Risk Factors Comparison 2025-03-06 to 2024-03-07 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

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. • ~~Our lead~~ **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 ~~candidate~~ **candidates as part** ~~utilizes a novel mechanism~~ of ~~action, which may result in greater research and development expenses, regulatory issues~~ that **collaboration** ~~could delay~~ or **other future collaborations** ~~prevent approval, or discovery of unknown or unanticipated adverse effects~~ . • 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** ~~virology, autoimmune diseases~~ and ~~neurology~~ **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 ~~10~~ **eight** programs with one clinical- stage drug candidate currently in Phase 1 development ~~and one drug candidate anticipated to begin clinical development this year~~ . 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. ~~We are currently conducting a Phase 1 dose escalation study of FHD- 286, a selective, allosteric ATPase inhibitor of BRM and BRG1, in combination with either decitabine or cytarabine in relapsed and / or refractory acute myeloid leukemia (" AML ") patients.~~ As part of our collaboration with ~~Loxo Oncology at~~ Eli Lilly and Company (" Lilly "), ~~we anticipate that~~ Lilly ~~will begin~~ **has initiated** a Phase 1 dose escalation ~~study~~ **trial** with FHD- 909 **(LY4050784)** , a selective ATPase inhibitor of ~~BRM~~ **SMARCA2** , ~~later this year~~ **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 new

patients annually. We believe that we have the potential to file **four** ~~six new~~ Investigational New Drug Applications (" INDs ") over the next ~~four~~ **two** years. Our current pipeline of product candidates and discovery programs **are** ~~is focused on oncology and is~~ shown below: ~~Foghorn' s science and potential have been validated by strategic collaborations with world- leading pharmaceutical companies, including Lilly.~~ 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 ~~research,~~ discover and develop therapeutic molecules directed to the **SMARCA2** ~~selective BRM~~ 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 ~~February~~ **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** ~~a selective BRM inhibitor, has~~ **as** ~~been selected by Lilly to advance to~~ the **primary patient population** ~~clinic, and we anticipate an IND filing by Lilly in the second quarter of 2024~~ . 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 epi- genomic tools, our proprietary high throughput screening technology and our expertise in medicinal chemistry to develop enzymatic inhibitors, protein degraders and transcription factor disruptors that target the chromatin regulatory system. While initially focused in oncology, we believe our platform is broadly applicable across other disease areas. Our Gene Traffic Control platform encompasses the following: • Target Identification and Validation — We use genomic screens, and a suite of epi- genome sequencing and computational tools, including aspects of artificial intelligence and machine learning, to characterize, identify, and validate targets within the chromatin regulatory system. Our epi- genome sequencing tools allow us to understand the mechanisms of how our drugs are modifying the chromatin structure. Our platform allows for the identification of genetically determined dependencies associated with the chromatin regulatory system. • Production of Chromatin Regulatory System Components at Scale and Proprietary Assays — We have built unique capabilities to purify and synthesize chromatin remodeling complexes, 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 ~~non~~ **E3** - **agnostic** ~~cereblon based~~ 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 ~~now~~ for several programs including ~~BRM~~ **SMARCA2** , CBP, ~~and~~ EP300 **and ARID1B** . We have developed capabilities with long- acting formulation of our protein degraders **,** which we believe has the potential to enable enhanced convenience and route of administration **. In addition, we are developing binders to a new ligase, UBR5. UBR5 operates in the nucleus to degrade various transcription factors, and our goal is to develop a new option to degrade transcription factors and other important targets** . • Translation to Clinic and Identification of Biomarkers — Early in the drug discovery process, we use various genome and epi- genome analyses to understand the mechanism of the genetic dependency of the disease on the chromatin regulatory system. Our understanding of the mechanism of the dependency enables us to identify biomarkers for patient identification and treatment. We seek to enrich our clinical studies with the genetically relevant patient populations that are most likely to benefit from treatment. Our 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 ~~15~~ **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 TCR2 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 ~~116~~ **112** employees as of December 31, ~~2023~~ **2024** ~~. Our Beginnings: Foghorn Therapeutics and Flagship Pioneering Foghorn Therapeutics was founded in 2015 by Flagship Pioneering, working together with academic co- founders Dr. Cigall Kadoch (Dana Farber Cancer Institute, Harvard University, Broad Institute and Howard Hughes Medical Institute) and Dr. Gerald Crabtree (Stanford University, Howard Hughes Medical Institute) to develop and commercialize a new category of first- in- class therapeutics to treat patients with cancer and other serious diseases. Our platform was inspired by work in the academic co- founders' laboratories at the Dana Farber Cancer Institute and Stanford. This seminal work made it possible to understand how mutations cause disease by disrupting the machinery — the chromatin regulatory system — that orchestrates how cells turn genes on and off. Such mutations are associated with up to 50 percent of cancer and play roles in many other diseases. A Flagship Labs innovation team at Flagship Pioneering, led by Flagship Managing Partner, Dr. Douglas Cole, and, subsequently, Foghorn' s research and development team, established a fully integrated drug discovery platform based on this seminal work, which we call our Gene Traffic Control platform~~ . Our Strategy Our mission is to leverage our unique insights into the chromatin regulatory system to pioneer the discovery, development and commercialization of a new class of therapies that transform the lives of patients suffering from a wide spectrum of diseases with high unmet need. Our approach is to identify and drug genetically determined dependencies within the chromatin regulatory system. Our initial focus is in cancer with a precision oncology approach. Every program we 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 ~~candidates~~ **candidate** , ~~FHD- 286 and~~ FHD- 909, through clinical development in patients **with NSCLC and** with select solid tumors **with partner Lilly** ~~and hematological cancers. FHD- 286 is a highly selective and potent enzymatic inhibitor that targets both the BRM and BRG1 enzymes of the BAF chromatin remodeling complex~~ . FHD- 909 is a ~~highly~~ **first- in- class oral SMARCA2** selective ~~and potent enzymatic~~ inhibitor ~~of just~~ **that has demonstrated in preclinical studies to have high selectivity over its closely related paralog SMARCA4, two proteins that are** the ~~BRM enzyme~~ **catalytic engines across all forms** of the BAF ~~chromatin remodeling~~ complex. ~~We believe our lead product candidates have the potential~~ **Selectively blocking SMARCA2 activity is a promising synthetic lethal strategy intended** to ~~address~~ **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** ~~unmet medical needs across multiple oncology indications~~ . • Expand our precision oncology pipeline by developing proprietary enzymatic inhibitors, degraders and disruptors that target genetically defined dependencies ~~within the chromatin regulatory system~~ . Based on our unique insights and understanding of the chromatin regulatory system, we continue to develop proprietary selective inhibitors, protein degraders and disruptors that modulate various components of the chromatin regulatory system. For example, using our proprietary platform, we have disclosed four distinct targets: ~~BRM~~ **SMARCA2** , ARID1B, CBP and EP300, that have genetically determined dependencies within the chromatin regulatory system ~~with the combined potential to treat over five hundred thousand patients per year~~ . We intend to use our platform to ~~consistently~~ develop novel product candidates to further deepen our precision oncology pipeline and **believe we** have the potential to file ~~six~~ **four** INDs over the next ~~four~~ **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 co-development and co- commercialization agreement for the selective ~~BRM~~ **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, protein degraders and transcription factor disruptors. • Enzyme inhibitors. These candidates have the potential to act on targets such as the ~~ATPases~~ **ATPase SMARCA2** ~~BRG1 and BRM~~ of the BAF complex. Our screening capabilities enable us to find allosteric inhibitors which afford additional selectivity over orthosteric, or direct, inhibitors. • Protein degraders. These candidates are 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. • Transcription factor disruptors. These candidates **are** ~~will be~~ direct small- molecule disruptors of the protein- protein interactions between transcription factors and chromatin remodeling complexes. We leverage the appropriate mechanism based on the target in the chromatin regulatory system. In some cases, we may take multiple approaches and remain modality agnostic in order to ensure we achieve the best approach and most appropriate molecule. 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. For transcription factor targets, we are leveraging where appropriate protein degradation and / or small molecule disruptors that can bind either to the transcription factor or its relevant binding partner (e. g., the BAF chromatin remodeling complex). 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. • Production of Chromatin Regulatory System Components at Scale and Proprietary Assays • **Development of Targeted Protein Degraders** The key features and capabilities of our platform are described below: We use genomic screens and a suite of epi- genome sequencing and computational tools to characterize, identify and validate targets within the chromatin regulatory system. Our epi- genome sequencing tools allow us to understand the mechanisms of how our drugs are modifying the chromatin structure. Our platform allows for the identification of genetically determined dependencies associated with the chromatin regulatory system. Specifically, we: • Conduct and leverage genomic screens to identify dependencies and relationships. We utilize both broad and specific genomic screens to identify dependencies and relationships associated with the chromatin regulatory system. We use a mix of internal and external data sets ~~that apply CRISPR and shRNA technology~~ to understand relationships **and synthetic lethality** across and within a range of cancer cell lines. • Perform broad epi- genome sequencing to validate dependencies in vitro. We apply cutting edge epi- genome sequencing tools in combination with proprietary tool compounds to further validate targets and enhance our understanding of the impact of drugging the chromatin regulatory system. These tools allow us to rapidly understand the gene expression profiles of specific cancer cell lines, the open / closed state of chromatin, and give us mechanistic understanding of how components of the system work together. • Apply machine learning and artificial intelligence to enhance discovery efforts. We have built tools that allow us to mine and interpret external and internal datasets that aid in our discovery efforts yielding unbiased and unsupervised computer analyses to identify targets and genetic dependencies on the chromatin regulatory system and to further understand mechanism of action. Examples of external data sets include data from the Cancer Genome Atlas and the Broad Institute. Internal data sets

include data from cell lines, data from xenograft models and epi- genomic information (RNA- seq, ATAC- seq, CHiP- seq, SNAP- seq). We also use these tools in the preclinical stage to evaluate cancer cell lines & patient samples to identify biomarkers for patient stratification and patient population identification. • Validate dependencies in vivo. Where possible, we endeavor to validate targets in various animal models with implanted cancer cells relevant to the disease we are aiming to treat. Specifically, we use mouse xenograft models with inducible CRISPR / shRNA **(short hairpin RNA)** to validate that knockdown of our target of interest results in tumor growth inhibition. We also apply epi- genome sequencing tools in the animal model setting to identify potential biomarkers. 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 ~~version~~ **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. We perform proprietary high throughput screens that leverage our ability to produce ~~the~~ chromatin regulatory system components at scale. An example screen is the use of the fully assembled BAF complex which is specific to its mutated or disease relevant form (e. g., screening the ~~BRM~~ **SMARCA2** form of BAF which corresponds to ~~BRG1~~ **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. For targets in the portfolio whose biology demonstrates that degradation could offer a therapeutic advantage, we develop small molecule heterobifunctional or ~~non~~ **E3** - **agnostic** ~~cereblon based~~ 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 ~~non~~ **unbiased and E3** - ~~cereblon~~ **agnostic** based 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~~ **ternary complex assays, ternary** complex structural determination and molecular modeling; • Global proteomics and mass spectrometry to measure selectivity in an unbiased fashion; • **Induced proximity and proximity labeling capabilities for** ~~Exploration~~ **exploration** of novel ligases; • **Oral and** ~~Long~~ **long** - acting formulation of protein degraders which enhances route of administration and **/ or** frequency of delivery; ~~and~~ • Degraders **compatible** ~~that may be used in conjunction~~ with antibody ~~technology~~ **conjugation and delivery as degrader antibody conjugates; and • Development of a new ligase, UBR5, which has potential to degrade transcription factors and other important factors** . We seek to enrich our clinical studies with the genetically relevant patient populations that are most likely to benefit from treatment. Early in the drug discovery process, we use various genome and epi- genome analyses to understand the genetic dependency of the cancer on the chromatin regulatory system. Our intent is to have clear genetic markers for patients whom we seek to potentially treat. As we progress a drug candidate, we analyze tumor models and where available direct patient samples to understand biomarkers of response (e. g., change in expression level of a particular gene or set of genes, change in protein level of a component of the chromatin regulatory system). We intend to use these biomarkers in our clinical studies to understand tumor response to our drug candidates. Additionally, we will retrospectively analyze our clinical studies for any other biomarkers that will further enhance patient stratification and response. Our Product Candidates We are developing a 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 ~~candidates~~ - **candidate is** ~~are FHD- 286 and~~ FHD- 909. ~~For FHD- 286, following a monotherapy dose escalation Phase 1 in relapsed and / or refractory AML / myelodysplastic syndromes (" MDS "), we initiated a Phase 1 combination study with either decitabine or cytarabine in relapsed and / or refractory AML in August 2023.~~ In February 2024, ~~we announced~~ **Lilly selected** FHD- 909 ~~had been selected by Lilly~~ for clinical development pursuant to the Lilly Collaboration Agreement, and **in May 2024, the** ~~we anticipate that Lilly will file an~~ IND **was cleared** ~~in the second quarter of 2024~~ . ~~We are currently advancing~~ **The first patient was dosed in the Phase 1 dose escalation trial for** FHD- **909** ~~286,~~ in **October 2024,** ~~a Phase 1 clinical study in patients~~ with **NSCLC** ~~relapsed and / or refractory AML in combination with either decitabine or cytarabine. FHD- 286 is a highly potent, selective, allosteric and orally available, small- molecule, enzymatic inhibitor of BRG1 and BRM, two highly similar proteins that serve~~ as the ~~ATPases, or the catalytic engines, across all forms of BAF. Our preclinical data in AML demonstrated encouraging anti- tumor activity. Additionally, the clinical data from our Phase 1 monotherapy study of FHD- 286 in relapsed and / or refractory AML and MDS suggested that FHD- 286 is a differentiation agent that could provide complimentary benefit if combined with other therapeutic agents. The multi- center, Phase 1 study is primarily~~ - **primary** ~~focused on assessing the safety and tolerability of FHD- 286 in combination with either decitabine or cytarabine in adult patients with relapsed and / or refractory AML. Secondary endpoints~~

include the pharmacokinetic and pharmacodynamic properties of FHD- 286 as well as clinical activity. Proof of mechanism will be based on indicators of target engagement in association with FHD- 286 combination treatment. As we further understand the therapeutic potential of FHD- 286 in the course of this study, we may pursue additional clinical studies in these and other indications. We expect initial clinical data for the combination dose escalation Phase 1 study of FHD- 286 in patients with relapsed and / or refractory AML in the second half of 2024. AML Disease Overview AML is a heterogeneous group of hematologic cancers characterized by a proliferation of myeloid precursors, commonly known as blasts, with limited ability to differentiate into more mature myeloid cells. These blasts replace normal hematopoietic tissue in the bone marrow, resulting in a decrease in all blood cell types, or pancytopenia, and the morbidities therefrom. AML is the second most common subtype of leukemia in adults. In major markets (United States, EU4, UK and Japan), approximately 35, 000 people with AML are diagnosed annually. This incidence is expected to increase approximately 17 percent over the next five years. Median age at diagnosis for people with AML is 69 and median age at death is 73, underscoring the short course of life in people with this disease. The average five- year survival rate for patients with AML is 20 percent, and there are significant differences in prognosis depending on several factors, including the age of the patient **population** and co- morbidities at diagnosis. For patients under the age of 60, the five- year survival rate is approximately 33 percent, while for those over the age of 60 it is less than 15 percent. There are likely multiple reasons for this discrepancy, including the ability of younger patients to tolerate more aggressive therapies. Current first- line treatments for patients with AML typically involve aggressive combination chemotherapy regimens with or without hematopoietic stem cell transplantation (" HSCT "). Older patients or patients who cannot tolerate HSCT, typically those with comorbidities, are often treated with cytarabine and daunorubicin induction followed by high- dose cytarabine consolidation. Patients who cannot tolerate combination chemotherapy receive low dose cytarabine, azacitidine, decitabine, venetoclax, some combination of these therapies, and / or enroll in clinical trials. There is a single biologic, gemtuzumab ozogamicin (Mylotarg ®), approved by the FDA for newly diagnosed and relapsed- refractory AML. Other, more recently approved therapeutics for AML target subsets of patients with tumors containing specific mutations such as midostaurin marketed as Rydapt ® by Novartis for those with FLT3 mutations, enasidenib marketed as Idhifa ® by Bristol Myers for those with mutations in IDH2, and ivosidenib, marketed as Tibsovo ® by Agios for those with mutations in IDH1. Despite these advances, the five- year disease- free survival rate among patients who do achieve remission is only 30- 40 percent because the majority of patients experience relapse. Elderly patients with AML have a relapse rate of 80- 90 percent. Younger patients have a relapse rate of 60- 80 percent. There remains a significant need for safe, durable and broadly effective AML treatments. Our Solution: FHD- 286 FHD- 286 is a highly potent, selective, allosteric and orally available, small molecule inhibitor of the enzymatic activity of both BRG1 and BRM. Either BRG1 or BRM can serve as the primary ATPase, or catalytic engine, of the BAF complex. BAF complexes will contain only BRG1 or BRM, as they are mutually exclusive subunits, as shown in the figure below. BRG1 or BRM are two proteins which are 76 percent identical at the amino acid level over their entire length and over 90 percent identical in the catalytic region. We are currently advancing FHD- 286 in a Phase 1 clinical study in patients with relapsed and / or refractory AML in combination with either decitabine or cytarabine. We expect initial clinical data for the combination dose escalation Phase 1 study of FHD- 286 in patients with relapsed and / or refractory AML in the second half of 2024 . Figure 1. The enzymatic activity of the BAF complex is provided by the BRM **SMARCA2** or BRG1 **SMARCA4** subunits. Phase 1 Monotherapy Study of FHD- 286 in Relapsed and / or Refractory AML and MDS We conducted a Phase 1 monotherapy study of FHD- 286 in patients with relapsed and / or refractory AML or MDS. The primary objective of this study was to assess the safety and tolerability of multiple ascending doses of FHD- 286. The secondary objectives of this study included an evaluation of preliminary clinical activity and pharmacokinetics. In this Phase 1 monotherapy study, the adverse event profile was consistent with a late- line AML population. The most frequently observed grade 3 or greater treatment related adverse events included: increased blood bilirubin, hypocalcemia, differentiation syndrome (" DS "), stomatitis, and increased alanine aminotransferase, or ALT. The study was placed on a full clinical hold by the Food and Drug Administration (the " FDA ") in August of 2022 due to the observation of potential DS and potential linkage to grade 5 safety events. DS is associated with AML therapeutics that induce differentiation of blast cells into normal myeloid cells, an effect that is believed to be on target for the proposed mechanism of FHD- 286. In June of 2023, the FDA lifted the full clinical hold. An expert panel was assembled to adjudicate the rate and severity of DS in this study. The adjudicated rate of DS by the panel was determined to be 15 percent (n = 6 out of 40 patients) and classified one case as definitive DS, five cases as indeterminate and with none contributing to a patient' s death. The Phase 1 monotherapy study provided an initial evaluation of clinical activity and efficacy. In the Phase 1 dose escalation study, reductions in both peripheral and bone marrow blast counts, as well as recoveries in absolute neutrophil count, were observed in a subset of heavily pre- treated patients with relapsed and / or refractory AML or MDS, irrespective of mutational status. Across a broad range of patients, differentiation was demonstrated both morphologically as well as through the expression of specific differentiation biomarkers. Patients with evaluable paired bone marrow biopsies (i. e., at screening and during FHD- 286 therapy) experienced differentiation as measured by changes in CD11b cells and CD34 cells. Data shown below in Figure 2 demonstrate that in paired bone marrow biopsies across the range of dose levels tested, markers of myeloid differentiation (CD11b) increased while markers of leukemic stemness (CD34) decreased across a range of different mutations. Figure 2. Paired bone marrow biopsies from the Phase 1 monotherapy study of FHD- 286 in relapsed and / or refractory AML / MDS demonstrate differentiation based on increases in CD11b and decreases in CD34. We performed single cell RNA- Seq of matched patient bone marrow samples on a panel of genes to evaluate changes from screening to on treatment. At screening, bone marrow samples were heavily infiltrated with leukemic stem cell like blasts and the gene signatures aligned accordingly. On FHD- 286 treatment, the bone marrow lost the leukemic stem cell phenotype and shifted to a more mature myeloid phenotype. Figure 3. Peripheral blood and bone marrow blast reductions and absolute neutrophil count recovery data at the 10 mg and 7. 5 mg dose levels in the Phase 1 FHD- 286 monotherapy study in patients with relapsed and / or refractory AML / MDS. Figure 4. Peripheral blood and bone marrow blast reductions and absolute

~~neutrophil count recovery data at the 5 mg and 2. 5 mg dose levels in the Phase 1 FHD- 286 monotherapy study in patients with relapsed and / or refractory AML / MDS. Phase 1 Combination Study of FHD- 286 with Decitabine or Cytarabine in Patients with Relapsed and / or Refractory AML We are currently conducting a Phase 1 dose escalation study of FHD- 286 in combination with either decitabine or cytarabine in patients with relapsed and / or refractory AML patients. This Phase 1 study uses a 3 3 design which enrolls three patients at each dose level and expands to include additional patients if a dose limiting toxicity is observed. The dose escalation portion is designed to evaluate multiple ascending oral doses of FHD- 286 in combination with either decitabine or cytarabine. The primary objective of this study is an evaluation of safety and tolerability, and the identification of the maximum tolerated dose and the recommended Phase 2 dose for combination. The secondary objectives include an evaluation of preliminary clinical activity and pharmacokinetics. At present there are two arms to this combination study. The first arm investigates the combination of FHD- 286 with decitabine in patients not receiving an azole antifungal classified as a strong CYP3A4 inhibitor. The second arm is testing the combination of FHD- 286 with decitabine in the presence of an azole anti- fungal agent classified as a strong CYP3A4 inhibitor. The rationale for having both arms is to determine the impact of azole antifungals commonly administered to patients with AML on FHD- 286 exposure given that such agents may inhibit the CYP3A4 through which FHD- 286 is metabolized. The starting dose for the weak azole arm is 2. 5 mg oral once daily and the starting dose for the strong azole arm is 1. 5 mg oral once daily. Both arms will dose escalate in parallel and are predicted to dose no higher than 7. 5 mg oral daily. We intend to explore the potential value of multiple biomarkers to further understand and accelerate drug development. Biomarkers include assessment of various tumor mutations, as well as expression levels of various proteins. These biomarkers may be used for future patient selection, measurements of target engagement and biochemical and cellular measures associated with efficacy. Prospective enrollment based on biomarker findings may be included in later studies. Potential Areas for Expansion and Other Ongoing Exploratory Activities for FHD- 286 Potential Immunomodulatory Applications Our study of FHD- 286 in metastatic uveal melanoma (" mUM ") along with data from syngeneic mouse models in several tumor types, have shown an impact of FHD- 286 on specific immune cells in the tumor microenvironment and synergism with anti- PD- 1 antibodies, respectively. Specifically, in patients with mUM treated with FHD- 286, we observed a log fold decrease in T- regulatory cells, a reduction of the presence of macrophages with an M2 phenotype (i. e., immunosuppressive tumor associated macrophages), and a reduction in PD- 1 expression on CD4 and CD8 T cells in the tumor microenvironment. Based on these data, there may be potential applications of FHD- 286 in combination with immuno- oncology agents, such as immune checkpoint inhibitors, in certain tumors. Potential Cancer Resistance Applications Based on published research as well as work performed at Foghorn, we are exploring the potential of FHD- 286 to combine with various tyrosine kinase inhibitors (" TKIs ") to (i) delay resistance to the TKI and / or (ii) overcome resistance in the setting of prior exposure to a TKI. Pre- clinical work in both an in vitro and in vivo context is ongoing. Other Potential Indications We have evaluated multiple tumor types in the preclinical setting to inform our indication expansion strategy for FHD- 286 which include non- small cell lung cancer, small cell lung cancer, prostate cancer, and non- Hodgkin's lymphoma. BRM-~~ Selective ~~Modulators~~ **SMARCA2 Inhibitor and Degrader** Broad cancer sequencing initiatives have shown that ~~BRG1~~ **SMARCA4** is one of the most highly mutated subunits of the BAF complex. ~~BRG1~~ **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 ~~ten~~ **10** percent of ~~Non- Small Cell Lung Cancer (" NSCLC ")~~ tumors. Beyond NSCLC, the MSK- IMPACT study highlighted ~~BRG1~~ **SMARCA4** mutations in over ~~thirty~~ **30** different types of tumors. In many cases, these mutations lead to a loss of enzymatic activity in the ~~BRG1~~ **SMARCA4** subunit, creating a genetically determined dependency on ~~BRM~~ **SMARCA2** . This loss of ~~BRG1~~ **SMARCA4** and subsequent dependency on ~~BRM~~ **SMARCA2** leads to a drugging opportunity. We are currently developing selective modulators of ~~BRM~~ **SMARCA2** to target this genetic dependency in ~~BRG1~~ **SMARCA4** mutated cancers. In December 2021, we entered into a strategic collaboration with Lilly to create novel oncology medicines. The Lilly collaboration includes a co- development and co- commercialization agreement for the selective ~~BRM~~ **SMARCA2** oncology program. In February 2024, Lilly declared FHD- 909, a first- in- class ~~BRG1~~ **SMARCA4** inhibitor, a development candidate pursuant to the Lilly Collaboration Agreement and ~~is targeting an~~ **in May 2024, the** IND ~~filing~~ **was cleared. The first patient was dosed** in the ~~second quarter of~~ **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** ~~BRG- 1~~ Mutations Figure ~~5~~ **2** . The above chart highlights the cancers with the highest prevalence of ~~BRG1~~ **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 ~~18 percent of all cancer deaths globally, or an estimated~~ 1. 8 million deaths per year. ~~There are~~ **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 ~~238~~ **235** , 000 new cases of lung cancer diagnosed and ~~127~~ **125** , 000 deaths in the United States ~~annually~~ **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 ~~. The standard of care for NSCLC has included conventional chemotherapy with or without a checkpoint inhibitor~~ . Targeted therapies developed for the proteins encoded by some of these genes such as the epidermal growth factor receptor (" 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 EGFR or ALK targeted therapies have tumors that express PD- L1 and are candidates for checkpoint inhibitor therapies **with or without conventional** ~~, which lead to significant improvements in progression free survival and overall survival compared to standard~~ chemotherapy. Despite the availability of both targeted and ~~conventional~~ **checkpoint inhibitor- based** therapies, the prognosis in NSCLC remains poor, with an overall relative five- year survival for all patients diagnosed with NSCLC of ~~28~~ **26. 7** percent **, according to SEER** . An analysis of genomic data in NSCLC cancer patients, collected as part of MSK- IMPACT, revealed that gene alterations in ~~BRG1~~ **SMARCA4** were found in

~~ten~~ **10** percent of NSCLC samples. In a retrospective analysis conducted by MSKCC it was observed that among patients with ~~BRG1~~ **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 ~~BRG1~~ **SMARCA4** - deficient NSCLC, highlighting the importance of developing novel therapeutics that address this unmet need. MSK- IMPACT: **SMARCA4** ~~BRG- 1~~ Mutated in 10 % of NSCLC Figure ~~6~~ **3** . ~~BRG1~~ **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 ~~BRM~~ **SMARCA2** via CRISPR revealed a genetic dependency of certain ~~BRG1~~ **SMARCA4** - mutated cancers on ~~BRM~~ **SMARCA2** . This finding suggests that selective inhibition or selective degradation of ~~BRM~~ **SMARCA2** has the potential to be therapeutically meaningful in certain cancers with ~~BRG1~~ **SMARCA4** mutations. Figure ~~7~~ **4** . In a screen of over 400 cancer cell lines, inactivation of the ~~BRM~~ **SMARCA2** gene resulted in selective inhibition of cell lines containing mutations in ~~BRG1~~ **SMARCA4** . Our Solution: Selective ~~BRM Modulators~~ **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 ~~BRM~~ **SMARCA2** . ~~One~~ **FHD- 909 is a first- in-** class **oral** ~~consists of~~ selective **SMARCA2** ~~, allosteric inhibitors -~~ **inhibitor** ~~of the ATPase activity of BRM. We~~ **that has demonstrated in preclinical studies to have high selectivity over its paralog SMARCA4, two proteins that** are ~~designing these -~~ **the catalytic engines across** ~~inhibitors to be more selective for BRM than the very similar ATPase BRG1. Through our proprietary gene control platform, we have identified and optimized highly selective small -~~ **all** ~~molecule inhibitors targeting BRM~~ **forms of the BAF complex. FHD- 909 is currently being studied in a Phase 1 open label multi- center clinical trial** . Figure ~~8~~ **5** . **FHD** ~~This panel showed BRM enzymatic inhibitor in vivo efficacy in a A549 -~~ ~~BRG1~~ **909 Monotherapy Demonstrated Strong In Vivo Preclinical Activity Across SMARCA4** Mutant NSCLC ~~Model~~ **Models at Tolerated Doses** ~~with corresponding body weight and plasma exposure versus the vehicle control and Cisplatin~~ . **Selective SMARCA2 Degrader** Our other approach to selective ~~BRM~~ **SMARCA2** modulation consists of protein degrader molecules that activate the cell' s ubiquitin proteasome degradation system to selectively destroy ~~BRM~~ **SMARCA2** . One domain of the ~~BRM~~ **SMARCA2** degrader molecule is a potent and selective binder of ~~BRM~~ **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 ~~BRM~~ **SMARCA2** while leaving ~~BRG1~~ **SMARCA4** untouched. Selective Degradation of ~~BRM~~ **SMARCA2** Figure ~~9~~ **6** . Selective ~~BRM~~ **SMARCA2** degrading molecules led to the degradation of over 75 percent of ~~BRM~~ **SMARCA2** while leaving the levels of ~~BRG1~~ **SMARCA4** virtually unchanged. Selective CBP Degrader for EP300 Mutated Cancers CREB binding protein 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 ~~10~~ **7** . In a screen of over ~~400~~ **1, 000** cancer cell lines, ~~inactivation~~ **CRISPR knockout** of the ~~EP300~~ **CBP** gene resulted in selective growth inhibition of cell lines containing mutations in ~~CBP~~ **EP300** , establishing the dependency on ~~EP300~~ **CBP** in these cell lines. CBP and EP300 are **paralog** chromatin regulators and histone acetyltransferases **with** ~~and are~~ highly homologous ~~with similar~~ 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. Data suggest that there are potentially over 100, 000 patients with EP300 mutations that could benefit from a therapy selectively targeting CBP. We are developing selective CBP degraders 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 ~~a~~ **increased anti- tumor activity resulting from the** tolerability advantage compared with non- selectively degrading both targets ~~. We have tested in vitro a selective degrader of CBP across multiple cancers including gastric, colorectal, and bladder, which has demonstrated significant responses in cell proliferation assays as shown in the figure below. As demonstrated in Figure 11 below, we have developed highly selective degraders of CBP that rapidly and durably suppress the CBP target with no degradation observed for the counter target EP300. Figure 11. A selective degrader of CBP tested across multiple cancers has demonstrated CBP- dependent cell killing in cell proliferation assays~~ . 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 ~~13~~ **8** 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. FHT- CBPd- 8, a slightly earlier version of the CBP degrader, achieves tumor growth inhibition in a colorectal model. Potential subsets of tumor types that harbor a mutation in EP300 and therefore would be reliant on CBP for their survival include but may not be limited to bladder ~~cancer~~ , melanoma, endometrial, gastric, breast, NSCLC, colorectal, and pancreatic **cancers** . Figure ~~12~~ **8** . ~~A selective~~ **Selective** ~~degrader of~~ CBP ~~tested~~ **Degradation Results** in **Significant Anti- Tumor Activity** ~~a CDX model of gastric cancer demonstrates regression and~~ in ~~CDX~~ **EP300mut Solid Tumor** ~~models~~ **Models** ~~of colorectal and bladder cancer demonstrates tumor growth inhibition~~ . 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 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 ~~13~~ **9** 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 ~~12~~ **8 (FHT- CBPd)** and Figure ~~16~~ **11 (FHT- EP300d)** . Figure ~~13~~ **9** . 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. The Selective EP300 program has potential in various cancers which include androgen receptor, or AR, positive prostate cancer, bladder cancer, NSCLC, various lymphomas and leukemias and could provide a new therapeutic option for potentially more than 100, 000 patients a year. Figure ~~14~~ **10** . In a screen of over ~~400~~ **1, 000** cancer cell lines, ~~inactivation~~ **CRISPR knockout** of the ~~CBP~~ **EP300** gene resulted in selective growth inhibition of cell lines containing mutations in ~~EP300~~ **CREBBP (CBP)** , establishing the dependency on ~~CBP~~ **EP300** in these cell lines. **Figure 11.** ~~We have tested in vitro a selective degrader of~~ EP300 ~~in a number of cell lines which has demonstrated degradation~~ **Degradation** ~~and~~ **Results in** ~~significant~~ **Significant** ~~responses~~ **Tumor Growth Inhibition** in **Multiple Myeloma, DLBCL** ~~cell proliferation assays as shown in the figure below: Figure 15. A selective degrader of EP300 tested in a number of cell lines has demonstrated degradation~~ and **Prostate Models** ~~EP300- dependent cell killing in cell proliferation assays~~ . With more advanced degraders of EP300, we have generated data in several CDX mouse models which include an AR positive prostate cancer and diffuse large ~~b~~ **B** - cell lymphoma (“ DLBCL ”). As seen in Figure **11** ~~16 below~~ , the degrader denoted as FHT- EP300d appears well- tolerated based on the limited mouse body weight percentage changes and achieves tumor growth inhibition in the **multiple myeloma, DLBCL models, and** prostate ~~and DLBCL~~ 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. ~~Figure 16. A selective degrader of EP300 tested in a CDX model of AR Prostate Cancer and in a CDX model of DLBCL demonstrates tumor growth inhibition.~~ 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 ovarian, endometrial, colorectal, bladder, and gastric cancers. Data suggest that there potentially are over 175, 000 patients with ARID1A mutations that could benefit from a therapy selectively targeting ARID1B. Figure ~~17~~ **12** . In a screen of over ~~400~~ **1, 000** cancer cell lines, ~~inactivation~~ **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** ~~not~~ **no** ~~an enzyme~~ **known enzymatic domains or function** , our strategy is to **utilize protein degradation to** selectively ~~degrade~~ **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 ~~chemical matter~~ **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. The resulting heterobifunctional degraders selectively degrade ARID1B over ARID1A. Using several controls we have demonstrated** that **these degraders function by engaging their intended E3 ligase and utilize the proteosome to achieve degradation. 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 activiator 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 ~~seeking to optimize as protein degrader product candidates~~ **evaluating the best opportunity for proof of concept in induced proximity** . Targeting Transcription Factors: Disrupting Transcription Factor Binding to Chromatin Remodeling Complexes Transcription factors work in concert with chromatin remodeling complexes, BAF as one example, to orchestrate gene expression. In tumor cells, genes encoding transcription factors are often amplified, deleted, rearranged via chromosomal translocation or subjected to point mutations that result in a gain or loss of function. We have developed a set of tools to visualize and study the interactions between transcription factors and chromatin remodeling complexes. To our knowledge, we are the only company with these capabilities. Our strategy is to disrupt the interaction between transcription factors and chromatin remodeling complexes. Our initial focus is on disrupting transcription factor interactions with the BAF complex. We believe that there are over 100 transcription factors in oncology that would be amenable to this new approach. Based on these insights, we are developing small molecule disruptors that block the interaction between transcription factors and the BAF complex. In addition to applications in cancer, we believe that such disruptors could be applied in other therapeutic areas. We used our Gene Traffic Control platform to produce and purify BAF complexes and multiple transcription factors to study the structural details as well as the biochemical and biophysical properties of their interactions. We observed that different transcription factors bind to different sites on the surface of the BAF complex. This suggests that there is specificity in these interactions. Therefore, it may be possible to block the interaction of a specific transcription factor with the BAF complex without blocking the interactions of other transcription factors. Figure ~~19~~ **13** . Illustrative locations of the binding sites of multiple transcription factors to the BAF complex. Using the insights of where and how tightly transcription factors bind, we have developed as part of our Gene Traffic Control platform the ability to conduct high throughput screens on chromatin remodeling complex – transcription factor interactions. We have already validated numerous BAF- transcription factor interactions for targets of interest in various cancers. We are applying our know- how to screen select BAF- transcription factor interactions to discover and develop transcription factor disruptors. 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., and C4~~ 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 **CellCentric Limited, IDEAYA Biosciences Inc., Novartis AG, Plexium, Inc.** Prelude Therapeutics Incorporated, ~~Plexium, Inc., Amgen Inc., Abbvie Inc., Genentech, Inc.,~~ and **Relay Therapeutics** ~~SK Life Science~~, Inc. 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, ~~2024~~ **2025**, we owned more than 10 pending U. S. provisional patent applications, more than 25 pending U. S. non- provisional patent applications, more than 10 pending PCT applications, and more than 100 pending ex- U. S. patent applications. We currently do not in- license any issued patents with respect to any of our product candidates ~~, including FHD- 286,~~ or our platform technology. As of March 1, ~~2024~~ **2025**, we owned ~~two~~ **one** U. S. ~~patents~~ **patent** ~~, seven~~ **and more than 50** pending U. S. **and ex-** ~~provisional patent applications, ten pending~~ U. S. non- provisional patent applications ~~and PCT patent applications, and more than 25 pending ex- U. S. patent applications~~ that relate to FHD- ~~286~~ **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. FHD- 286 In December 2024, we announced our decision to discontinue the independent development of FHD- 286, a highly potent, selective, allosteric and orally available, small- molecule, enzymatic inhibitor of SMARCA2 and SMARCA4, in combination with decitabine in patients with relapsed and / or refractory acute myeloid leukemia. As of March 1, 2025, we owned three U. S. patents, one pending U. S. provisional patent applications, fifteen pending U. S. non- provisional patent applications and PCT patent applications, and more than 25 pending ex- U. S. patent applications that relate to FHD- 286, including its composition and various methods of use. Any U. S. or ex- U. S. patent that may issue from these patent applications would be scheduled to expire between** 2039- ~~2044~~ **2045**, 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** ~~selective BRM~~ 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 ~~BRM~~ **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 ~~BRM~~ **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 system regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. The FDA' s review of an initial PMA is required by statute to take between six to ten months, although the process typically takes longer, and may require several years to complete, and PMA approval is not guaranteed. If the FDA evaluations of both the PMA and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually

contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA' s evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny the approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. Once granted, PMA approval may be withdrawn by the FDA if compliance with post- approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing. On July 31, 2014, the FDA issued a final guidance document addressing the development and approval process for " In Vitro Companion Diagnostic Devices. " According to the guidance document, for novel therapeutic products that depend on the use of a diagnostic test and where the diagnostic device could be essential for the safe and effective use of the corresponding therapeutic product, the companion diagnostic device should be developed and approved or cleared contemporaneously with the therapeutic, although the FDA recognizes that there may be cases when contemporaneous development may not be possible. However, in cases where a drug cannot be used safely or effectively without the companion diagnostic, the FDA' s guidance indicates it will generally not approve the drug without the approval or clearance of the diagnostic device. The FDA also issued a draft guidance in July 2016 setting forth the principles for co- development of an in vitro companion diagnostic device with a therapeutic product. The draft guidance describes principles to guide the development and contemporaneous marketing authorization for the therapeutic product and its corresponding in vitro companion diagnostic. Once cleared or approved, the companion diagnostic device must adhere to post- marketing requirements including the requirements of the FDA' s QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging, and shipping of all medical devices, as well as adverse event reporting, recalls and corrections along with product marketing requirements and limitations. Medical devices, including companion diagnostics, may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. Like drug makers, companion diagnostic makers are subject to unannounced FDA inspections at any time during which the FDA will conduct an audit of the product (s) and the company' s facilities, facility records, and manufacturing processes for compliance with its authorities. Marketing Exclusivity Market exclusivity provisions authorized under the FD & C Act can delay the submission or the approval of certain marketing applications. The FD & C Act provides a five- year period of non- patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application (" 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 and regulations, 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 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 healthcare providers, marketing expenditures or pricing or require the licensing or registration of sales representatives. 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 in the United States 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 health care reform efforts. Drug pricing and payment reform was a focus of the Trump Administration and has been a focus of the Biden Administration. For example, federal legislation enacted in 2021 eliminates a statutory cap on Medicaid drug rebate program rebates effective January 1, 2024. As another 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, which have varying implementation dates, 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 and a drug price negotiation program for certain high spend Medicare Part B and D drugs. Although the impact of the IRA remains uncertain pending ongoing implementation, the IRA is likely to have a significant effect on the healthcare industry and prescription drug pricing overall. As another example, in 2022, subsequent to the enactment of the IRA, the Biden administration released an executive order directing the HHS to report on how the Center for Medicare and Medicaid Innovation (" CMMI ") could be leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. The report was issued in 2023 and proposed various models that CMMI is currently developing which seek to lower the cost of drugs, promote accessibility and improve quality of care, including a model addressing payment for drugs that receive accelerated approval from the FDA. Healthcare reform efforts have been and may continue to be subject to scrutiny and legal challenge. For example, with respect to the Affordable Care Act, tax reform legislation was enacted that eliminated the tax penalty established for individuals who do not maintain mandated health insurance coverage beginning in 2019 and, in 2021, the U. S. Supreme Court dismissed the latest judicial challenge to the Affordable Care Act brought by several states without specifically ruling on the constitutionality of the Affordable Care Act. As another example, revisions to regulations under the federal anti- kickback statute would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to pharmacy benefit managers and health plans. Pursuant to court order, the removal was delayed and recent legislation imposed a moratorium on implementation of the rule until January 2032. As another example, the IRA drug price negotiation program has been challenged in litigation filed by various pharmaceutical manufacturers and industry groups. There have also been efforts by federal and state government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products, including legislation on drug importation. Recently, there has been considerable public and government scrutiny of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. 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. General legislative cost control measures may also affect reimbursement for our product candidates. 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. Adoption of new legislation 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, ~~2023~~ **2024** , we had ~~116~~ **112** 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. ~~54~~ **57** of our employees have M. D. or Ph. D. degrees. Within our workforce, ~~88~~ **84** 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 500 Technology Square, Suite 700, Cambridge, Massachusetts, 02139, and our phone number is 617- 586- 3100. Our website address is https: / / foghorntx. com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10- K. We are an " emerging growth company " as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering (" IPO "), (b) in which we have total annual gross revenue of at least $ 1. 235 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non- affiliates exceeds $ 700. 0 million as of the prior June 30th, and (ii) the date on which we have issued more than $ 1. 0 billion in non- convertible debt during the prior three- year period. We are also a " smaller reporting company " as defined in the Securities and Exchange Act of 1934, as amended (the " Exchange Act "). We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non- voting common stock held by non- affiliates is more than $ 250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $ 100 million during the most recently completed fiscal year and our voting and non- voting common stock held by non- affiliates is more than $ 700 million measured on the last business day of our second fiscal quarter. Available Information Our Internet address is https: / / foghorntx. com. Our Annual Reports on Form 10- K, Quarterly Reports on Form 10- Q, Current Reports on Form 8- K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13 (a) and 15 (d) of the Exchange Act are available through the " Investors " portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information on our website is not part of this Annual Report on Form 10- K or any of our other securities filings unless specifically incorporated herein by reference. In addition, our filings with the SEC may be accessed through the SEC' s Electronic Data Gathering, Analysis and Retrieval system at http: / / www. sec. gov. All statements made in any of our securities filings, including all forward- looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law. 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 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. ~~We~~ **As part of our collaboration with Lilly, we** are currently in a Phase 1 ~~clinical~~ **dose escalation** trial ~~for FHD-286 and anticipate an IND filing by Lilly~~ for FHD- 909 ~~in the second quarter of 2024~~. 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. Since inception, we have incurred significant operating losses. As of December 31, ~~2023~~ **2024**, we had an accumulated deficit of $ ~~471~~ **558** . ~~6~~ **2** million. We have financed our operations primarily through private placements of our preferred stock and our IPO; our former collaboration agreement with Merck; ~~and~~ our strategic collaboration with Lilly and Lilly ~~'~~**'** s concurrent investment in our equity **; and proceeds from the May 2024 Offering** . 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: • ~~advance our FHD- 286 product candidate and~~ 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. We have one **Lilly-partnered** product candidate **, FHD- 909,** in Phase 1 clinical development **. In December** ~~and anticipate an IND filing for our partnered candidate with Lilly in the second quarter of~~ 2024 ~~. In April 2023~~ , we ~~decided not~~ **announced our decisions** to **discontinue the** ~~pursue a Phase 1~~ independent **clinical development of** ~~dose expansion study for~~ FHD- ~~609 after the study was placed on partial clinical hold~~ **286 in combination with decitabine in patients with relapsed and / or refractory acute myeloid leukemia** . We have not initiated clinical development of our other 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 ~~stage for our most advanced product candidate, FHD- 286 and anticipate an IND filing by Lilly~~ for FHD- 909 **as part** ~~in the second quarter~~ of ~~2024~~ **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, armed conflicts and wars, including the Russia- Ukraine war, the Israeli- Palestine Conflict, and attacks in the Red Sea. 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. ~~For example, in May 2022, our Phase 1 study of FHD- 286 in AML / MDS was placed on a full clinical hold by the FDA in August of 2022 due to the observation of potential DS and potential linkage to grade 5 safety events. DS is associated with AML therapeutics that induce differentiation of blast cells into normal myeloid cells, an effect that is believed to be on target for the proposed mechanism of FHD- 286. The full clinical hold was lifted in June of 2023 by the FDA. An expert panel was assembled to adjudicate the rate and severity of DS in this study. The adjudicated rate of DS by the panel was determined to be 15 percent (n = 6 out of 40 patients) and classified one case as definitive DS, five cases as indeterminate and none contributing to a patient' s death. Even if we are able to demonstrate that all future serious adverse events are not product- related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial, and the FDA could potentially impose or reimpose a clinical hold in the future on studies evaluating FHD- 286.~~ 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. ~~Specifically, we expect that our product candidates will compete against approved drugs for the treatment of AML, including Idhifa ® by Bristol Myers Squibb, Tibsovo ® by Servier Pharmaceuticals, and Rydapt ® by Novartis International AG.~~ 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. " ~~Our lead product candidate, FHD- 286, utilizes a novel mechanism of action, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects. In addition, a novel mechanism of action may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post- approval limitations or restrictions. The novel mechanism of action also means that fewer people are trained in or experienced with product candidates of this type, which may make it more difficult to find, hire and retain personnel for research, development and manufacturing positions.~~ 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- ~~286~~ **909, which is partnered with Lilly** , in Phase 1 clinical development ~~and anticipate that Lilly will file an IND and begin a Phase 1 for our partnered product candidate, FHD- 909, later this year~~ ; 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 ~~may~~ **are** not be able to exert unilateral control over the development of product candidates when part of a collaboration. Under our 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 ~~FHD- 286 or~~ **our** ~~any other~~ product candidates is critical to our success. The timing of our clinical trials depends on our ability to recruit patients to participate in our studies as well as the dosing of such patients and completion of required follow- up periods. Our competitors may compete for the same limited patient populations. If we or our collaborators are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other analogous regulatory authorities outside the United States, or as needed to provide appropriate statistical power for a given trial, we may not be able to initiate or continue clinical trials for our current and future product candidates. Additionally, we may face similar challenges or delays in our other or potential future clinical trials. If patients are unwilling to participate in our studies because of negative publicity from adverse events related to the biotechnology field, competitive clinical trials for similar patient populations or for other reasons, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of ~~FHD- 286 or~~ **our** ~~any other~~ product candidates may be delayed. These delays could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of the clinical trials altogether. 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 current or 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 ~~FHD- 286 or~~ **our** ~~any other~~ product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit, or terminate clinical trials for ~~FHD- 286 or~~ **our** ~~our other~~ product candidates, or expand to additional jurisdictions, which could impose additional challenges on our company and expose us to risks. If we are not successful in conducting our clinical trials as planned, it would have an adverse effect on our business, financial condition, results of operations, and prospects. Any favorable preclinical results may not be predictive of results that may be observed in

clinical trials. Data obtained from preclinical activities are subject to varying interpretations and analyses, which may delay, limit or prevent regulatory approval. Many companies that have believed their product candidates performed satisfactorily in preclinical studies have nonetheless failed to demonstrate results in clinical studies. As we generate preclinical results, such results will not ensure that later preclinical studies or clinical trials will demonstrate similar results. There is a high failure rate for drugs and biologics proceeding through clinical trials. Even 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. Although our research and development efforts to date have resulted in our discovery and preclinical development of FHD- **909, FHD-** 286 **, and FHD- 609 for the treatment of cancer** , FHD- 909 and **any** ~~FHD- 609 for the~~ **other** ~~treatment of~~ cancer **product candidates we may advance into the clinic** ~~, FHD- 286, FHD- 909 and FHD- 609~~ may not be safe or effective as cancer treatments, and we may not be able to develop any other product candidates. We may not be successful in identifying further targets in the chromatin regulatory system that are relevant in cancer, or other diseases, and which can be " basketed " into a group that is large enough to present a sufficient commercial opportunity or that is druggable with one chemical compound. Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future, which likely would result in significant harm to our financial position and adversely affect our stock price. 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 ~~. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities~~ . Risks Related to Employee Matters, Managing Growth and Information Technology 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, ~~2023~~ **2024** , we had ~~116~~ **112** 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 Cambridge, Massachusetts. The Massachusetts region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all ~~. On January 5, 2023, the Federal Trade Commission released a notice of proposed rulemaking that, if finalized, would ban employers from entering into or maintaining post- termination non- compete clauses with employees, which could adversely effect our business in the event key personnel leave us for employment at key competitors~~ . 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. Risks Related to Our Intellectual Property Our commercial success will depend in part on our ability and the ability of our licensors to obtain and maintain proprietary or intellectual property protection in the United States and other countries for our product candidates, and our core technologies, including aspects of our Gene Traffic Control platform. We rely on trade secrets, know- how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. In particular, our Gene Traffic Control platform is not the subject of patent applications. We seek to protect our proprietary product candidates by filing patent applications in the United States and abroad related to our product candidates that are important to our business. If we or our licensors are unable to obtain or maintain patent protection with respect to our current and future product candidates, competitors and other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates and other product candidates that we may pursue may be impaired. As a result, our business, financial condition, results of operations and prospects could be materially harmed. Currently, our patent portfolio ~~, including our portfolio related to our product candidate FHD- 286,~~ 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 ~~two~~ **three** issued U. S. patents related to FHD- 286 **and 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- 286 **, 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 ~~Foghorn~~ **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 introduced 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- 286 and~~ 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 ~~FHD- 286 and some of~~ our ~~other future~~ product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our future revenue, if any, to be reduced. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200, 000 in the United States, or a patient population greater than 200, 000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United

States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user- fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan 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 ~~FHD- 286, and for~~ some or all of our ~~future~~ product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life- threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to candidate products considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we intend to seek Breakthrough Therapy designation for some or all of our future product candidates for the treatment of various cancers, there can be no assurance that we will receive breakthrough therapy designation. Our relationships with healthcare providers, physicians, and third- party payors will be subject to applicable anti- kickback, fraud and abuse, anti- bribery, transparency and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings. Our future arrangements with third- party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell, and distribute our medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following, 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 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. 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. Healthcare legislative reform measures may have a material adverse effect on our business and results of operations. The U. S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our current or future product candidates or any future product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. In particular, in the U. S., there have been and continue to be a number of legislative initiatives at the federal and state level to contain healthcare costs, including specifically the cost of drugs. For example, the implementation of the IRA enacted in 2022 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. Although the impact of the IRA remains uncertain pending ongoing implementation, the IRA it is likely to have a significant effect on the healthcare industry and prescription drug pricing overall. See " Business Section — Government Regulation — Current and Future Healthcare Reform Legislation ." Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record- keeping requirements. Further, healthcare reform may result in changes to payment methodologies, the implementation of pharmaceutical and biological product price controls, and reductions in Medicare and other healthcare funding. If any such changes were to be imposed, they could adversely affect the operation of our business. The successful commercialization of our product candidates will depend in part on the extent to which third- party payors establish coverage, adequate reimbursement levels and pricing policies. Our ability to obtain coverage and adequate reimbursement for our product candidates by governmental healthcare programs, private health insurers, and other third- party payors will have an effect on our ability to successfully commercialize our product candidates. We cannot be sure that coverage and reimbursement will be available for our product candidates or any 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. 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 ~~39~~ **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. We are an " emerging growth company, " and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors. We are an " emerging growth company, " as defined in the Jumpstart Our Business Startups Act of

2012 (the " JOBS Act "), and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002 (" SOX "), not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. In this annual report, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to " opt out " of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to " opt out " of such extended transition period or (ii) no longer qualify as an emerging growth company. Therefore, the reported results of operations contained in our consolidated financial statements may not be directly comparable to those of other public companies. ~~We incur certain costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives and corporate governance practices. In October 2020, we completed our IPO. As a public company, we incur significant legal, accounting, and other expenses that we did not incur as a private company. These expenses will increase once we are no longer an " emerging growth company " pursuant to applicable securities rules and regulations. The Sarbanes- Oxley Act of 2002, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance, and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company. Our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements, which will increase our legal and financial compliance costs and will make certain activities more time- consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We are currently evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Pursuant to SOX Section 404, we are required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10- K with the SEC after we become a public company. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with SOX Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by SOX Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.~~ 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. ~~62~~