balances at December 31, 2023	42,282,040	$ 4	$ 395,196	$ (826)	$ (471,564)	$ (77,190)
Issuance of common stock and pre-funded warrants, net of underwriting discounts, commissions, and offering costs	12,743,039	2	102,814	—	—	102,816
Issuance of common stock upon exercise of stock options and employee stock purchase plan	569,052	—	2,612	—	—	2,612
Stock-based compensation expense	—	—	11,893	—	—	11,893
Unrealized gains on marketable securities	—	—	—	961	—	961
Net loss	—	—	—	—	(86,620)	(86,620)
Balances at December 31, 2024	55,594,131	6	512,515	135	(558,184)	(45,528)
Issuance of common stock upon exercise of stock options and employee stock purchase plan	236,075	—	483	—	—	483
Issuance of common stock upon exercise of pre-funded warrants	725,949	—	—	—	—	—
Issuance of common stock under the ATM Facility, net of issuance costs	101,174	—	540	—	—	540
Stock-based compensation expense	—	—	10,399	—	—	10,399
Unrealized losses on marketable securities	—	—	—	(111)	—	(111)
Net loss	—	—	—	—	(74,283)	(74,283)
Balances at December 31, 2025	56,657,329	$ 6	$ 523,937	$ 24	$ (632,467)	$ (108,500)

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

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

	Year ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (74,283)	$ (86,620)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	10,399	11,893
Depreciation and amortization expense	3,332	3,120
Loss on disposal of property and equipment	31	—
Gain on lease modification	(1,632)	—
Impairment of long-lived assets	5,914	2,398
Noncash lease expense	4,206	5,682
Accretion of discount on marketable securities	(1,926)	(4,613)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	2,827	1,317
Accounts payable	481	(2,475)
Accrued expenses and other liabilities	2,204	(564)
Operating lease liabilities	(6,743)	(7,942)
Deferred revenue	(30,909)	(22,602)
Net cash used in operating activities	(86,099)	(100,406)
Cash flows from investing activities:		
Purchases of property and equipment	(50)	(906)
Purchases of marketable securities	(131,247)	(261,470)
Proceeds from maturities of marketable securities	243,337	232,472
Net cash provided by (used in) investing activities	112,040	(29,904)
Cash flows from financing activities:		
Proceeds from offerings of common stock and pre-funded warrants, net of underwriting discounts and commissions	—	103,401
Payments of public offering costs	—	(585)
Proceeds from issuance of common stock upon exercise of stock options and employee stock purchase plan	483	2,612
Proceeds from issuance of common stock under the ATM Facility, net of issuance costs	540	—
Net cash provided by financing activities	1,023	105,428
Net increase (decrease) in cash, cash equivalents and restricted cash	26,964	(24,882)
Cash, cash equivalents and restricted cash at beginning of period	57,162	82,044
Cash, cash equivalents and restricted cash at end of period	$ 84,126	$ 57,162
Supplemental cash flow information:		
Cash paid for taxes	$ 9	$ 860
Supplemental disclosure and noncash investing and financing information:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ —	$ 22
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 80,876	$ 55,454
Restricted cash (current and non-current)	3,250	1,708
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 84,126	$ 57,162

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

Foghorn Therapeutics Inc.

Notes to Consolidated Financial Statements

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

Nature of Business

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

The Company is subject to risks similar to those of other clinical-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, 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.

Going concern

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. Since inception, the Company has funded its operations primarily with proceeds from sales of preferred stock, upfront and milestone payments from a collaboration agreements, public offerings and a stock purchase agreement. The Company has incurred recurring losses, including net losses of $74.3 million and $86.6 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, the Company had an accumulated deficit of $632.5 million. The Company expects to continue to generate operating losses in the foreseeable future. As of the issuance date of these consolidated financial statements the Company expects that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months.

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

Basis of presentation

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

2. Summary of Significant Accounting Policies

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, revenue recognition and the accrual of research and development expenses. The Company bases its estimates on historical experience, known trends and

other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Actual results may differ from those estimates or assumptions.

Concentrations of credit risk and of significant suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

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

Cash equivalents

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

Marketable Securities

The Company's marketable securities are classified as available-for-sale and are carried at fair value with the unrealized gains and losses reported as a component of accumulated other comprehensive loss in stockholders' equity. The Company classifies its marketable securities with maturities beyond one year as short-term, based on their highly liquid nature and because such marketable securities are available for current operations.

The Company reviews marketable securities whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying value is not recoverable. For available-for-sale debt securities, the credit allowance is limited to the amount that fair value is less than amortized cost. Unrealized gains (losses) are evaluated for impairment under ASC 326, *Financial Instruments - Credit Losses*, to determine if the impairment is credit-related or noncredit-related. Credit-related impairment is recognized as an allowance on the consolidated balance sheets with a corresponding adjustment to earnings, and noncredit-related impairment is recognized in other comprehensive loss. Evidence considered in this assessment includes reasons for the impairment, compliance with our investment policy, the severity of the impairment, collectability of the security, and any adverse conditions specifically related to the security, an industry, or geographic area.

Unrealized gains and losses are included as a component of accumulated other comprehensive loss in the consolidated balance sheets and consolidated statements of stockholders' deficit and a component of total comprehensive loss. Realized gains and losses are included as a component of other income, net based on the specific identification method.

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. These amounts are classified as restricted cash in the Company's consolidated balance sheets.

Property and equipment

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

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

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

Impairment of long-lived assets

The Company evaluates its long-lived assets, which consist primarily of property and equipment and operating lease right-of-use assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. For the years ended December 31, 2025 and 2024, the Company recorded a non-cash impairment charge of $5.9 million and $2.4 million, respectively, on the consolidated statements of operations and comprehensive loss. See Note 10 Leases and Note 4 Property and Equipment, Net, for additional information.

Fair value measurements

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

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

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

Collaboration Agreements

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* ("ASC 808") to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. When the Company has concluded that it has a customer relationship with one of its collaborators, the Company follows the guidance in ASC Topic 606, *Revenue From Contracts With Customers* ("ASC 606").

Revenue recognition

The Company accounts for its collaboration arrangement under ASC 606, as the Company concluded that it has a customer relationship with its collaborator. For additional information on the Company's collaboration agreements, see Note 8, Collaboration Agreement, to these consolidated financial statements. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

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

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

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

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

If an arrangement includes development and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The Company generally recognizes revenue using the cost incurred to date as compared to the total estimated cost. The impact on revenue of changes in total estimated costs are recognized on a cumulative basis in the period that the change occurs. If estimates of the total cost change, or if contract amendments change the scope of the performance obligation, the required adjustments to revenue could be material.

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

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

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

Research and development costs

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

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

Patent costs

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

Leases

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 consolidated statements of operations and comprehensive loss as incurred 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.

The Company received payments and income from a sublease on a portion of the Company's Cambridge, Massachusetts office lease prior to the sublease's termination (see Note 10). The Company recognized sublease income on a straight-line basis over the lease term in other income, net, net on the consolidated statements of operations and comprehensive loss, net of any revenue share due to the Company's lessor.

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. Compensation expense for the awards is recognized over the requisite service period for employees and directors and as services are delivered for non-employees, both of which are generally the vesting period of the respective award. The Company uses the straight-line method to record the expense of awards with only service-based vesting conditions. The Company uses the graded-vesting method to record the expense of awards with both service-based and performance-based vesting conditions, commencing once achievement of the performance condition becomes probable. The Company accounts for forfeitures of share-based awards as they occur.

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

Net loss per share

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 dividing net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period, adjusted for potential dilutive common shares.

In periods in which the Company reported a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

The Company reported a net loss attributable to common stockholders for the years ended December 31, 2025 and 2024.

The following pre-funded warrants outstanding at each period end were included in the basic and diluted net loss per share calculation:

	December 31,	
	2025	2024
Pre-funded warrants to purchase common stock	6,494,829	7,220,794

For the year ended December 31, 2025, 725,965 pre-funded warrants were exercised. For the year ended December 31, 2024, no pre-funded warrants were exercised.

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

	December 31,	
	2025	2024
Stock options to purchase common stock	10,257,501	8,989,893
Warrants to purchase common stock	18,445	18,445
	10,275,946	9,008,338

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. See Note 14 for additional disclosures related to segment reporting.

Comprehensive loss

Comprehensive loss includes net loss as well as other changes in stockholders’ equity that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2025 and 2024, the Company’s only element of other comprehensive loss was unrealized gains and losses on available for sale debt securities.

Income taxes

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

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

Recently issued accounting pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date.

In December 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures." The standard enhances the existing income tax disclosures to provide information to better assess how an entity's operations and related tax risks and tax planning and operational opportunities affect its tax rate and prospects for future cash flows. The standard is effective for annual periods beginning after December 15, 2024. The Company adopted ASU 2023-09 during the year ended December 31, 2025 on a prospective basis. The expanded disclosures are included in the consolidated financial statements (Note 9).

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures , which is intended to improve disclosures about a public company's expenses including the disclosure of certain expenses included and aggregated in captions such as cost of sales, selling general & administrative and research and development expenses on the consolidated financial statements on an interim and annual basis. The standard is effective for annual periods beginning after December 15, 2026 and interim periods within annual periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of the standard on the presentation of its consolidated financial statements and footnotes.

3. Marketable Securities and Fair Value Measurements

As of December 31, 2025, available for sale marketable securities by security type consisted of (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government agencies (due within one year)	1,500	—	—	1,500
Commercial paper (due within one year)	35,286	4	(3)	35,287
Corporate notes and bonds (due within one year)	41,208	23	—	41,231
Total	$ 77,994	$ 27	$ (3)	$ 78,018

As of December 31, 2024, available for sale marketable securities by security type consisted of (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. treasury notes (due within one year)	$ 35,366	$ 28	$ —	$ 35,394
Commercial paper (due within one year)	44,959	35	—	44,994
Corporate notes and bonds (due within one year)	100,662	112	(30)	100,744
Corporate notes and bonds (due after one year through two years)	7,171	—	(10)	7,161
Total	$ 188,158	$ 175	$ (40)	$ 188,293

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, 2025 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 56,357	$ —	$ —	$ 56,357
Commercial paper	—	24,227	—	24,227
Marketable securities:				
U.S. government agencies	—	1,500	—	1,500
Commercial paper	—	35,287	—	35,287
Corporate notes and bonds	—	41,231	—	41,231
Total	$ 56,357	$ 102,245	$ —	$ 158,602

	Fair Value Measurements at December 31, 2024 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 28,027	$ —	$ —	$ 28,027
U.S. treasury notes	—	14,500	—	14,500
Commercial paper	—	2,748	—	2,748
Marketable securities:				
U.S. treasury notes	—	35,394	—	35,394
Commercial paper	—	44,994	—	44,994
Corporate notes and bonds	—	107,905	—	107,905
Total	$ 28,027	$ 205,541	$ —	$ 233,568

For the years ended December 31, 2025 and 2024, there were no transfers between Level 1, Level 2 and Level 3.

4. Property and Equipment, Net

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

	December 31,	
	2025	2024
Laboratory equipment	$ 8,035	$ 7,119
Furniture and fixtures	839	839
Computer equipment and software	46	67
Leasehold improvements	—	17,023
	8,920	25,048
Less: Accumulated depreciation and amortization	(7,005)	(15,084)
	$ 1,915	$ 9,964

Depreciation and amortization expense was $3.3 million and $3.1 million for the years ended December 31, 2025 and 2024, respectively. The Company recognized a non-cash impairment of leasehold improvements of $5.9 million and $0.8 million for the years ended December 31, 2025 and 2024, respectively, see Note 10, Leases, for additional information.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2025	2024
Accrued employee compensation and benefits	$ 5,921	$ 4,742
Accrued external research and development expenses	4,194	3,076
Accrued professional fees	842	712
Other	400	1
	$ 11,357	$ 8,531

6. Common Stock

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

In May 2024, the Company entered into an underwriting agreement with Jefferies LLC, TD Securities (USA) LLC and Evercore Group LLC relating to the issuance and sale of an aggregate of 12,743,039 shares of its common stock at a public offering price of $5.51 per share to certain investors. In addition, the Company issued and sold to certain investors in lieu of common stock the Pre-funded Warrants to purchase 7,220,794 shares of its common stock at a public offering price of $5.5099 per pre-funded warrant, which represents the public offering price per share of the common stock less the $0.0001 exercise price per share of each pre-funded warrant. The offering closed on May 22, 2024, resulting in net proceeds of $102.8 million after deducting underwriting discounts and commissions and other offering expenses.

As the Pre-funded Warrants are indexed to the Company’s common stock (and otherwise meet the requirements to be classified in equity), the Company recorded the consideration received from the issuance of the pre-funded warrants as additional paid-in capital on the Company’s consolidated balance sheets and statements of stockholders’ deficit.

The Pre-funded Warrants are exercisable at any time.

On April 15, 2022, the Company entered into a sales agreement (the “Sales Agreement”) with Cowen and Company, LLC (“Cowen”) with respect to an at-the-market offering (the “ATM Offering”) pursuant to which the Company, at its discretion, may offer and sell shares of its common stock having an aggregate offering price of up to $200.0 million from time to time through Cowen as its sales agent. Sales of common stock through Cowen, if any, will be made by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended. The Company will pay Cowen a commission of up to 3.0% of the gross sales price of any common stock sold through Cowen under the Sales Agreement.

On March 20, 2025, the Company and TD Securities (USA) LLC, as successor to Cowen (“TD Cowen”) entered into amended the sales agreement (the “Amended Sales Agreement”), which, among other things, reduced the amount of shares of common stock that may be sold under the ATM Offering to up to $100 million of shares of common stock.

In the fourth quarter of 2025, the Company issued and sold 101,174 shares of its common stock under the ATM Facility for net proceeds of $0.5 million.

7. Stock-Based Compensation

2020 Equity Incentive Plan

The Company’s 2020 Equity Incentive Plan (the “2020 Plan”) provides for the grant of incentive stock options, non-qualified options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares initially reserved for issuance under the 2020 Plan was (i) 2,200,000 shares (the “share pool”), plus (ii) the number of shares of common stock available for issuance under the Company’s 2016 Stock Incentive Plan (the “2016 Plan”) as of the effective date of the 2020 Plan, plus the number of shares of common stock underlying awards under the 2016 Plan that on or after the date of adoption expire or become unexercisable without delivery of shares, are forfeited to, or repurchased for cash, are settled in cash, or otherwise become available again for grant under the 2016 Plan, in each case, in accordance with its terms (up to an aggregate of 5,078,295 shares). As of December 31, 2025, 3,486,615 shares remained available for future grant under the 2020 Plan.

The share pool will automatically increase on January 1 of each year from 2021 to 2030 by the lesser of (i) four percent of the number of shares of our common stock outstanding as of the close of business on the immediately preceding December 31 and

(ii) the number of shares determined by the board of directors on or prior to such date for such year. The number of shares reserved for issuance under the 2020 Plan was increased by 2,266,293 shares effective January 1, 2026.

The 2020 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 with service-based vesting conditions generally vest over four years and expire after ten years. The exercise price for stock options granted is not less than the fair value of common stock on the date of grant. The Company bases fair value of common stock on the quoted market price.

2020 Employee Stock Purchase Plan

On October 21, 2020, the Company's board of directors adopted and its stockholders approved the 2020 Employee Stock Purchase Plan (the "ESPP"), which became effective on October 21, 2020. The aggregate number of shares of common stock available for purchase pursuant to the exercise of options under the ESPP is 360,000 shares, plus an automatic annual increase, as of January 1 of each year from 2021 to 2030, equal to the lesser of one percent of the number of shares of common stock outstanding as of the close of business on the immediately preceding December 31 and (ii) the number of shares determined by the board of directors on or prior to such date for such year (up to a maximum of 3,220,520 shares). As of December 31, 2025, 2,077,652 shares remained available for future grant under the ESPP. The number of shares reserved for issuance under the ESPP was increased by 566,573 shares effective January 1, 2026.

Eligible employees may authorize payroll deductions of up to 15% of their eligible compensation during an offering period. The purchase of shares is done at a 15% discount on the lesser of (i) the Fair Market Value of a share of Stock on the first day of the offering period and (ii) the Fair Market Value of a share of Stock on the last day of the offering period. The Company currently holds two offering periods, September 1 and March 1, respectively. For the years ended December 31, 2025 and 2024, the Company recognized a de minimis amount and $0.1 million, respectively, of expense related to the ESPP.

Stock option valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. The Company currently 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 for the years ended December 31, 2025 and 2024 which was as follows:

	Year Ended December 31,	
	2025	2024
Risk-free interest rate	4.3 %	4.1 %
Expected volatility	93.5 %	89.3 %
Expected dividend yield	—	—
Expected term (in years)	5.8	6.1

The following table summarizes the Company's option activity for the year ended December 31, 2025 which was as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value
			(in years)	(in thousands)
Outstanding as of December 31, 2024	8,989,893	$ 8.34	7.1	$ 6,388
Granted	2,531,222	4.38		
Exercised	(213,710)	1.85		
Forfeited/Expired	(1,049,904)	8.23		
Outstanding as of December 31, 2025	10,257,501	$ 7.51	6.7	$ 9,690
Options exercisable as of December 31, 2025	6,334,480	$ 9.00	5.5	$ 5,556

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 for the years ended December 31, 2025 and 2024 was $0.5 million and $1.8 million, respectively

The weighted average grant-date fair value of stock options granted for the years ended December 31, 2025 and 2024 was $3.32 per share and $3.14 per share, respectively.

Stock-based compensation

The Company recorded stock-based compensation expense related to common stock options in the following expense categories of its consolidated statements of operations and comprehensive loss for the years ended December 31, 2025 and 2024 which was as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development expenses	$ 4,336	$ 4,955
General and administrative expenses	6,063	6,938
	$ 10,399	$ 11,893

As of December 31, 2025, total unrecognized compensation cost related to unvested options was $11.7 million, which is expected to be recognized over a weighted average period of 2.1 years.

8. Collaboration Agreement

Lilly Collaboration Agreement and Stock Purchase Agreement

In December 2021, the Company entered into the Lilly Collaboration Agreement with Lilly to create novel oncology medicines by applying Foghorn's proprietary Gene Traffic Control platform. The collaboration includes a co-development and co-commercialization agreement for the Company's selective SMARCA2 (BRM) oncology target, consisting of two programs, and one additional undisclosed oncology target (collectively, the "Joint Programs"). The collaboration also includes three additional discovery targets or programs (collectively, the "Discovery Programs") for a total of six programs directed at five targets.

With respect to the Joint Programs, the Company will lead discovery and early research activities through the successful completion of dose finding toxicity studies for the identified compound, while Lilly will lead development and commercialization activities of the identified compound with participation from the Company in development activities and 50% cost sharing until registrational clinical trials. The Company and Lilly may jointly develop and commercialize the Joint Program compound though the Company may, in its sole discretion, opt-out on a program-by-program basis of further participation in the development and commercialization efforts prior to the first registrational clinical trial. If the Company does not opt-out, Lilly and the Company will continue to share in the costs to further develop and commercialize the Joint Program compound on a worldwide basis, equally share in the U.S. profits on product sales, subject to certain adjustments and receive royalties on sales outside of the United States ("Ex-U.S.") at royalty rates ranging from low double digits to high twenties. If the Company opts-out of further development and commercialization efforts, it will have no further obligations to share in the development and commercialization costs, will receive royalties rather than profit share on U.S. sales and will receive royalties at a lower rate on Ex-U.S. sales.

With respect to the Discovery Programs, the Company will lead discovery and early research activities through the successful completion of dose finding toxicity studies for the identified compounds. The Company may, in its sole discretion, opt-in on a program-by-program basis after the successful completion of dose finding toxicity to participate in the further development and commercialization efforts of the Discovery Program compounds. If the Company opts-in to the development and commercialization of the Discovery Program compounds, it will be eligible to receive milestone payments of up to $10.0 million per program upon specified research and development milestones and up to $180.0 million per program upon achievement of specified regulatory and commercial milestones and will also be eligible to share in the U.S. profits at pre-determined percentages on product sales. The Company would also be eligible to receive tiered Ex-U.S. royalty rates, calculated on a product-by-product and country-by-country basis, on net sales outside of the United States, if any, ranging from low single digits to low double digits, but less then teens. If the Company does not opt-in to further development and commercialization efforts for the Discovery Programs, it will be eligible to receive milestone payments of up to $70.0 million per program upon specified research and development milestones and up to $360.0 million per program upon achievement of specified regulatory and commercial milestones per approved product, if any. The Company would also be eligible to receive tiered royalties on net sales of products worldwide at royalty rates ranging from low single digits to low double digits, but less than teens.

Lilly has the right to make substitutions for each of the five targets during the research term of each program, subject to certain limitations. Pursuant to the Lilly Collaboration Agreement, the Company will also participate in joint decision-making through the joint steering committee and subcommittees. Unless terminated earlier, the Lilly Collaboration Agreement will continue on a product-by-product basis until the expiration of all royalty obligations under the Lilly Collaboration Agreement and when neither the Company nor Lilly is developing, commercializing or manufacturing any product under the Lilly Collaboration Agreement. The Company or Lilly may terminate the Lilly Collaboration Agreement upon an uncured material breach by the other party. Lilly may also terminate the Lilly Collaboration Agreement in its entirety or on a target-by-target, program-by-program or product-by-product basis for any reason upon certain notice to the Company.

Under the terms of the Lilly Collaboration Agreement, Lilly agreed to make a nonrefundable upfront payment of $300.0 million to the Company within thirty (30) business days following the effective date of the agreement. Simultaneously with the execution of the Lilly Collaboration Agreement, the Company and Lilly entered into a stock purchase agreement with Lilly (the "Lilly SPA"), pursuant to which Lilly purchased 4,000,000 shares of the Company's common stock at $20.00 per share, for an aggregate purchase price of $80.0 million.

The Company determined that the Lilly Collaboration Agreement and the Lilly SPA should be evaluated as a combined contract in accordance with ASC 606. The Company determined the fair value of the shares sold under the Lilly SPA to be $37.8 million less than the contractual purchase price stipulated in the Lilly SPA. In accordance with the applicable accounting guidance in ASC 815-40, *Contracts in Entity's Own Equity*, the Company determined that the sale of stock should be recorded at fair value and therefore allocated the excess consideration received under the Lilly SPA to the Lilly Collaboration Agreement, which along with the non-refundable payment of $300.0 million will be recognized as revenue over the total estimated period of performance.

The Company accounted for the arrangement under ASC 606 as the Company concluded it has a customer relationship with Lilly. The Company determined that: (1) the research activities performed by the Company for both the Joint Programs and the Discovery Programs, (2) the development activities and cost sharing for the Joint Program development efforts after dose finding toxicity until registrational clinical trials, (3) the research, development, manufacture and commercialization licenses, and (4) service on the joint steering committee and subcommittees represent a single performance obligation under the Lilly Collaboration Agreement. The Company determined that Lilly cannot benefit from the licenses separately from the research activities, the development activities until registrational clinical trials and participation on the joint steering committee and subcommittees because these services are specialized and rely on the Company's expertise such that these activities are highly interrelated and therefore not distinct. Accordingly, the promised goods and services represent one combined performance obligation, and the entire transaction price was allocated to that single combined performance obligation. The performance obligation will be satisfied over time as the Company performs the research activities, participates and shares in the cost of the development activities for the Joint Programs and participates in a joint steering committee and subcommittees to oversee these activities.

The Company's options to share in further development and commercialization efforts via its opt-in/opt-out rights will be assessed and accounted for as separate units of accounting under the relevant guidance if, and when, such options are exercised by the Company.

During the third quarter of 2023, the Company transitioned the SMARCA2 (BRM) Selective inhibitor, FHD-909, into development activities for which Lilly leads and the Company participates and shares in 50% of the costs until at least registrational trials. Costs incurred will continue to be included in research and development expenses on the consolidated statements of operations and comprehensive loss.

The transaction price of $337.8 million was initially recorded as deferred revenue and is being recognized as revenue as the performance obligation is satisfied. The Company recognizes revenue using the cost-to-cost method, which it believes best depicts the transfer of control to the customer over time. Under the cost-to-cost method, the extent of progress towards completion is measured based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the identified performance obligation. Under this method, revenue is recorded as a percentage of the estimated transaction price based on the extent of progress towards completion. As of December 31, 2025, the potential research, development and regulatory milestone payments that the Company is eligible to receive were excluded from the transaction price as they were fully constrained by uncertain events. The Company will reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and if necessary, the Company will adjust its estimate of the transaction price. Any additions to the transaction price would be reflected in the period as a cumulative revenue catch-up based on the ratio of costs incurred to the total estimated costs expected applied to the revised transaction price. Sales-based royalties and milestone payments, which predominantly relate to the license, will be recognized if and when the related sales occur.

As of December 31, 2025, the aggregate amount of the transaction price related to the unsatisfied portion of the performance obligation was $249.2 million, which is expected to be recognized as revenue through 2029 or beyond depending on the timing

of certain clinical development activities. The Company does not expect collaboration revenue to be recognized evenly over this period as it will be recognized on a percentage of completion basis (using cost-to-cost method) as the Company performs the research and development activities and participates on the joint steering committee and subcommittees, which will likely vary from period to period. In estimating the total costs to satisfy its single performance obligation pursuant to the Lilly Collaboration Agreement, the Company is required to make significant estimates including the expected time and expected costs to fulfill the performance obligation. If estimates of the total estimated cost change, or if contract amendments change the scope of the performance obligations, the impacts could be material. The cumulative effect of revisions to the total estimated costs to complete the Company's single performance obligation will be recorded in the period in which the changes are identified, and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods and the classification of deferred revenue between short-term and long-term.

For the years ended December 31, 2025 and 2024, the Company recorded $30.9 million and $22.6 million, respectively, of revenue under the Lilly Collaboration Agreement, which was included in deferred revenue at the beginning of the respective periods. As of December 31, 2025 and 2024, the Company had a payable to Lilly of $1.0 million and $0.6 million, respectively, recorded in accrued expenses and other current liabilities on the Company's consolidated balance sheets.

9. Income Taxes

For the years ended December 31, 2025 and 2024 the Company recorded no income tax benefits for the net deferred tax assets comprised primarily of net operating losses incurred and research and development tax credits generated in each year, due to its uncertainty of realizing a benefit from these items.

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

A reconciliation of the U.S. federal statutory income tax rate of 21% to the Company's effective income tax rate, post the adoption of ASU 2023-09, is as follows (in thousands, except percentages):

	Year Ended December 31, 2025	
	Amount	Percent
Income taxes at U.S. federal statutory rate	$ (15,600)	21.0 %
State income taxes, net of federal benefit	6	—
Nontaxable or nondeductible items		
Stock-based compensation expense	1,142	(1.5)
Limitation on executive compensation	811	(1.1)
Other	88	(0.1)
Tax Credits		
Federal research and development tax credits	(2,242)	3.0
Change in valuation allowance	15,803	(21.3)
Other adjustments	(8)	—
Income tax expense and effective income tax rate	$ —	0.0 %

For the year ended December 31, 2025, state income taxes in Massachusetts make up the majority (greater than 50%) of the state income taxes, net of federal benefit category.

A reconciliation of the U.S. federal statutory income tax rate of 21% to the Company's effective income tax rate, prior to the adoption of ASU 2023-09, is as follows:

	Year Ended December 31, 2024
Income taxes at U.S. federal statutory rate	21.0 %
State income taxes, net of federal benefit	4.8
Federal and state research and development tax credits	4.9
Stock-based compensation expense	(0.9)
Nondeductible/nontaxable permanent items	(0.1)
Other	(2.6)
Change in valuation allowance	(27.1)
Effective income tax rate	0.0 %

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

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 55,169	$ 14,519
Capitalized research expenditures	44,554	59,481
Research and development tax credit carryforwards	13,086	10,044
Capitalized start-up costs	92	108
Deferred revenue	68,069	76,259
Accrued expenses	6	3
Stock-based compensation	4,048	3,861
Operating lease liabilities	11,536	10,112
Total deferred tax assets	196,560	174,387
Deferred tax liabilities:		
Depreciation	(234)	(1,785)
Operating lease right-of-use assets	(8,691)	(6,172)
Total deferred tax liabilities	(8,925)	(7,957)
Valuation allowance	(187,635)	(166,430)
Net deferred tax assets	$ —	$ —

As of December 31, 2025, the Company had U.S. federal and state net operating loss carryforwards of $198.5 million and $213.5 million, respectively. The U.S. federal net operating loss carryforwards can be carried forward indefinitely but limited to offset 80% of annual taxable income. The state net operating loss carryforwards will begin to expire in 2039. As of December 31, 2025, the Company also had U.S. federal and state research and development tax credit carryforwards of $9.4 million and $3.7 million, respectively, which may be available to offset future tax liabilities and expire at various dates beginning in 2043 and 2037, respectively.

The Tax Cuts and Jobs Act ("TCJA") requires taxpayers to capitalize and amortize, rather than deduct, research and development ("R&D") expenditures under section 174 of the Internal Revenue Code of 1986, as amended (the "Code") for tax years beginning after December 31, 2021. The Company will amortize these costs for tax purposes over 5 years if the R&D was performed in the U.S. and over 15 years if the R&D was performed outside the U.S. These rules became effective for the Company during the year ended December 31, 2022. The Company has capitalized foreign R&D costs of $25.2 million and $25.0 million for the tax years ended December 31, 2025 and December 31, 2024, respectively.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted, providing taxpayers the option to fully deduct or continue capitalizing and amortizing domestic R&D expenditures under new Code Section 174A, effective for tax years beginning after December 31, 2024. The OBBBA also provides certain eligible taxpayers with the option to accelerate and deduct the remaining unamortized domestic R&D costs incurred during taxable years ending after December 31, 2021 and before January 1, 2025. The Company has implemented the two-year accelerated expensing for all domestic R&D costs

incurred during taxable years ending after December 31, 2021 and before January 1, 2025. As of December 31, 2025, $75.2 million remains unamortized related to domestic R&D costs. Final elections will be made with the 2025 tax return filing.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products that would generate revenue from product sales and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2025 and 2024. Management reevaluates the positive and negative evidence at each reporting period.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products that would generate revenue from product sales and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2025 and 2024. Management reevaluates the positive and negative evidence at each reporting period.

The valuation allowance increased by $21.2 million and $23.5 million for the years ended December 31, 2025 and 2024, respectively, primarily as a result of the increase in total deferred tax assets.

Ownership changes may limit the amount of net operating loss carryforwards or research and development tax credit carryforwards that can be utilized to offset future taxable income or tax liability. In general, an ownership change, as defined by Sections 382 and 383 of the Code, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% (by value) over a three-year period. If the Company has experienced a change of control, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Sections 382 and 383 of the Code. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. To the extent there was a change in control, the Company's tax attributes could be subject to limitation. However, a full valuation allowance has been provided against the deferred tax assets related to the Company's net operating loss and tax credit carryforwards and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance.

As of December 31, 2025 and 2024, the Company had not recorded any amounts for unrecognized tax benefits. The Company files income tax returns in the U.S. federal tax jurisdiction and Massachusetts and various other state tax jurisdictions as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. Since the Company is in a loss carryforward position, it is generally subject to examination by the U.S. federal, state, and local income tax authorities for all tax years in which a loss carryforward is available.

The Company made the following income tax payments (net of refunds received) during the year ended December 31, 2025 (in thousands):

	Year Ended December 31, 2025
US state and local	
Massachusetts	$ 9
Tennessee	(105)
Total income tax payments (net of refunds received)	$ (96)

10. Leases

Lease agreements

Through December 2025, the Company occupied space in 500 Tech Square, Cambridge, Massachusetts under a lease agreement for 81,441 square feet of office and laboratory space that was set to expire in September 2028 (the "Office Lease"). In June 2025, the Company entered into a new lease agreement with its existing landlord of the Office Lease for new premises consisting of 72,846 square feet of laboratory and office space in Watertown, Massachusetts (the "New Lease"). The term of the New Lease commenced in December 2025 once the landlord completed its building improvements as defined in the New Lease (the "New Premises Delivery Date") and extends through September 2035. The lease is subject to fixed-rate rent escalations and the option to extend the lease for two terms of five years each, which were not reasonably certain of exercise as of December 31, 2025. The estimated minimum lease payments under the New Lease total $60.8 million over the term, inclusive of free and reduced rent periods in the first three years of the term. Additionally, the Company is obligated to pay real estate taxes and other costs related to the premises, including operating costs and management of the leased premises, which are

variable in nature. The variable costs are expensed as incurred and are disclosed as variable lease costs. The lease contains a tenant improvement allowance of $3.6 million and the landlord holds rights to the tenant improvements. The construction of the building improvements made prior to the New Premises Delivery Date were conducted by the landlord. The Company moved operations from its existing premises to the new premises in December 2025.

The Company is required to maintain a cash balance of $2.0 million to secure a letter of credit associated with the New Lease. This amount was classified as restricted cash (non-current) on the consolidated balance sheet as of December 31, 2025.

In conjunction and concurrent with the New Lease, in June 2025, the Company amended the Office Lease, which originally had a term through September 2028, to reduce the fixed lease payments and shorten the remaining term for a portion of the leased space from September 2028 to December 31, 2026, to provide for the termination of space the Company was subleasing contingent upon the New Premises Delivery Date and the landlord entering into a direct lease with the Company's subtenant, to provide for the reduction of payments contingent upon the New Premises Delivery Date, and to provide for the early termination of the Office Lease contingent upon the New Premises Delivery Date.

In December 2025, upon the New Premises Delivery Date, contingencies related to the New Premises Delivery Date were resolved. The lease related to the portion of space being sublet was terminated immediately upon the New Premises Delivery Date. Additionally, under the amended Office Lease, the term of the remaining portions of the lease was shortened from September 2028 to the date the landlord provides a 15-day notice of termination, which the landlord can provide starting February 1, 2026, with an outside termination date of December 31, 2026. As of the New Premises Delivery Date in December 2025 the Company is not obligated to make any further payments with respect to the Office Lease and the Company vacated the Office Lease space in December 2025.

Lease accounting

The Company accounted for the amendment to the Office Lease and the New Lease as one combined contract under ASC 842, *Leases (Topic 842)* because the agreements were entered into at the same time, with the same counterparty and were negotiated as a package with the same commercial objective.

In June 2025, in connection with the shortened term to December 31, 2026 for a portion of the leased space and the reduction of fixed payments, the Company remeasured the right-of-use asset and lease liability related to the Office Lease for the non-contingent modification at the modification date, which resulted in a reduction to the right-of-use asset and lease liabilities of $8.8 million. With respect to the contingent modifications of other portions of the lease, as the New Premises Delivery Date and the related Office Lease termination dates were not in the control of the Company, the Company did not remeasure the term for these portions of the Office Lease for financial accounting purposes until the contingencies were resolved in December 2025.

In December 2025, upon resolution of contingencies related to the New Premises Delivery Date, the Company remeasured the right-of-use asset and lease liabilities related to the shortened lease term and elimination of remaining payments for the Office Lease, which resulted in a reduction to lease liabilities of $21.3 million related to the elimination of future payments under the Office Lease and a reduction to the remaining right-of-use asset of $9.6 million to reduce the right-of-use asset balance to zero. The reduction to the lease liability that would have reduced the right-of-use asset to below zero, or negative amount, was first recorded as a gain on lease modification of $1.6 million in the consolidated statement of operations and comprehensive loss, representing a previous impairment amount recorded on the Office Lease. Because the portion related to the previously recognized impairment is not an element of the arrangement with the lessor, and therefore, it is not akin to a lease incentive. The remaining negative amount $10.1 million was recorded as a lease incentive to reduce the right-of-use asset related to the New Lease, as the amendment to the Office Lease and the New Lease were combined and accounted for as a single transaction with the same counterparty.

In December 2025, upon commencement of the New Lease, which was the date the landlord made the premises available to the Company for its use, the Company recorded a right-of-use asset of $31.0 million, net of the $10.1 million remaining negative amount from the Office Lease, and lease liabilities of $41.1 million. As of December 31, 2025, the balances of the lease liability and right-of-use asset for the Office Lease were zero.

The components of lease expense were as follows for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Operating lease cost	$ 6,060	$ 7,921
Variable lease cost	2,655	3,054
	$ 8,715	$ 10,975

Supplemental disclosure of cash flow information and non-cash investing and financing activities related to leases was as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Supplemental cash flow information:		
Cash paid for amounts included in the measurement of operating lease liabilities	$ 8,775	$ 10,736
Non-cash investing and financing activities:		
Financing lease liabilities arising from obtaining right-of-use assets	1,200	—
Reduction of right-of-use assets from remeasurement of lease liabilities	18,382	—
Operating lease liabilities arising from obtaining right-of-use assets	41,143	—

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

	2025	2024
Weighted-average remaining lease term—operating leases (in years)	9.7	3.7
Weighted-average discount rate—operating leases	7.24 %	5.30 %

As the Company's leases do not provide an implicit rate, the Company's estimated incremental borrowing rate was used to calculate the present value of the leases. In determining its incremental borrowing rate, the Company considered its credit quality and assessed interest rates available in the market for similar borrowings, adjusted for the impact of collateral over the term of the leases.

Future payments for the Company's operating lease liabilities as of December 31, 2025 are as follows (in thousands):

2026	$ 979
2027	4,280
2028	5,713
2029	6,774
2030	6,977
Thereafter	36,088
Total future minimum lease payments	60,811
Less: estimated tenant improvement allowance	(364)
Less: imputed interest	(19,177)
Total operating lease liabilities	$ 41,270

	Year Ended December 31,	
Included in the consolidated balance sheets (in thousands):	2025	2024
Current operating lease liabilities	$ 923	$ 9,067
Operating lease liabilities, net of current portion	40,347	28,064
Total operating lease liabilities	$ 41,270	$ 37,131

Impairments and sublease agreement

In connection with the New Premises Delivery and relocating operations from premises under the Office Lease to premises under the New Lease, the Company recognized an impairment charge during the year ended December 31, 2025 of $5.9 million in the consolidated statements of operations and comprehensive loss for the abandoned leasehold improvements related to the Office Lease.

In connection with a sublease for a portion of the Office Lease entered into in May 2024, which qualified as a triggering event for an asset impairment assessment, the Company recognized a non-cash impairment charge during the year ended December 31, 2024 of $2.4 million in the consolidated statements of operations and comprehensive loss of which $1.6 million was allocated to its right-of-use asset and $0.8 million was allocated to leasehold improvements.

Through December 2025, the Company had subleased portions of premises under the Office Lease. For the years ended December 31, 2025 and 2024, the Company recorded other income of $3.4 million and $4.2 million, respectively, related to its subleases. As of December 31, 2025, the Company has no subleases.

11. Commitments and Contingencies

Leases

The Company's commitments under its leases are described in Note 10.

License agreements

The Company has entered into various exclusive and non-exclusive license agreements for certain technologies. Under the terms of these license agreements, the Company could be required to reimburse the licensors for patent expenses and remit amounts in the low single-digit as sales-based royalties upon the occurrence of specific events as outlined in the corresponding license agreements. The Company is also required to make annual license maintenance fees of less than $0.1 million and pay up to $1.1 million in regulatory milestones on each licensed product upon the occurrence of specific events as outlined in one of the license agreements. None of our current product candidates utilizes technologies covered by these licenses.

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.

12. 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. For the years ended December 31, 2025 and 2024, the Company recorded $0.3 million of expense related to 401(k) discretionary match.

13. Related Parties

In October 2015, the Company entered into a five-year consulting agreement with a scientific founder of the Company who is also a shareholder. In October 2020, this agreement was amended and extended to January 1, 2022, subject to automatic one-year renewal terms thereafter until terminated if notice is provided more than 30 days before the current end of term date. On January 1, 2026, the agreement was automatically renewed and extended to January 1, 2027. For the years ended December 31, 2025 and 2024, the Company paid the scientific founder $0.2 million. As of December 31, 2025 and 2024, the Company had no accounts payable due to the scientific founder.

On December 10, 2021, we entered into the Lilly Collaboration Agreement with Lilly. Concurrent with the Lilly Collaboration Agreement the Company also entered into the Lilly SPA where the Company issued and sold Lilly 4,000,000 shares of our common stock at a price of $20.00 per share, making them a 5% or greater shareholder in the Company for the years ended December 31, 2025 and 2024. We are obligated to make certain payments to Lilly pursuant to the Lilly Collaboration Agreement. For the years ended December 31, 2025 and 2024, the Company paid Lilly $8.2 million and $8.4 million, respectively. As of December 31, 2025 and 2024, the Company had a payable of $1.0 million and $0.6 million, respectively, due to Lilly.

14. Segment Reporting

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 manages its operations as a single segment (the "Segment") for the purposes of assessing performance and making operating decisions. The CODM of the Segment is the Company's chief executive officer. The Segment is focused on pioneering the discovery and development of a new class of medicines targeting genetically determined dependencies within the chromatin regulatory system. The Segment's revenue is derived entirely from the recognition of deferred revenue related to our collaboration agreement with Lilly and funds received under the Lilly SPA

(see Note 8). The accounting policies for the Segment are the same as those described in Note 2, Summary of Significant Accounting Policies.

The CODM assesses the performance of the Segment and decides how to allocate resources based on net loss that is reported on the consolidated statements of operations and comprehensive loss. Further, the following represents information about segment revenue, segment loss and significant segment expenses (in thousands):

	Year Ended December 31,	
	2025	2024
Collaboration revenue	$ 30,909	$ 22,602
Less:		
Research and development:		
Personnel expenses	22,734	22,472
FHD-286	916	11,136
Lilly partnered programs	22,509	17,325
Proprietary programs	16,658	18,416
Research and development operating and administrative costs	5,866	6,252
General and administrative:		
Personnel expenses	11,010	9,848
External expenses	7,929	8,586
Facilities and IT related expenses, net of sublease income	8,223	9,667
Other expenses, net[(1)]	18,092	17,420
Plus:		
Interest income	8,745	11,900
Net loss	$ (74,283)	$ (86,620)

(1) Inclusive of $10.4 million and $11.9 million of stock compensation expense for the years ended December 31, 2025 and 2024, respectively; $3.3 million and $3.1 million of depreciation and amortization expense for the years ended December 31, 2025 and 2024, respectively; non-cash impairment charges of $5.9 million and $2.4 million for the years ended December 31, 2025 and 2024, respectively; and a gain on lease modification of $1.6 million for the year ended December 31, 2025.

15. Subsequent Events

January 2026 Offering

On January 9, 2026, the Company entered into securities purchase agreements (the "Purchase Agreements") with certain leading life sciences investors (the "Investors"), relating to the issuance and sale of 2,030,314 shares of its Common Stock and, in lieu of Common Stock, pre-funded warrants to purchase 5,421,250 shares of Common Stock (the "Pre-Funded Warrants"). The Company sold the shares of Common Stock and Pre-Funded Warrants together with two series of warrants, Series 1 Warrants and Series 2 Warrants, to purchase an aggregate of 7,451,564 shares of the Common Stock (the "Series Warrants"). The Pre-Funded Warrants were exercisable immediately upon issuance at an initial exercise price of $0.0001 per share and have a term of 20 years. The shares of Common Stock, or Pre-Funded Warrants, and the accompanying Series Warrants were immediately separable and were issued separately, but they were purchased together in the offering.

The Series Warrants are immediately exercisable. Each Series 1 Warrant has an initial exercise price of $13.42 per share of Common Stock, subject to certain adjustments, and expires on June 30, 2027. Each Series 2 Warrant has an initial exercise price of $20.13 per share of Common Stock, subject to certain adjustments, and expires on December 31, 2030. For the Series Warrants, the Investor may elect to receive, in lieu of shares of Common Stock, pre-funded warrants to purchase an equivalent number of shares of Common Stock.

The offering price for the shares of Common Stock is $6.71 per share (or $6.7099 for each Pre-Funded Warrant, which equals the price per share of the Common Stock less the exercise price of the Pre-Funded Warrants). The aggregate gross proceeds to the Company from this offering were approximately $50.0 million before any offering expenses, and excluding any proceeds the Company may receive upon exercise of the Pre-Funded Warrants and Series Warrants. No underwriter or placement agent participated in the offering.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Principal Executive Officer (our Chief Executive Officer) and Principal Financial and Accounting Officer (our Chief Financial Officer), has evaluated the effectiveness of our disclosure controls and procedures as of period end. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2025, our Principal Executive Officer and Principal Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Internal Control Over Financial Reporting

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. generally accepted accounting principles ("GAAP"). Internal control over financial reporting is a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that accurately and fairly reflect in reasonable detail the transactions and dispositions of the assets of our company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurances regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material adverse effect on our financial statements.

Management assessed our internal control over financial reporting as of December 31, 2025, the end of our fiscal year. Management based its assessment on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment.

Based on this assessment, management has concluded that our internal controls over financial reporting were effective as of December 31, 2025 and provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with GAAP. We reviewed the results of management's assessment with the Audit Committee of our Board of Directors.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Our independent registered public accounting firm will not be required to opine on the

effectiveness of our internal control over financial reporting until we are no longer a non-accelerated filer within the meaning of the Exchange Act.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Internal Controls

In designing and evaluating the disclosure controls and procedures, management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud.

ITEM 9B. OTHER INFORMATION

During the three months ended December 31, 2025, none of our directors or officers (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended) entered into, modified (as to amount, price or timing of trades) or terminated any “Rule 10b5-1 trading arrangements” or any “non-Rule 10b5-1 trading arrangements,” as such terms are defined in Item 408 of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

1. Financial Statements

For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page 89 of this Annual Report on Form 10-K, incorporated into this Item by reference.

2. Financial Statement Schedules

Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

3. Exhibits

The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K.

ITEM 16. FORM 10-K SUMMARY

None.

Exhibit number	Description of document
3.1	Third Amended and Restated Certificate of Incorporation of Foghorn Therapeutics Inc.(Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39634), filed on October 27, 2020).
3.2	Amended and Restated By-laws of Foghorn Therapeutics Inc., dated March 7, 2023 (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39634), filed on March 9, 2023).
4.1	Specimen stock certificate evidencing shares of common stock (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
4.2	Amended and Restated Investors' Rights Agreement, by and among Foghorn Therapeutics Inc. and the investors party thereto, dated as of December 18, 2018 (Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
4.3	Amendment to the Investors' Rights Agreement and the Voting Agreement, dated December 18, 2018, by and among Foghorn Therapeutics Inc. and the investors party thereto, dated as of April 17, 2020 (Incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 2, 2020).
4.4	Form of Warrant to Purchase Series A-2 Preferred Stock of the Registrant issued to Silicon Valley Bank, dated November 29, 2016 (Incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 2, 2020).
4.5	Form of Warrant to Purchase Common Stock of the Registrant issued to Oxford Finance LLC (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-39634), filed on November 25, 2020).
4.6	Description of Registrant's Securities (Incorporated by reference to Exhibit 4.6 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2024 (File No. 001-39634), filed on March 6, 2025).
4.7	Amendment to Amended and Restated Investors' Rights Agreement dated December 18, 2018, by and among Foghorn Therapeutics Inc. and the investors party thereto, dated as of December 10, 2021 (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-39634), filed on December 13, 2021).

Exhibit number	Description of document
4.8	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-39634), filed on May 22, 2024).
4.9	Form of Series Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-39634), filed on January 12, 2026).
4.10	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-39634), filed on January 12, 2026).
10.1	Lease Agreement by and between ARE-Tech Square, LLC and Foghorn Therapeutics Inc., dated October 23, 2019 (Incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 2, 2020).
10.2	First Amendment to Lease by and between ARE-Tech Square, LLC and Foghorn Therapeutics Inc. dated June 29, 2020 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report for the quarter ended March 31, 2022 (File No. 001-39634), filed on May 9, 2022.
10.3++	Exclusive Collaboration and License Agreement, by and between Merck Sharp & Dohme Corp. and Foghorn Therapeutics Inc., dated as of July 2, 2020 (Incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 2, 2020).
10.4^	Foghorn Therapeutics Inc. 2016 Stock Incentive Plan, as amended (Incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 2, 2020).
10.5^	Form of Stock Restriction Agreement under the Foghorn Therapeutics Inc. 2016 Stock Incentive Plan (Incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 2, 2020).
10.6^	Form of Incentive Stock Option Grant Notice under the Foghorn Therapeutics Inc. 2016 Stock Incentive Plan (Incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264) filed on October 2, 2020).
10.7^	Form of Non-Qualified Stock Option Grant Notice under the Foghorn Therapeutics Inc. 2016 Stock Incentive Plan (Incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 2, 2020).
10.8	Form of Indemnification Agreement between Foghorn Therapeutics Inc. and its directors and officers (Incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 2, 2020).
10.9^	Amended and Restated Letter Agreement between Foghorn Therapeutics Inc. and Adrian Gottschalk, dated October 14, 2020 (Incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
10.10^	Foghorn Therapeutics Inc. 2020 Equity Incentive Plan (Incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
10.11^	Form of Incentive Stock Option Agreement under the Foghorn Therapeutics Inc. 2020 Equity Incentive Plan (Incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
10.12^	Form of Non-Statutory Stock Option Agreement (Employees) under the Foghorn Therapeutics Inc. 2020 Equity Incentive Plan (Incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
10.13^	Form of Non-Statutory Stock Option Agreement (Non-Employee Directors) under the Foghorn Therapeutics Inc. 2020 Equity Incentive Plan (Incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).

Exhibit number	Description of document
10.14^	Foghorn Therapeutics Inc. 2020 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
10.15^	Foghorn Therapeutics Inc. 2020 Cash Incentive Plan (Incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 19, 2020).
10.16	Stock Purchase Agreement by and between Foghorn Therapeutics Inc. and Eli Lilly and Company, dated as of December 10, 2021 (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-39634), filed on December 13, 2021).
10.17++	Collaboration Agreement between Eli Lilly and Company and Foghorn Therapeutics Inc., dated as of December 10, 2021 (Incorporated by reference to Exhibit 10.21 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2021 (File No. 001-39634), filed on March 10, 2022).
10.18^	Amended and Restated Letter Agreement between Foghorn Therapeutics Inc. and Steve Bellon, Ph.D., dated January 26, 2022 (Incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2021 (File No. 001-39634), filed on March 10, 2022).
10.19^	Amended and Restated Letter Agreement between Foghorn Therapeutics Inc. and Michael LaCascia, dated October 29, 2020 (Incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2021 (File No. 001-39634), filed on March 10, 2022).
10.20^	Form of Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement for use between Foghorn Therapeutics Inc. and its executive officers, updated July 2022 (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 (File No. 001-39634), filed on August 9, 2022).
10.21^	Amended and Restated Letter Agreement between Foghorn Therapeutics Inc. and Carlos Costa, dated July 15, 2022 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 (File No. 001-39634), filed on August 9, 2022).
10.22^	Letter Agreement between Foghorn Therapeutics Inc. and Alfonso Quintás Cardama, M.D., dated August 4, 2023 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 (File No. 001-39634), filed on November 2, 2023).
10.23^	Letter Agreement between Foghorn Therapeutics Inc. and Kristian Humer, dated April 16, 2024 (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-39634), filed on April 16, 2024).
10.24^	Letter Agreement between Foghorn Therapeutics Inc. and Anna Rivkin, dated July 18, 2024 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 (File No. 001-39634), filed on November 4, 2024).
10.25^	Letter Agreement between Foghorn Therapeutics Inc. and Ryan Maynard, dated February 17, 2026 (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-39634), filed on February 23, 2026).
10.26	Lease Agreement, by and between Foghorn Therapeutics Inc. and ARE-MA Region No. 77, LLC, dated June 27, 2025 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-39634), filed on July 1, 2025).
10.27	Lease Termination Agreement and Voluntary Surrender of Premises, by and between Foghorn Therapeutics Inc. and ARE-Tech Square, LLC, dated June 27, 2025 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-39634), filed on July 1, 2025).
10.28	Form of Securities Purchase Agreement between the Company and the Investors, dated January 9, 2026, incorporated by reference to Exhibit 99.3 to the Registrant's Current Report on Form 8-K (File No. 001-39634), filed on January 12, 2026).

Exhibit number	Description of document
19.1	Foghorn Therapeutics Inc. Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2024 (File No. 001-39634), filed on March 6, 2025).
21.1	List of Subsidiaries of Foghorn Therapeutics Inc. (Incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-249264), as amended, filed on October 2, 2020).
23.1*	Consent of Deloitte & Touche LLP
31.1*	Rule 13a—14(a) / 15d—14(a) Certification—Principal Executive Officer.
31.2*	Rule 13a—14(a) / 15d—14(a) Certification—Principal Financial Officer.
32.1**	Section 1350 Certification—Principal Executive Officer.
32.2**	Section 1350 Certification—Principal Financial Officer.
97	Foghorn Therapeutics Inc. Policy for Recoupment of Incentive Compensation (Incorporated by reference to Exhibit 97 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2023 (File No. 001-39634), filed on March 7, 2024).
101*	Financial statements from the Annual Report on Form 10-K of the Company as of and for the period ended December 31, 2025, formatted in Extensible Business Reporting Language (XBRL): (i) Balance Sheets; (ii) Statements of Operations; (iii) Statements of Changes in Redeemable Preferred Stock and Stockholders' Equity; (iv) Statements of Cash Flows; and (v) Notes to Financial Statements.

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

FOGHORN THERAPEUTICS INC.

Date: March 11, 2026

By: /s/ Ryan Maynard
Ryan Maynard
Chief Financial Officer
(Principal Accounting and Financial Officer)

SIGNATURES AND POWER OF ATTORNEY

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Adrian Gottschalk Adrian Gottschalk	President, Chief Executive Officer and Director (Principal Executive Officer)	March 11, 2026
/s/ Ryan Maynard Ryan Maynard	Chief Financial Officer (Principal Accounting and Financial Officer)	March 11, 2026
/s/ Scott Biller Scott Biller, Ph.D.	Director	March 11, 2026
 Douglas Cole, M.D.	Director	March 11, 2026
/s/ Stuart Duty Stuart Duty	Director	March 11, 2026
/s/ Neil Gallagher Neil Gallagher, M.D., Ph.D.	Director	March 11, 2026
/s/ Simba Gill Simba Gill, Ph.D.	Director	March 11, 2026
/s/ Thomas Lynch Jr. Thomas Lynch Jr., M.D.	Director	March 11, 2026
/s/ Michael Mendelsohn Michael Mendelsohn, M.D.	Director	March 11, 2026
/s/ B. Lynne Parshall B. Lynne Parshall, Esq.	Director	March 11, 2026
/s/ Ian Smith Ian Smith	Director	March 11, 2026

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-284476 on Form S-3 and Registration Statement Nos. 333-284473, 333-279128, 333-271710, 333-262713, and 333-252119 on Form S-8 of our report dated March 11, 2026, relating to the financial statements of Foghorn Therapeutics Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 11, 2026

Exhibit 31.1

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

I, Adrian Gottschalk, certify that:

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

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: March 11, 2026

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

Exhibit 31.2

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

I, Ryan Maynard, certify that:

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

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: March 11, 2026

/s/ Ryan Maynard
Ryan Maynard
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

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

In connection with the Annual Report of Foghorn Therapeutics Inc. (the "Company") on Form 10-K for the year ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 11, 2026

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

Exhibit 32.2

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

In connection with the Annual Report of Foghorn Therapeutics Inc. (the "Company") on Form 10-K for the year ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 11, 2026

/s/ Ryan Maynard
Ryan Maynard
Chief Financial Officer
(Principal Accounting and Financial Officer)