Beam Therapeutics Inc.

(Exact name of Registrant as specified in its Charter)

Delaware
(State or other jurisdiction of incorporation or organization)

02139
(I.R.S. Employer Identification No.)

26 Landsdowne Street
Cambridge, MA
(Address of principal executive offices)

Registrant’s telephone number, including area code: 857-327-8775

Indicate by check mark whether the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☒

Indicate by check mark whether the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act. ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). ☒

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

Large accelerated filer ☒
Non-accelerated filer ☒
Emerging growth company ☒

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

Indicate by check mark whether the registrant is a shell company as defined in Rule 12b-2 of the Exchange Act. ☐

The registrant’s common stock began trading on the Nasdaq Global Select Market (“Nasdaq”) on February 6, 2020. The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant was $982,172,604 based on the closing price of the registrant’s common stock on Nasdaq on June 30, 2020, the last business day of the registrant’s most recently completed second quarter.

The number of shares of registrant’s common stock outstanding as of March 08, 2021 was 62,415,481.

Portions of the registrant’s definitive proxy statement that will be filed for the 2021 Annual Meeting of Stockholders are incorporated by reference in Part III.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Such forward-looking statements reflect, among other things, our current expectations and anticipated results of operations, all of which are subject to known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements, market trends, or industry results to differ materially from those expressed or implied by such forward-looking statements. Therefore, any statements contained herein that are not statements of historical fact may be forward-looking statements and should be evaluated as such. Without limiting the foregoing, the words “anticipate,” “expect,” “suggest,” “plan,” “believe,” “intend,” “project,” “forecast,” “estimates,” “targets,” “projections,” “should,” “could,” “would,” “may,” “might,” “will,” and the negative thereof and similar words and expressions are intended to identify forward-looking statements. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “Risk Factors” in Part I, Item 1A of this report. Unless legally required, we assume no obligation to update any such forward-looking information to reflect actual results or changes in the factors affecting such forward-looking information. These forward-looking statements reflect, among other things:

• our expectations regarding the initiation, timing, progress and results of our research and development programs and preclinical and clinical studies, including our intention to file an Investigational New Drug, or IND, application for BEAM-101 during the second half of 2021, our plans to initiate IND-enabling studies for BEAM-102 and BEAM-201 during 2021, and our belief that we are on track to nominate our first development candidate from our liver portfolio in the second half of 2021;
• our plans for pre-clinical studies for product candidates in our pipeline, including our expectation that we will receive initial data from our non-human primate studies to evaluate our LNP formulation in the first half of 2021;
• our plans to quickly leverage our initial programs and to progress additional programs to create a clinical portfolio, including to rapidly advance our portfolio of novel base editing programs and successfully complete any clinical studies, including the manufacture of any such product candidates;
• our ability to pursue a broad suite of clinically validated delivery modalities and to successfully develop our distinct pipelines and obtain and maintain approval for our product candidates;
• our expectations regarding our ability to generate additional novel LNPs that we believe could accelerate novel nonviral delivery of gene editing payloads to tissues beyond the liver and our ability to expand the reach of gene editing, including as a result of our acquisition of Guide Therapeutics;
• our expectations regarding the build-out of our facilities, including our ability to successfully establish and maintain a commercial-scale current Good Manufacturing Practice, or cGMP, manufacturing facility and that this facility will be operational by the first quarter of 2023, and our belief that our lease agreement with the Massachusetts Institute of Technology for office and laboratory space in Cambridge, Massachusetts will commence at the earliest in late 2021 upon completion of construction of the facility;
• our ability to establish and maintain protection for intellectual property rights covering our product candidates and technology;
• the expected timing, progress and success of our collaborations with third parties and our ability to identify and enter into future license agreements and collaborations;
• our expectations regarding the strategic and other potential benefits of our acquisition of Guide Therapeutics; and
• the impact of the coronavirus disease of 2019, or COVID-19, pandemic on our business.

When we use the terms “Beam,” the “Company,” “we,” “us” or “our” in this Annual Report on Form 10-K, we mean Beam Therapeutics Inc. and its subsidiaries on a consolidated basis, unless the context indicates otherwise.

TRADEMARKS

We use BEAM, REPAIR and RESCUE and other marks as trademarks in the United States and/or in other countries. This Annual Report on Form 10-K contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this report, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.
MARKET AND INDUSTRY DATA

Unless otherwise indicated, information contained in this Annual Report on Form 10-K concerning our industry and the markets in which we operate, including our general expectations, market position and market opportunity, is based on our management’s estimates and research, as well as industry and general publications and research, surveys and studies conducted by third parties. We believe that the information from these third-party publications, research, surveys and studies included in this report is reliable. Management’s estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable. This data involves a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in “Risk Factors” in Part I, Item 1A of this report. These and other factors could cause our future performance to differ materially from our assumptions and estimates.

RISK FACTORS SUMMARY

An investment in our common stock involves risks. You should consider carefully the following risks, which are discussed more fully in “Item 1.A. Risk Factors”, and all of the other information contained in this Annual Report on Form 10-K before investing in our common stock. These risks include, but are not limited to, the following:

- Base editing is a novel technology that is not yet clinically validated for human therapeutic use. The approaches we are taking to discover and develop novel therapeutics are unproven and may never lead to marketable products.
- We have incurred significant losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- We will need substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce, or eliminate our research and product development programs or future commercialization efforts.
- Our short operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We may not be successful in our efforts to identify and develop potential product candidates. If these efforts are unsuccessful, we may never become a commercial stage company or generate any revenues.
- We are very early in our development efforts. All of our product candidates are still in preclinical development or earlier stages and it will be many years before we or our collaborators commercialize a product candidate, if ever. If we are unable to advance our product candidates to clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- If any of the product candidates we may develop or the delivery modalities we rely on cause serious adverse events, undesirable side effects or unexpected characteristics, such events, side effects or characteristics could delay or prevent regulatory approval of the product candidates, limit the commercial potential, or result in significant negative consequences following any potential marketing approval.
- We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop.
- The continuing effects and impacts of the COVID-19 pandemic could have a material adverse effect on our business, financial condition, results of operations and growth prospects.
- We have not tested any of our proposed delivery modes and product candidates in clinical trials and any favorable preclinical results are not predictive of results that may be observed in clinical trials.
- Adverse public perception of genetic medicines, and gene editing and base editing in particular, may negatively impact regulatory approval of, and/or demand for, our potential products.
- The gene editing field is relatively new and is evolving rapidly. We are focusing our research and development efforts on gene editing using base editing technology, but other gene editing technologies may be discovered that provide significant advantages over base editing, which could materially harm our business.
- Because base editing is novel and the regulatory landscape that will govern any product candidates we may develop is uncertain and may change, we cannot predict the time and cost of obtaining regulatory approval, if we receive it at all, for any product candidates we may develop.
• Genetic medicines are novel, and any product candidates we develop may be complex and difficult to manufacture. We could experience delays in satisfying regulatory authorities or production problems that result in delays in our development or commercialization programs, limit the supply of our product candidates we may develop, or otherwise harm our business.

• We currently contract with third parties for the manufacture of materials for our research programs and preclinical studies and unless and until our internal manufacturing facility becomes operational, we expect to continue to do so for clinical trials of all of our product candidates. Even if our internal manufacturing facility becomes operational, we may contract with third parties for manufacturing of materials for clinical trials and potential commercialization of certain of our viral delivery product candidates. This reliance on third parties, and the risk that we are not able to successfully build-out our internal manufacturing facility, increases the risk that we will not have sufficient quantities of such materials, product candidates, or any medicines that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

Because we are developing product candidates in the field of genetics medicines, a field that includes gene therapy and gene editing, in which there is little clinical experience, there is increased risk that the FDA, the EMA, or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results and that these results may be difficult to analyze.

• If we are unable to obtain and maintain patent protection for any product candidates we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, or if we or our licensors are unable to successfully defend our or our licensors’ patents against third-party challenges or enforce our or our licensors’ patents against third parties our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.

• Our rights to develop and commercialize technology and product candidates are subject, in part, to the terms and conditions of licenses granted to us by others.

• The intellectual property landscape around genome editing technology, including base editing, is highly dynamic, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and may prevent, delay or otherwise interfere with our product discovery and development efforts.

• Our owned and in-licensed patents and other intellectual property may be subject to priority disputes or inventorship disputes or we may be subject to claims that we have infringed, misappropriated or otherwise violated the intellectual property of a third party and similar proceedings. If we or our licensors are unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop, which could have a material adverse impact on our business.
Overview
We are a biotechnology company committed to establishing the leading, fully integrated platform for precision genetic medicines. Our vision is to provide life-long cures to patients suffering from serious diseases. To achieve this vision, we have assembled a platform that includes a suite of gene editing and delivery technologies and are in the process of developing internal manufacturing capabilities. Our suite of gene editing technologies is anchored by our proprietary base editing technology, which potentially enables an entirely new class of precision genetic medicines that target a single base in the genome without making a double-stranded break in the deoxyribonucleic acid, or DNA. This approach uses a chemical reaction designed to create precise, predictable and efficient genetic outcomes at the targeted sequence. Our novel base editors have two principal components: (i) a clustered regularly interspaced short palindromic repeats, or CRISPR, protein, bound to a guide ribonucleic acid, or RNA, that leverages the established DNA-targeting ability of CRISPR, but modified to not cause a double-stranded break; and (ii) a base editing enzyme, such as a deaminase, which carries out the desired chemical modification of the target DNA base. We believe this design contributes to a more precise and efficient edit compared to traditional gene editing methods, which operate by creating targeted double-stranded breaks in the DNA; these breaks can result in unwanted DNA modifications. We believe that the precision of our editors will dramatically increase the impact of gene editing for a broad range of therapeutic applications.

To unlock the full potential of our base editing technology across a wide range of therapeutic applications, we are pursuing a broad suite of clinically validated and novel delivery modalities. For a given tissue type, we use the delivery modality with the most compelling biodistribution. Our current programs are organized by delivery modality into three distinct pipelines: electroporation for efficient delivery to blood cells and immune cells ex vivo; lipid nanoparticles, or LNPs, for non-viral in vivo delivery to the liver and potentially other organs in the future; and adeno-associated viral vectors, or AAV, for in vivo viral delivery to the eye and central nervous system, or CNS.

The elegance of the base editing approach combined with a tissue specific delivery modality, provides the basis for a targeted efficient, precise, and highly versatile gene editing system, capable of gene correction, gene silencing/gene activation, or multiplex editing of several genes simultaneously. We are currently advancing a broad, diversified portfolio of base editing programs against distinct editing targets, utilizing the full range of our development capabilities. We believe the flexibility and versatility of our base editors may lead to broad therapeutic applicability and transformational potential for the field of precision genetic medicines.

We continue to make meaningful advancements across our programs. Within our ex vivo platform, we have identified three development candidates to date — two candidates targeting hemoglobinopathies and one candidate in our T-cell therapy program:

• BEAM-101 reproduces single base changes seen in individuals with Hereditary Persistence of Fetal Hemoglobin, or HPFH, to potentially protect them from the effects of mutations causing sickle cell disease or beta thalassemia. We have achieved proof-of-concept in vivo with long-term engraftment of base edited human CD34 cells in mice for BEAM-101. Persistence of engraftment and high levels of editing have been confirmed in several preclinical studies, including in studies using material generated at a clinically relevant scale. Following conversations with regulators and supported by our off-target biology assays, we initiated IND-enabling studies in 2020 and expect to file an IND for BEAM-101 during the second half of 2021.

• BEAM-102 directly corrects the causative mutation in sickle cell disease by recreating a naturally-occurring normal human hemoglobin variant, HbG-Makassar. During the second quarter of 2020, we published preclinical data on BEAM-102 demonstrating that our adenine base editors, or ABEs, can efficiently convert the causative Hemoglobin S, or HbS, point mutation, to HbG-Makassar, with high efficiency (more than 80%). In this preclinical study, the Makassar variant does not cause hemoglobin to polymerize and red blood cells to sickle and, therefore, edited cells are cured through elimination of the disease-causing protein. The results from this study confirmed the ability of the Makassar variant to protect cells from sickling, even in the context of mono-allelic editing (with one sickle allele and one corrected allele). We plan to initiate IND-enabling studies for BEAM-102 during 2021.

• BEAM-201 is a potent and specific anti-CD7, multiplex edited, allogeneic chimeric antigen receptor T cell, or CAR-T, development candidate for the treatment of relapsed/refractory T-cell acute lymphoblastic leukemia, or T-ALL, a severe disease affecting children and adults with a five-year overall survival of less than 25%. BEAM-201 is produced using a Good Manufacturing Practice, or GMP, compliant, clinical-scale process in which T-cells derived from healthy donors are simultaneously base edited at four genomic loci, then transduced with a lentivirus coding for an anti-CD7 CAR. The resulting cells are universally-compatible, allogeneic (“off the shelf”) CD7-targeting CAR-T cells, resistant to both fratricide and immunosuppression. We plan to initiate IND-enabling studies for BEAM-201 during 2021.
We also continue to advance our liver disease programs. In 2020, we showed the ability to directly correct the mutation causing Alpha-1 antitrypsin deficiency, providing both in vitro and in vivo preclinical proof-of-concept for base editing to correct this disease. We have also achieved editing levels in vivo, in preclinical models, for the correction of the two most prevalent mutations causing Glycogen Storage Disease Type IA, or GSD1a, that could be clinically relevant if reproduced in humans. An important next step for the liver disease programs is finalizing our LNP formulation, and we are making progress on developing a formulation using proof-of-concept targets. To date, with this formulation, we have shown high levels of editing in mice at doses consistent with clinical use. We are currently conducting non-human primate studies to evaluate our LNP formulation and anticipate initial data in the first half of 2021. We believe we are on track to nominate our first development candidate from our liver portfolio in the second half of 2021.

The modularity of our platform means that establishing preclinical proof-of-concept of base editing using a particular delivery modality will potentially reduce risk and accelerate the timeline for additional product candidates that we may develop targeting the same tissue. In some cases, a new product candidate may only require changing the guide RNA. Subsequent programs using the same delivery modality can also take advantage of shared capabilities and resources of earlier programs. In this way, we view each delivery modality as its own unique pipeline, where the success of any one program may pave the way for a large number of additional programs to progress quickly to the clinic.

**Background on current methods in genetic medicines**

The human genome has four types of bases found in DNA: adenine (A), cytosine (C), guanine (G), and thymine (T). Adenine pairs with thymine, and cytosine pairs with guanine. The genome is comprised of over three billion of these base pairs in two intertwining strands of DNA; the sequence of these bases encodes genes. In a living cell, these DNA sequences are continuously copied into short ribonucleic acid transcripts, called messenger RNA, or mRNA, which are then translated into proteins that perform the functions of life. By precisely modulating the DNA sequence, it is possible to develop different therapeutic approaches. One of these approaches involves correcting misspellings in genes, known as mutations, which can yield proteins that are dysfunctional or missing altogether, causing disease. An additional example, involves modulating genes in immune cells that can improve the ability of these cells to kill certain cancers as, for example, in the case of CAR-T cells.

In the last decade, the field of genetic medicine has reached an inflection point, with groundbreaking advances in gene therapy, cell therapy, oligonucleotides and, most recently, gene editing. Several medicines have been approved using a number of these technologies, including gene therapies, such as Luxturna®, Zolgensma®, Strimvelis®, and Zynteglo®; genetically modified cell therapies, such as Kymriah® and Yescarta®; oligonucleotide therapies, such as Onpattro® and Spinraza®; as well as the successful progression of several gene editing approaches to clinical trials in the United States and Europe. With the exception of oligonucleotides, which must be dosed chronically, each of these therapies has the potential for life-long outcomes with a single treatment.

We believe we are well-positioned to accelerate progression of our base editing programs to clinical trials through potential approval by leveraging the clinical, regulatory, and manufacturing advancements made to date in the field of genetic medicine. In addition, we believe base editing technology has the potential to provide life-long cures after a single treatment by overcoming challenges associated with current methods in gene therapy and gene editing.

**Current challenges in gene therapy**

Gene therapy involves using viral vectors, including AAV or retroviruses such as lentiviruses, to deliver new copies of genes, or transgenes, to cells. Fine-tuning the level of expression of the transgene in different cell types and/or diseases can be challenging. Because transgenes are not inserted into the appropriate locus of the host genome, they do not benefit from endogenous regulation. In addition, since the mutated, disease-causing gene is still present, the effectiveness of the transgene may be diminished due to competition with the mutated protein.

In the case of AAV gene therapy, life-long expression of the transgene is a significant hurdle, as life-long persistence of AAV expression has not yet been achieved in several organs, especially in muscles and the liver. Lack of persistence can be further exacerbated when treating children, since the transgene becomes diluted as the child grows and cells are rapidly dividing, as his/her organs expand. Finally, preexisting immunity may limit use in some patients altogether and certain immune responses may prevent redosing in the context of lack of persistence or low expression.

Retroviral vectors, including lentiviral vectors, work by inserting a gene payload into the patient’s chromosome, typically ex vivo, and have demonstrated improved durability compared to AAV therapies. However, these vectors bear the risk of random genomic integration, which creates the potential of disrupting important genes or activating cancer-causing genes.

**Current challenges in gene editing**

Gene editing works by disrupting, inserting, or modifying genes in the natural context of the genome. The vast majority of existing gene editing methods rely on a class of enzymes, called nucleases, to make a double-stranded break in the DNA at a targeted location. These enzymes include CRISPR, Zinc Fingers, Arcuses, and TAL Nucleases, and, while these approaches have distinct technical features relative to each other, they make the same type of edit and, therefore, share several similar limitations.
First, there is a lack of predictability in genetic outcomes when altering gene sequences with nucleases. The dominant, naturally-occurring DNA repair system that corrects double-stranded breaks within cells is called Non-Homologous End Joining, or NHEJ. This system can patch the broken ends of the chromosomes back together but will simultaneously insert or delete sequences at random near the location where the break occurs. While this NHEJ approach can be effective if the desired outcome is to knock out or switch off the whole gene, it does not allow for precise control of the specific genetic outcome at the target site and may vary from individual to individual.

Second, there are potential toxicities associated with double-stranded breaks, such as cell death response and genomic instability. In addition, if the double-stranded break occurs in the wrong place, the break can also lead to unwanted gene disruptions. Multiple edits, and thus multiple double-stranded breaks, can complicate this issue and lead to large-scale genomic translocations and rearrangements, potentially limiting the applicability of nuclease-based approaches in multiplex editing.

Third, while gene disruption with nucleases is efficient, making specific sequence changes to correct or modify genes remains largely inefficient. To change a gene sequence, gene editing using nucleases relies on a DNA repair pathway called Homology Directed Repair, or HDR. HDR is a low-efficiency DNA repair pathway, typically yielding single digit percentage editing. This pathway also requires the simultaneous delivery of an additional DNA template containing the desired, corrected gene sequence, which needs to be positioned at the precise location where the double-stranded break has occurred. The requirement of an additional DNA template also significantly increases the complexity of delivery. More recently, approaches have been developed to insert sequences into certain highly expressed genes, such as the albumin locus in liver cells. This strategy can only be used to address diseases that are associated with circulating proteins, and the efficiency of these approaches remains low.

Finally, gene editing through HDR does not allow for the correction of genes in non-dividing cells, since this DNA repair machinery is only expressed in dividing cells, further limiting their applications, given that the majority of cells in the adult body are non-dividing.

**Base editors: A potential new class of medicines that perform precision chemistry on genes**

Errors of a single base, known as point mutations, are the most common class of genetic mutations, representing approximately 58% of all known genetic errors associated with disease. Other natural genetic variations of a single base among human populations, revealed by population-level genomic studies, are known to protect against certain diseases. Existing gene editing technologies, including CRISPR, Zinc Fingers, Arcuses and TAL Nucleases, typically do not edit at the single base level, due to the low efficiency of HDR. Instead, these technologies operate by creating a targeted double-stranded break in the DNA, and then rely on cellular mechanisms to complete the editing process. Such approaches can be effective in disruption of gene expression; however, they lack control of the editing outcome, have low efficiency of precise gene correction, and can result in unwanted DNA modifications.

Our base editing technology is an entirely new therapeutic approach, potentially capable of altering the human genome at the foundational level of genetic information – a single base - without making a double-stranded break in the DNA. Base editing involves the enzymatic modification of a single type of base, at a targeted location directly on the gene; specifically C-to-T or A-to-G. The elegance and simplicity of this approach can be thought of as a “pencil”, where the error is erased and the correct letter is written. This approach, is designed to create precise, predictable and efficient genetic outcomes at a targeted sequence, which can be used in a variety of editing strategies, including the correction of single mutations or the engineering of advanced cell therapies, aimed at providing a compelling therapeutic benefit. We believe, therefore, that base editors may have broad therapeutic applicability and transformational potential for the field of precision genetic medicines.

**Advantages of base editing**

We believe our base editing platform offers meaningful advantages over existing approaches in gene editing and gene therapy, including:

- **Highly precise and predictable gene editing, designed to make only one type of base edit at the desired target location**
- **Highly efficient and therapeutically relevant levels of gene correction, which are generally unachievable by nuclease-based methods**
- **Broad applicability in a wide range of cell types, including both dividing and non-dividing cells**
- **Direct chemical modification of DNA with no requirement for delivery of the corrected DNA sequence**
- **Avoidance of unwanted DNA modifications associated with double-stranded breaks, including gene disruptions and chromosomal rearrangements, such as translocations or deletions**
- **The potential for permanent editing of genes, creating the opportunity for a life-long therapeutic outcome, including the ability to treat infants or young children since the edit will be passed on by dividing cells as the child grows**
Our base editing platform

Our novel DNA base editors have two principal components that are fused together to form a single protein: (i) a CRISPR protein, bound to a guide RNA, that leverages the established DNA-targeting ability of CRISPR, but modified to not cause a double-stranded break, and (ii) a base editing enzyme, such as a deaminase, which carries out the desired chemical modification of the target DNA base. This proprietary combination enables the precise and targeted editing of a single base pair of DNA, which has not been previously possible.

CRISPR proteins enable precise targeting of genomic DNA sequences. They have been adapted and engineered over the years to target specific genomic locations with high specificity in human cells. CRISPR proteins incorporate a programmable component called a guide RNA. The guide RNA includes a region of approximately 20 bases, which allows the CRISPR protein to recognize any DNA sequence that is complementary to the guide RNA.

This complementary sequence on DNA, also approximately 20 bases, is known as a protospacer. The short sequence of about three bases immediately following the protospacer on the genomic DNA is referred to as the protospacer adjacent motif, or PAM. The presence of the PAM is necessary for RNA-DNA pairing to occur when a matching protospacer sequence is present.

The figure below is a graphical representation of the base editor and its components, including the guide RNA with the single-stranded portion that is complementary to the protospacer in the genomic DNA.

In our base editors, the first component is the CRISPR protein. We use a CRISPR associated protein 9, or Cas9, protein for our DNA base editors. We also have ongoing efforts to create base editors with other CRISPR associated, or Cas, proteins, including CRISPR associated protein 12b, or Cas12b, a nuclease that is proprietary to Beam. The targeting ability of the CRISPR protein has been preserved, but the cutting ability has been modified such that the CRISPR protein does not make a double-stranded break in the DNA. Our base editors benefit from an additional feature of the CRISPR protein, which, upon binding to its double-stranded DNA target, opens a four to five base single-stranded segment, known as the editing window.

The second component of our base editors is a deaminase, a class of naturally occurring enzymes. For our Cytosine Base Editors, referred to as “CBEs,” we use a deaminase that acts only on single-stranded DNA. This helps to minimize edits in other parts of the genome, where DNA is predominantly double-stranded. Similarly, for our Adenine Base Editors, referred to as “ABEs,” we use a different, engineered deaminase that also acts only on single-stranded DNA.
The deaminase makes a predictable chemical modification, called deamination, of the amine group on either adenine or cytosine. As shown in the figure below, the conversion of an amine group of A results in the formation of inosine, which is read by the DNA polymerase as a G, which subsequently leads to an A-to-G change. The deaminase in a CBE will convert an amine group of C, resulting in the formation of uracil, which is read by the DNA polymerase as a T, which subsequently leads to a C-to-T change.

As shown in the figure below, the two components of our base editors, the CRISPR protein and the deaminase, are fused together to form a single protein. When introduced into a cell, the CRISPR targets the desired genomic location by recognizing a complementary section on the DNA to the section encoded in the guide RNA. The deaminase then makes the desired edit to a target base in the editing window.

In the example shown, a C is edited to a U on one strand of the DNA, which is read as a T. Once this strand has been edited, the intermediate DNA consists of an edited strand, containing a U at the target locus, and an unedited strand with a G. The U:G is a mismatch, which the cell will normally attempt to repair in a process that can potentially lose the edit. In order to preserve the editing, we modify the CRISPR in our base editors to cleave the unedited single strand of the DNA, referred to as nicking, rather than creating double-stranded breaks. Nicking increases the efficiency of editing by inducing the cell to use the newly edited strand, and not the unedited strand, as the template for repair, resulting in a U:A pair without any translocations. Upon DNA repair or replication, the U is read as a T, resulting in a T:A pair. Therefore, the permanent conversion of a C:G base pair to a T:A base pair is completed.

Analogously, when an ABE is used instead of a CBE, an A:T pair is converted to a G:C pair. Because the DNA is double-stranded, by targeting the non-coding strand, we can also convert a T:A pair to a C:G and a G:C pair to a A:T pair in the coding strand. For example, using ABE to install an A-to-G edit on the non-coding strand of the DNA will cause a T-to-C change in the coding sequence of the gene once the base pair has been fully modified.

The modular and individual components of our base editors can be rapidly customized for specific diseases, creating new therapeutic programs with significant efficiencies in development. By changing the guide RNA portions of the CRISPR protein, we can quickly and precisely retarget base editors to different genomic locations based on their gene sequences. By changing the deaminase, we can control which base is edited (e.g., C or A). As a result, we believe our base editing platform is highly versatile, efficient, and scalable for the discovery of drug candidates.
Diverse therapeutic applications of base editing

We believe the unique advantages of our base editing platform – single base editing precision, predictable editing outcome, high editing efficiency, and the avoidance of double-stranded breaks – make base editing a compelling approach for a wide range of therapeutic applications. This includes gene correction, gene silencing and gene activation, as well as multiplex editing of several genes simultaneously.

- **Gene Correction** - Errors of a single base, known as point mutations, are the most common form of genetic mutations, representing approximately 58% of all the known genetic errors associated with disease. For example, sickle cell disease is caused by a single point mutation at position 6 in the adult hemoglobin gene, while alpha-1 antitrypsin deficiency is caused by a single point mutation at position 342 in the SERPINA1 gene. We believe base editors may be an ideal tool for repairing point mutations.

- **Gene Silencing or Activation** - Upregulation or downregulation, including silencing and activation, of gene expression is a desirable therapeutic approach to cure many diseases. The high level of precision of base editors is ideally suited to alter regulatory regions of genes, ensuring that only a few bases at precise locations are altered to achieve the desired effect without causing broader disruptions to adjacent regions that may still have important regulatory functions. For example, we have demonstrated re-activation of expression of fetal hemoglobin by precisely changing the regulatory region of the relevant genes, thus preventing one or more repressor proteins, including B-cell lymphoma/leukemia 11A, or BCL11A, from binding. Both our C and A base editors can also be used to silence the expression of genes, with editing rates that are highly comparable to those achieved with nuclease-based editors but without requiring a double-stranded break. Gene silencing, such as targeting surface proteins in a CAR-T cell, can be achieved either by the conversion of certain short gene sequences, called codons, into STOP codons or by the disruption of splice donor-acceptor sites, in each case with a single base conversion.

- **Multiplex base editing** - By avoiding the creation of double-stranded breaks, base editors are particularly advantageous for situations in which multiple sequences in the genome must be simultaneously edited. This could include targeting duplicated or repetitive sequences in the genome, as is the case with the identical regulatory regions of the two neighboring genes for fetal hemoglobin, or targeting several genes at once, such as in the creation of advanced cell therapies like CAR-T cells with a combination of features that could dramatically enhance their therapeutic potential. Base editors do not create double-stranded breaks, and we have demonstrated in cell lines that they can edit multiple locations simultaneously without causing any detectable chromosomal rearrangements. Additionally, there are manufacturing benefits as cells that have three or more nuclease edits appear to have a significant growth deficit compared to cells that have been edited the same number of times with a base editor. We believe that our base editors can provide a significant and meaningful advancement in therapies where more complex genome editing is required, such as targeting multiple sequences across the genome or creating highly engineered cellular therapies.

**Delivery of genetic medicines**

To complement our next-generation gene editing technologies, we are also making significant investments in a broad suite of delivery technologies to deliver our gene editing payloads to the right cells to enable potentially curative therapy. These delivery technologies include ex vivo electroporation, nonviral vectors such as LNPs, and viral vectors such as AAVs. In our pipeline, we have initially focused on applications of these technologies that are clinically-validated, such as ex vivo editing of blood stem cells or LNP delivery to the liver. Longer term, we are also investing in more innovative delivery options, such as LNPs that could target other organs beyond the liver, or novel viral vectors beyond AAV. We have also developed critical enabling capabilities such as mRNA manufacturing and cell processing for autologous and allogeneic cell therapy.

Consistent with this approach, our recent acquisition of Guide Therapeutics, Inc., or Guide, expands our ability to explore new tissues and disease indications with our editing technologies. Guide’s proprietary platform technology, which utilizes DNA barcodes to enable high throughput in vivo LNP screening, provides us with access to an existing broad library of lipids and lipid formulations, and the ability to generate additional novel LNP that we believe could accelerate novel nonviral delivery of gene editing payloads to tissues beyond the liver.
As shown in the figure below, we believe that building an integrated platform combining our gene editing capabilities with advanced delivery and manufacturing capabilities will give us the maximum flexibility to develop our own sustainable portfolio and to create a hub for partnering with other companies to unlock the full potential of precision genetic medicine across all possible applications.

Our base editing portfolio

We believe building a diversified portfolio leveraging the full breadth of our delivery technologies in parallel will maximize our ability to provide life-long therapies to patients over the broadest possible range of diseases. We plan to advance multiple programs through clinical development in parallel, with each one potentially capable of delivering proof-of-concept in Phase 1 clinical studies in genetically defined patient populations and potentially reaching approval on an accelerated pathway. Our portfolio is purposefully built around a mix of strategic and technical profiles, creating significant optionality and risk diversification. We prioritize and advance programs based on a number of criteria, including high unmet medical need, editing feasibility, clinically validated delivery modalities, favorable clinical and regulatory development pathways, and evidence that base editing offers potentially compelling advantages for patients over available standards-of-care and novel therapeutic modalities in development.

Our programs are organized by delivery modality into three distinct pipelines: electroporation for hematology and oncology cell therapy, LNP for the liver, and AAV for the eye and CNS. The following table summarizes the status of certain of our most advanced programs:

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<th>DELIVERY</th>
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<td>ELECTRO-PORATION</td>
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<td>BEAM-101</td>
<td>Sickle Cell Disease Beta Thalassemia</td>
<td>Fetal hemoglobin activation</td>
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<td>Sickle Cell Disease</td>
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<td>T-cell Acute Lymphoblastic Leukemia</td>
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Ex vivo electroporation for hematology: Sickle cell disease and beta-thalassemia

Electroporation is a clinically validated technology for the ex vivo delivery of various therapeutic constructs into harvested cells, which are then reintroduced into the body. Electroporation introduces nucleic acid or proteins into cells by discharging an electrical pulse across a cell membrane. With electroporation, we introduce the base editor into the hematopoietic stem cells, or HSCs isolated from the patient’s blood, either as a messenger RNA, or mRNA, encoding the editor, or as a purified protein along with the guide RNA for a given target. Prior to receiving his/her edited cells, the patient undergoes a standard myeloablation procedure, which is also used in allogeneic hematopoietic stem cell transplant therapy, to remove all endogenous bone marrow HSCs. After the myeloablative procedure, the patient’s edited HSCs are re-infused back into the same patient. Once reinfused, the HSCs begin repopulating a portion of the bone marrow in a process known as engraftment. The engrafted, edited HSCs give rise to progenitor cell types with the corrected gene sequences. Our ex vivo portfolio includes two hematology programs, BEAM-101 (sickle cell disease and beta thalassemia) and BEAM-102 (sickle cell disease) and our lead oncology program, BEAM-201 (T-ALL).

Sickle cell disease, a severe inherited blood disease, is caused by a single point mutation, E6V, in the beta globin gene. This mutation causes the mutated form of HbS to aggregate into long, rigid molecules that bend red blood cells into a sickle shape under conditions of low oxygen. Sickled cells obstruct blood vessels and die prematurely, ultimately resulting in anemia, severe pain (crises), infections, stroke, organ failure, and early death. Sickle cell disease is the most common inherited blood disorder in the United States, affecting an estimated 100,000 individuals, of which a significant proportion are of African-American descent (1:365 births). Beta-thalassemia is another inherited blood disorder characterized by severe anemia caused by reduced production of functional hemoglobin due to insufficient expression of the beta globin protein. Transfusion-dependent beta-thalassemia, or TDTB, is the most severe form of this disease, often requiring multiple transfusions per year. Patients with TDTB suffer from failure to thrive, persistent infections, and life-threatening anemia. The incidence of symptomatic beta-thalassemia is estimated to be 1:100,000 worldwide, including 1:10,000 in Europe. In the United States, based on affected birth incidence of 0.7 in 100,000 births, and increasing survival rates, we expect the population of individuals affected by this disease to be more than 1,400 and rising. The only potentially curative therapy currently available for patients with sickle cell disease or beta-thalassemia is allogeneic Hematopoietic Stem Cell Transplant, or HSCT; however, this procedure holds a high level of risk, particularly Graft-versus-Host Disease, or GvHD, resulting in a low number of patients opting for this treatment.

We are using base editing to pursue two complementary approaches to treating sickle cell disease and one to treat beta-thalassemia:

- a differentiated approach to elevating fetal hemoglobin which could be used in treatments for both sickle cell disease and beta-thalassemia (BEAM-101); and
- a novel approach to directly correcting the sickle mutation (BEAM-102).

BEAM-101: Recreating naturally-occurring protective mutations to activate fetal hemoglobin

The beneficial effects of the fetal form of hemoglobin, or HbF, to compensate for mutations in adult hemoglobin were first identified in individuals with a condition known as HPFH. Individuals who carry mutations that would have typically caused them to be beta-thalassemia or sickle cell disease patients, but who also have HPFH, are asymptomatic or experience a much milder form of their disease. HPFH is caused by single base changes in the regulatory region of the genes, HBG1 and HBG2, which prevents binding of one or more repressor proteins and increases the expression of gamma globin, which forms part of the HbF tetramer.

Using base editing, we reproduce these specific, naturally occurring base changes in the regulatory elements of the gamma globin genes, preventing binding of repressor proteins and leading to re-activation of gamma globin expression, and thus the increase in gamma globin levels. Our in vitro and in vivo characterization of BEAM-101 using ex vivo delivery achieved precise and efficient editing of human CD34+ hematopoietic stem and progenitor cells, or HSPCs, resulting in long-term engraftment and therapeutically-relevant increases in target gene expression in mice. Additionally, there have been no observed guide-dependent or guide-independent off-target events for this program.

In vitro characterization of BEAM-101:

- We demonstrated greater than 90% editing in healthy donor CD34 cells in vitro.
- We demonstrated gamma globin upregulation following erythroid differentiation is highly correlated (R²=0.993) with editing rates, where, at greater than 90% editing we achieve greater than 60% increase in gamma globin in healthy donor CD34+ cells.
- Successful editing of CD34+ cells from a homozygous sickle cell disease patient, demonstrating a greater than 60% increase in gamma globin levels with a concomitant decrease to less than 40% sickle beta globin levels in vitro after in vitro differentiation.
In vivo performance of BEAM-101:

- We demonstrated that edited CD34+ cells from a healthy human donor engraft with high chimerism and maintain greater than 90% editing after 16 weeks in immunocompromised mice.
- We demonstrated after 16-week engraftment that base edited cells lead to successful multilineage reconstitution with greater than 90% base editing achieved in sorted human HSPCs, myeloid, lymphoid and erythroid cells.
- We replicated these findings with cells from a second donor at 18 weeks post-engraftment.

Off-target profile of BEAM-101:

- Two theoretical types of off-target events that are possible as a consequence of these edits are guide-dependent and guide-independent deamination.
- To determine the potential for guide-dependent off-target editing, Beam evaluated BEAM-101 in a homology-dependent biochemical assay. No guide-dependent off-target effects were observed in CD34+ hematopoietic stem and progenitor cells (HSPCs) edited at a supra-saturating dose of BEAM-101.
- Additionally, Beam assessed guide-independent off-target effects using single-clone whole genome sequencing, which revealed that no significant fold change of guide-independent A-to-G DNA mutations occurred in edited cells compared to unedited controls.
- Further, whole transcriptome sequencing and somatic variant calling showed no guide-independent RNA deamination in CD34+ HSPCs edited at a supra-saturating dose of BEAM-101.
- Together, the findings support precision editing with BEAM-101 with a very low risk for potential off-target toxicities.

BEAM-102: Direct correction of the sickle cell mutation

Our second base editing approach for sickle cell disease, BEAM-102, is a direct correction of the causative sickle mutation at position 6 of the beta globin gene. By making a single A-to-G edit, we have demonstrated in primary human CD34+ cells isolated from sickle cell disease patients the ability to create the naturally occurring Makassar variant of hemoglobin. This variant, which was identified in humans and first published in 1970, has the same function as the wild-type variant and does not cause sickle cell disease. Distinct from other approaches, cells that are successfully edited in this way are fully corrected, no longer containing the sickle protein.

BEAM-102 uses ex vivo delivery of our ABEs to edit CD34+ HSPCs. In cells isolated from donors with sickle cell disease, we achieved greater than 80% correction of the sickle point mutation to the HbG-Makassar variant, following in vitro erythroid differentiation. Importantly, we observed a simultaneous reduction of HbS to less than 20% of control levels, a level that is lower that that typically observed in sickle trait individuals, who are asymptomatic. More than 70% of erythroid colonies derived from edited patient cells showed biallelic editing (yielding cells that are potentially cured, no longer producing any sickle protein at all), and another 20% of cells had monoallelic editing (with one sickle allele and one corrected allele, conferring a level of protection expected to be similar to patients with “sickle cell trait” who do not show significant symptoms of disease) – adding up to 93% of cells with potential elimination of sickle cell disease. Further, the correction of the HbS protein to the HbG-Makassar variant was shown to significantly reduce the propensity of in vitro differentiated erythroid cells to sickle when subjected to hypoxia. These findings represent therapeutic levels of correction if translated into the clinic and support advancement of this program to potentially address the underlying genetic cause of sickle cell disease. Published modeling studies suggest that at least 20% of cells no longer having the propensity to sickle, either by expressing HbF or because of the elimination of HbS, may be sufficient to cure the disease. With upregulation levels of more than 60% of gamma globin for Beam-101 or by generating more than 90% of cells having at least one HbS allele corrected in the case of BEAM-102, we have shown, in preclinical models, correction levels significantly above those expected to be disease modifying.

Long-term in vivo data generated using an early version of the Makassar base editor, yielded approximately 50% conversion of the sickle allele to a Makassar allele. At 16 weeks post-transplant of CD34+ cells containing the sickle trait, we observed equivalent human chimerism between unedited and edited cells and evidence of multi-lineage reconstitution in mouse models. Levels of editing were sustained after long-term hematopoietic engraftment. Further, editing of the sickle allele led to the expression of the Makassar globin protein in vivo.

Ex vivo electroporation for multiplex editing: CAR-T cell therapies

The starting material for our multiplex allogeneic CAR-T cell products is white blood cells from a healthy donor, which are collected using a standard blood bank procedure known as leukapheresis. Using a single electroporation, we introduce the base editor as mRNA, and the guides encoding the target sequences. The edited cells are subsequently transduced with a lentivirus expressing the CAR. Once the T cells have been engineered, they are expanded and frozen. After the patient is lymphodepleted, the multiplexed, allogenic cell product is infused.
We believe base editing is a powerful tool to simultaneously multiplex edit many genes without unintended on-target effects, such as genomic rearrangements or activation of the p53 pathway, that can result from simultaneous editing with nucleases through the creation of double-stranded breaks. The ability to create a large number of multiplex edits in T cells could endow CAR-T cells and other cell therapies with combinations of features that may dramatically enhance their therapeutic potential in treating hematological or solid tumors. The initial indications that we plan to target with these product candidates are relapsed, refractory, T-ALL, and Acute Myeloid Leukemia, or AML. We believe that our approach has the potential to produce higher response rates and deeper remissions than existing approaches. Our proof-of-concept pre-clinical experiments have demonstrated the ability of base editors to efficiently modify up to 8 genomic loci simultaneously in primary human T cells with efficiencies ranging from 85-95% as measured by flow cytometry of target protein knockdown. Importantly, these results are achieved without the generation of chromosomal rearrangements, as detected by sensitive methods such as UDiTaSTM or G-banded Karyotyping and with no loss of cell viability from editing. The proof-of-concept experiments have also demonstrated robust T cell killing of target tumor cells both in vitro and in vivo.

BEAM-201: Universal CD7-targeting CAR-T cells

BEAM-201 is a development candidate comprising T cells derived from healthy donors that are simultaneously edited at TRAC, CD7, CD52 and PDCD1 and then transduced with a lentivirus encoding for an anti-CD7 CAR to create allogenic CD7 targeting CAR-T cells, resistant to both fratricide and immunosuppression. To our knowledge, Beam-201 is the first cell therapy featuring four simultaneous edits. Using our cytosine base editor, or CBE, cells are edited to confer the following benefits:

- **TRAC**: Prevent graft-vs-host disease via the elimination of the existing TCR to ensure that the CAR-T cell only attacks the CAR antigen on the tumor and not the patient’s healthy cells.
- **CD52**: Enable an allogeneic cell source by masking BEAM-201 cells to anti-CD52 lymphodepleting agents to reduce host rejection of BEAM-201 cells.
- **PDCD1**: Minimize immunosuppression of BEAM-201 cells by the tumor microenvironment and prolong efficacy for attacking the tumor.
- **CD7**: Prevent fratricide (i.e., CAR-T cells attacking each other before they can attack the tumor) by eliminating antigens that are shared between malignant cells and CAR-T cells.

In vitro characterization of BEAM-201 and comparison to nuclease editing:

- Simultaneous base editing at four target loci in primary human T cells using a clinical-scale process, produced 96-99% on-target editing of each of the four genes as measured by next-generation sequencing.
- Simultaneous quad base editing of T cells resulted in no detected genomic rearrangements; Cas9 nuclease editing with the same four guide RNAs produced chromosomal aberrations in 22 of 100 cells evaluated in G-banded karyotyping.
- Multiplex base editing did not negatively affect cell expansion during manufacturing, while nuclease editing induced significant loss of cell expansion.
- CBE-edited cells decreased expression of the four target genes with minimal effect on other genes, including key members of the p53 pathway that are upregulated in response to DNA double-stranded breaks produced by multiplex editing with nucleases.

Further characterization of BEAM-201 in vitro and in a tumor mouse model:

- The GMP-compliant, clinical-scale process resulted in final BEAM-201 CAR-T cell populations with on-target editing efficiencies between 96-99.9% at each of the four target loci, and 85% CAR-expressing cells. As a result, we estimate that 91% of cells are bi-allelically quad base edited and 77% of cells have all five genetic modifications. We believe this is the highest level and uniformity of CAR expression and simultaneous editing across four target sites reported at clinical scale to date.
- BEAM-201 cells demonstrated robust in vitro CD7-dependent cytokine production, and rapid in vitro cytotoxicity.
- BEAM-201 cells also demonstrated dose-dependent clearance or control, across a 25-fold dose range, of an aggressive disseminated CCRF-CEM T-ALL tumor mouse model.
Non-viral delivery for liver diseases: Alpha-1 antitrypsin deficiency and glycogen storage disorder 1a

LNPs are a clinically validated technology for delivery of nucleic acid payloads to the liver. LNPs are multi-component particles that encapsulate the base editor mRNA and guide(s) and protect them from degradation while in an external environment, enabling the transient delivery of the base editor in vivo. Multiple third-party clinical trials have demonstrated the effective delivery of silencing RNA, or siRNAs, to the liver using LNPs. We have developed several proprietary LNP formulations. Because only one dose of a base editing therapy may be needed in a course of treatment, LNPs are a suitable delivery modality that we believe is unlikely to face complications seen with chronic use of LNPs, such as when delivering oligonucleotides or mRNA for gene therapy. All of the components of the LNP, as well as the mRNA encoding the base editor, are well-defined and can be made synthetically, providing the opportunity for scalable manufacturing. We are currently using a variety of cationic lipids from various sources to advance our programs for genetic liver diseases, which include Alpha-1 Antitrypsin Deficiency, or Alpha-1, and GSD1a, also known as Von Gierke disease.

Alpha-1 is a severe inherited genetic disorder that can cause progressive lung and liver disease. The most severe form of Alpha-1 arises when a patient has a point mutation in both copies of the SERPINA1 gene at amino acid 342 position (E342K, also known as the PiZ mutation or the “Z” allele). This point mutation causes Alpha-1 antitrypsin, or AAT, to misfold, accumulating inside liver cells rather than being secreted, resulting in very low levels (10%-15%) of circulating AAT. As a consequence, the lung is left unprotected from neutrophil elastase, resulting in progressive, destructive changes in the lung, such as emphysema, which can result in the need for lung transplants. The mutant AAT protein also accumulates in the liver, causing liver inflammation and cirrhosis, which can ultimately cause liver failure or cancer and require patients to undergo a liver transplant. It is estimated that approximately 60,000 individuals in the United States have two copies of the Z allele. There are currently no curative treatments for patients with Alpha-1.

With the high efficiency and precision of our base editors, we aim to utilize our ABEs to precisely correct the E342K point mutation back to the wild type sequence.

For a recent study, we engineered novel ABEs and guide RNAs capable of correcting the PiZ mutation, and then used a proprietary non-viral lipid nanoparticle formulation to deliver the optimized reagents to the livers of a PiZ transgenic mouse model. This direct editing approach resulted in an average of 16.9% correction of beneficial alleles at seven days and 28.8% at three months. This significant increase over the period suggests that corrected hepatocytes may have a survival advantage relative to uncorrected cells. In addition, treated mice demonstrate decreased Alpha-1-antitrypsin-mediated globule burden within the liver and a durable, significant increase in serum AAT active protein at three months, approximately 4.9-fold higher than in controls at the end of the study, levels which we believe would be clinically relevant if achieved in patients. These data indicate the potential for base editing as a one-time therapy to treat both lung and liver manifestations of Alpha-1.

GSD1a is an inborn disorder of glucose metabolism caused by mutations in the G6PC gene, which results in low blood glucose levels that can be fatal if patients do not adhere to a strict regimen of slow-release forms of glucose, administered every one to four hours (including overnight). There are no disease-modifying therapies available for patients with GSD1a.

Our approach to treating patients with GSD1a is to apply base editing via LNP delivery to repair the two most prevalent mutations that cause the disease, R83C and Q347X. It is estimated that these two-point mutations account for 900 and 500 patients, respectively, in the United States, representing approximately 59% of all GSD1a patients in this country. Animal studies have shown that as little as 11% of normal G6Pase activity in liver cells is sufficient to restore fasting glucose; however, this level must be maintained in order to preserve glucose control and alleviate other serious, and potentially fatal, GSD1a sequelae.

We have engineered novel ABEs that, in preclinical models, have achieved high levels of precise correction of the two most prevalent GSD1a mutations, R83C and Q347X, in both in vitro and in vivo settings. Correction of at least 11% is expected to be clinically relevant and potentially disease modifying for GSD1a patients.

In vitro studies have shown up to 80% correction of the alleles in cells harboring the Q347X point mutation and approximately 60% of the alleles in cells harboring the R83C mutation.

Significant, potentially disease-modifying levels of in vivo correction of both mutations by ABEs was observed in the livers of two strains of transgenic mice, each carrying one of the two relevant G6PC mutations. Next-generation sequencing data from whole liver extracts reveals approximately 40% and 70% A-to-G correction of R83C and Q347X, respectively. These significant levels of mutation correction greatly surpass those expected to restore glucose homeostasis and functional studies are ongoing to correlate pathophysiology to the extent of mutation correction by base-editing. Further, these levels of in vivo correction for GSD1a by base-editing are achieved without creation of double-stranded breaks. In total, these data support base-editing technology as a promising approach for precise correction of two of the most prevalent causative mutations in GSD1a.
Viral delivery for ocular and CNS disorders: Stargardt disease

AAV is a clinically validated technology that has been extensively used for gene delivery to a variety of tissues. AAV is a small, non-pathogenic virus that can be repurposed to carry a therapeutic payload, making it an suitable vector for delivery of gene editing therapies. Several clinical trials have been conducted or are in progress with different AAV variants for multiple diseases, including diseases of the eye, liver, muscle, lung and CNS. We have an option to in-license a variety of AAV variants that could be selected for optimal distribution to multiple organs. Because our DNA base editors are larger than the approximate 4.5kb packaging limit of AAV vectors, we use a novel split intein technology that is designed to deliver the base editor and guide RNA by co-infection with two viruses, where each virus contains approximately one half of the editor.

We are currently evaluating this technology to correct one of the most prevalent mutations in the ABCA4 gene causing Stargardt disease, a progressive macular degeneration. This mutation is known as the G1961E point mutation and approximately 1,500 individuals in the United States are affected. Disease modeling using tiny light stimuli through holes that are equivalent in size to a single photoreceptor cell, suggests that only 12%-20% of these cells are sufficient to preserve vision. We anticipate, therefore, that editing percentages in the range of 12%-20% of these cells would be disease-modifying, since each edited cell will be fully corrected and protected from the biochemical defect.

In a human retinal pigment epithelial cell line (ARPE-19 cells) in which we have knocked in the ABCA4 G1961E point mutation, we have demonstrated the precise correction of approximately 75% of the disease alleles at 5 weeks after dual infection with the split AAV system.

Our portfolio of precision gene editing technologies

Building on the expertise of our academic founders and our innovative research culture, we plan to explore new and complementary technologies in base editing, gene editing, and genetic medicine over the long term to advance a broad portfolio across multiple delivery pipelines. As part of this strategy, we have licensed a portfolio of three additional complementary technologies – RNA base editing, Cas12b nuclease editing, and prime editing for certain fields. Combined with base editing, we have assembled a broad and versatile portfolio of next generation gene editing technologies for the potential treatment of many severe diseases.

Our license agreement with the Broad Institute gives us access to RNA base editing technology, a two-part modular system using an RNA-directed CRISPR protein for targeting RNA strands and a deaminase for editing. This CRISPR protein, known as Cas13, is modified so that it cannot break the RNA strand, and is fused to a deaminase capable of making a single base edit at a specific target location within the RNA strand. This enables us to change protein expression, potentially correcting or altering the function of the resulting protein and correcting disease. Our RNA base editing technologies include the REPAIR™ system for A-to-I editing, as well as the RESCUE™ system for C-to-U editing. When delivered through a long-lasting viral vector, RNA base editing may provide a complementary approach to DNA base editing for permanent correction of gene expression. Additionally, RNA editing could potentially be beneficial in situations where a transient change is desirable, such as in regenerative medicine.

Our Broad Institute license also gives us access to the Cas12b nuclease family, which provides several potential strategic advantages for our portfolio. First, the distinct PAM sequence and conformation of Cas12b allows us to create DNA base editors that can bind to different target sites in the genome, further expanding the range of sites that we can edit. Second, having a nuclease allows us to make “cut” edits, which may be appropriate for some applications that require a double stranded break, or to use the general gene targeting ability of Cas12b for other genome editing applications.

We also have a license to technology referred to as “prime editing,” that is controlled by Prime Medicine, Inc. Prime editing may be able to achieve the “rewriting” of short sequences of DNA at a target location. Prime editing utilizes a CRISPR protein to target a mutation site in DNA and to nick a single strand of the target DNA. The guide RNA allows the CRISPR protein to recognize a DNA sequence that is complementary to the guide RNA and also carries a primer for reverse transcription and a replacement template. The reverse transcriptase copies the template sequence in the nicked site, installing the edit. As with base editing, prime editing does not cause double-stranded breaks in the target DNA, resulting in lower insertion and deletion, or indel, rates than gene editing technologies that rely on double stranded breaks.

We have the exclusive right to develop prime editing technology for the creation or modification of any single base transition mutations, as well as for the treatment of sickle cell disease. Transition mutations (i.e., A-to-G, G-to-A, C-to-T, or T-to-C) are the largest single class of disease-associated genetic mutations and include all of our current targets for base editing programs.

Leveraging our deep scientific expertise and significant ongoing investment in our platform, we also expect to develop insights into other innovative gene editing and delivery modalities. We believe that our delivery, manufacturing, and development capabilities could position us to effectively evaluate and rapidly develop such novel technologies and further extend our leadership in the field of genetic medicine.
Ex vivo electroporation for hematologic diseases and oncology

Boston Children’s Hospital

In July 2020, we formed a strategic alliance with Boston Children’s Hospital. Under the terms of the agreement, we will sponsor research programs at Boston Children’s to facilitate development of disease-specific therapies using our proprietary base editing technology. Boston Children’s will also serve as a clinical site to advance bench-to-bedside translation of our pipeline across certain therapeutic areas of interest, including programs in sickle cell disease and pediatric leukemias and exploration of new programs targeting other diseases.

Magenta Therapeutics

In June 2020, we announced a non-exclusive research and clinical collaboration agreement with Magenta Therapeutics to evaluate the potential utility of MGTA-117, Magenta’s novel targeted ADC for conditioning of patients with sickle cell disease and beta-thalassemia receiving our base editing therapies. Conditioning is a critical component necessary to prepare a patient’s body to receive the edited cells, which carry the corrected gene and must engrant in the patient’s bone marrow in order to be effective. Today’s conditioning regimens rely on nonspecific chemotherapy or radiation, which are associated with significant toxicities. MGTA-117 precisely targets only hematopoietic stem and progenitor cells, sparing immune cells, and has shown high selectivity, potent efficacy, wide safety margins and broad tolerability in non-human primate models. MGTA-117 may be capable of clearing space in bone marrow to support long-term engraftment and rapid recovery in patients. Combining the precision of our base editing technology with the more targeted conditioning regimen enabled by MGTA-117 could further improve therapeutic outcomes for patients suffering from these severe diseases. We will be responsible for clinical trial costs related to development of our base editors when combined with MGTA-117, while Magenta will continue to be responsible for all other development costs of MGTA-117.

Non-Viral delivery for liver diseases

Verve Therapeutics

In April 2019, we entered into a collaboration and license agreement with Verve, a company focused on developing genetic medicines to safely edit the genome of adults to permanently lower LDL cholesterol and triglyceride levels and thereby treat coronary heart disease. This collaboration allows us to fully realize the potential of base editing in treating cardiovascular diseases, an area outside of our core focus where the Verve team has significant, world-class expertise. Under the terms of the agreement, Verve received exclusive access to our base editing technology, gene editing, and delivery technologies for human therapeutic applications against certain cardiovascular targets. In exchange, we received 2,556,322 shares of Verve common stock. Additionally, we will receive milestone payments for certain clinical and regulatory events and we retain the option, after the completion of Phase 1 studies, to participate in future development and commercialization, and share 50 percent of U.S. profits and losses, for any product directed against these targets. Verve granted to us a non-exclusive license under know-how and patents controlled by Verve, and an interest in joint collaboration technology. Either party may owe the other party other milestone payments for certain clinical and regulatory events related to the delivery technology products. Royalty payments may become due by either party to the other based on the net sales of any commercialized delivery technology products under the agreement.

In June 2020, Verve reported preclinical proof-of-concept data in non-human primates that demonstrated the successful use of adenine base editors to turn off a gene in the liver. Utilizing ABE technology licensed from us and an optimized guide RNA packaged in an engineered lipid nanoparticle, Verve evaluated in vivo liver base editing to turn off proprotein convertase subtilisin/kexin type 9 (PCSK9), a gene whose protein product elevates blood LDL cholesterol or angiopoietin-like protein 3 (ANGPTL3), a gene whose protein product elevates blood triglyceride-rich lipoproteins. We believe these proof-of-concept data, which show we can safely edit the primate genome, represent the first successful application of the base editing technology in non-human primates.

In two separate studies, seven animals were treated with the drug product targeting the PCSK9 gene and seven additional animals with the drug product targeting the ANGPTL3 gene. Whole liver editing, blood protein and lipid levels were measured at two weeks and compared to baseline. The program targeting PCSK9 showed an average of 67% whole liver PCSK9 editing, which translated into an 89% reduction in plasma PCSK9 protein and resulted in a 59% reduction in blood LDL cholesterol levels. The program targeting ANGPTL3 showed an average of 60% whole liver ANGPTL3 editing, which translated into a 95% reduction in plasma ANGPTL3 protein and resulted in a 64% reduction in blood triglyceride levels and 19% reduction in LDL cholesterol levels. In addition, in studies in primary human hepatocytes, clear evidence of on-target editing was observed with no evidence of off-target editing.

Per the terms of our agreement with Verve, we can exercise our right to participate in the future development and commercialization of any programs at the completion of Phase 1 studies.
In July 2020, we announced a research collaboration with the Institute of Molecular and Clinical Ophthalmology Basel, or IOB. Founded in 2018 by a consortium that includes Novartis, the University Hospital of Basel and the University of Basel, IOB is a leader in basic and translational research aimed at treating impaired vision and blindness. Clinical scientists at IOB have also helped to develop better ways to measure how vision is impacted by Stargardt disease. Additionally, researchers at IOB have developed living models of the retina, known as organoids, which can be used to test novel therapies. Under the terms of the agreement, the companies will leverage IOB’s unique expertise in the field of ophthalmology along with our novel base editing technology to advance programs directed to the treatment of certain ocular diseases, including Stargardt disease.

**Manufacturing**

To realize the full potential of base editors as a new class of medicines and to enable our parallel investment strategy in multiple delivery modalities, we are building customized and integrated capabilities across discovery, manufacturing, and preclinical and clinical development. Due to the critical importance of high-quality manufacturing and control of production timing and know-how, we have taken steps toward establishing our own manufacturing facility, which will provide us the flexibility to manufacture numerous different drug product modalities. We believe this investment will maximize the value of our portfolio and capabilities, the probability of technical success of our programs, and the speed at which we can provide life-long cures to patients.

In August 2020, we entered into a lease agreement with Alexandria Real Estate Equities, Inc. to build a 100,000 square foot current Good Manufacturing Practice, or cGMP, compliant manufacturing facility in Research Triangle Park, North Carolina intended to support a broad range of clinical programs. We will anticipate investing up to $83.0 million over a five-year period and anticipate that the facility will be operational by the first quarter of 2023. The project will be facilitated, in part, by a Job Development Investment Grant approved by the North Carolina Economic Investment Committee, which authorizes potential reimbursements based on new tax revenues generated through the project. The facility will be designed to support manufacturing for our ex vivo cell therapy programs in hematology and oncology and in vivo non-viral delivery programs for liver diseases, with flexibility to support manufacturing of our viral delivery programs, and ultimately, scale-up to support potential commercial supply.

For our initial waves of clinical programs, we will use contract manufacturing organizations, or CMOs, with relevant manufacturing experience in genetic medicines.

**Competition**

The pharmaceutical and biotechnology industries, including the gene therapy and gene editing fields, are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on intellectual property. While we believe that our differentiated technology, scientific expertise, and intellectual property position provide us with competitive advantages, we face potential competition from a variety of companies in these fields. Within these industries, we will compete with existing large pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies.

There are several other companies utilizing CRISPR/Cas9 nuclease technology, including Caribou Biosciences, Editas Medicine, CRISPR Therapeutics, and Intellia Therapeutics. Several additional companies utilize other nuclease-based genome editing technologies, including Zinc Fingers, Arcuses, and TAL Nucleases, including Sangamo Biosciences, Precision BioSciences, bluebird bio, Allogene Therapeutics, and Cellectis. Additionally, newer genome editing modalities are emerging, including Prime Medicine, Tessler, Shape Therapeutics, and PerkinElmer (formerly Horizon Discovery), which is developing base editing technology. In addition, we face competition from companies utilizing gene therapy, oligonucleotides, and CAR-T therapeutic approaches.

We are also aware of companies with products in development in our disease areas where we will compete with approved therapies, those in development today, and those emerging in the future. For hemoglobinopathies, these companies include Global Blood Therapeutics, CRISPR Therapeutics, Novartis Pharmaceuticals, Sangamo Therapeutics, Editas Medicine, Homology Medicines, Graphite Bio, and Trucode Gene Repair. For T-cell malignancies, these include Gracell Bio, iCellGene, PersonGen, and Wugen. More broadly in the immuno-oncology cell therapy space, these include Allogene Therapeutics, Cellectis, bluebird bio, Bristol Myers Squibb, Fate Therapeutics, Gilead Sciences, Novartis Pharmaceuticals, Poseida Therapeutics, Precision Bio, Legend Bio, Autolus Therapeutics. For our liver targeted therapies, these include Intellia Therapeutics, Editas Medicines, CRISPR Therapeutics, Ultragenyx, Apic Bio, Arrowhead, LogicBio, Generation Bio, and Vertex.

Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future that are approved to treat the same diseases for which we may obtain approval for our product candidates. This may include other types of therapies, such as small molecule, antibody, and/or protein therapies.
In addition, many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials and approved products than we do today. Mergers and acquisitions in the pharmaceutical, biotechnology and gene therapy industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We also compete with these companies in recruiting, hiring and retaining qualified scientific and management talent, establishing clinical trial sites and patient registration for clinical trials, obtaining manufacturing slots at contract manufacturing organizations, and in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, particularly if they represent cures, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Our competitors also may 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. The key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety, convenience, and availability of reimbursement.

COVID-19

With the ongoing concern related to the COVID-19 pandemic, we have maintained and expanded the business continuity plans to address and mitigate the impact of the COVID-19 pandemic on our business. In March 2020, to protect the health of our employees, and their families and communities, we restricted access to our offices to personnel who performed critical activities that must be completed on-site, limited the number of such personnel that can be present at our facilities at any one time, and requested that most of our employees work remotely. In May 2020, as certain states eased restrictions, we established new protocols to better allow our full laboratory staff access to our facilities. These protocols included several shifts working over a seven-day-week protocol. We expect to continue incurring additional costs to ensure we adhere to the guidelines instituted by the CDC and to provide a safe working environment to our onsite employees.

The extent to which the COVID-19 pandemic impacts our business, our corporate development objectives, results of operations and financial condition, including and the value and market for our common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements, and the effectiveness of actions taken globally to contain and treat the disease. Disruptions to the global economy, disruption of global healthcare systems, and other significant impacts of the COVID-19 pandemic could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

While the COVID-19 pandemic did not significantly impact our business or results of operations during the year ended December 31, 2020, the length and extent of the pandemic, its consequences, and containment efforts will determine the future impact on our operations and financial condition.

Intellectual property

Our success depends in part on our ability to obtain and maintain proprietary protection for our platform technology, our programs, and know-how related to our business, defend and enforce our intellectual property rights, in particular, our patent rights, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating any valid and enforceable intellectual property rights of others. We seek to protect our proprietary position by, among other things, exclusively licensing and filing U.S. and certain foreign patent applications related to our platform technology, existing and planned programs, and improvements that are important to the development of our business, where patent protection is available.

Notwithstanding these efforts, we cannot be sure that patents will be granted with respect to any patent applications we have licensed or filed or may license or file in the future, and we cannot be sure that any patents we have licensed or patents that may be licensed or granted to us in the future will not be challenged, invalidated, or circumvented or that such patents will be commercially useful in protecting our technology. For more information regarding the risks related to our intellectual property, please see Item 1A., Risk factors—Risks related to our intellectual property, in this Annual Report on Form 10-K.

Our wholly owned and our in-licensed patents and patent applications cover various aspects of our base editing platform and our programs, including:

- C-to-T DNA base editors
- A-to-G DNA base editors
- A-to-I RNA base editors, or REPAIR
- C-to-U RNA base editors, or RESCUE
- CRISPR/Cas12b systems for nuclease editing
- Novel guide RNA sequences
Systems and methods for increasing the specificity of base editing
Multiplex base editing in immune cells ex vivo
Methods for evaluating base editing specificity
Therapeutic methods
Delivery modality

We also have an option to license patents and patent applications relating to CRISPR/Cas9 systems. We intend to continue to pursue, when possible, additional patent protection, including composition of matter, method of use, and process claims, directed to each component of our platform technology and the programs in our portfolio. We also intend to obtain rights to delivery modalities through one or more licenses from third parties and to protect our own intellectual property to delivery modalities.

As of December 31, 2020, we owned approximately three pending U.S. provisional patent applications, six pending U.S. patent applications, 25 pending international patent applications, or PCT applications, and 33 pending ex-U.S. patent applications. The patent applications outside of the United States were filed in Australia, Brazil, Canada, China, Europe, India, Japan, Korea, and South Africa. Our owned patent applications are related to our DNA base editing technology, including claims to base editor variants with enhanced activities (e.g., nucleobase deaminating activity) or novel properties (e.g., PAM recognition), methods of using such base editors, methods of using such base editors for therapeutic indications, multiplex base editing in immune cells ex vivo, guide RNAs that target base editors to therapeutically relevant DNA sequences, and methods for evaluating base editing specificity. One of these PCT applications is co-owned with Broad Institute and President and Fellows of Harvard College, or Harvard. If issued as U.S. patents, and if the appropriate maintenance fees are paid, the U.S. patents would be expected to expire between 2039 and 2042, excluding any additional term for patent term adjustments or patent term extensions.

DNA base editing
As of December 31, 2020, we in-licensed approximately 24 U.S. patents, 23 pending U.S. patent applications, three pending PCT applications, 43 ex-U.S. patents, and 149 pending ex-U.S. patent applications, related to DNA base editing from Broad Institute, Harvard, Editas Medicine Inc., or Editas, and Bio Palette Co., Ltd., or Bio Palette. The patents and patent applications outside of the United States were filed primarily in Europe, Japan, and China, although some of our in-licensed patent families were filed in a larger number of countries. The patents and applications from our in-licensed portfolio for DNA base editing include claims to novel base editors, claims to engineered deaminase enzymes (e.g., evolved TadA) used in the base editors, compositions including the base editor or engineered deaminase as a component, methods of using such base editors, including methods of using such base editors for therapeutic indications, guide RNAs that target base editors to therapeutically relevant DNA sequences. The in-licensed patents and applications also cover various aspects related to the platform technology, including base editing systems that employ S. pyogenes Cas9, S. aureus Cas9, Cas9 PAM variants, inactive forms of Cas9, and/or Cas9 nickases, and systems for delivery of base editors. Our current in-licensed patents and patent applications on DNA base editing, if the appropriate maintenance fees are paid, are expected to expire between 2034 and 2038, excluding any additional term for patent term adjustments or patent term extensions (or the corresponding foreign equivalent).

RNA Base Editing
As of December 31, 2020, we in-licensed approximately 10 pending U.S. patent applications, one ex-U.S. patent, and 47 pending ex-U.S. patent applications, related to RNA base editing from Broad Institute. The patents and patent applications outside of the United States were filed in Australia, Canada, Europe, and Russia. The patents and applications from our in-licensed portfolio for RNA base editing include claims to novel base editors, compositions including the base editor as a component, guide RNAs that target base editors to therapeutically relevant RNA sequences, and methods of using such base editors, including methods of using such base editors for therapeutic indications. Our current in-licensed patents and patent applications on RNA base editing, if the appropriate maintenance fees are paid, are expected to expire between 2036 and 2038, excluding any additional term for patent term adjustments or patent term extensions (or the corresponding foreign equivalent).

CRISPR/Cas12b
As of December 31, 2020, we in-licensed approximately seven pending U.S. patent applications, and eight pending ex-U.S. patent applications, related to editing using Cas12b from Broad Institute. The patents and patent applications outside of the United States were filed in Australia, Canada, Europe, and Russia. The patents and applications from our in-licensed portfolio for Cas12b editing include claims to methods of using Cas12b to modify DNA (e.g., nuclease cleavage of DNA) and engineered and/or non-naturally occurring compositions including Cas12b as a component. Our current in-licensed patents and patent applications on Cas12b base editing, if the appropriate maintenance fees are paid, are expected to expire between 2036 and 2039, excluding any additional term for patent term adjustments or patent term extensions (or the corresponding foreign equivalent).
Rest of platform
As of December 31, 2020, we in-licensed approximately 22 U.S. patents, 28 pending U.S. patent applications, 44 ex-U.S. patents, and 159 pending ex-U.S. patent applications, related to the balance of our platform from universities and institutions. The patents and patent applications outside of the United States were filed primarily in Europe, Japan, and China, although some of our in-licensed patent families were filed in a larger number of countries. The patents and patent applications filed in the United States were exclusively licensed to us, while the patent applications outside of the United States were exclusively licensed to us by their respective universities or institutions. In addition, we have in-licensed approximately 22 U.S. patents, 28 pending U.S. patent applications, 44 ex-U.S. patents, and 159 pending ex-U.S. patent applications, related to the balance of our platform from universities and institutions. The patents and patent applications outside of the United States were filed primarily in Europe, Japan, and China, although some of our in-licensed patent families were filed in a larger number of countries. The patents and patent applications filed in the United States were exclusively licensed to us, while the patent applications outside of the United States were exclusively licensed to us by their respective universities or institutions.

CRISPR/Cas9 and CRISPR/Cas12a
We have a nonexclusive license to conduct research activities and an option to exclusively license certain patents and patent applications directed to Cas9 and Cas12a from Editas, who in turn has licensed such patents from various academic institutions. In the case of Cas9, a number of the U.S. patents are subject to an interference declared by the Patent and Trademark office, and a number of the European patents are the subject of one or more oppositions. For more information regarding the risks related to our intellectual property, please see Item 1A., Business—Intellectual property—Intellectual property licenses and Item 1A., Risk factors—Risks related to our intellectual property, in this Annual Report on Form 10-K.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. However, the actual protection afforded by a patent varies 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. In the United States, a patent’s term may, in certain cases, be lengthened by patent term adjustment, or PTA, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened (e.g., if a patent is terminally disclaimed over a commonly owned patent having an earlier expiration date). In some instances, such a PTA may result in a U.S. patent term extending beyond 20 years from the earliest date of filing a non-provisional patent application related to the U.S. patent. Patent term extensions, or PTE, under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, are also possible for patents that cover an FDA-approved drug as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a PTE of up to five years beyond the expiration of the patent. The length of the PTE is related to the length of time the drug is under regulatory review. PTE cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug, a method for using it, or a method of manufacturing it, may be extended. Similar provisions are available in Europe and certain other jurisdictions to extend the term of a patent that covers an approved drug. In the future, if our products receive regulatory approval, we may be eligible to apply for PTEs on patents covering such products, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such PTE should be granted, and if granted, the length of such PTE. For more information regarding the risks related to our intellectual property, please see Item 1A., Risk factors—Risks related to our intellectual property, in this Annual Report on Form 10-K.

We also rely on trade secrets, know-how, continuing technological innovation, and confidential information to develop and maintain our proprietary position and protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have implemented measures to protect and preserve our trade secrets, such measures can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. For more information regarding the risks related to our intellectual property, please see Item 1A., Risk factors—Risks related to our intellectual property, in this Annual Report on Form 10-K.

Trademarks
As of December 31, 2020, we owned two registered U.S. trademarks with the Patent and Trademark Office for BEAM THERAPEUTICS, six ex-U.S. registered trademarks, and 21 ex-U.S. pending trademark applications for BEAM THERAPEUTICS.

As of December 31, 2020, we in-licensed two registered U.S. trademarks, approximately 10 allowed/registered ex-U.S. trademarks, and approximately eight pending ex-U.S. trademark applications, for the use of REPAIR™ and RESCUE™ from Broad Institute.
Intellectual property licenses

We are a party to a number of license agreements under which we license patents, patent applications, and other intellectual property from third parties. The licensed intellectual property covers, in part, CRISPR-related compositions of matter and their use for base editing. These licenses impose various diligence and financial payment obligations on us. We expect to continue to enter into these types of license agreements in the future. We consider the following license agreements to be material to our business.

Collaborations

We believe our base editing technology has potential across a broad array of genetic diseases. To fully realize this potential, we have established and will continue to seek out innovative collaborations, licenses, and strategic alliances with pioneering companies and with leading academic and research institutions. Additionally, we have and will continue to pursue relationships that potentially allow us to accelerate our preclinical research and development efforts. These relationships will allow us to aggressively pursue our vision of maximizing the potential of base editing to provide life-long cures for patients suffering from serious diseases.

License Agreement with The President and Fellows of Harvard College

In June 2017, we entered into a license agreement with Harvard, as amended, pursuant to which we received an exclusive, worldwide, royalty-bearing, sublicensable license under certain patent rights owned or controlled by Harvard to make, have made, offer for sale, sell, have sold and import products in the field of the prevention or treatment of any and all human diseases and conditions, excluding human germline modification and products for non-human animal and plant applications. We refer to this license agreement as the Harvard License Agreement.

The licensed patents are directed, among other things, to C-to-T, A-to-G, and C-to-G base editors, for the treatment of certain diseases and conditions and to base editing, more generally.

Under the Harvard License Agreement, we are required to use commercially reasonable efforts to develop products incorporating the base editing technology covered in the licensed patents, in accordance with a development plan that we prepared and submitted to Harvard. The development plan includes certain development milestones that we are required to meet, as well as the timelines for the completion thereof, and we may update the development plan from time to time in our discretion to better position us to meet such milestones. If we are successfully able to gain regulatory approval in any country to introduce a licensed product into the commercial market in such country, then we are also required to use commercially reasonable efforts to commercialize such licensed product and make such licensed product reasonably available to the public. If we fail to meet any of the deadlines for the development milestones, then Harvard may terminate the Harvard License Agreement, subject to certain exceptions and opportunities for us to cure such failure. Additionally, we are required to initiate a discovery program in accordance with the development plan and development milestones for the development of a licensed product covered by certain sub-categories of licensed patents.

The licenses granted to us under the Harvard License Agreement are expressly subject to certain preexisting rights held by Harvard and certain third parties. For example, certain of the licensed patents were developed by employees of the Howard Hughes Medical Institute and were subsequently assigned to Harvard but remain subject to a non-exclusive license between Harvard and Howard Hughes, pursuant to which Howard Hughes received a license from Harvard under certain of the licensed patents for research purposes with the right to sublicense to non-profit and governmental entities. In addition, certain of the licensed patents claim or cover inventions resulting from research that was sponsored by the U.S. government, and the U.S. government retains certain rights with respect to such licensed patents under applicable U.S. law. Harvard additionally retains limited rights for itself and for other non-profit research organizations to practice the licensed patents for research, educational, and scholarly purposes. Furthermore, Harvard retains the right, beginning a certain period of time after regulatory approval of any licensed product in the U.S. or certain European countries, to grant third parties the non-exclusive right to develop, manufacture, have manufactured, import, have imported, offer for sale, sell, have sold or otherwise distribute or have distributed such licensed product or an equivalent thereof solely for sale on a locally-affordable basis in certain specified developing countries in which the we do not have plans to seek regulatory approval.

Although the licenses granted to us under the Harvard License Agreement are exclusive, Harvard may grant a license to a third party under the licensed patents to research, develop, and commercialize a product directed to a particular target, or a proposed product, in the field under limited circumstances. If a third party that is not a specified competitor of ours inquires with Harvard for such a license, attempts to enter into a sublicense agreement with us and fails to do so after a certain period of time and presents to Harvard a proposal including certain information describing the proposed development and commercialization of such a proposed product, then Harvard may notify us of such proposal. If we are not researching, developing or commercializing such a proposed product, then we can notify Harvard as to whether we are interested in developing such proposed product, entering into a sublicense agreement with such third party to develop such proposed product, or entering into a sublicense with another third party to develop the same proposed product. If we inform Harvard that we are interested in developing such proposed product, then we will prepare a development plan, similar in scope to the development plan under the Harvard License Agreement, to develop such proposed product. If we inform Harvard that we are interested in entering into a sublicense agreement pursuant to which a third party would receive a sublicense from us under the licensed patents to develop such proposed product, then we will have a specified period of time to enter into such a sublicense agreement and provide reasonable evidence thereof. If we are not researching, developing, or commercializing such a
proposed product, fail to provide a development plan, or fail to enter into a sublicense agreement with respect to such proposed product, in each case, within specified time periods, then Harvard may grant a license to the applicable third party under the licensed patents to research, develop, and commercialize such proposed product.

We are permitted to further sublicense our rights under the Harvard License Agreement to third parties, provided that any such sublicense agreement with a third party must remain in compliance with and be consistent with the terms of the Harvard License Agreement, and certain rights granted to us under the Harvard License Agreement can only be sublicensed to bona fide collaboration partners who are working with us to develop one or more licensed products. In addition, any such sublicense agreement must include certain customary provisions to ensure our ability to comply with the Harvard License Agreement.

We are also responsible for any breaches of a sublicense agreement by the applicable sublicensee, if such breach results in a material breach of the Harvard License Agreement.

In exchange for the licenses granted to us under the Harvard License Agreement, we initially issued to Harvard 101,363 shares of our common stock and subsequently issued 765,549 shares of our common stock pursuant to anti-dilution rights in the Harvard License Agreement. We are also required to pay to Harvard an annual license maintenance fee ranging from low-to-mid five figures to low six figures, depending on the particular calendar year. Harvard is also entitled to receive potential clinical and regulatory milestones in the mid-to-high eight figure range, subject to our receipt of regulatory approval in the United States, Japan, and the European Union, or EU. If we undergo a change of control during the term of the Harvard License Agreement, then certain of the milestone payments would be increased. We paid Harvard a total of $9.0 million upon the completion of our Series A and Series B financings. We may additionally owe Harvard success payments ranging from $5.0 million to a maximum total of $105.0 million.

With respect to the sale of licensed products by us, our affiliates or our sublicensees, Harvard is entitled to receive low single digit royalties on net sales of licensed products until, on a country-by-country basis, the latest of the expiration of (i) the last to expire licensed patent covering the applicable licensed product, (ii) the period of exclusivity associated with such licensed product in such country or (iii) a certain number of years after the first commercial sale of such licensed product in such country. We are entitled to certain reductions and offsets on these royalties with respect to a licensed product in a given country and certain increases in the event we, our affiliates or sublicensees bring patent challenges relating to any licensed patents (subject to a cure period for us to terminate the sublicense that has taken the applicable action). If we sublicense our rights to develop or commercialize a licensed product under the Harvard License Agreement to a third party and we receive non-royalty sublicense income, then Harvard is entitled to a percentage of such consideration, ranging from the high single digits to an amount between 10% and 20% depending on the date in which such sublicense agreement is executed and the stage of development our licensed products at such time.

Harvard is responsible for the prosecution and maintenance of all licensed patents, provided that we have customary consultation, comment, and review rights with respect to such prosecution and maintenance activities. We are responsible for Harvard’s documented out-of-pocket expenses with respect to such prosecution and maintenance, but if Harvard enters into a license agreement with a third party pursuant to which it grants such third party a license under the licensed patents outside of our field, then Harvard must use reasonable efforts to include a provision in such agreement that provides for an apportionment of prosecution and maintenance costs between us and such third party with respect to such licensed patents. If we choose to no longer pay for the prosecution and maintenance costs of a given licensed patent, then we will be relieved of such payment obligation, but our license with respect to such licensed patent will also terminate.

Unless earlier terminated, the Harvard License Agreement will remain in effect until the later of the last-to-expire valid claim of a licensed patent covering our licensed products or the end of the last to expire royalty term. We may terminate the Harvard License Agreement at our convenience following written notice to Harvard. Either party may terminate the Harvard License Agreement for a material breach of the other party, subject to a notice and cure period. Harvard may also terminate the Harvard License Agreement in the event of our bankruptcy or insolvency or if we fail to procure and maintain insurance. Upon expiration or termination of the Harvard License Agreement, the licenses granted to us will terminate and all rights under the licensed patent rights will revert to Harvard.

License Agreement with Editas Medicine, Inc.

In May 2018, we entered into a license agreement with Editas pursuant to which we received an exclusive (even as to Editas), royalty-bearing, sublicensable, worldwide license under certain patent rights owned or controlled by Editas related to certain base editing technologies and CRISPR technology to develop, commercialize, make, have made, use, offer for sale, sell and import base editing products for the treatment of human diseases or conditions. We refer to this license agreement as the Editas License Agreement. The license we received is non-exclusive with respect to certain specified targets. Our licensed field excludes the treatment of certain diseases and certain fields of use that have already been licensed to other partners of Editas, provided that our licensed field may expand if the fields licensed to other Editas partners are reduced or are otherwise modified as a result of any termination, expiration, or amendment to Editas’ agreements with such partners. In addition, we received a royalty-free, non-sublicensable, non-exclusive license under a separate set of patent rights owned or controlled by Editas to conduct research activities in our licensed field and for which we have an option to obtain an exclusive license from Editas.
Certain of the patents licensed to us under the Editas License Agreement were licensed to Editas from Broad Institute and Harvard and certain of the patents for which we have an option to obtain a license were licensed to Editas from the Massachusetts General Hospital, or MGH. Accordingly, the licenses granted to us under the Editas License Agreement are subject to the terms and conditions set forth in each of the license agreements concerning the licensed patents between Broad Institute, Harvard and Editas, or the Broad/Harvard Head Licenses, and each of the license agreements concerning the patents for which we have an option to obtain a license between MGH and Editas, or the MGH Head Licenses.

As described above, Editas granted us an exclusive option to obtain an exclusive license under certain patents on a patent family-by-patent family basis. If we so exercise the option with respect to a patent family of such optioned patents, then we would receive an exclusive license to such patent family of the same scope as the other patents exclusively licensed to us under the Editas License Agreement. In order to exercise an option with respect to a patent family of these optioned patents we would pay an eight-figure option exercise fee, depending on the date in which particular option is exercised.

Under the Editas License Agreement, we are required to use commercially reasonable efforts to develop a licensed product in our licensed field in each of the United States, Japan, the United Kingdom, or U.K., Germany, France, Italy and Spain, including filing the first IND for a licensed product within a certain period of time following the execution of the Editas License Agreement. If we are successfully able to gain regulatory approval in any country for a licensed product, then we are also required to use commercially reasonable efforts to commercialize such licensed product in such country. We also have sole control and responsibility over all regulatory activities with respect to the development of licensed products.

We are permitted to further sublicense certain of our rights under the Editas License Agreement to third parties, provided that any such sublicense agreement with a third party must remain in compliance with and be consistent with the terms of the Editas License Agreement and the Broad/Harvard Head Licenses and MGH Head Licenses, as applicable. We are also responsible for any breaches of a sublicense agreement by the applicable sublicensee and are responsible for all payments due under the Editas License Agreement by operation of any such sublicense. Following the signing of the Editas License Agreement, we obtained the right to further sublicense our rights under the licensed patents from Broad Institute and Harvard to third parties, provided that we comply with certain sublicensing requirements under each of the Broad/Harvard Head Licenses as if we were Editas, as well as certain other customary conditions. We have not obtained any such right from MGH allowing us to further sublicense our rights under the licensed patents from MGH to third parties and will require written consent in the event we wish to further sublicense such rights to a third party.

Upon the execution of the Editas License Agreement, we paid Editas an upfront fee of $180,000. We also issued to Editas 1,833,333 shares of our Series A-1 Preferred Stock and 1,222,222 shares of our Series A-2 Preferred Stock. In addition, if any of our commercial, regulatory, development or sales activities with respect to the licensed products triggers a milestone payment or sublicense income that Editas owes under the Broad/Harvard Head Licenses or the MGH Head Licenses, then we are required to pay Editas the full amount of such milestone payment or sublicense income, as applicable; provided that we will not pay Editas for any sublicense income due as a result of the upfront fee we paid to Editas, our issuance of Series A-1 Preferred Stock and Series A-2 Preferred Stock to Editas, or our payment of any option exercise fee to Editas. Aggregate milestone amounts under the Editas License Agreement could equal up to $86.8 million for each product developed and commercialized using rights related to certain base editing technologies and CRISPR technology; in the event we develop and commercialize products covered by claims from the additional patent families licensed or optioned to us under the Editas License Agreement, aggregate milestone payments could equal up to $74.0 million per product. The percentage of sublicense income we would owe under the Editas License Agreement ranges from none to amounts between 10% and 20%. In addition, we agreed to pay for a portion of the annual license maintenance fees and prosecution and maintenance costs that Editas incurs itself or owes under the Broad /Harvard Head Licenses and the MGH Head Licenses with respect to the licensed patents. The upfront fee, equity issuance, and option exercise payments we make to Editas under the Editas License Agreement constitute both consideration for the licenses granted to us under the Editas License Agreement and reimbursement for prosecution and maintenance costs for the licensed patents.

With respect to the sale of licensed products by us, our affiliates or our sublicensees, we are required to pay to Editas an amount equal to the royalty rates that it owes to Broad Institute, Harvard, or MGH under its applicable in-licenses, plus an additional low- to mid-single digit royalty on net sales of licensed products, depending on whether such licensed product is covered by an Editas-owned patent and based on the aggregate worldwide net sales of licensed products in a given calendar year. We are entitled to certain reductions and offsets on these royalties with respect to a licensed product in a given country and if Editas is entitled to receive any reductions or offsets in respect to its royalty payment obligations under the relevant Broad/Harvard Head Licenses or MGH Head Licenses, then Editas will use reasonable efforts to avail itself of such reductions, which in turn would reduce our royalty payment obligations under the Editas License Agreement. The royalty term expires on licensed product-by-licensed product and country-by-country basis upon the later of (i) the last-to-expire royalty term in such country under any applicable Broad/Harvard Head License or MGH Head License, and, if such product is covered by a licensed Editas-owned patent, (ii) the date at which such product is no longer covered by a valid claim of a licensed Editas-owned patent in such country.

Editas is responsible for the prosecution and maintenance of all licensed patents, provided that we have certain information, comment, and review rights for certain of the licensed patents.
Unless earlier terminated, the Editas License Agreement will expire on a licensed product-by-licensed product and country-by-country basis on the expiration of the applicable royalty term with respect to such licensed product in such country. We may terminate the Editas License Agreement following written notice to Editas. Either party may terminate the Editas License Agreement for a material breach of the other party, subject to a notice and cure period. Editas may also terminate the Editas License Agreement if we challenge the validity of any of the licensed patents, subject to customary carveouts. Upon expiration or termination of the Editas License Agreement in its entirety or with respect to a family of patents, the licenses granted to us will immediately terminate in its entirety or solely with respect to the expired or terminated patent family, as the case may be; however, if we have the right to terminate the Editas License Agreement due to Editas’ material breach of the Editas License Agreement, then in lieu of so terminating the Editas License Agreement, we can elect to reduce our royalty payment obligations under the Editas License Agreement by certain specified percentages.

License Agreement with The Broad Institute, Inc.

In May 2018, our affiliate, Blink Therapeutics Inc., or Blink, entered into a license agreement, as amended, with Broad Institute. Under the Broad License Agreement, Blink is granted certain rights to RNA base editing technology, including the RNA editor platforms RESCUE™ and REPAIR™, which use Cas13 linked to a deaminase to deliver single base A-to-I or C-to-U editing of RNA transcripts, respectively, as well as the Cas12b nuclease family of gene editing enzymes.

More specifically, under the Broad License Agreement, Broad Institute granted Blink an exclusive license under certain patent rights to the extent owned or controlled by Broad Institute (including via an interinstitutional agreement with the Massachusetts Institute of Technology, or MIT, and Harvard) comprising of (i) an exclusive license under certain patent rights claiming or disclosing novel CRISPR enzymes and systems (including those related to DNA cleaving) or systems, methods and compositions for targeted nucleic acid editing, in each case to exploit products covered by such patents, (ii) an exclusive license under certain product-specific patent rights claiming or disclosing novel CRISPR enzymes and systems, methods and compositions for targeted nucleic acid editing, in each case to exploit base editor products covered by such patents and (iii) an exclusive license under certain patent rights generally related to gene targeting to exploit base editor products covered by such patents.

Under the Broad License Agreement, Blink has also been granted (i) a non-exclusive license under all patents exclusively licensed to Blink under the Broad License Agreement to exploit certain products in our field that were made, discovered, developed or determined to have utility through the use of such patents in a research or discovery program commencing before May 2021 or through the use of transferred materials from Broad Institute but that are not covered by the licensed patents and (ii) a non-exclusive internal research license under all patents exclusively licensed to Blink. All licenses granted to Blink by Broad Institute exclude human germline modification, the stimulation of biased inheritance of particular genes or, with certain exceptions, traits within a plant or animal population and certain modifications of the tobacco plant and are subject to certain retained rights of Broad Institute, Harvard and MIT and the U.S. federal government. Broad Institute additionally retains limited rights for itself, Harvard and MIT and for other non-profit research organizations to practice the licensed patents for research, educational, and scholarly purposes.

Under the Broad License Agreement, Blink is required to use commercially reasonable efforts to develop licensed products in accordance with a development plan that Blink prepared and submitted to Broad Institute. The development plan includes certain development milestones that Blink is required to meet, as well as the timelines for the completion thereof, and Blink may update the development plan from time to time if Blink believes, in its good faith judgment, that such update is needed in order to improve Blink’s ability to meet such development milestones. Blink will not be able to delay such development milestone timelines without providing a reasonable explanation and plan to Broad Institute and provided further that Broad Institute’s approval of the explanation and plan in its reasonable discretion is required for any milestone timeline extension of more than a specified number of years. If Blink is successfully able to gain regulatory approval in any country to introduce a licensed product into the commercial market in such country, then Blink is also required to use commercially reasonable efforts to commercialize such licensed product and make such licensed product reasonably available to the public.

Additionally, Blink is required to use commercially reasonable efforts to pursue the viability of the technology covered, claimed or disclosed in certain sub-categories of licensed patents and must initiate a discovery program for the development of a licensed product covered by a valid claim, or otherwise generally enabled, by the use of such sub-category of the licensed patents during a certain period of time following the execution of the Broad License Agreement and submit an updated development plan and development milestones reasonably acceptable to Broad Institute for such sub-category of the licensed patents within such period of time. If Blink fails to use commercially reasonable efforts to pursue the viability of such technology or to initiate a discovery program or to submit an updated development plan in the specified time period then the license under such sub-category of the licensed patents will terminate and, if such sub-category of the licensed patents consists of base editor patent rights, Blink’s rights with respect to gene targeting licensed patents shall convert to non-exclusive so that such rights may be licensed for use to such terminated base editor licensed patents.

Broad Institute, MIT, and Harvard also retain the right to grant further licenses under specified circumstances to third parties, other than specified entities, that wish to research, develop, and commercialize a product that would otherwise fall within the scope of our exclusive license grant from Broad Institute and Harvard pursuant to Broad Institute, Harvard and MIT’s inclusive innovation model.
If, after a specified period of time, such a third party inquires with Broad Institute for such a license and presents to Broad Institute a proposal including information describing the proposed development and commercialization of such a proposed product, then Broad Institute may notify Blink of the request and requestor, and the nature of the specific proposed product. Broad Institute is not required to share any other information provided by the requestor to Blink in connection with the inclusive innovation model. If Blink is not researching, developing or commercializing such a product, then Blink can notify Broad Institute as to whether in good faith it is interested in developing such proposed product, entering into a sublicense agreement with such requesting third party to develop such proposed product, or entering into a sublicense with another third party to develop such proposed product. If Blink informs Broad Institute that it is interested in developing such proposed product, then Blink will prepare a development plan, similar in scope to the development plan under the Broad License Agreement, to develop such proposed product and must commence the development program for such proposed product within a specified period. If Blink informs Broad Institute that it is interested in entering into a sublicense agreement pursuant to which the inquiring third party or another third party would receive a sublicense from Blink under the licensed patents to develop such proposed product, then Blink may enter into such a sublicense agreement and provide reasonable evidence thereof during the period. If Blink declines to conduct the foregoing activities or does not complete such activities within the specified period, which period is reduced by the period of time the requesting third party has previously negotiated with Blink, then Broad Institute may grant a license to the applicable third party under the licensed patents to research, develop, and commercialize such proposed product.

Blink is permitted to sublicense the licensed patents to affiliates and third parties, provided that any such sublicense agreement must remain in compliance with and be consistent with the terms of the Broad License Agreement. In addition, any such sublicense agreement must include certain customary provisions to ensure Blink’s ability to comply with the Broad License Agreement. Blink is also responsible for any breaches of a sublicense agreement by the applicable sublicensee and is responsible for all payments due under the Broad License Agreement by operation of any such sublicense.

As partial consideration for the rights granted under the Broad License Agreement, Broad Institute received 1,940,000 shares of Blink’s common stock. The shares issued to Broad Institute were exchanged into 865,240 shares of our common stock in connection with our acquisition of Blink on September 25, 2018.

Under the Broad License Agreement, Blink is also required to pay Broad Institute an annual license maintenance fee ranging from the low- to mid-five figures to the low-six figures, depending on the particular calendar year. Broad Institute is also entitled to receive clinical and regulatory milestones totaling in the mid-to-high eight figure range. We paid Broad Institute a total of $9.0 million upon the completion of our Series A and Series B financings. Blink may additionally owe Broad Institute success payments ranging from $5.0 million to a maximum total of $105.0 million.

Blink is also required to pay royalties in the low single digits for products covered by the licensed patents with such royalty reduced by a certain percentage for products enabled by the licensed patents, but not covered by the licensed patents. The royalty rate payable by Blink is subject to customary reductions and offsets on these royalties with respect to a product in a given country. The royalty term for a product in a country will terminate on the later of the expiration of (i) the last to expire licensed patent covering the applicable product, (ii) the period of exclusivity associated with such product in such country or (iii) a certain period of time after the first commercial sale of such product in such country. If Blink sublicenses its rights to develop or commercialize a licensed product under the Broad License Agreement to a third party and receives non-royalty sublicense income, then Broad Institute is entitled to a percentage of such consideration, ranging from the high single digits to an amount between 10% and 20%, dependent on the development stage of products under the Broad License Agreement at the time of sublicense execution.

Broad Institute is responsible for the prosecution and maintenance of all licensed patents, provided that Blink has certain consultation, comment, and review rights with respect to such prosecution and maintenance activities of exclusively licensed patent rights.

Unless earlier terminated, the Broad License Agreement will remain in effect until the later of the last-to-expire valid claim of a licensed patent covering our licensed products or the end of the last to expire royalty term. Blink may terminate the Broad License Agreement for its convenience following written notice to Broad Institute. Either party may terminate the Broad License Agreement for a material breach of the other party, subject to a notice and cure period. Broad Institute may also terminate the Broad License Agreement in the event of Blink’s bankruptcy or insolvency, if Blink fails to procure and maintain insurance or if Blink, its affiliates or sublicensees bringing patent challenges relating to any licensed patents (subject to a cure period for Blink to terminate the sublicensees that has taken the applicable action).

**License Agreement with Bio Palette Co., Ltd.**

On March 27, 2019, we entered into a license agreement with Bio Palette Co., Ltd., or Bio Palette, pursuant to which we received an exclusive (even as to Bio Palette), sublicensable license under certain patent rights related to base editing owned or controlled by Bio Palette to exploit products for the treatment of human disease throughout the world, but excluding products in the microbiome field in Asia. We refer to this agreement as the Bio Palette License Agreement. In addition, we granted Bio Palette an exclusive (even as to Beam) license under certain patent rights related to base editing and gene editing owned or controlled by Beam to exploit products in the microbiome field in Asia. Each party to the agreement retains non-exclusive rights to develop and manufacture products in the...
microbiome field worldwide for the sole purpose of exploiting those products in its own territory. Each party agrees to certain coordination obligations in the microbiome field in the event that either party determines not to exploit their rights in such field.

If Bio Palette comes into the control of any other patent right that is useful within a certain defined field and intends to grant a license under that patent right in certain defined fields in certain defined territories, we have the exclusive right of first negotiation for an exclusive license under that patent right in those fields and territories. If we come into the control of any other patent right that is useful in certain defined fields and intend to grant a license under that patent right in those fields in certain defined territories, Bio Palette has the exclusive right of first negotiation for an exclusive license under that patent right in those fields and territories.

As part of the agreement, if we form a Scientific Advisory Board, then Bio Palette will have the right to appoint two representatives to such board for a period of five years. Additionally, we and Bio Palette agree to communicate with each other regarding potential base editing collaborations in Japan.

We are required to use commercially reasonable efforts to develop a licensed product in the United States, Japan, the U.K., France, Germany, Italy and Spain. For any licensed product in our licensed field and territory that receives regulatory approval, we are required to use commercially reasonable efforts to commercialize that licensed product in the relevant country. Bio Palette is required to use commercially reasonable efforts to develop a licensed product in Japan. For any licensed product in the microbiome field in Asia that receives regulatory approval, Bio Palette is required to use commercially reasonable efforts to commercialize such licensed product in the relevant country.

Certain of the patents licensed to us under the Bio Palette License Agreement were licensed to Bio Palette from Kobe University under a license agreement we refer to as the Kobe Head License. Accordingly, the licenses granted to us under the Bio Palette License Agreement are subject to the terms and conditions set forth in the Kobe Head License, which include provisions providing for certain rights to be retained by third parties including governmental authorities.

We and Bio Palette are both permitted to sublicense the licensed patents to affiliates and third parties, provided that the applicable terms of the Bio Palette License Agreement and the applicable head licenses would apply to such affiliates and third parties. The sublicensing party is also responsible for any breaches of such terms by the applicable sublicensee and is responsible for all payments due under the Bio Palette License Agreement by operation of any such sublicense.

Upon the execution of the Bio Palette License Agreement, we paid Bio Palette an upfront fee of $0.5 million. In connection with the execution of the Bio Palette License Agreement, we issued to Bio Palette 16,725 shares of our common stock, with an agreement to issue additional shares of our common stock in the low six figures in the event that the referenced Bio Palette patent issues in the United States. Upon the issuance of a certain Bio Palette patent in the United States in June 2020, we made a milestone payment of $2.0 million and, in July 2020, issued to Bio Palette 175,000 shares of our common stock valued at $0.3 million. We also agreed to pay a royalty at a fraction of a percent on net sales of products that are covered by the patents licensed by Bio Palette to us, and Bio Palette agreed to pay a royalty at a fraction of a percent on net sales of products that are covered by the patents licensed by us to Bio Palette. The royalty term for a product in a country will terminate on the later of the expiration of (i) patent-based exclusivity with respect to such licensed product in such country or (ii) regulatory exclusivity with respect to such licensed product in such country.

Any intellectual property arising out of activities under the Bio Palette License Agreement will be owned by the party inventing such intellectual property. Bio Palette is responsible for the prosecution and maintenance of all patents licensed by Bio Palette to us, provided that we have customary consultation, comment and review rights with respect to such prosecution and maintenance activities solely with respect to national entries of a certain specified PCT application. We are responsible for the prosecution and maintenance of patents licensed by us to Bio Palette.

Unless earlier terminated, the Bio Palette License Agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the expiration of the applicable royalty term for each such licensed product and country. Each party has the right to terminate the Bio Palette License Agreement for convenience with respect to the license granted to such party subject to a specified notice period. Either party may terminate the Bio Palette License Agreement with respect to the license granted to the other party for a material breach by the other party, subject to a specified notice and cure period. Additionally, either party may also terminate the Bio Palette License Agreement in the event of the other party’s bankruptcy or insolvency or if the other party, its affiliates or sublicensees brings a patent challenge relating to any licensed patents (but, in the case of such a patent challenge by a sublicensee, subject to a cure period for such party to terminate its agreement with the sublicensee that has taken the applicable action).

**Government regulation**

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the EU, extensively regulate, among other things, the research, development, testing, manufacturing, packaging, labeling, storage, record keeping, reimbursement, advertising, promotion, distribution, post-approval monitoring and reporting and import and export, pricing and reimbursement of pharmaceutical products, including biological products. Failure to comply with the applicable regulatory requirements at any time during the product development process or post-approval may subject an applicant for marketing approval to delays in development or approval, as well as administrative and judicial sanctions.
The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions and compliance with applicable statutes and regulatory requirements, both pre- and post-approval, and obtaining reimbursement status will continue to require the expenditure of substantial time and financial resources. The regulatory requirements applicable to drug and biological product development, approval, and marketing are subject to change, and regulations and administrative guidance often are revised or reinterpreted by the agencies in ways that may have a significant impact on our business. Ethical, social and legal concerns about gene therapy, genetic testing and genetic research could result in additional regulations restricting or prohibiting the processes we may use. We cannot predict whether legislative changes will be enacted or if regulatory authorities’ guidance or interpretations will change.

Licensure and regulation of biologics in the United States

In the United States, our candidate products are regulated as biological products, or biologics, under the Public Health Service Act, or the PHSA, and the Federal Food, Drug and Cosmetic Act, or the FDCA, the implementing regulations of the FDA and other federal, state and local statutes and regulations.

An applicant seeking approval to market and distribute a new biologic in the United States generally must satisfactorily complete each of the following steps:

• preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
• submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
• approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
• performance of adequate and well-controlled human clinical trials to establish the safety, potency, and purity of the product candidate for each proposed indication, in accordance with current Good Clinical Practices, or GCP;
• preparation and submission to the FDA of a Biologics License Application, or BLA, requesting marketing of the biological product for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product and proposed labelling;
• review of the BLA by an FDA advisory committee, where applicable;
• satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements; to assure that the facilities, methods, and controls are adequate to preserve the product’s identity, strength, quality, and purity; and, if applicable, the FDA's current good tissue practice, or cGTP, requirements for the use of human cellular and tissue products;
• satisfactory completion of any FDA audits of the non-clinical and clinical trial sites to assure compliance with GLPs and GCPs and the integrity of clinical data in support of the BLA;
• payment of the application fee under the Prescription Drug User Fee Act, or PDUFA, unless exempted; and
• FDA review and approval of the BLA, which may be subject to additional post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and any post-approval studies required by the FDA.

Preclinical studies and investigational new drug application

Before testing any investigational biological product in humans, including a gene editing product candidate, the product candidate must undergo preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate the potential for efficacy and toxicity in animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements, including applicable Good Laboratory Practices requirements. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application.

An IND is an exemption from the FDCA that allows an unapproved drug or biological product to be shipped in interstate commerce for use in an investigational clinical trial. The IND seeks FDA authorization to test the drug or biological product candidate in humans and automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trials can begin. Preclinical or nonclinical testing typically continues even after the IND is submitted.
FDA may, at any time during the initial 30-day IND review period or while clinical trials are ongoing under the IND, impose a partial or complete clinical hold based on concerns for patient safety and/or noncompliance with regulatory requirements. This order issued by the FDA would delay a proposed clinical study or cause suspension of an ongoing study until all outstanding concerns have been adequately addressed, and the FDA has notified the company that investigations may proceed. Imposition of a clinical hold could cause significant delays or difficulties in completing planned clinical studies in a timely manner.

**Expanded access to an investigational drug for treatment use**

Expanded access, sometimes called “compassionate use,” is the use of investigational products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. FDA regulations allow access to investigational products under an IND by the company or the treating physician for treatment purposes on a case-by-case basis for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the investigational product under a treatment protocol or treatment IND application.

There is no requirement for a manufacturer to provide expanded access to an investigational product. However, if a manufacturer decides to make its investigational product available for expanded access, FDA reviews requests for expanded access and determines if treatment may proceed. Expanded access may be appropriate when all of the following criteria apply: patient(s) have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated; and the expanded use of the investigational drug for the requested treatment will not interfere with initiation, conduct, or completion of clinical investigations that could support marketing approval of the product or otherwise compromise the potential development of the product.

Under the FDCA, sponsors of one or more investigational products for the treatment of a serious disease(s) or condition(s) must make publicly available their policy for evaluating and responding to requests for expanded access for individual patients. Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 study; or 15 days after the investigational drug or biologic receives designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

In addition, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides an additional mechanism for patients with a life-threatening condition who have exhausted approved treatments and are unable to participate in clinical trials to access certain investigational products that have completed a Phase I clinical trial, are the subject of an active IND, and are undergoing investigation for FDA approval. Unlike the expanded access framework described above, the Right to Try Pathway does not require FDA to review or approve requests for use of the investigational product. There is no obligation for a manufacturer to make its investigational products available to eligible patients under the Right to Try Act.

**Human clinical trials in support of a BLA**

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of qualified principal investigators, generally physicians not employed by or under the trial sponsor’s control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation. Clinical trials are conducted under study protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. When a foreign clinical trial is not conducted under an IND, the sponsor must ensure that the trial complies with certain FDA regulatory requirements in order to use the trial as support for an IND or application for marketing approval in the U.S. Specifically, the FDA requires that such trials be conducted in accordance with GCP requirements intended to ensure the protection of human subjects and the quality and integrity of the study data, including requirements for review and approval by an independent ethics committee and obtaining subjects’ informed consent.

For clinical trials conducted in the United States, an IND is required, and each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, the safety of human subjects, and the possible liability of the institution. An IRB must operate in compliance with FDA regulations. Clinical trials must also comply with extensive GCP rules and the requirements for obtaining subjects’ informed consent. The FDA, IRB, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements, including GCP, or the subjects or patients are being exposed to an unacceptable health risk.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group may recommend continuation of the study as planned, changes in
study conduct, or cessation of the study at designated checkpoints based on access to certain data from the study. Finally, research activities involving infectious agents, hazardous chemicals, recombinant DNA, and genetically altered organisms and agents may be subject to review and approval of an Institutional Biosafety Committee, or IBC, in accordance with NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- **Phase 1** clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion, and pharmacodynamics in healthy humans or, on occasion, in the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, in patients, such as cancer patients.

- **Phase 2** clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials.

- **Phase 3** clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Clinical trials are undertaken within an expanded patient population at multiple geographically dispersed clinical study sites to further evaluate dosage, provide substantial evidence of clinical efficacy, and further test for safety. A well-controlled, statistically robust Phase 3 trial may be designed to deliver the data that regulatory authorities will use to decide whether or not to approve, and, if approved, how to appropriately label a biologic; such Phase 3 studies are referred to as “pivotal.”

In some cases, the FDA may approve a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate’s safety or effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products. The FDA generally recommends that sponsors observe subjects for potential gene-therapy related delayed adverse events in a long-term follow-up study of fifteen years for integrating vectors, up to fifteen years for herpes virus vectors capable of establishing latency, up to fifteen years for microbial vectors known to establish persistent infection, up to fifteen years for genome editing products, and up to five years for AAV vectors. FDA recommends that these long-term follow-up studies include, at a minimum, five years of annual physical examinations followed by annual queries, either in-person or by phone or written questionnaire, for the remaining observation period.

Under the Pediatric Research Equity Act of 2003, or PREA, a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product 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. Sponsors must submit a pediatric study plan to FDA outlining the proposed pediatric study or studies they plan to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The FDA may then review the information submitted, consult with the sponsor, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

For products intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of an applicant, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments. In addition, FDA will meet early in the development process to discuss pediatric study plans with sponsors and FDA must meet with sponsors by no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than 90 days after FDA’s receipt of the study plan. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements, under specified circumstances. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on its ClinicalTrials.gov website. Similar requirements for posting clinical trial information in clinical trial registries exist in the EU and in other countries outside the United States.

**Special regulations and guidance governing gene therapy products**

It is possible that the procedures and standards applied to gene therapy products and cell therapy products may be applied to any CRISPR/Cas9 product candidates we may develop, but that remains uncertain at this point. The FDA has defined a gene therapy product as one that mediates its effects by transcription and/or translation of transferred genetic material and/or by integrating into the host genome and which are administered as nucleic acids, viruses, or genetically engineered microorganisms. The products may be used to modify cells in vivo or be transferred to cells ex vivo prior to administration to the recipient. The Center for Biologics
Compliance with cGMP and cGTP requirements

Before approving a BLA, 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 full compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The PHSA emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined. Material changes in manufacturing equipment, location, or process post-approval, may result in additional regulatory review and approval.

For a gene therapy product, the FDA also will not approve the product if the manufacturer is not in compliance with cGTP. These standards are found in FDA regulations and guidance documents that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission, and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing.

Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Any product manufactured by or imported from a facility that has not registered, whether foreign or domestic, is deemed misbranded under the FDCA. The manufacturing facilities may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. If a manufacturing facility is not in substantial compliance with the applicable regulations and requirements imposed when the product was approved, regulatory enforcement action may be taken, which may include a warning letter or an injunction against shipment of products from the facility and/or recall of products previously shipped.

Review and approval of a BLA

The results of product candidate development, preclinical testing, and clinical trials, along with descriptions of the manufacturing process, information on the chemistry, manufacturing, and controls, or CMC, information that should be included in an IND application; the proper design of tests to measure product potency in support of an IND or BLA application; measures to observe delayed adverse effects in subjects who have been exposed to investigational gene therapies; and gene therapy products for the treatment of rare diseases. Further, the FDA usually recommends that sponsors observe subjects for potential gene therapy-related delayed adverse events for a 15-year period, including a minimum of five years of annual examinations followed by 10 years of annual queries, either in person or by questionnaire.

If a gene therapy trial is conducted at, or sponsored by, institutions receiving any NIH funding for research involving recombinant or synthetic nucleic acid molecules, the trial must be conducted in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules. Research conducted at such institutions that involves the transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into human subjects must undergo review and approval by an IBC before it commences. Many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether it is sufficiently complete to permit substantive review. Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from filing in which to complete its initial review of a standard application and respond to the applicant, and six months for a priority review application. A major amendment to a BLA submitted at any time during the review cycle, including in response to a request from the FDA, may extend the goal date by three months. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs.
During its review of a BLA, the FDA may refer the application to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved and under what conditions. In particular, the FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions about a BLA.

Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure, and potent and that the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure, and potent.

On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of non-clinical and clinical trial sites to assure compliance with GCP, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific labeling for specific indications. If the application is not approved, the FDA will issue a complete response letter, which will contain the conditions that must be met in order to secure approval of the application, and when possible will outline recommended actions the sponsor might take to obtain approval of the application. Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the issues identified by the FDA. Such resubmissions are classified under PDUFA as either Class 1 or Class 2. The classification of a resubmission is based on the information submitted by an applicant in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has two months to review a Class 1 resubmission and six months to review a Class 2 resubmission. The FDA will not approve an application until issues identified in the complete response letter have been addressed.

If the FDA approves a new product, it may limit the approved indications for use of the product. It may also require that contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including Phase 4 clinical trials, to further assess the product’s safety or efficacy after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many 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.

**Fast track, breakthrough therapy, priority review and regenerative advanced therapy designations**

The FDA has several programs designed to expedite the development and approval of drugs and biological products intended to treat serious or life-threatening diseases or conditions. These programs include fast track designation, breakthrough therapy designation, priority review designation, and regenerative medicine advanced therapy (RMAT) designation. These designations are not mutually exclusive, and a product candidate may qualify for one or more of these programs. While these programs are intended to expedite product development and approval, they do not alter the standards for FDA approval.

The FDA may grant a product fast track designation if it is intended for the treatment of a serious or life-threatening disease or condition, and nonclinical or clinical data demonstrate the potential to address an unmet medical need for such disease or condition. For fast track products, sponsors may have greater interactions with the FDA, and the FDA may initiate review of sections of a fast track product’s marketing application before the application is complete in some circumstances. Fast track designation may be rescinded if FDA believes that the product no longer meets the qualifying criteria.

A product may be designated as a breakthrough therapy if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to aid sponsors in designing the clinical trials in an efficient manner. Breakthrough designation may be rescinded if a product no longer meets the qualifying criteria.

With passage of the 21st Century Cures Act in December 2016, Congress authorized an additional expedited program for regenerative medicine advanced therapies. A product is eligible for RMAT designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such disease or condition. The benefits of RMAT designation include the benefits available to breakthrough therapies, including potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints. RMAT designation may be rescinded if a product no longer meets the qualifying criteria.
FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of such condition. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and it shortens the FDA's goal for taking action on a marketing application from ten months to six months.

**Accelerated approval pathway**

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

For drugs granted accelerated approval, FDA generally requires sponsors to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product’s clinical benefit. Failure to conduct required post-approval studies with due diligence, failure to confirm a clinical benefit during the post-approval studies, or dissemination of false or misleading promotional materials would allow the FDA to withdraw the product approval on an expedited basis. All promotional materials for product candidates approved under accelerated approval are subject to prior review by the FDA unless FDA informs the applicant otherwise.

**Post-approval regulation**

Upon FDA approval of a BLA, the sponsor must comply with extensive post-approval regulatory requirements applicable to biological products, including any additional post-approval requirements that the FDA may impose as part of the approval process. These post-approval requirements include, among other things:

- record keeping requirements;
- reporting of certain adverse experiences with the product and production problems to the FDA;
- submission of updated safety and efficacy information to the FDA;
- drug sampling and distribution requirements;
- notifying FDA and gaining its approval of specified manufacturing and labeling changes; and
- compliance with requirements concerning advertising, promotional labeling, industry-sponsored scientific and educational activities and other promotional activities.

Additionally, the sponsor and its third-party manufacturers are subject to periodic unannounced regulatory inspections for compliance with ongoing regulatory requirements, including cGMP and pharmacovigilance regulations. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

The FDA strictly regulates the advertising and labeling of prescription drug products, including biological products. Promotional claims about a drug’s safety or effectiveness are prohibited before the drug is approved. In addition, the sponsor of an approved drug in the United States may not promote that drug for unapproved, or off-label, uses, although a physician may prescribe a drug for an off-label use in accordance with the practice of medicine. If a company is found to have promoted off-label uses, it may become subject to administrative and judicial enforcement by the FDA, the DOJ, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

After approval, some types of changes to the approved product, such as adding new indications or dosing regimens, manufacturing changes, or additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.
The FDA may withdraw product approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency or issues with manufacturing processes, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety signals; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product recall, seizure, or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

**Orphan drug designation**

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for the treatment of rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for certain tax credits. In addition, if a drug candidate that has orphan drug designation subsequently receives the first FDA approval for that drug 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 to market the same drug for the same indication for seven years following product approval unless the subsequent product candidate is demonstrated to be clinically superior. Absent a showing of clinical superiority, FDA cannot approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor or the sponsor is unable to provide sufficient quantities.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first drug. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation. To qualify for orphan exclusivity, however, the drug must be clinically superior to the previously approved product that is the same drug for the same condition.

Gene therapy products present novel issues for assessing when two products are the “same” for orphan exclusivity purposes. On January 28, 2020, the FDA issued a non-binding draft guidance document describing its current thinking on when a gene therapy product is the “same” as another product for purposes of orphan exclusivity. Under the draft guidance, if either the transgene or vector differs between two gene therapy products in a manner that does not reflect “minor” differences, the two products would be considered different drugs for orphan drug exclusivity purposes. FDA will determine whether two vectors from the same viral class are the same on a case-by-case basis and may consider additional key features in assessing sameness. While the guidance provides some additional clarity on FDA’s approach to assessing “sameness,” significant ambiguity and uncertainty remain as to how FDA will assess viral vectors in the same class, what differences in vector or transgene are considered minor, and what additional features may be considered.

**Pediatric exclusivity**

Pediatric exclusivity is another type of non-patent regulatory exclusivity in the United States. Specifically, the Best Pharmaceuticals for Children Act provides for the attachment of an additional six months of exclusivity, which is added on to the term of any remaining regulatory exclusivity or patent periods at the time the pediatric exclusivity is granted. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data, even if the data do not show the product to be effective in the pediatric population studied.

**Biosimilars and exclusivity**

The 2010 Patient Protection and Affordable Care Act, or PPACA, which was signed into law in March 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA. The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars.
Under the BPCIA, a manufacturer may submit an application for licensure of a biological product that is “biosimilar to” or “interchangeable with” a previously approved biological product or “reference product.” In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was first licensed. This 12-year exclusivity period is referred to as the reference product exclusivity period and bars approval of a biosimilar but notably does not prevent approval of a competing product pursuant to a full BLA (i.e., containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the product). The BPCA also created certain exclusivity periods for biosimilars approved as interchangeable products. The law also includes an extensive process for the innovator biologic and biosimilar manufacturer to litigate patent infringement, validity, and enforceability prior to the approval of the biosimilar.

There have been ongoing federal legislative and administrative efforts as well as judicial challenges seeking to repeal, modify or invalidate some or all of the provisions of the PPACA. While none of those efforts have focused on changes to the provisions of the ACA related to the biosimilar regulatory framework, if those efforts continue and if the ACA is repealed, substantially modified, or invalidated, it is unclear what, if any, impact such action would have on biosimilar regulation.

**Patent term restoration and extension**

A patent claiming a new biological product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for a single patent for an approved product as compensation for patent term lost during product development and FDA regulatory review. The restoration period granted on a patent covering a product is typically one-half the time between the effective date a clinical investigation involving human beings is begun and the submission date of a marketing application less any time during which the applicant failed to exercise due diligence, plus the time between the submission date of an application and the ultimate approval date less any time during which the applicant failed to exercise due diligence. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product’s approval date. Only one patent applicable to an approved product is eligible for the extension, only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended and 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.

**FDA approval of companion diagnostics**

In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and in vitro companion diagnostics. According to the guidance, for novel drugs, a companion diagnostic device and its corresponding therapeutic should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product’s labeling. Approval or clearance of the companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population. In July 2016, the FDA issued a draft guidance intended to assist sponsors of the drug therapeutic and in vitro companion diagnostic device on issues related to co-development of the products.

Under the FDCA, in vitro diagnostics, including companion diagnostics, are regulated as medical devices. In the United States, the FDCA 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 applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution.

The FDA previously has required in vitro companion diagnostics intended to select the patients who will respond to the product candidate to obtain premarket approval, or PMA, simultaneously with approval of the therapeutic product candidate. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device’s safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee, which exceeds $250,000 for most PMAs; for federal fiscal year 2021, the standard fee for review of a PMA is $365,657 and the small business fee is $91,414. A clinical trial is typically required for a PMA application and, in a small percentage of cases, the FDA may require a clinical study in support of a 510(k) submission. A manufacturer that wishes to conduct a clinical study involving the device is subject to the FDA’s IDE regulation. The IDE regulation distinguishes between significant and non-significant risk device studies and the procedures for...
obtaining approval to begin the study differ accordingly. Also, some types of studies are exempt from the IDE regulations. A significant risk device presents a potential for serious risk to the health, safety, or welfare of a subject. Significant risk devices are devices that are substantially important in diagnosing, curing, mitigating, or treating disease or in preventing impairment to human health. Studies of devices that pose a significant risk require both FDA and an IRB approval prior to initiation of a clinical study. Many companion diagnostics are considered significant risk devices due to their role in diagnosing a disease or condition. Non-significant risk devices are devices that do not pose a significant risk to the human subjects. A non-significant risk device study requires only IRB approval prior to initiation of a clinical study.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices 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. A medical device manufacturer’s manufacturing processes and those of its suppliers are required to comply with the applicable portions of the Quality System Regulation, which covers the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

California Consumer Privacy Act

In 2018, California passed into law the California Consumer Privacy Act (CCPA), which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of “sales” of their personal information. The CCPA contains significant penalties for companies that violate its requirements. It also provides California residents a private right of action, including the ability to seek statutory damages, in the event of a breach involving their personal information. Compliance with the CCPA is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance. On November 3, 2020, California voters passed a ballot initiative for the California Privacy Rights Act (CPRA), which will significantly expand the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA will also expand personal information rights of California residents, including creating a right to opt out of sharing of personal information with third parties for advertising, expanding the lookback period for the right to know about personal information held by businesses, and expanding the right to erasure for information held by third parties. Most CPRA provisions will take effect on January 1, 2023, though the obligations will apply to any personal information collected after January 1, 2022.

Regulation and procedures governing approval of medicinal products in the EU and the U.K.

In order to market any product outside of the United States, a company must also 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 products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the EU generally follows the same lines as in the United States. It entails satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product. The process also requires the submission to the relevant competent authorities of a marketing authorization application, or MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the EU.

Marketing authorization

To obtain a marketing authorization for a gene therapy product under the EU regulatory system, an applicant must submit an application via the centralized procedure administered by the European Medicines Agency (EMA). Specifically, the grant of marketing authorization in the EU for products containing viable human tissues or cells such as gene therapy medicinal products is governed by Regulation 1394/2007/EC on advanced therapy medicinal products, read in combination with Directive 2001/83/EC of the European Parliament and of the Council, commonly known as the Community code on medicinal products. Regulation 1394/2007/EC lays down specific rules concerning the authorization, supervision, and pharmacovigilance of gene therapy medicinal products, somatic cell therapy medicinal products, and tissue engineered products. Manufacturers of advanced therapy medicinal products must demonstrate the quality, safety, and efficacy of their products to the EMA’s Committee for Advance Therapies which provides a draft opinion regarding the application for marketing authorization and which is subject to final approval by the EMA’s Committee for Medicinal Products for Human Use. The European Commission grants or refuses marketing authorization in light of that final approval.

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Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

In the EU, new chemical entities approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity pursuant to Regulation (EC) No 726/2004, as amended, and Directive 2001/83/EC, as amended. Data exclusivity prevents regulatory authorities in the EU from referencing the innovator’s data to assess a generic (abbreviated) application for a period of eight years. This also applies to biosimilars. During the additional two-year period of market exclusivity, a generic marketing authorization application can be submitted, and the innovator’s data may be referenced, but no generic medicinal product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies. In addition, if a pediatric investigation plan is accepted, then a further year of market exclusivity might be obtained (or in the alternative a patent extension (SPC) of a further 6 months). For orphan medicinal products, the periods are separate and different in that there is a total of 10-year data exclusivity and if they have a PIP, there is a further two-year extension to that 10-year period. Even if a compound is considered to be a new chemical or biological entity so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

**Periods of authorization and renewals**

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the drug on the EU market (in the case of the centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

**Regulatory requirements after marketing authorization**

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the EU’s stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized products, must also be conducted in strict compliance with the EMA’s GMP requirements and comparable requirements of other regulatory bodies in the EU, which mandate the methods, facilities, and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. The marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the EU under Directive 2001/83/EC, as amended.

**Clinical trial approval**

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the EU has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of each EU member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the local competent ethics committee has issued a favorable opinion. In April 2014, the EU adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC six months after the clinical trial portal is announced by the European Commission to be ready for use. This new legislation, which will be directly applicable in all member states, aims at simplifying and streamlining the approval of clinical trials in the EU by allowing for a streamlined application procedure via a single-entry point and strictly defined deadlines for the assessment of clinical trial applications.

**Conditional marketing authorization**

For medicinal products where the benefit of immediate availability outweighs the risk of less comprehensive data than normally required, based on the scope and criteria defined in legislation and guidelines, it is possible to obtain from the EMA a conditional marketing authorization with a 12 month validity period and annual renewal pursuant to Regulation No 507/2006. These are granted only if the CHMP finds that all four requirements are met: (i) the benefit-risk balance of the product is positive; (ii) it is likely that the
applicants will be able to provide comprehensive data; (iii) unmet medical needs will be fulfilled; and (iv) the benefit to public health of the medicinal product’s immediate availability on the market outweighs the risks due to need for further data.

**PRIME designation in the EU**

The EU has a Priority Medicines, or PRIME, scheme that is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted.

**Orphan drug designation and exclusivity**

Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the EU when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the EU and that without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the EU or, if such method exists, the drug will be of significant benefit to those affected by that condition.

**Brexit and the regulatory framework in the U.K**

The withdrawal of the U.K. from the EU occurred on January 31, 2020, which is commonly known as “Brexit.” A “transition period” through December 31, 2020 has been established to allow the U.K. and EU to negotiate the terms of the U.K.’s withdrawal. Since the regulatory framework for pharmaceutical products in the U.K. relating to quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit will materially impact the future regulatory regime which applies to products and the approval of product candidates in the U.K. In the first instance, a separate U.K. authorization from any centralized authorization for the EU would need to be applied before the end of any agreed transition period. In the immediately foreseeable future, the process is likely to remain very similar to that applicable in the EU, albeit that the processes for applications will be separate. Longer term, the U.K. is likely to develop its own legislation that diverges from that in the EU.

**General data protection regulation**

The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the European Economic Area (EEA), and the processing of personal data that takes place in the EEA, is subject to the EU’s General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, and it imposes heightened requirements on companies that process health and other sensitive data, such as requiring in many situations that a company obtain the consent of the individuals to whom the sensitive personal data relate before processing such data. Examples of obligations imposed by the GDPR on companies processing personal data that fall within the scope of the GDPR include providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, appointing a data protection officer, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance. In July 2020, the Court of Justice of the European Union, or the CJEU, invalidated the EU-U.S. Privacy Shield framework, or Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the U.S. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the U.S. While we were not self-certified under the Privacy Shield, this CJEU decision may lead to increased scrutiny on data transfers from the EU to the U.S. generally and increase our costs of compliance with data privacy legislation. Following the withdrawal of the U.K. from the EU, the U.K. Data Protection Act 2018 applies to the processing of personal data that takes place in the U.K. and includes parallel obligations to those set forth by GDPR.

**Coverage, pricing, and reimbursement**

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may seek regulatory approval by the FDA or other government authorities. 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. Patients are unlikely to use any product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates. Sales of our products will depend, in significant part, on the availability of coverage and the adequacy of reimbursement from third-party payors.

Within the United States, third-party payors include government authorities or government healthcare programs, such as Medicare and Medicaid, and private entities, such as managed care organizations, private health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Some third-party payors may manage utilization of a particular product by requiring pre-approval (known as “prior authorization”) for coverage of particular prescriptions (to allow the payor to assess medical necessity). Moreover, a third-party payor’s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain net price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for drug products can differ significantly from payor to payor. One third-party payor’s decision to cover a particular drug product or service does not ensure that other payors will also provide coverage for the drug product or will provide coverage at an adequate reimbursement rate.

Third-party payors are increasingly challenging the price and examining the cost-effectiveness of new products and services in addition to their safety and efficacy. To obtain or maintain coverage and reimbursement for any current or future product, we may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our product. These studies will be in addition to the studies required to obtain regulatory approvals. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. Thus, obtaining and maintaining reimbursement status is time-consuming and costly.

As noted above, the marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and other third-party payors fail to provide coverage and adequate reimbursement. There is an emphasis on cost containment measures in the United States and we expect the pressure on pharmaceutical pricing will increase. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we receive regulatory approval from one or more third party payors, less favorable coverage policies and reimbursement rates may be implemented in the future.

If we obtain appropriate approval in the future to market any of our current product candidates in the United States, we may be required to provide discounts or rebates under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal healthcare programs such as Medicaid. Participation in such programs may require us to track and report certain drug prices. We may be subject to fines and other penalties if we fail to report such prices accurately.

Outside the United States, ensuring adequate coverage and payment for any product candidates we may develop will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of any product candidates we may develop to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts.

In the EU, pricing and reimbursement schemes vary widely from country to country because this is not yet the subject of harmonized EU law. Many countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval and others with “peg” their pricing to a basket of other countries. EU member states may approve a specific price for a product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Some member states, in addition to controlling pricing will monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the EU have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on health care costs is in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states, and parallel trade (arbitrage between low-priced and high-priced member states), can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries.

**Healthcare law and regulation**

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Arrangements with providers, consultants, third-party payors, and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, reporting of payments to healthcare providers and patient privacy...
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 to get a false claim paid;

• federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

• the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, in addition to privacy protections applicable to the federal Food, Drug, and Cosmetic Act, or the FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers analogous state and foreign laws and regulations, such as state anti-bribery, anti-kickback and false claims laws, which may apply to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

• the federal Food, Drug, and Cosmetic Act, or the FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;

• federal laws 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;

• the so-called “federal sunshine” law, which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to the Center for Medicare & Medicaid Services within the U.S. Department of Health and Human Services for re-disclosure to the public, as well as ownership and investment interests held by physicians and their immediate family members;

• state laws requiring pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to health care providers or marketing expenditures; and

• analogous state and foreign laws and regulations, such as state anti-bribery, anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Health care and other reform

In the United States, there have been and continue to be a number of significant legislative initiatives to contain healthcare costs. Federal and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, health care, which include initiatives to reduce the cost of healthcare. For example, in March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, or the Healthcare Reform Act, which expanded health care coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and which included changes to the coverage and reimbursement of drug products under government healthcare programs. Under the Trump administration, there were ongoing efforts to modify or repeal all or certain provisions of the Healthcare Reform Act. For example, tax reform legislation was enacted at the end of 2017 that eliminated the tax penalty established under Healthcare Reform Act for individuals who do not maintain mandated health insurance coverage beginning in 2019. The Healthcare Reform Act has been subject to judicial challenge. The case Texas v. Azar, which challenges the constitutionality of the Healthcare Reform Act, including provisions that are unrelated to healthcare reform but were enacted as part of the Healthcare Reform Act, was argued before the Supreme Court in November 2020. Pending resolution of the litigation, all of the Healthcare Reform Act but the individual mandate to buy health insurance remains in effect.

Beyond the Healthcare Reform Act, there have been ongoing health care reform efforts, including a number of recent actions. Some recent healthcare reform efforts have sought to address certain issues related to the COVID-19 pandemic, including an expansion of telehealth coverage under Medicare and accelerated or advanced Medicare payments to healthcare providers. Other reform efforts affect pricing or payment for drug products. For example, the Medicaid Drug Rebate Program has been subject to statutory and regulatory changes and the discount that manufacturers of Medicare Part D brand name drugs must provide to Medicare Part D beneficiaries during the coverage gap increased from 50% to 70%. A number of regulations were issued in late 2020 and early 2021. For example, revisions to regulations under the federal anti-kickback statute would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to PBMs and health plans. Some of these changes have been and may continue to be subject to legal challenge. For example, courts temporarily enjoined a new “most favored nation” payment model for select drugs covered under Medicare Part B that was to take effect on January 1, 2021 and would limit payment based on international drug price.

The nature and scope of health care reform in the wake of the transition from the Trump administration to the Biden administration remains uncertain. The Department of Justice under the Biden administration informed the Supreme Court that the government no
longer takes the position that the individual mandate is unconstitutional and cannot be severed from the rest of the Healthcare Reform Act. President Biden has temporarily halted implementation of new rules issued immediately prior to the transition that had not yet taken effect (which include a number of health care reforms) to allow for review by the new administration. The revisions to the federal anti-kickback statute regulations referenced above were initially scheduled to take effect in 2022 but have now been delayed to 2023. More generally, President Biden supported reforms to lower drug prices during his campaign for the presidency.

General legislative cost control measures may also affect reimbursement for our product candidates. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2030 (except May 1, 2020 to March 31, 2021) 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 changes to the Healthcare Reform Act or other 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.

Employees
As of December 31, 2020, we had 181 full-time employees. Of these full-time employees, 149 were engaged in research and development activities. None of our employees is represented by a labor union or covered by a collective bargaining agreement or represented by a trade or labor union.

Corporate Information
We were incorporated in Delaware in January 2017. Our principal executive offices are located at 26 Landsdowne Street, 2nd Floor, Cambridge, MA 02139, and our telephone number is 857-327-8775.

Available Information
Our website address is www.beamtx.com, and our investor relations website is located at investors.beamtx.com. Information on our website is not incorporated by reference herein. We will make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains an Internet site (http://www.sec.gov) containing reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.
Item 1A. Risk Factors.

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 appearing at the end of this Annual Report on Form 10-K, in evaluating our company. 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. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

Risks related to our financial position and need for additional capital

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

Since inception, we have incurred significant operating losses. Our net loss was $194.6 million and $78.3 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $397.6 million. We have financed our operations primarily through private placements of our preferred stock and proceeds from sales of our common stock. We have devoted all of our efforts to research and development. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if and as we:

• continue our current research programs and our preclinical development of product candidates from our current research programs;
• seek to identify additional research programs and additional product candidates;
• initiate preclinical testing and clinical trials for any product candidates we identify and develop;
• maintain, expand, enforce, defend and protect our intellectual property portfolio and provide reimbursement of third-party expenses related to our patent portfolio;
• seek marketing approvals for any of our product candidates that successfully complete clinical trials;
• establish a sales, marketing, and distribution infrastructure to commercialize any medicines for which we may obtain marketing approval;
• further develop our base editing platform;
• hire additional personnel, including research and development, clinical, and commercial personnel;
• add operational, financial, and management information systems and personnel, including personnel to support our product development;
• acquire or in-license products, intellectual property, medicines, and technologies;
• build and maintain a commercial-scale cGMP manufacturing facility; and
• continue to operate as a public company.

We have not initiated clinical development of any product candidate and expect that it will be many years, if ever, before we have a product candidate ready for commercialization. To become and remain profitable, we must develop and, either directly or through collaborators, eventually commercialize a medicine or medicines with significant market potential. This will require us to be successful in a range of challenging activities, including identifying product candidates, completing preclinical testing and clinical trials of product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing, and selling those medicines for which we may obtain marketing approval, and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. We are currently only in the preclinical testing stages for all of our research programs. Because of the numerous risks and uncertainties associated with developing base editing product candidates, 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. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations.
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, product candidates. In addition, if we obtain marketing approval for any product candidates we may develop, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution to the extent that such sales, marketing, manufacturing, and distribution are not the responsibility of a collaborator. Furthermore, since the closing of our IPO, we have incurred and expect to continue to incur additional costs associated with operating as a public company. 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.

At December 31, 2020, our cash, cash equivalents, and marketable securities were $299.7 million. In January 2021, we issued and sold 2,795,700 shares of our common stock in a private placement at an offering price of $93.00 per share for aggregate gross proceeds of $260.0 million. We received $252.1 million in net proceeds after deducting estimated offering expenses.

We believe that our existing cash, cash equivalents, and marketable securities will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. However, our operating plan may change as a result of factors currently unknown to us, and we may need to seek additional funding sooner than planned. Our future capital requirements will depend on many factors, including:

- the cost of continuing to build our base editing platform;
- the costs of acquiring licenses for the delivery modalities that will be used with our product candidates;
- the scope, progress, results, and costs of discovery, preclinical development, laboratory testing, manufacturing, and clinical trials for the product candidates we may develop;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights, and defending intellectual property-related claims;
- the costs, timing, and outcome of regulatory review of the product candidates we may develop;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, distribution, coverage and reimbursement for any product candidates for which we receive regulatory approval;
- the success of our license agreements and our collaborations;
- our ability to establish and maintain additional collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any additional collaboration agreements we obtain;
- the extent to which we acquire or in-license products, intellectual property and technologies;
- the costs of operating as a public company; and
- the costs of obtaining, building and expanding manufacturing capacity.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, even if we successfully identify and develop product candidates and those are approved, we may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of medicines that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and, 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. Our license agreements and any future collaboration agreements may also be terminated if we are unable to meet the payment or other obligations under the agreements. We could be required to seek collaborators for product candidates we may develop at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to product candidates we may develop in markets where we otherwise would seek to pursue development or commercialization ourselves.

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

**Raising additional capital may cause dilution to our stockholders restrict our operations or require us to relinquish rights to our technologies or product candidates we may develop.**

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, and possibly other restrictions.

If we raise funds through additional collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates we may develop, or we may have to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, we have and may in the future enter collaboration and acquisition agreements, pursuant to which we are required to issue additional shares of our common stock in connection with future milestone payment obligations. These and other future issuances to our partners and collaborators may cause substantial dilution to our stockholders.

**Our short operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.**

We are an early-stage company. We were founded and commenced operations in January 2017. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our platform and technology, identifying potential product candidates, and undertaking preclinical studies. All of our research programs are still in the preclinical or research stage of development, and their risk of failure is high. We have not yet demonstrated an ability to initiate or successfully complete any clinical trials, including large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale medicine, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes about 10 to 15 years to develop a new medicine from the time it is discovered to when it is available for treating patients. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Our limited operating history, particularly in light of the rapidly evolving base editing and gene editing field, may make it difficult to evaluate our technology and industry and predict our future performance. Our short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by very early stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer.

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

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

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with collaborative partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, product candidates we may identify for development. We do not anticipate generating revenues from product sales for the next several years, if ever. Our ability to generate future revenues from product sales depends heavily on our, or our collaborators’, ability to successfully:

- identify product candidates and complete research and preclinical and clinical development of any product candidates we may identify;
- seek and obtain regulatory and marketing approvals for any of our product candidates for which we complete clinical trials;
• launch and commercialize any of our product candidates for which we obtain regulatory and marketing approval by establishing a sales force, marketing, and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
• qualify for adequate coverage and reimbursement by government and third-party payors for any of our product candidates for which we obtain regulatory and marketing approval;
• develop, maintain, and enhance a sustainable, scalable, reproducible, and transferable manufacturing process for the product candidates we may develop;
• manufacture materials in compliance with cGMP and establish the infrastructure necessary to support and develop large-scale manufacturing capabilities;
• establish and maintain supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products, and services to support clinical development and the market demand for any of our product candidates for which we obtain regulatory and marketing approval;
• obtain market acceptance of any product candidates we may develop as viable treatment options;
• address competing technological and market developments;
• implement internal systems and infrastructure, as needed;
• negotiate favorable terms in any collaboration, licensing, or other arrangements into which we may enter and performing our obligations in such collaborations;
• maintain, protect, enforce, defend, and expand our portfolio of intellectual property rights, including patents, trade secrets, and know-how;
• avoid and defend against third-party interference, infringement, and other intellectual property claims; and
• attract, hire, and retain qualified personnel.

Even if one or more of the product candidates we may develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, the EMA, or other regulatory authorities to perform clinical and other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved product candidates, we may not become profitable and may need to obtain additional funding to continue operations. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

**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 of such carryforwards in the case of carryforwards generated prior to 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. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an “ownership change,” generally defined as one or more shareholders or groups of shareholders who own at least 5% of the corporation’s equity increasing their ownership in the aggregate by 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. In addition, we may experience ownership changes in the future as a result 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. Additional limitations on our ability to utilize our NOLs to offset future taxable income may arise as a result of our corporate structure whereby NOLs generated by certain of our subsidiaries or controlled entities may not be available to offset taxable income earned by our subsidiaries or other controlled entities. In addition, under legislation commonly referred to as the Tax Cuts and Jobs Act of 2017, or the Tax Act, the amount of post-2017 NOLs that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year. The Tax Act generally eliminates the ability to carry back any NOLs to prior taxable years, while allowing post-2017 unused NOLs to be carried forward indefinitely. There is a risk that due to changes under the Tax Act, regulatory changes, or other unforeseen reasons, our existing NOLs or business tax credits could expire or otherwise be
of the use of transposons, or development of genetic medicines or that other gene editing technologies will not be considered better or more attractive for the development of medicines. TALENs, but to date none has obtained marketing approval for a product candidate. There can be no certainty that base editing technology will lead to the development of gene editing technologies using zinc finger nucleases, engineered meganucleases, and transcription activator-like effector nucleases, or to date, we have focused our efforts on gene editing technologies using base editing. Other companies have previously undertaken research and development of gene editing technologies using zinc finger nucleases, engineered meganucleases, and transcription activator-like effector nucleases, or TALENs, but to date none has obtained marketing approval for a product candidate. There can be no certainty that base editing technology will lead to the development of genetic medicines or that other gene editing technologies will not be considered better or more attractive for the development of medicines. For example, Feng Zhang’s group at MIT and Broad Institute, and, separately, Samuel Sternberg’s group at Columbia University announced the discovery of the use of transposons, or

Risks related to discovery, development, and commercialization

Base editing is a novel technology that is not yet clinically validated for human therapeutic use. The approaches we are taking to discover and develop novel therapeutics are unproven and may never lead to marketable products.

We are focused on developing potentially curative medicines utilizing base editing technology. Although there have been significant advances in the field of gene therapy, which typically involves introducing a copy of a gene into a patient’s cell, and gene editing in recent years, base editing technologies are new and largely unproven. The technologies that we have licensed and that we intend to develop and intend to license have not yet been clinically tested, nor are we aware of any clinical trials for safety or efficacy having been completed by third parties using our base editing or similar technologies. The scientific evidence to support the feasibility of developing product candidates based on these technologies is both preliminary and limited, and base editing and delivery modalities for it are novel. Successful development of product candidates by us will require solving a number of issues, including safely delivering a therapeutic into target cells within the human body or in an ex vivo setting, optimizing the efficiency and specificity of such product candidates, and ensuring the therapeutic selectivity of such product candidates. There can be no assurance we will be successful in solving any or all of these issues, or that we will be able to progress our preclinical studies in accordance with anticipated timelines.

We have concentrated our research efforts to date on preclinical work to bring therapeutics to the clinic for our initial indications, and our future success is highly dependent on the successful development of base editing technologies, cellular delivery methods and therapeutic applications of that technology. While some of the existing gene editing technologies have progressed to clinical trials, they continue to suffer from various limitations, and such limitations may affect our future success. We may decide to alter or abandon our initial programs as new data become available and we gain experience in developing base editing therapeutics. We cannot be sure that our technologies will yield satisfactory products that are safe and effective, scalable or profitable in our initial indications or any other indication we pursue.

Development activities in the field of base editing are currently subject to a number of risks related to the ownership and use of certain intellectual property rights that are subject to patent interference proceedings in the United States and opposition proceedings in Europe. For additional information regarding the risks that may apply to our and our licensors’ intellectual property rights, see the section entitled “—Risks related to our intellectual property” for more information.

We may not be successful in our efforts to identify and develop potential product candidates. If these efforts are unsuccessful, we may never become a commercial stage company or generate any revenues.

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

In addition, although we believe base editing will position us to rapidly expand our portfolio of product candidates beyond our current product candidates we may develop after only minimal changes to the product candidate construct, we have not yet successfully developed any product candidate and our ability to expand our portfolio may never materialize.

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

The gene editing field is relatively new and is evolving rapidly. We are focusing our research and development efforts on gene editing using base editing technology, but other gene editing technologies may be discovered that provide significant advantages over base editing, which could materially harm our business.

To date, we have focused our efforts on gene editing technologies using base editing. Other companies have previously undertaken research and development of gene editing technologies using zinc finger nucleases, engineered meganucleases, and transcription activator-like effector nucleases, or TALENs, but to date none has obtained marketing approval for a product candidate. There can be no certainty that base editing technology will lead to the development of genetic medicines or that other gene editing technologies will not be considered better or more attractive for the development of medicines. For example, Feng Zhang’s group at MIT and Broad Institute, and, separately, Samuel Sternberg’s group at Columbia University announced the discovery of the use of transposons, or
jumping genes, in June 2019. Transposons can insert themselves into different places in the genome and can be programmed to carry specific DNA sequences to specific sites, without the need for making double-stranded breaks in DNA. In addition, one of our founders, David Liu, and his group at Broad Institute developed a novel gene editing technology. We have secured an exclusive license from Prime Medicine, a company founded by David Liu, to pursue this new technology in certain fields and for certain applications similar to those we are already pursuing with base editing. Our license does not cover all fields and applications of this new technology for gene editing and Prime Medicine retains broad rights to use this technology outside of the fields licensed to us. It is possible that this gene editing technology developed by David Liu’s group is competitive with our business, and it is also possible that such gene editing technology may potentially be considered more attractive than base editing. Therefore, Prime Medicine may pursue this technology in other fields and for other applications and may develop competing products using such technology. David Liu recently reported results from his lab related to base editing in mitochondria; this is accomplished by splitting the deaminase into two halves, which are reassembled at the desired regions of the mitochondrial DNA. This new technology could be used to treat mitochondrial diseases. Our current technology cannot edit within the mitochondria. In addition, Geoffrey von Maltzahn and others recently launched a company called Tessera Therapeutics, which is focused on a technology they call “Gene Writing.” This technology, which utilizes mobile genetic elements, can alter the genome by inserting genes and exons, introducing small insertions and deletions, or by changing single or multiple DNA base pairs. Similarly, another new gene editing technology that has not been discovered yet may be determined to be more attractive than base editing. Moreover, if we decide to develop gene editing technologies other than those involving base editing, we cannot be certain we will be able to obtain rights to such technologies. Although all of our founders who currently provide consulting and advisory services to us in the area of base editing technologies have assignment of inventions obligations to us with respect to the services they perform for us, these assignment of inventions obligations are subject to limitations and do not extend to their work in other fields or to the intellectual property arising from their employment with their respective academic and research institutions. To obtain intellectual property rights assigned by these founders to such institutions, we would need to enter into license agreements with such institutions, which may not be available on commercially reasonable terms or at all. Further, while our three founders have non-competition clauses in their respective consulting agreements, the non-competition obligation is limited to the field of base editing for human therapeutics, and our founders have developed and may in the future develop new technologies that are outside of the field of their non-competition obligations but may be competitive to our business. For example, as discussed above, David Liu and his group at Broad Institute have developed novel gene editing technology outside of the field of his non-competition obligations that may be used to develop products that compete with our business. Any of these factors could reduce or eliminate our commercial opportunity, and could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We are very early in our development efforts. All of our product candidates are still in preclinical development or earlier stages and it will be many years before we or our collaborators commercialize a product candidate, if ever. If we are unable to advance our product candidates to clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts and have focused our research and development efforts to date on base editing technology, identifying our initial targeted disease indications and our initial product candidates. We have not yet achieved preclinical proof-of-concept in vivo for the majority of our programs and there is no guarantee that we will achieve it for these programs. Our future success depends heavily on the successful development of our base editing product candidates. Currently, all of our product candidates are in preclinical development or in discovery. We have invested substantially all of our efforts and financial resources in building our base editing platform, and the identification and preclinical development of our current product candidates. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any product, and we may never be able to develop or commercialize a marketable product.

Commencing clinical trials in the United States is also subject to acceptance by the FDA of our IND application, and finalizing the trial design based on discussions with the FDA and other regulatory authorities. In the event that the FDA requires us to complete additional preclinical studies or we are required to satisfy other FDA requests, the start of our first clinical trials may be delayed. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trial or change their position on the acceptability of our data, trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter requirements for approval than we currently expect. There are equivalent processes and risks applicable to clinical trial applications in other countries, including in Europe.

Commercialization of our product candidates we may develop will require additional preclinical and clinical development; regulatory and marketing approval in multiple jurisdictions, including by the FDA and the EMA; obtaining manufacturing supply, capacity and expertise; building of a commercial organization; and significant marketing efforts. The success of product candidates we may identify and develop will depend on many factors, including the following:

- sufficiency of our financial and other resources to complete the necessary preclinical studies, IND-enabling studies, and clinical trials;
• regulator acceptance of IND applications or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for our product candidates;
• successful enrollment in, and completion of, clinical trials;
• receipt of marketing approvals from applicable regulatory authorities;
• establishment of arrangements with third-party manufacturers for clinical supply and commercial manufacturing and, where applicable, commercial manufacturing capabilities;
• successful development of our internal manufacturing processes and transfer to larger-scale facilities operated by either a CMO, or by us;
• obtaining and maintaining patent, trade secret, and other intellectual property protection and non-patent exclusivity for our medicines;
• launching commercial sales of the medicines, if and when approved, whether alone or in collaboration with others;
• acceptance of the products, if and when approved, by patients, the medical community, and third-party payors;
• effectively competing with other therapies and treatment options;
• a continued acceptable safety profile of the medicines following approval;
• enforcing and defending intellectual property and proprietary rights and claims; and
• supplying the product at a price that is acceptable to the pricing or reimbursement authorities in different countries.

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

If any of the product candidates we may develop, or the delivery modes we rely on to administer them, cause serious adverse events, undesirable side effects, or unexpected characteristics, such events, side effects or characteristics could delay or prevent regulatory approval of the product candidates, limit the commercial potential, or result in significant negative consequences following any potential marketing approval.

We have not evaluated any product candidates in human clinical trials. Moreover, there have been only a limited number of clinical trials involving the use of gene editing technologies and none involving base editing technology similar to our technology. It is impossible to predict when or if any product candidates we may develop will prove safe in humans. In the genetic medicine field, there have been several significant adverse events from gene therapy treatments in the past, including reported cases of leukemia, serious blood disorders and death. There can be no assurance that base editing technologies, or components of our product candidates or methods of delivery, will not cause undesirable side effects, as improper editing of a patient’s DNA and other effects could lead to lymphoma, leukemia, or other cancers, other serious conditions or syndromes or other aberrantly functioning cells.

A significant risk in any base editing product candidate is that “off-target” edits may occur, which could cause serious adverse events, undesirable side effects or unexpected characteristics. For example, Erwei Zuo et al. reported that cytosine base editors generated substantial off-target edits, that is, edits in unintended locations on the DNA, when tested in mouse embryos. Such unintended edits are referred to as “spurious deamination.” We cannot be certain that off-target editing will not occur in any of our planned or future clinical studies, and the lack of observed side effects in preclinical studies does not guarantee that such side effects will not occur in human clinical studies. There is also the potential risk of delayed adverse events following exposure to base editing therapy due to the permanence of edits to DNA or due to other components of product candidates used to carry the genetic material. Further, because base editing makes a permanent change, the therapy cannot be withdrawn, even after a side effect is observed. In addition, Rees et al. and Grunewald et al. have reported that the deaminases we currently use in our C base editors and our A base editors for use in DNA base editing also cause unintended mutations in RNA for as long as the editor is present in the cell.

Although we and others have demonstrated the ability to engineer base editors to improve the specificity of their edits in a laboratory setting, we cannot be sure that our engineering efforts will be effective in any product candidates that we may develop. For example, we might not be able to engineer an editor to make the desired change or a by-stander edit could diminish the effectiveness of an edit that we make.

In certain rare DNA sequence contexts, where more than one edit occurs on a contiguous piece of DNA, the repair of two or more nicks may lead to a deletion. For example, in our BEAM-101 program, where we are simultaneously editing two positions in the promoters of the HBG2 and HBG1 genes, which share >99% sequence identity and are contiguous due to a gene duplication event, we observed a 5 kb deletion in HBG2. We are currently conducting studies to determine the extent to which such deletion occurs. We do not believe that such a deletion represents a safety or efficacy concern because healthy individuals, including those with hereditary
In certain of our programs, we plan to use LNPs to deliver our base editors. LNPs have been shown to induce oxidative stress in the liver at certain doses, as well as initiate systemic inflammatory responses that can be fatal in some cases. While we aim to continue to optimize our LNPs, there can be no assurance that our LNPs will not have undesired effects. Our LNPs could contribute, in whole or in part, to one or more of the following: immune reactions; infusion reactions; complement reactions; opsonization reactions; antibody reactions including IgA, IgM, IgE or IgG or some combination thereof; or reactions to the PEG from some lipids or PEG otherwise associated with the LNP. Certain aspects of our investigational medicines may induce immune reactions from either the mRNA or the lipid as well as adverse reactions within liver pathways or degradation of the mRNA or the LNP, any of which could lead to significant adverse events in one or more of our future clinical trials. Many of these types of side effects have been seen for legacy LNPs. There may be uncertainty as to the underlying cause of any such adverse event, which would make it difficult to accurately predict side effects in future clinical trials and would result in significant delays in our programs.

Our viral vectors including AAV or lentiviruses, which are relatively new approaches used for disease treatment, also have known side effects, and for which additional risks could develop in the future. In past clinical trials that were conducted by others with non-AAV vectors, several significant side effects were caused by gene therapy treatments, including reported cases of leukemia and death. Other potential side effects could include an immunologic reaction and insertional oncogenesis, which is the process whereby the insertion of a functional gene near a gene that is important in cell growth or division results in uncontrolled cell division, which could potentially enhance the risk of malignant transformation. If the vectors we use demonstrate a similar side effect, or other adverse events, we may be required to halt or delay further clinical development of any potential product candidates. Furthermore, the FDA has stated that lentiviral vectors possess characteristics that may pose high risks of delayed adverse events. Such delayed adverse events may occur in other viral vectors, including AAV vectors, at a lower rate.

In addition to side effects and adverse events caused by our product candidates, the conditioning administration process or related procedures which may be used in our electroporation pipeline also can cause adverse side effects and adverse events. Additionally, we have and may continue to collaborate with third parties to develop alternative conditioning regimes. We cannot predict if alternative conditioning regimes will be compatible with our product candidates. If in the future we are unable to demonstrate that such adverse events were caused by the conditioning regimens used, or administration process or related procedure, the FDA, the European Commission, EMA or other regulatory authorities could order us to cease further development of, or deny or limit approval of, our product candidates for any or all target indications. Even if we are able to demonstrate that adverse events are not related to the drug product or the administration of such drug product, such occurrences could affect patient recruitment, the ability of enrolled patients to complete the clinical trial, or the commercial viability of any product candidates that obtain regulatory approval.

If any product candidates we develop are associated with 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.

If in the future we are unable to demonstrate that any of the above adverse events were caused by factors other than our product candidate, the FDA, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any product candidates we are able to develop for any or all targeted indications. 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. Moreover, if we, elect, or are required, to delay, suspend or terminate any clinical trial of any product candidate we may develop, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to identify and develop product candidates, and may harm our business, financial condition, result of operations, and prospects significantly.

Additionally, if we successfully develop a product candidate and it receives marketing approval, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of treatment with such product candidate outweighs the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, extensive patient monitoring, or distribution systems and processes that are highly controlled, restrictive, and more costly than what is typical for the industry. Furthermore, if we or others later identify undesirable side effects caused by any product candidate that we develop, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label or limit the approved use of such product candidate;
we may be required to conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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, and results of operations.

**We have not tested any of our proposed delivery modalities and product candidates in clinical trials and any favorable preclinical results are not predictive of results that may be observed in clinical trials.**

We have not tested any of our proposed delivery modalities in clinical trials. For example, we intend to use novel split intein technology for AAV gene therapy that allows us to deliver the base editor and guide RNA construct by co-infection with two viruses, where each virus contains one half of the editor. The scientific evidence to support the feasibility of developing product candidates based on this technology is both preliminary and limited. We also intend to use LNPs to deliver some of our base editors. While LNPs have been used to deliver smaller molecules, such as RNAi, they have not been clinically proven to deliver larger RNA molecules, such as the ones we intend to use for our base editors. Furthermore, as with many AAV-mediated gene therapy approaches, certain patients’ immune systems might prohibit the successful delivery, thereby potentially limiting treatment outcomes of these patients.

Even if initial clinical trials in any of our product candidates we may develop are successful, these product candidates we may develop may fail to show the desired safety and efficacy in later stages of clinical development despite having successfully advanced through preclinical studies and initial clinical trials.

There is a high failure rate for drugs and biologics proceeding through clinical trials. 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 earlier stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit, or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development. Any such adverse events may cause us to delay, limit, or terminate planned clinical trials, any of which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the results of preclinical studies may not be predictive of the results of later-stage preclinical studies or clinical trials. To date, we have not generated preclinical or clinical trial results. If we generate preclinical results, such results will not ensure that later preclinical studies or clinical trials will demonstrate similar results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates.

**We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.**

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications among many potential options. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable medicines. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Any such event could have a material adverse effect on our business, financial condition, results of operations, and prospects.

**Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize a product candidate we may develop in the United States or any other jurisdiction, and any such approval may be for a more narrow indication than we seek.**

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if any product candidates we may develop meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials, and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require labeling that
includes precautions or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of any product candidates we may develop. Any of the foregoing scenarios could materially harm the commercial prospects for any product candidates we may develop and materially adversely affect our business, financial condition, results of operations, and prospects.

Marketing approval by the FDA in the United States, if obtained, does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product candidate testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates we may develop in those countries. The foreign regulatory approval process involves all of the risks associated with FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our product candidates will be unrealized.

**Even if any product candidates we may develop receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors, and others in the medical community necessary for commercial success.**

The commercial success of any of our product candidates we may develop will depend upon its degree of market acceptance by physicians, patients, third-party payors, and others in the medical community. Ethical, social, and legal concerns about genetic medicines generally and base editing technologies specifically could result in additional regulations restricting or prohibiting the marketing of our product candidates we may develop. Even if any product candidates we may develop receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors, and others in the medical community. The degree of market acceptance of any product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the potential and perceived advantages compared to alternative treatments;
- the limitation to our targeted patient population and limitations or warnings contained in approved labeling by the FDA or other regulatory authorities;
- the ability to offer our medicines for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA, the EMA, or other regulatory agencies;
- public attitudes regarding genetic medicine generally and gene editing and base editing technologies specifically;
- the willingness of the target patient population to try novel therapies and of physicians to prescribe these therapies, as well as their willingness to accept a therapeutic intervention that involves the editing of the patient’s gene;
- product labeling or product insert requirements of the FDA, the EMA, or other regulatory authorities, including any limitations or warnings contained in a product’s approved labeling;
- relative convenience and ease of administration;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- the strength of marketing and distribution support;
- sufficient third-party coverage or reimbursement; and
- the prevalence and severity of any side effects.

Even if any of our product candidates we may develop are approved, such products may not achieve an adequate level of acceptance, we may not generate significant product revenues, and we may not become profitable.
If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have limited experience in the sale, marketing, or distribution of pharmaceutical products. To achieve commercial success for any approved medicine for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing, and commercial support infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates we may develop if and when they are approved.

Factors that may inhibit our efforts to commercialize our product candidates we may develop on our own include:

- our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future medicines;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;
- restricted or closed distribution channels that make it difficult to distribute our product candidates we may develop to segments of the patient population;
- the lack of complementary medicines to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenues or the profitability of these product revenues to us may be lower than if we were to market and sell any medicines we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates we may develop or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our medicines effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates we may develop.

We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop.

The development and commercialization of new drug products is highly competitive. Moreover, the base editing field is characterized by rapidly changing technologies, significant competition, and a strong emphasis on intellectual property. We will face competition with respect to any product candidates that we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we have research programs. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches.

There are several other companies utilizing CRISPR/Cas9 nuclease technology, including Caribou Biosciences, Editas Medicine, CRISPR Therapeutics, and Intellia Therapeutics. Several additional companies utilize other nuclease-based genome editing technologies, including Zinc Fingers, Arcuses, and TAL Nuclease, which includes Sangamo Biosciences, Precision BioSciences, bluebird bio, Allogene Therapeutics, and Cellectis. Additionally, newer genome editing modalities are emerging, including Prime Medicine, Tessera Therapeutics, Shape Therapeutics, and PerkinElmer (formerly Horizon Discovery), which is developing base
Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future that are approved to treat the same diseases for which we may obtain approval for our product candidates we may develop. This may include other types of therapies, such as small molecule, antibody, and/or protein therapies.

Many of our current or potential competitors, either alone or with their collaboration partners, may 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. Mergers and acquisitions in the pharmaceutical, biotechnology, and gene therapy industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also 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 commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any product candidates that we may develop or that would render any product candidates that we may develop obsolete or non-competitive. Our competitors also may obtain FDA or other regulatory approval for their product candidates 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. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors’ products. The availability of our competitors’ products could limit the demand, and the price we are able to charge, for any product candidates that we may develop and commercialize.

**Adverse public perception of genetic medicines, and gene editing and base editing in particular, may negatively impact regulatory approval of, and/or demand for, our potential products.**

Our potential therapeutic products involve editing the human genome. The clinical and commercial success of our potential products will depend in part on public understanding and acceptance of the use of gene editing therapy for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene editing is unsafe, unethical, or immoral, and, consequently, our product candidates may not gain the acceptance of the public or the medical community. For example, a public backlash developed against gene therapy following the death of a patient in 1999 during a gene therapy clinical trial. The death of the clinical trial subject was due to complications related to AAV vector administration. In addition, in June 2020, a patient in Audentes Therapeutics’ clinical trial investigating AT132 (a gene therapy product candidate which was being delivered via AAV administration) for X-linked myotubular myopathy (XLMR) died. Preliminary findings indicated that the immediate cause of death was sepsis, which followed progressive liver dysfunction that occurred within the first 4-6 weeks following AT132 dosing, and which did not respond to standard treatment. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

In addition, gene editing technology is subject to public debate and heightened regulatory scrutiny due to ethical concerns relating to the application of gene editing technology to human embryos or the human germline. For example, academic scientists in several countries, including the United States, have reported on their attempts to edit the gene of human embryos as part of basic research. In addition, in November 2018, Dr. Jiankui He, a Chinese biophysics researcher who was an associate professor in the Department of Biology of the Southern University of Science and Technology in Shenzhen, China, reportedly claimed he had created the first human genetically edited babies, twin girls. This claim, and another that Dr. He had helped create a second gene-edited pregnancy, was subsequently confirmed by Chinese authorities and was negatively received by the public, in particular those in the scientific community. News reports indicate that Dr. He was sentenced to three years in prison and fined $430,000 in December 2019 by the Chinese government for illegal medical practice in connection with such activities. In the wake of the claim, the World Health Organization established a new advisory committee to create global governance and oversight standards for human gene editing and announced plans for a new global registry to track research on human genome editing. The Alliance for Regenerative Medicine also released principles for the use of gene editing in therapeutic applications endorsed by a number of companies that use gene editing technologies.

Regulation of gene editing technology varies across jurisdictions. In the United States, germline editing for clinical application has been expressly prohibited since enactment of a December 2015 FDA ban on such activity. Prohibitions are also in place in the U.K., across most of Europe, in China, and many other countries around the world. In the United States, the National Institutes of Health, or NIH, has announced that the agency would not fund any use of gene editing technologies in human embryos, noting that there are
Moreover, in an annual worldwide threat assessment report delivered to the U.S. Congress in February 2016, the U.S. Director of National Intelligence stated that research into gene editing that is conducted under different regulatory standards than those of Western countries probably increases the risk of the creation of potentially harmful biological agents or products, including weapons of mass destruction. He noted that given the broad distribution, low cost, and accelerated pace of development of gene editing technology, its deliberate or unintentional misuse could have far-reaching economic and national security implications.

Although we do not use our technologies to edit human embryos or the human germline, such public debate about the use of gene editing technologies in human embryos and heightened regulatory scrutiny could prevent or delay our development of product candidates. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair our development and commercialization of product candidates or demand for any product candidates we may develop. Adverse events in our preclinical studies or clinical trials or those of our competitors or of academic researchers utilizing gene editing technologies, even if not ultimately attributable to product candidates we may identify and develop, and the gene publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of potential product candidates we may identify and develop, stricter labeling requirements for those product candidates that are approved, and a decrease in demand for any such product candidates. Use of gene editing technology by a third party or government to develop biological agents or products that threaten U.S. national security could similarly result in such negative impacts to us.

Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, and reimbursement for new medicines vary widely from country to country. Some countries require approval of the sale price of a medicine before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a medicine in a particular country, but then be subject to price regulations that delay or might even prevent our commercial launch of the medicine, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the medicine in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates we may develop, even if any product candidates we may develop obtain marketing approval.

Our ability to commercialize any medicines successfully also will depend in part on the extent to which reimbursement for these medicines and related treatments will be available from government authorities or healthcare program, private health plans, and other organizations. Government authorities and third-party payors, such as private health plans, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are challenging the prices charged for medical products and requiring that drug companies provide them with predetermined discounts from list prices. Novel medical products, if covered at all, may be subject to enhanced utilization management controls designed to ensure that the products are used only when medically necessary. Such utilization management controls may discourage the prescription or use of a medical product by increasing the administrative burden associated with its prescription or creating coverage uncertainties for prescribers and patients. We cannot be sure that reimbursement will be available for any medicine that we commercialize and, if reimbursement is available, that the level of reimbursement will be adequate. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved medicines, and coverage may be more limited than the purposes for which the medicine is approved by the FDA, the EMA or other regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any medicine will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the medicine and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines and may be incorporated into existing payments for other services. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved medicines we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize medicines, and our overall financial condition.
Due to the novel nature of our technology and the potential for any product candidates we may develop to offer therapeutic benefit in a single administration or limited number of administrations, we face uncertainty related to pricing and reimbursement for these product candidates.

Our initial target patient populations are relatively small, as a result of which the pricing and reimbursement of any product candidates we may develop, if approved, must be adequate to support the necessary commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell any such product candidates will be adversely affected. The manner and level at which reimbursement is provided for services related to any product candidates we may develop (e.g., for administration of our product candidate to patients) is also important. Inadequate reimbursement for such services may lead to physician and payor resistance and adversely affect our ability to market or sell our product candidates we may develop. In addition, we may need to develop new reimbursement models in order to realize adequate value. Payors may not be able or willing to adopt such new models, and patients may be unable to afford that portion of the cost that such models may require them to bear. If we determine such new models are necessary but we are unsuccessful in developing them, or if such models are not adopted by payors, our business, financial condition, results of operations, and prospects could be adversely affected.

We expect the cost of a single administration of genetic medicines, such as those we are seeking to develop, to be substantial, when and if they achieve regulatory approval. We expect that coverage and reimbursement by government and private payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of any such product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of any product candidates we may develop will be paid by government authorities, private health plans, and other third-party payors. Payors may not be willing to pay high prices for a single administration. Coverage and reimbursement by a third-party payor may depend upon several factors, including the third-party payor’s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical, and cost-effectiveness data. There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize any product candidates we may develop. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment.

Moreover, the downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new product candidates such as ours. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell any product candidates we may develop will be harmed.

If the market opportunities for any product candidates we may develop are smaller than we believe they are, our potential revenues may be adversely affected, and our business may suffer. Because the target patient populations for many of the product candidates we may develop are small, we must be able to successfully identify patients and achieve a significant market share to maintain profitability and growth.

We focus our research and product development on treatments for rare genetically defined diseases. Many of our product candidates we may develop are expected to target a single mutation; as a result, the relevant patient population may therefore be small. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with product candidates we may develop, are based on estimates. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe, and elsewhere may turn out to be lower than expected, and patients may not be amenable to treatment with our product candidates we may develop, or may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations, and prospects. Additionally, because of the potential that any product candidates we develop could cure a target disease, we may not receive recurring revenues from patients and may deplete the patient population prevalence through curative therapy.
Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any medicines that we may develop.

We face an inherent risk of product liability exposure related to the testing in human clinical trials of any product candidates we may develop and will face an even greater risk if we commercially sell any medicines that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or medicines caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or medicines that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant time and costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any medicines that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage when we begin clinical trials and if we successfully commercialize any medicine. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers’ compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws, regulations, and permitting requirements. These current or future laws, regulations, and permitting requirements may impair our research, development, or production efforts. Failure to comply with these laws, regulations, and permitting requirements also may result in substantial fines, penalties, or other sanctions or business disruption, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Any third-party contract manufacturers and suppliers we engage will also be subject to these and other environmental, health, and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.
Any product candidates we may develop will likely require processing steps that are more complex than those required for most chemical pharmaceuticals. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as the product candidates we intend to develop cannot be fully characterized. As a result, assays of the finished product candidate may not be sufficient to ensure that the product candidate will perform in the intended manner. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims, insufficient inventory, or potentially delay progression of our potential IND filings. If we successfully develop product candidates, we may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, EMA or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs. For example, the current approach of manufacturing AAV vectors may fall short of supplying required number of doses needed for advanced stages of pre-clinical studies or clinical trials, and the FDA may ask us to demonstrate that we have the appropriate manufacturing processes in place to support the higher-dose group in our future pre-clinical studies or clinical trials. In addition, our product candidates we may develop will require complicated delivery modalities, such as electroporation, LNPs, or viral vectors, each of which will introduce additional complexities in the manufacturing process.

Furthermore, we intend to use novel split intein technology for any AAV gene therapy that allows us to deliver the base editor and guide RNA construct by co-infection with two viruses, where each virus contains one half of the editor. The scientific evidence to support the feasibility of developing product candidates based on this technology is both preliminary and limited.

We also may encounter problems hiring and retaining the experienced scientific, quality control, and manufacturing personnel needed to manage our manufacturing process, which could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements. Given the nature of biologics manufacturing, including for the lentivirus vectors and AAV vectors, there is a risk of contamination during manufacturing. Any contamination could materially harm our ability to produce product candidates on schedule and could harm our results of operations and cause reputational damage. Some of the raw materials that we anticipate will be required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall, or restriction on the use of biologically derived substances in the manufacture of any product candidates we may develop could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially harm our development timelines and our business, financial condition, results of operations, and prospects.

Any problems in our manufacturing process or the facilities with which we contract could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs. Problems in third-party manufacturing process or facilities also could restrict our ability to ensure sufficient clinical material for any clinical trials we may be conducting or are planning to conduct and meet market demand for any product candidates we develop and commercialize.

Risks related to regulatory review

Because base editing is novel and the regulatory landscape that will govern any product candidates, we may develop is uncertain and may change, we cannot predict the time and cost of obtaining regulatory approval, if we receive it at all, for any product candidates we may develop.

The regulatory requirements that will govern any novel base editing product candidates we develop are not entirely clear and may change. Within the broader genetic medicine field, we are aware of a limited number of cellular and gene therapy products that have received marketing authorization from the FDA and the EMA. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. Regulatory requirements governing gene therapy products and cell therapy products have changed frequently and will likely continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. For example, in the United States, the FDA has established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Gene therapy clinical trials are also subject

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to review and oversight by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at the institution participating in the clinical trial. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation.

The same applies in the EU. The EMA's Committee for Advanced Therapies, or CAT, is responsible for assessing the quality, safety, and efficacy of advanced-therapy medicinal products. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a gene therapy medicinal candidate that is submitted to the Committee for Medicinal Products for Human Use, or CHMP, before CHMP adopts its final opinion. In the EU, the development and evaluation of a gene therapy medicinal product must be considered in the context of the relevant EU guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. As a result, the procedures and standards applied to gene therapy products and cell therapy products may be applied to any product candidates we may develop, but that remains uncertain at this point.

Adverse developments in post-marketing experience or in clinical trials conducted by others of gene therapy products, cell therapy products, or products developed through the application of a base editing or other gene editing technology may cause the FDA, the EMA, and other regulatory bodies to revise the requirements for development or approval of any product candidates we may develop or limit the use of products utilizing base editing technologies, either of which could materially harm our business. Moreover, the FDA recommends a long-term follow-up observation period of 15 years or longer for all patients who receive treatment using gene therapies, and we may need to adopt and support such an observation period for our product candidates. In addition, the clinical trial requirements of the FDA, the EMA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for novel product candidates such as the product candidates we may develop can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing base editing technology in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays, or other impediments to our research programs or the commercialization of resulting products.

The regulatory review committees and advisory groups described above and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates, or lead to significant post-approval limitations or restrictions. As we advance our research programs and develop future product candidates, we will be required to consult with these regulatory and advisory groups and to comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of any product candidates we identify and develop.

Because we are developing product candidates in the field of genetic medicines, a field that includes gene therapy and gene editing, in which there is little clinical experience, there is increased risk that the FDA, the EMA, or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results and that these results may be difficult to analyze.

During the regulatory review process, we will need to identify success criteria and endpoints such that the FDA, the EMA, or other regulatory authorities will be able to determine the clinical efficacy and safety profile of any product candidates we may develop. As we are initially seeking to identify and develop product candidates to treat diseases in which there is little clinical experience and since we are using new technologies, there is heightened risk that the FDA, the EMA, or other regulatory authorities may not consider the clinical trial endpoints that we propose to provide clinically meaningful results (reflecting a tangible benefit to patients). In addition, the resulting clinical data and results may be difficult to analyze. Even if the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoints to a degree of statistical significance. This may be a particularly significant risk for many of the genetically defined diseases for which we plan to develop product candidates because many of these diseases, including T-cell acute lymphoblastic leukemia, glycogen storage disorder and Stargardt disease, have small patient populations, and designing and executing a rigorous clinical trial with appropriate statistical power is more difficult than with diseases that have larger patient populations. Further, even if we do achieve the pre-specified criteria, we may produce results that are unpredictable or inconsistent with the results of the non-primary endpoints or other relevant data. The FDA also weighs the benefits of a product against its risks, and the FDA may view the efficacy results in the context of safety as not being supportive of regulatory approval. Other regulatory authorities in the EU and other countries may make similar comments with respect to these endpoints and data. Any product candidates we may develop will be based on a novel technology that makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval. No gene editing therapeutic product has been approved in the United States or in Europe.
If clinical trials of any product candidates we may identify and develop fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidates we identify and develop, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. We and our collaborators, if any, 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 any product candidates we may identify and develop, including:

- delays in reaching a consensus with regulators on trial design and endpoints;
- regulators, institutional review boards, or IRBs, or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- delays in reaching or failing to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective contract research organizations, or CROs, and clinical trial sites;
- clinical trials of any product candidates we may develop may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development or research programs;
- difficulty in designing well-controlled clinical trials due to ethical considerations which may render it inappropriate to conduct a trial with a control arm that can be effectively compared to a treatment arm;
- difficulty in designing clinical trials and 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 number of patients required for clinical trials of any product candidates we may develop may be larger than we anticipate; enrollment of suitable participants in these clinical trials, which may be particularly challenging for some of the rare genetically defined diseases we are targeting in our most advanced programs, may be delayed or slower than we anticipate; or patients may drop out of these clinical trials at a higher rate than we anticipate;
- 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, IRBs, or independent ethics committees may require that we or our investigators suspend or terminate clinical research or clinical trials of any product candidates we may develop for various reasons, including noncompliance with regulatory requirements, a finding of undesirable side effects or other unexpected characteristics, or that the participants are being exposed to unacceptable health risks or after an inspection of our clinical trial operations or trial sites;
- the cost of clinical trials of any product candidates we may develop may be greater than we anticipate;
- the supply or quality of any product candidates we may develop or other materials necessary to conduct clinical trials of any product candidates we may develop may be insufficient or inadequate, including as a result of delays in the testing, validation, manufacturing, and delivery of any product candidates we may develop to the clinical sites by us or by third parties with whom we have contracted to perform certain of those functions;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical trial sites dropping out of a trial;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- occurrence of serious adverse events associated with any product candidates we may develop that are viewed to outweigh their potential benefits;
- occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors;
- disruption to the operations of the FDA; and
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols or otherwise complying with additional requirements.
If we or our collaborators are required to conduct additional clinical trials or other testing of any product candidates we may develop beyond those that we currently contemplate, if we or our collaborators are unable to successfully complete clinical trials or other testing of any product candidates we may develop, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we or our collaborators may:

- be delayed in obtaining marketing approval for any such product candidates we may develop or not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of a REMS or through modification to an existing REMS;
- be sued; or
- experience damage to our reputation.

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

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

We or our collaborators may not be able to initiate or continue clinical trials for any product candidates we identify or develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the EMA or other analogous regulatory authorities outside the United States, or as needed to provide appropriate statistical power for a given trial. Enrollment may be particularly challenging for some of the rare genetically defined diseases we are targeting in our most advanced programs, as well as for some of our product candidates for pediatric populations, and delays related to the COVID-19 pandemic could exacerbate delays in enrolling for new clinical trials. In addition, if patients are unwilling to participate in our base editing trials because of negative publicity from adverse events related to the biotechnology, gene therapy, or gene editing fields, competitive clinical trials for similar patient populations, clinical trials in competing products, or for other reasons, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of any product candidates we may develop may be delayed. Moreover, some of our competitors may have ongoing clinical trials for product candidates that would treat the same indications as any product candidates we may develop, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors’ product candidates.

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;
- availability of genetic testing for potential patients;
- 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;
perceived risks and benefits of base editing as a therapeutic approach;
• efforts to facilitate timely enrollment in clinical trials;
• patient referral practices of physicians;
• ability to monitor patients adequately during and after treatment; and
• proximity and availability of clinical trial sites for prospective patients, especially for those conditions which have small patient pools.

Our ability to successfully initiate, enroll, and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

• difficulty in establishing or managing relationships with CROs and physicians;
• different standards for the conduct of clinical trials;
• different standard-of-care for patients with a particular disease;
• difficulty in locating qualified local consultants, physicians, and partners; and
• potential burden of complying with a variety of foreign laws, medical standards, and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment and of gene editing technologies.

Enrollment delays in our clinical trials may result in increased development costs for any product candidates we may develop, which would cause the value of our company to decline and limit our ability to obtain additional financing. If we or our collaborators have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit, or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business, financial condition, results of operations, and prospects.

**If we are unable to successfully identify patients who are likely to benefit from therapy with any product candidates we develop, or experience significant delays in doing so, we may not realize the full commercial potential of any medicines we may develop.**

Our success may depend, in part, on our ability to identify patients who are likely to benefit from therapy with any medicines we may develop, which requires those potential patients to have their DNA analyzed for the presence or absence of a particular sequence. If we, or any third parties that we engage to assist us, are unable to successfully identify such patients, or experience delays in doing so, then:

• our ability to develop any product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials; and
• we may not realize the full commercial potential of any product candidates we develop that receive marketing approval if, among other reasons, we are unable to appropriately select patients who are likely to benefit from therapy with our medicines.

Any product candidates we develop may require use of a companion diagnostic to identify patients who are likely to benefit from therapy. If safe and effective use of any of our product candidates we may develop depends on a companion diagnostic, we may not receive marketing approval, or marketing approval may be delayed, if we are unable to or are delayed in developing, identifying, or obtaining regulatory approval or clearance for the companion diagnostic product for use with our product candidate. Identifying a manufacturer of the companion diagnostic and entering into an agreement with the manufacturer could also delay the development of our product candidates.

As a result of these factors, we may be unable to successfully develop and realize the commercial potential of any product candidates we may identify and develop, and our business, financial condition, results of operations, and prospects would be materially adversely affected.

**Risks related to our relationships with third parties**

We expect to rely on third parties to manufacture components of our product candidates we may develop, conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, or testing.

We expect to rely on third parties, such as CMOs, CROs, clinical data management organizations, medical institutions, and clinical investigators, to manufacture components of our product candidates we may develop and to conduct our clinical trials. We currently rely and expect to continue to rely on third parties to conduct some aspects of our research and preclinical testing. For example, we rely on a third party to conduct electroporation; we rely on a third party to supply LNPs; and we rely on third parties to manufacture viral vectors. Any of these third parties may terminate their engagements with us at any time under certain criteria. If we need to enter into alternative arrangements, it may delay our product development activities.
Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA, EMA and other regulatory authorities require us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. In the United States, we also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions.

Although we intend to design the clinical trials for our product candidates, CROs will conduct some or all of the clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future preclinical studies and clinical trials will also result in less direct control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our preclinical studies and clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs and other third parties do not perform preclinical studies and future clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates, or our development programs may be materially and irreversibly harmed. If we are unable to rely on preclinical and clinical data collected by our CROs and other third parties, we could be required to repeat, extend the duration of, or increase the size of any preclinical studies or clinical trials we conduct and this could significantly delay commercialization and require greater expenditures.

We contract with third parties for the manufacture of materials for our research programs and preclinical studies and expect to continue to do so for at least a portion of the manufacturing process for our research programs, preclinical studies, clinical trials and for commercialization of any product candidates that we may develop. This reliance on third parties increases the risk that we will not have sufficient quantities of such materials, product candidates, or any medicines that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We do not have any manufacturing facilities at the present time. We currently rely on third-party manufacturers for the manufacture of our materials for preclinical studies and may continue to do so for at least a portion of the manufacturing process for our research programs, preclinical studies, clinical testing and for commercial supply of any product candidates that we may develop and for which we or our collaborators obtain marketing approval. We do not have a long-term supply agreement with any of the third-party manufacturers, and we purchase our required supply on an order-by-order basis.

While we announced that we are building a manufacturing facility designed to support manufacturing for our ex vivo cell therapy programs in hematology and oncology and in vivo non-viral delivery programs for liver diseases in Research Triangle Park, North Carolina, this facility is not yet operational and we cannot be certain that we will be able to build out our internal manufacturing capacity, or on the timeliness we expect.

We may be unable to establish long-term supply agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish long-term supply agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- reliance on the third party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting; and
• the possible inability of third-party suppliers to supply and/or transport materials, components and products to us in a timely manner as a result of disruptions to the global supply chain in connection with the COVID-19 pandemic, or as a result of supply shortages in connection with large-scale production of COVID-19 vaccines.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or medicines, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business, financial condition, results of operations, and prospects.

Any medicines that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing drug components and drug products necessary for gene editing. In addition, multiple third parties have contracted with commercial manufacturers to manufacture materials required for large-scale production of COVID-19 vaccines, including mRNA. If supply of mRNA is limited, we may not be able to obtain mRNA for use in our pre-clinical studies, which may result in research and development delays.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply of all drug components and drug products necessary for gene editing. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there are several potential alternative manufacturers who could manufacture any product candidates we may develop, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of any product candidates we may develop may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis.

We may enter into collaborations with third parties for the research, development, and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates.

We may seek third-party collaborators for the research, development, and commercialization of certain of the product candidates we may develop. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. Our ability to generate revenues from these arrangements will depend on our collaborators’ abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our research programs or any product candidates we may develop pose numerous risks to us, including the following:

• Collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations.
• Collaborators may not pursue development and commercialization of any product candidates we may develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator’s strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities.
• Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing.
• Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our medicines or product candidates we may develop if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.
• Collaborators with marketing and distribution rights to one or more medicines may not commit sufficient resources to the marketing and distribution of such medicine or medicines.
• Collaborators may not properly obtain, maintain, enforce, or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.
• Disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of our medicines or product candidates or that result in costly litigation or arbitration that diverts management attention and resources.

• We may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control.

• Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates we may develop.

• Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished, or terminated.

If our collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval, and commercialization described in this Annual Report on Form 10-K apply to the activities of our collaborators.

These relationships, or those like them, may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration agreement will depend, among other things, upon our assessment of the collaborator’s resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator’s evaluation of several factors. If we license rights to any product candidates, we may develop or our collaborators may develop, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Some of our academic collaborators and strategic partners are conducting multiple product development efforts within each area that is the subject of the collaboration with us. Our collaborators or strategic partners, however, may develop, either alone or with others, products in related fields that are competitive with the product candidates we may develop that are the subject of these collaborations with us. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for our product candidates we may develop.

Some of our collaborators or strategic partners could also become our competitors in the future. Our collaborators or strategic partners could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts.

If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our product development and research programs and the potential commercialization of any product candidates we may develop will require substantial additional cash to fund expenses. For some of the product candidates we may develop, we may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator’s resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator’s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, the EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market
business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home,
limitations on our business operations by local, state, or the federal government that could impact our ability to conduct our preclinical activities,
the duration of the outbreak, the initiation of any future clinical trials, as well as our business generally, include:

Some factors from the COVID-19 pandemic that could delay or otherwise adversely affect the completion of our preclinical activities and, depending on our activities for our programs in geographies which are currently being affected by COVID-19, including Massachusetts and North Carolina.

Additionally, timely completion of preclinical activities is dependent upon the availability of, for example, preclinical sites, researchers and investigators, regulatory agency personnel, and materials, which may be adversely affected by global health matters, such as pandemics. We plan to conduct preclinical activities for our programs in geographies which are currently being affected by COVID-19, including Massachusetts and North Carolina.

The COVID-19 pandemic has also impacted, and may continue to impact, our third-party suppliers, including through the effects of facility closures, reductions in operating hours, staggered shifts and other social distancing efforts, labor shortages, decreased productivity and unavailability of materials or components. While we maintain an inventory of materials necessary to conduct our pre-clinical studies, a prolonged outbreak could lead to shortages in these materials.

Additionally, timely completion of preclinical activities is dependent upon the availability of, for example, preclinical sites, researchers and investigators, regulatory agency personnel, and materials, which may be adversely affected by global health matters, such as pandemics. We plan to conduct preclinical activities for our programs in geographies which are currently being affected by COVID-19, including Massachusetts and North Carolina.

Some factors from the COVID-19 pandemic that could delay or otherwise adversely affect the completion of our preclinical activities and, depending on the duration of the outbreak, the initiation of any future clinical trials, as well as our business generally, include:

- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing limitations, travel limitations, cyber security and data accessibility, or communication or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees, manufacturing sites, research sites and other important agencies and contractors;
- limitations on our business operations by local, state, or the federal government that could impact our ability to conduct our preclinical activities, including completing our IND-enabling studies;
• limitations on travel that could hinder our timelines;
• interruption in global shipping affecting the transport of key materials; and
• interruption of, or delays in receiving, key materials from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages, increased demand from third parties for key materials related to COVID-19 research and vaccine development and disruptions in delivery systems.

These and other factors arising from COVID-19 could worsen in countries that are already afflicted with COVID-19 or could continue to spread to additional countries, each of which could further adversely impact our ability to conduct preclinical or any future clinical trials, and, in general, our business, and could have a material adverse impact on our operations and financial condition and results.

Additionally, the extent and duration of the impact of COVID-19 pandemic on our stock price and other biopharmaceutical companies is uncertain and may make us look less attractive to investors and, as a result, there may be a less active trading market for our common stock, our stock price may be more volatile, and our ability to raise capital could be impaired.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the outbreak may impact our business, preclinical studies and any future clinical trials will highly depend on future developments, which are very uncertain and cannot be predicted with confidence, such as the duration of the outbreak, travel restrictions and other actions to contain the outbreak or address its impact, such as social distancing and quarantines or lockdowns in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and address the disease.

The COVID-19 pandemic may also have the effect of heightening many of the other risks described in this section titled “Item 1A. Risk Factors”, such as risks related to our need to raise additional funding, fluctuation of our quarterly financial results, and our ability to obtain and maintain regulatory approvals.

Risks related to our intellectual property

If we are unable to obtain and maintain patent and other intellectual property protection for any product candidates we develop and for our base editing platform technology, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop, and our base editing platform technology may be adversely affected.

Our commercial success will depend in large part on our ability to obtain and maintain patent, trademark, trade secret and other intellectual property protection of our base editing platform technology, product candidates and other technology, methods used to manufacture them and methods of treatment, as well as successfully defending our patent and other intellectual property rights against third-party challenges. It is difficult and costly to protect our base editing platform technology and protect candidates, and we may not be able to ensure their protection. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, importing or otherwise commercializing our product candidates we may develop is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

We seek to protect our proprietary position by in-licensing intellectual property relating to our platform technology and filing patent applications in the United States and abroad related to our base editing platform technology and 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 base editing platform technology and product candidates we may develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours and our ability to commercialize any product candidates we may develop may be adversely affected.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.
The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. The field of genome editing, especially in the area of base editing technology, has been the subject of extensive patenting activity and litigation. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain, and we may become involved in complex and costly litigation. Our pending and future patent applications may not result in patents being issued which protect our base editing platform technology and product candidates we may develop, or which effectively prevent others from commercializing competitive technologies and product candidates.

No consistent policy regarding the scope of claims allowable in the field of genome editing, including base editing technology, has emerged in the United States. The scope of patent protection outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, enforce and defend our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patent rights. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will be valid and enforceable and provide sufficient protection from competitors.

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

In addition, 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 intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned and in-licensed patents and patent applications are, and may in the future be, co-owned by us with third parties. For example, a patent application directed to our potential HBG1 and HBG2 product candidates is co-owned by us, the President and Fellows of Harvard College, or Harvard, and Broad Institute. At present, we do not have a license to the ownership interest of Harvard or Broad Institute. If we are unable to obtain an exclusive license to such third-party co-owners’ interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our rights to develop and commercialize our base editing platform technology and product candidates are subject, in part, to the terms and conditions of licenses granted to us by others.

We depend on intellectual property licensed from third parties, and our licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated, or if disputes regarding these licenses arise, we could lose significant rights that are important to our business.

We have licensed and are dependent on certain patent rights and proprietary technology from third parties that are important or necessary to the development of our base editing technology and product candidates. For example, we are a party to license agreements with the Broad Institute, Editas, Harvard, and Bio Palette, and others, pursuant to which we in-license key patents and patent applications for our base editing platform technology and product candidates (the Broad License Agreement, the Editas License Agreement, the Harvard License Agreement and the Bio Palette License Agreement, respectively). These license agreements impose various diligence, milestone payment, royalty, insurance, and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate our license, in which event we would not be able to develop or market our base editing platform or any other technology or product candidates covered by the intellectual property licensed under these agreements. For example, under the Harvard License Agreement, we are required to initiate a discovery program in accordance with the development plan and development milestones for the development of a licensed product covered by certain sub-categories of licensed patents. If we fail to initiate such a discovery program, our rights with respect to the sub-category of licensed patents will terminate.

These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our base editing platform technology and product candidates in the future. Some licenses granted to us are expressly subject to certain preexisting rights held by the licensor or certain third parties. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in certain territories or fields. For example, certain licensed patents developed by employees of the Howard Hughes Medical Institute, or HHMI, and subsequently assigned to Harvard and licensed to us under the Harvard License Agreement remain subject to a non-exclusive
license between Harvard and HHMI. The Editas License Agreement provides that our field of use excludes the diagnosis, treatment, and prevention of human cancers through certain engineered T-cells, which are licensed to Juno Therapeutics, Inc. (a subsidiary of Bristol-Myers Squibb Company). If we determine that rights to such excluded field are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to continue developing, manufacturing or marketing our product candidates. We may not be able to obtain such a license on an exclusive basis, on commercially reasonable terms, or at all, which could prevent us from commercializing our product candidates or allow our competitors or others the chance to access technology that is important to our business.

Under the Broad License Agreement, rights granted to us include certain patent applications directed to Cas12b or Cas13 that are limited to the United States. The co-owners of these patent applications include Broad Institute, Harvard, MIT, the State University of New Jersey, or Rutgers, Skolkovo Institute of Science and Technology, or Skoltech, and the NIH. At present, we do not have a license to the ownership interest of Rutgers, Skoltech, or the NIH. If we are unable to obtain an exclusive license to Rutgers, Skoltech, and the NIH’s interest in such patent applications, Rutgers, Skoltech, and the NIH may be able to license its rights to other third parties, including our competitors, and such third parties could market competing products and technology. In addition, we may need the cooperation of Rutgers, Skoltech, or the NIH in order to enforce patents issuing from these patent applications against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, pursuant to our license agreement with Broad Institute and our license agreement with Harvard, under certain specific circumstances (in each case), Broad Institute or Harvard (as applicable) may grant a license to the patents that are the subject of such license agreement to a third party in the same field as such patents are licensed to us. Such third party may then have full rights that are the subject of the Broad License Agreement or the Harvard License Agreement (as applicable), which could impact our competitive position and enable a third party to commercialize products similar to our potential future product candidates and technology. Any grant of rights to a third party in this scenario would narrow the scope of our exclusive rights to the patents and patent applications we have in-licensed from Broad Institute and/or Harvard, as applicable.

We do not have complete control in the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. For example, pursuant to each of our intellectual property licenses with Broad Institute, Harvard, Editas and Bio Palette, our licensors retain control of preparation, filing, prosecution, and maintenance, and, in certain circumstances, enforcement and defense of their patents and patent applications. It is possible that our licensors’ enforcement of patents against infringers or defense of such patents against challenges of validity or claims of enforceability may be less vigorous than if we had conducted them ourselves, or may not be conducted in accordance with our best interests. We cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, our right to develop and commercialize any of our product candidates may develop that are the subject of such licensed rights could be adversely affected and we may not be able to prevent competitors from making, using, and selling competing products.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights to our in-licensed patents, the license granted to us in jurisdictions where the consent of a co-owner is necessary to grant such a license may not be valid and such co-owners may be able to license such patents to our competitors, and our competitors could market competing products and technology. In addition, our rights to our in-licensed patents and patent applications are dependent, in part, on inter-institutional or other operating agreements between the joint owners of such in-licensed patents and patent applications. If one or more of such joint owners breaches such inter-institutional or operating agreements, our rights to such in-licensed patents and patent applications may be adversely affected. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Furthermore, inventions contained within some of our in-licensed patents and patent applications were made using U.S. government funding. We rely on our licensors to ensure compliance with applicable obligations arising from such funding, such as timely reporting, an obligation associated with our in-licensed patents and patent applications. The failure of our licensors to meet their obligations may lead to a loss of rights or the unenforceability of relevant patents. For example, the U.S. government has certain rights in such in-licensed patents, including a non-exclusive license authorizing the U.S. government to use the invention or to have others use the invention on its behalf. If the U.S. government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. The U.S. government’s rights may also permit it to disclose the funded inventions and technology to third parties and to exercise march-in rights to use or allow third parties to use the technology we have licensed that was developed using U.S. government funding. The U.S. government may also exercise its march-in rights if it determines that action is necessary because we or our licensors failed to achieve practical application of the U.S. government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such in-licensed U.S. government-funded inventions may be subject to certain requirements to manufacture product candidates embodying such inventions in the United States. Any of the foregoing could harm our business, financial condition, results of operations, and prospects significantly.
In the event any of our third-party licensors determine that, in spite of our efforts, we have materially breached a license agreement or have failed to meet certain obligations thereunder, it may elect to terminate the applicable license agreement or, in some cases, one or more license(s) under the applicable license agreement and such termination would result in us no longer having the ability to develop and commercialize product candidates and technology covered by that license agreement or license. In the event of such termination of a third-party in-license, or if the underlying patents under a third-party in-license fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our owned and in-licensed patents and patent applications may not provide sufficient protection of our base editing platform technologies, our product candidates and our future product candidates or result in any competitive advantage.

We have in-licensed a number of issued U.S. patents and patent applications that cover base editing and gene targeting technologies. We have applied for provisional patent applications or Patent Cooperation Treaty, or PCT, applications intended to specifically cover our base editing platform technology and uses with respect to treatment of particular diseases and conditions, but do not currently own any issued U.S. patents. Each U.S. provisional patent application is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non-provisional patent application within this timeline could cause us to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications. We cannot be certain that any of these patent applications will issue as patents, and if they do, that such patents will cover or adequately protect our base editing platform technologies or our product candidates, or that such patents will not be challenged, narrowed, circumvented, invalidated or held unenforceable. Any failure to obtain or maintain patent protection with respect to our base editing platform technology and product candidates could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our owned patent applications and in-licensed patents and patent applications contain claims directed to compositions of matter on our base editing product candidates, as well as methods directed to the use of such product candidates for gene therapy treatment. Method-of-use patents do not prevent a competitor or other third party from developing or marketing an identical product for an indication that is outside the scope of the patented method. Moreover, with respect to method-of-use patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, providers may recommend that patients use these products off-label, or patients may do so themselves.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own, or in-license, may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. For example, while our patent applications are pending, we may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in interference or derivation proceedings, or equivalent proceedings in foreign jurisdictions. Even if patents do successfully issue, third parties may challenge their inventorship, validity, enforceability or scope, including through opposition, revocation, reexamination, post-grant and inter partes review proceedings. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our owned or in-licensed patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or one or our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our licensor’s priority of invention or other features of patentability with respect to our owned or in-licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we own or the patents and patent applications we in-license with respect to our base editing platform technology and product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in development, testing, and regulatory review of new product candidates, the period of time during which we could market our product candidates under patent protection would be reduced.

Given that patent applications in the United States and other countries are confidential for a period of time after filing, at any moment in time, we cannot be certain that we or our licensors were in the past or will be in the future the first to file any patent application related to our base editing technology or product candidates. In addition, some patent applications in the United States may be maintained in secrecy until the patents are issued. As a result, there may be prior art of which we or our licensors are not aware that may affect the validity or enforceability of a patent claim, and we or our licensors may be subject to priority disputes. For our in-licensed patent portfolios, we rely on our licensors to determine inventorship, and obtain and file inventor assignments of priority applications before their conversion as PCT applications. A failure to do so in a timely fashion may give rise to a challenge to entitlement of priority for foreign applications nationalized from such PCT applications. For example, the European Patent Office, or
the EPO, Opposition Division, or the EPO Opposition Division, has revoked our optioned Broad Institute patent European Patent No. EP2771468 following a third-party challenge to its priority rights. The patent was revoked due to loss of priority. We or our licensors are subject to and may in the future become a party to proceedings or priority disputes in Europe or other foreign jurisdictions. The loss of priority for, or the loss of, these European patents could have a material adverse effect on the conduct of our business.

We may be required to disclaim part or all of the term of certain patents or patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we or our licensors are aware, but which we or our licensors do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that, if challenged, our patents would be declared by a court, patent office or other governmental authority to be valid or enforceable or that even if found valid and enforceable, a competitor’s technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, that block our efforts or potentially result in our product candidates or our activities infringing such claims. It is possible that our competitors may have filed, and may in the future, file, patent applications covering our products or technology similar to ours. Those patent applications may have priority over our owned patents or in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. The possibility also exists that others will develop products that have the same effect as our product candidates on an independent basis that do not infringe our patents or other intellectual property rights, or will design around the claims of our patent applications or our in-licensed patents or patent applications that cover our product candidates.

Likewise, our currently owned patent applications, if issued as patents, and in-licensed patents and patent applications, if issued as patents, directed to our proprietary base editing technologies and our product candidates are expected to expire from 2034 through 2042, without taking into account any possible patent term adjustments or extensions. Our owned or in-licensed patents may expire before, or soon after, our first product candidate achieves marketing approval in the United States or foreign jurisdictions. Additionally, no assurance can be given that the USPTO or relevant foreign patent offices will grant any of the pending patent applications we own or in-license currently or in the future. Upon the expiration of our current in-licensed patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, financial condition, results of operations and prospects.

**Our owned patent applications and in-licensed patents and patent applications and other intellectual property may be subject to priority disputes or to inventorship disputes and similar proceedings. If we or our licensors are unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop, which could have a material adverse impact on our business.**

Although we have an option to exclusively license certain patents and patent applications directed to Cas9 and Cas12a from Editas, who in turn has licensed such patents from various academic institutions including the Broad Institute, we do not currently have a license to such patents and patent applications. Certain of the U.S. patents and one U.S. patent application to which we hold an option are co-owned by the Broad Institute and MIT, and in some cases co-owned by the Broad Institute, MIT, and Harvard, which we refer to together as the Boston Licensing Parties, and were involved in U.S. interference No. 106,048 with one U.S. patent application co-owned by the University of California, the University of Vienna, and Emmanuelle Charpentier, which we refer to together as the University of California. On September 10, 2018, the Court of Appeals for the Federal Circuit, or the CAFC, affirmed the Patent Trial and Appeal Board of the USPTO’s, or PTAB’s, holding that there was no interference-in-fact. An interference is a proceeding within the USPTO to determine priority of invention of the subject matter of patent claims filed by different parties.

On June 24, 2019, the PTAB declared an interference (U.S. Interference No. 106,115) between 10 U.S. patent applications ((U.S. Serial Nos. 15/947,680; 15/947,700; 15/947,718; 15/981,807; 15/981,808; 15/981,809; 16/136,159; 16/136,165; 16/136,168; and 16/136,175) that are co-owned by the University of California, and 13 U.S. patents and one U.S. patent application (U.S. Patent Nos. 8,697,359; 8,771,945; 8,795,965; 8,865,406; 8,871,445; 8,889,356; 8,895,308; 8,906,616; 8,932,814; 8,945,839; 8,995,233; 8,999,641; and 9,840,713, and U.S. Serial No. 14/704,551)) that are co-owned by the Boston Licensing Parties, which we have an option to under the Editas License Agreement. In the declared interference, the University of California has been designated as the junior party and the Boston Licensing Parties have been designated as the senior party.

As a result of the declaration of interference, an adversarial proceeding in the USPTO before the PTAB has been initiated, which is declared to ultimately determine priority, specifically and which party was first to invent the claimed subject matter. Following oral arguments on the parties’ motions in May 2020, the PTAB issued a decision in September 2020, which included, in part, denying the Boston Licensing Parties motion that the University of California should be estopped in the current proceeding by the PTAB’s decision in the prior interference proceeding between the parties (No. 106,048), finding that the Boston Licensing Parties remain the senior party in the proceeding, and holding that the interference will proceed to the second, priority phase. An interference is typically divided into two phases. The first phase is referred to as the motions or preliminary motions phase while the second is referred to as
the priority phase. In the first phase, each party may raise issues including but not limited to those relating to the patentability of a party’s claims based on prior art, written description, and enablement. A party also may seek an earlier priority benefit or may challenge whether the declaration of interference was proper in the first place. Priority, or a determination of who first invented the commonly claimed invention, is determined in the second phase of an interference. Although we cannot predict with any certainty how long the priority phase will actually take, it may take approximately a year or longer before a decision is made by the PTAB. The 10 University of California patent applications and the 13 U.S. patents and one U.S. patent application co-owned by the Boston Licensing Parties involved in U.S. Interference No. 106,115 generally relate to CRISPR/Cas9 systems or eukaryotic cells comprising CRISPR/Cas9 systems having fused or covalently linked RNA and the use thereof in eukaryotic cells. There can be no assurance that the U.S. interference will be resolved in favor of the Boston Licensing Parties. If the U.S. interference resolves in favor of University of California, or if the Boston Licensing Parties’ patents and patent application are narrowed, invalidated, or held unenforceable, we may lose the ability to license the optioned patents and patent application and our ability to commercialize our product candidates may be adversely affected if we cannot obtain a license to relevant third parties that cover our product candidates. We may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our base editing platform technology or product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

We or our licensors may also be subject to claims that former employees, collaborators, or other third parties have an interest in our owned patent applications or in-licensed patents or patent applications or other intellectual property as an inventor or co-inventor. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in such patent applications, such co-owners may be able to license their rights to other third parties, including our competitors. In addition, we may need the cooperation of any such co-owners to enforce any patents that issue from such patent applications against third parties, and such cooperation may not be provided to us.

If we or our licensors are unsuccessful in any interference proceedings or other priority, validity (including any patent oppositions), or inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more of our owned, licensed, or optioned patents, or such patent claims may be narrowed, invalidated, or held unenforceable, or through loss of exclusive ownership of or the exclusive right to use our owned or in-licensed patents. In the event of loss of patent rights as a result of any of these disputes, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and product candidates. Even if we or our licensors are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations, or prospects.

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our patents and intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Moreover, the initiation of proceedings by third parties to challenge
the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We have entered into license agreements with third parties and may need to obtain additional licenses from our existing licensors and others to advance our research or allow commercialization of product candidates we may develop. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In either event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including base editing technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

In each of our license agreements, we are generally responsible for bringing any actions against any third party for infringing on the patents we have licensed. Certain of our license agreements, also require us to meet development thresholds to maintain the license, including establishing a set timeline for developing and commercializing products. In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of or base editing platform technology or product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and growth prospects. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights to third parties under our collaborative development relationships;
- our diligence obligations under the license agreement with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or broaden what we believe to be the scope of the licensor’s rights to our intellectual property and technology, or increase what we believe to be our financial or other obligations under the relevant agreement, any of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. As a result, any termination of or disputes over our intellectual property licenses could result in the loss of our ability to develop and commercialize our base editing platform or other product candidates or we could lose other significant rights, any of which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. It is also possible that a third party could be granted limited licenses to some of the same technology, in certain circumstances.
We may not be successful in acquiring or in-licensing necessary rights to key technologies or any product candidates we may develop.

We currently have rights to intellectual property, through licenses from third parties, to identify and develop product candidates, and we expect to seek to expand our product candidate pipeline in part by in-licensing the rights to key technologies. The future growth of our business will depend in part on our ability to in-license or otherwise acquire the rights to additional product candidates and technologies. Although we have succeeded in licensing technologies from third party licensees including Harvard, Broad Institute, Editas, and Bio Palette in the past, we cannot assure you that we will be able to in-license or acquire the rights to any product candidates or technologies from third parties on acceptable terms or at all.

For example, our agreements with certain of our third-party licensors provide that our field of use excludes particular fields, for example, the diagnosis, treatment, and prevention of human cancers through certain engineered T-cells, which are licensed exclusively or non-exclusively to a third-party licensee. If we determine that rights to such fields are necessary to commercialize our drug candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to continue developing, manufacturing or marketing our drug candidates. We may not be able to obtain such a license on an exclusive basis, on commercially reasonable terms, or at all, which could prevent us from commercializing our drug candidates or allow our competitors or others the chance to access technology that is important to our business.

Furthermore, there has been extensive patenting activity in the field of genome editing, and pharmaceutical companies, biotechnology companies, and academic institutions are competing with us or are expected to compete with us in the field of genome editing technology and filing patent applications potentially relevant to our business and we are aware of certain third-party patent applications that, if issued, may allow the third party to circumvent our patent rights. For example, we are aware of several third-party patents, and patent applications, that, if issued, may be construed to cover our base editing technology and product candidates. In order to market our product candidates, we may find it necessary or prudent to obtain licenses from such third-party intellectual property holders. However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for product candidates we may develop and base editing technology. We may also require licenses from third parties for certain non-base editing technologies including certain delivery methods that we are evaluating for use with product candidates we may develop. In addition, some of our owned patent applications and in-licensed patents and patent applications are co-owned with third parties. With respect to any patents co-owned with third parties, we may require licenses to such co-owners’ interest to such patents. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

Additionally, we may collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution’s rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

In addition, the licensing or acquisition of third-party intellectual property rights is a highly competitive area, and a number of more established companies are also pursuing strategies to license or acquire third party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

The intellectual property landscape around genome editing technology, including base editing, is highly dynamic, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and may prevent, delay or otherwise interfere with our product discovery and development efforts.

The field of genome editing, especially in the area of base editing technology, is still in its infancy, and no such product candidates have reached the market. 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. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be subject to and may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our base editing platform technology and any product candidates we may develop, including interference proceedings, post-grant review, inter partes review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the EPO. Numerous U.S. and foreign issued patents and pending patent applications that are owned by third parties exist in the fields in which we are developing our product candidates and they may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit.

As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our base editing platform 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. We are aware of certain third-party patent applications that, if issued, may be construed to cover our base editing technology and product candidates. There may also 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.

Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. Our product candidates make use of CRISPR-based technology, which is a field that is highly active for patent filings. In November 2018, it was reported that 211 patent families and 1835 patent family members worldwide referenced CRISPR or Cas in the title, abstracts or claims. The extensive patent filings related to CRISPR and Cas make it difficult for us to assess the full extent of relevant patents and pending applications that may cover our base editing platform technology and product candidates and their use or manufacture. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our base editing platform technology and product candidates. For example, we are aware of a patent portfolio that is co-owned by the University of California, University of Vienna and Emmanuelle Charpentier, or the University of California Portfolio, which contains multiple patents and pending applications directed to gene editing. The University of California portfolio includes, for example, U.S. Patent Nos. 10,266,850; 10,227,611; 10,000,772; 10,113,167; 10,301,651; 10,308,961; 10,337,029; 10,351,878; 10,407,697; 10,358,659; 10,358,658; 10,385,360; 10,400,253; 10,421,980; 10,415,061; 10,443,076; 10,487,341; 10,513,712; 10,519,467; 10,526,619; 10,533,190; 10,550,407; 10,563,227; 10,570,419; 10,577,631; 10,597,680; 10,612,045; 10,626,419; 10,642,791; 10,669,560; 10,676,759; 10,752,920; 10,774,344; 10,793,878, which are expected to expire around March 2033, excluding any additional term for patent term adjustment, or PTA, or patent term extension, or PTE, and any disclaimed term for terminal disclaimers. The University of California portfolio also includes numerous additional pending patent applications. If these patent applications issue as patents, they are expected to expire around March 2033, excluding any PTA, PTE, and any disclaimed term for terminal disclaimers. As discussed above, certain applications in the University of California Portfolio are currently subject to U.S. Interference No. 106,115 with certain U.S. patents and one U.S. patent application that are co-owned by the Boston Licensing Parties to which we have an option under the Editas License Agreement. Although we have an option to exclusively license certain patents and patent applications directed to Cas9 and Cas12a from Editas, who in turn has licensed such patents from various academic institutions including Broad Institute, we do not currently have a license to such patents and patent applications. Certain members of the University of California Portfolio are being opposed in Europe by multiple parties. For example, the EPO Opposition Division has initiated opposition proceedings against European Patent Nos. EP3,241,902 B1, EP2,800,811 B1, and EP3401400 B1, which are estimated to expire in March 2033 (excluding any patent term adjustments or extensions). The opposition procedure before the EPO allows one or more third parties to challenge the validity of a granted European patent within nine months after grant date of the European patent. Opposition proceedings may involve issues including, but not limited to, priority, patentability of the claims involved, and procedural formalities related to the filing of the patent application. As a result of the opposition proceedings, the Opposition Division can revoke a patent, maintain the patent as granted, or maintain the patent in an amended form. It is uncertain when or in what manner the Opposition Division will act on the opposition proceedings of European patent EP3,241,902 B1 and how oppositions filed against EP3,401,400 B1 will be resolved. Most of the claims of European patent EP 2,800,811 B1 were maintained without amendment by the Opposition Division, but this decision is being appealed. If these patents are maintained by the Opposition Division with claims similar to those that are currently opposed, our ability to commercialize our product candidates may be adversely affected if we do not obtain a license to these patents. We may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. If we are unable to obtain a necessary license to a third-party patent on
commercially reasonable terms, we may be unable to commercialize our base editing platform technology or product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Numerous other patents and patent applications have been filed by other third parties directed to gene editing, guide nucleic acids, PAM sequence variants, split inteins, Cas12b or gene editing in the context of immune therapy or chimeric antigen receptors.

Because of the large number of patents issued and patent applications filed in our field, third parties may allege they have patent rights encompassing our product candidates, technologies or methods. Third parties may assert that we are employing their proprietary technology without authorization and may file patent infringement claims or lawsuit against us, and if we are found to infringe such third-party patents, we may be required to pay damages, cease commercialization of the infringing technology, or obtain a license from such third parties, which may not be available on commercially reasonable terms or at all.

Our ability to commercialize our product candidates in the United States and abroad may be adversely affected if we cannot obtain a license on commercially reasonable terms to relevant third-party patents that cover our product candidates or base editing platform technology. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe a third party’s intellectual property rights, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing, and marketing any product candidates we may develop and our technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our base editing platform technology or product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or product candidates. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys’ fees, if we are found to have willfully infringed a patent or other intellectual property right. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects.

Defense of third-party claims of infringement of misappropriation, or violation of intellectual property rights involves substantial litigation expense and would be a substantial diversion of management and employee time and resources from our business. Some third parties may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, results of operations and prospects. There could also 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. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may become involved in lawsuits to protect or enforce our future patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful and could result in a finding that such patents are unenforceable or invalid.

Competitors may infringe our future patents or the patents of our licensing partners, or we may be required to defend against claims of infringement. In addition, our future patents or the patents of our licensing partners also are, and may in the future become, involved in inventorship, priority, validity or enforceability disputes. Countering or defending against such claims can be expensive and time consuming. In an infringement proceeding, a court may decide that a patent owned or in-licensed by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our owned and in-licensed patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly.

In patent litigation in the United States, defendant countersuits alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. These types of mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). These types of proceedings could result in revocation or amendment to our patents such that they no longer cover our product candidates. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be
certain that there is no invalidating prior art, of which we, our licensors, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our technology and/or product candidates. Defense of these types of claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Conversely, we may choose to challenge the patentability of claims in a third party’s U.S. patent by requesting that the USPTO review the patent claims in re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). We are currently challenging, and in the future may choose to challenge, third party patents in patent opposition proceedings in the EPO or another foreign patent office. Even if successful, the costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates, base editing platform technology or other or proprietary technologies.

For example, as discussed above, elements of the University of California patent portfolio are being opposed in Europe by multiple parties and we are participating in the opposition proceedings. The EPO Opposition Division, or the Opposition Division, has initiated opposition proceedings against European patents estimated to expire in March 2033 (excluding any patent term adjustments or extensions) and co-owned by the University of California. The opposition procedure before the EPO allows one or more third parties to challenge the validity of a granted European patent within nine months after grant date of the European patent. Opposition proceedings may involve issues including, but not limited to, priority, patentability of the claims involved, and procedural formalities related to the filing of the patent application. As a result of the opposition proceedings, the Opposition Division can revoke a patent, maintain the patent as granted, or maintain the patent in an amended form. It is uncertain when or in what manner the Opposition Division will act on the opposition proceedings of these European patents. If these patents are maintained by the Opposition Division with claims similar to those that are currently opposed, our ability to commercialize our product candidates may be adversely affected if we do not obtain a license to these patents. We may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our base editing platform technology or product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. 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 conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications are due to be paid to the USPTO and foreign patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and foreign patent agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. While an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations, however, in which non-compliance can result a partial or complete loss of patent rights in the relevant jurisdiction. Were a noncompliance event to occur, our competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Changes in patent law in the United States and in non-U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our base editing platform technology and product candidates.
As is the case with other biotech and pharmaceutical 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.

Changes in either the patent laws or interpretation of the patent laws could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of our issued patents. For example, in March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, the United States transitioned from a “first to invent” to a “first-to-file” patent system. Under a “first-to-file” system, assuming that other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on an invention regardless of whether another inventor made the invention earlier. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either file any patent application related to our technology or product candidates or invent any of the inventions claimed in our or our licensor’s patents or patent applications. The America Invents Act also includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted, allowing third party submission of prior art and establish a new post-grant review system including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The effects of these changes are currently unclear as the USPTO continues to promulgate new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the “first-to-file” provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on the specific patents discussed in this filing have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case, Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. We cannot predict how this and future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse changes in the patent laws of other jurisdictions could also have a material adverse effect on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. The terms of individual patents depend upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest non-provisional filing date in the applicable country. However, the actual protection afforded by a patent varies 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. Various extensions including PTE and PTA, may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after we or our partners commercialize those candidates. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain PTE 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 may be eligible for limited PTE under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments PTE term of up to five years as compensation for patent term lost during the FDA regulatory review process. A PTE cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent per product 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, even if we were to seek a PTE, it may not be granted because of, for example, the failure to exercise due diligence during the testing phase or regulatory review process, the failure
to apply within applicable deadlines, the failure to apply prior to expiration of relevant patents, or any other failure 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 PTE or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

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

In addition to seeking patents for our technology and product candidates, we also rely on know-how and trade secret protection, as well as confidentiality agreements, non-disclosure agreements and invention assignment agreements with our employees, consultants and third-parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable.

It is our policy to require our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed by or made known to the individual or entity during the course of the party’s relationship with us is to be kept confidential and not disclosed to third parties, except in certain specified circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and that are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In the case of consultants and other third parties, the agreements provide that all inventions conceived in connection with the services provided are our exclusive property. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Additionally, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know-how can be difficult to protect. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and any recourse we might take against this type of misconduct may not provide an adequate remedy to protect our interests fully. In addition, trade secrets may be independently developed by others in a manner that could prevent us from receiving legal recourse. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any of that information was independently developed by a competitor, our competitive position could be harmed.

In addition, some courts inside and outside the United States are sometimes less willing or unwilling to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. Even if we are successful, these types of lawsuits may consume our time and other resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

**Third parties may assert that our employees, consultants, or advisors have wrongfully used or disclosed confidential information or misappropriated trade secrets.**

As is common in the biotechnology and pharmaceutical industries, we employ individuals that are currently or were previously employed at universities, research institutions or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual’s current or former employer. Also, we have in the past and may in the future be subject to claims that these individuals are violating non-compete agreements with their former employers. We may then have to pursue litigation to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities, and we may not have sufficient financial or other resources to adequately conduct this type of litigation or proceedings. For example, some of our
competitors may be able to sustain the costs of this type of litigation or proceedings more effectively than we can because of their substantially greater financial resources. In any case, uncertainties resulting from the initiation and continuation of intellectual property litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

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

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

Intellectual property rights do not necessarily address all potential threats.

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

• any product candidates we may develop will eventually become commercially available in generic or biosimilar product forms;
• others may be able to make gene therapy products that are similar to any product candidates we may develop or utilize similar base editing technology but that are not covered by the claims of the patents that we license or may own in the future;
• we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
• we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
• we, or our license partners or current or future collaborators, may fail to meet our obligations to the U.S. government regarding any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
• others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
• it is possible that our pending, owned or licensed patent applications or those that we may own in the future will not lead to issued patents;
• it is possible that there are prior public disclosures that could invalidate our owned or in-licensed patents, or parts of our owned or in-licensed patents;
• it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our product candidates or technology similar to ours;
• it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
• issued patents that we hold rights to may be held invalid, unenforceable, or narrowed in scope, including as a result of legal challenges by our competitors;
• the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
• the laws of foreign countries may not protect our proprietary rights or the proprietary rights of license partners or current or future collaborators to the same extent as the laws of the United States;
the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;

our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents;

we may not develop additional proprietary technologies that are patentable;

any product candidates we develop may be covered by third parties’ patents or other exclusive rights;

the patents of others may harm our business; or

we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks related to regulatory and other legal compliance matters

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming, and uncertain and may prevent us from obtaining approvals for the commercialization of any product candidates we may develop. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, product candidates we may develop, and our ability to generate revenue will be materially impaired.

Any product candidates we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale, import, export, and distribution, are subject to comprehensive regulation by the FDA, the EMA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third parties to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the biological product candidate’s safety, purity, and potency. Securing regulatory approval also requires the submission of extensive information about the product manufacturing process, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical, or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved medicine not commercially viable.

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

Failure to obtain marketing approval in foreign jurisdictions would prevent any product candidates we may develop from being marketed in such jurisdictions, which, in turn, would materially impair our ability to generate revenue.

In order to market and sell any product candidates we may develop in the EU and other foreign jurisdictions, we or our third-party collaborators must obtain separate marketing approvals (a single one for the EU) and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it
is required that the product candidate be approved for reimbursement before the product candidate can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our medicines in any jurisdiction, which would materially impair our ability to generate revenue.

The withdrawal of the U.K. from the EU occurred on January 31, 2020, which is commonly known as “Brexit.” A “transition period” through December 31, 2020 has been established to allow the United Kingdom and EU to negotiate the terms of the United Kingdom’s withdrawal from the EU.

Since the regulatory framework for pharmaceutical products in the U.K. relating to quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit will materially impact the future regulatory regime which applies to products and the approval of product candidates in the U.K. In the first instance, a separate U.K. authorization from any centralized authorization for the EU would need to be applied before the end of any agreed transition period. In the immediately foreseeable future, the process is likely to remain very similar to that applicable in the EU, albeit that the processes for applications will be separate. Longer term, the U.K. is likely to develop its own legislation that diverges from that in the EU.

Even if we, or any collaborators we may have, obtain marketing approvals for any product candidates we develop, the terms of approvals and ongoing regulation of our product candidates could require the substantial expenditure of resources and may limit how we, or they, manufacture and market our product candidates, which could materially impair our ability to generate revenue.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for such medicine, will be subject to continual requirements of and review by the FDA, EMA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, facility registration and drug listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the medicine may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine.

Accordingly, assuming we, or any collaborators we may have, receive marketing approval for one or more product candidates we develop, we, and such collaborators, and our and their contract manufacturers will continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, and quality control. If we and such collaborators are not able to comply with post-approval regulatory requirements, we and such collaborators could be subject to enforcement actions or have the marketing approvals for our products withdrawn by regulatory authorities and our, or such collaborators’, ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our business, operating results, financial condition, and prospects.

Any product candidate for which we obtain marketing approval could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our medicines, when and if any of them are approved.

The FDA, the EMA, and other regulatory agencies closely regulate the post-approval marketing and promotion of medicines to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA, the EMA and other regulatory agencies impose stringent restrictions on manufacturers’ communications regarding off-label use, and if we market our medicines for off-label use, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice. Violation of the Federal Food, Product, and Cosmetic Act and other statutes, including the False Claims Act, and equivalent legislation in other countries relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state and other countries’ health care fraud and abuse laws and state consumer protection laws. Even if it is later determined we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters.

In addition, later discovery of previously unknown problems with our medicines, manufacturers, or manufacturing processes, or failure to comply with regulatory requirements, may yield various negative consequences, including:

- restrictions on such medicines, manufacturers, or manufacturing processes;
- restrictions on the labeling or marketing of a medicine;
- restrictions on the distribution or use of a medicine;
requirements to conduct post-marketing clinical trials;

• receipt of warning or untitled letters;

• withdrawal of the medicines from the market;

• refusal to approve pending applications or supplements to approved applications that we submit;

• recall of medicines;

• fines, restitution, or disgorgement of profits or revenue;

• restrictions on future procurements with governmental authorities;

• suspension or withdrawal of marketing approvals;

• suspension of any ongoing clinical trials;

• refusal to permit the import or export of our medicines;

• product seizure; and

• injunctions or the imposition of civil or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any product candidates we may develop and adversely affect our business, financial condition, results of operations, and prospects.

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

Healthcare providers, physicians, and third-party payors play a primary role in the recommendation and prescription of any product candidates that we may develop for which we obtain marketing approval. 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 market, sell, and distribute our medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, including certain laws and regulations applicable only if we have marketed products, include the following:

• 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 to get a false claim paid;

• federal healthcare program anti-kickback law, 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;

• the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

• the federal Food, Drug, and Cosmetic Act, or the FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;

• federal laws 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;

• the so-called “federal sunshine” law under the Healthcare Reform Act, which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to the Center for Medicare & Medicaid Services within the U.S. Department of Health and Human Services for re-disclosure to the public, as well as ownership and investment interests held by physicians and their immediate family members;
state laws also requiring pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to health care providers or marketing expenditures; 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.

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. 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.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of EU Member States, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

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

**Healthcare and other reform legislation may increase the difficulty and cost for us and any collaborators we may have to obtain marketing approval of and commercialize any product candidates we may develop and affect the prices we, or they, may obtain.**

In the United States and some foreign jurisdictions, there have been and continue to be ongoing efforts to implement legislative and regulatory changes regarding the healthcare system. Such changes could prevent or delay marketing approval of any product candidates that we may develop, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Although we cannot predict what healthcare or other reform efforts will be successful, such efforts may result in more rigorous coverage criteria, in additional downward pressure on the price that we, or our future collaborators, may receive for any approved products or in other consequences that may adversely affect our ability to achieve or maintain profitability.

Within the United States, the federal government and individual states have aggressively pursued healthcare reform, as evidenced by the passing of the Healthcare Reform Act and the ongoing efforts to modify or repeal that legislation. The Healthcare Reform Act substantially changed the way healthcare is financed by both governmental and private insurers and contains a number of provisions that affect coverage and reimbursement of drug products and/or that could affect the demand for pharmaceutical products such as increasing drug rebates under state Medicaid programs for brand name prescription drugs and extending those rebates to Medicaid managed care and assessing a fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid. There were ongoing efforts under the Trump administration to modify and repeal the Healthcare Reform Act as well as implement other healthcare reforms, including a number of actions taken in 2020 and early 2021. There is significant uncertainty regarding the scope and nature of healthcare reform in the wake of the transition from the Trump administration to the Biden administration. Under the Biden administration, there are already indications of different positions on health care reform and action has been taken to delay or reconsider certain reforms. See “Government Regulation—Health care and other reform.” We cannot 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, and we cannot predict how future federal or state legislative, judicial or administrative changes relating to healthcare reform will affect our business.

Federal and state governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, waivers from Medicaid drug rebate law requirements, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. The private sector has also sought to control healthcare costs by limiting coverage or reimbursement or requiring discounts and rebates on products. We are unable to predict what additional legislation, regulations or policies, if any, relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost containment measures could significantly decrease the available coverage and the price we might establish for our potential products, which would have an adverse effect on our net revenues and operating results.
Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations for biological products will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA’s approval and decision-making processes may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Fast track, breakthrough, or regenerative medicine advanced therapy designation by the FDA may not actually lead to a faster development or regulatory review or approval process and does not assure FDA approval of any product candidates we may develop.

FDA’s fast track, breakthrough, and regenerative medicine advanced therapy, or RMAT, programs are intended to expedite the development of certain qualifying products intended for the treatment of serious diseases and conditions. If a product candidate is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the product’s potential to address an unmet medical need for this condition, the sponsor may apply for FDA fast track designation. A product candidate may be designated as a breakthrough therapy if it is intended to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A product candidate may receive RMAT designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening condition, and preliminary clinical evidence indicates that the product candidate has the potential to address an unmet medical need for such condition. While we may seek fast track, breakthrough, and/or RMAT designation, there is no guarantee that we will be successful in obtaining any such designation. Even if we do obtain such designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A fast track, breakthrough, or RMAT designation does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. In addition, the FDA may withdraw fast track, breakthrough, or RMAT designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track, breakthrough, and/or RMAT designation alone do not guarantee qualification for the FDA’s priority review procedures.

Priority review designation by the FDA may not lead to a faster regulatory review or approval process and, in any event, does not assure FDA approval of any product candidates we may develop.

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

We may not be able to obtain orphan drug exclusivity for one or more of our product candidates, and even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan product candidates by the EMA in the EU. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for another product candidate for the same orphan therapeutic indication for that time period. The applicable period is seven years in the United States and ten years in the EU. The exclusivity period in the EU can be reduced to six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified.

The FDA’s standards for granting orphan drug exclusivity in the gene therapy context are unclear and evolving. In order for the FDA to grant orphan drug exclusivity to one of our product candidates, the agency must find that the product candidate is indicated for the treatment of a condition or disease that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product candidate available for the disease or condition will be recovered from sales of the product in the United States. The FDA may conclude that the condition or disease for which we seek orphan drug exclusivity does not meet this standard. Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different product candidates can be approved for the same condition. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later product candidate is...
clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care compared with the product that has orphan exclusivity. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

On August 3, 2017, the Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA's pre-existing regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority.

On January 28, 2020, the FDA issued a draft guidance document describing its current thinking on when a gene therapy product is the “same” as another product for purposes of orphan exclusivity. Under the Draft Guidance, if either the transgene or vector differs between two gene therapy products in a manner that does not reflect “minor” differences, the two products would be considered different drugs for orphan drug exclusivity purposes. FDA will determine whether two vectors from the same viral class are the same on a case-by-case basis and may consider additional key features in assessing sameness. There remains significant ambiguity and uncertainty under FDA's draft guidance, and the FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

Our employees, principal investigators, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, consultants, and commercial partners, and, if we commence clinical trials, our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the EU and other jurisdictions, provide accurate information to the FDA, the EMA, and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA, the EMA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations, and prospects, including the imposition of significant fines or other sanctions.

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

We are subject to numerous laws and regulations in each jurisdiction outside the United States in which we operate. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Similarly, the U.K. Bribery Act 2010 has extra-territorial effect for companies and individuals having a connection with the U.K. The U.K. Bribery Act prohibits inducements both to public officials and private individuals and organizations. Compliance with the FCPA and the U.K. Bribery Act is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

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Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expansion outside of the United States has required, and will continue to require, us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain drugs and drug candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies and contractual obligations could adversely affect our business.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the U.S., EU and U.K. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation.

If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. The U.S. Department of Health and Human Services, of HHS, has the discretion to impose penalties without attempting to resolve violations through informal means. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

In 2018, California passed into law the California Consumer Privacy Act (CCPA), which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of “sales” of their personal information. The CCPA contains significant penalties for companies that violate its requirements. It also provides California residents a private right of action, including the ability to seek statutory damages, in the event of a breach involving their personal information. Compliance with the CCPA is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance. On November 3, 2020, California voters passed a ballot initiative for the California Privacy Rights Act, or CPRA, which will significantly expand the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA will also expand personal information rights of California residents, including creating a right to opt out of sharing of personal information with third parties for advertising, expanding the lookback period for the right to know about
personal information held by businesses, and expanding the right to erasure for information held by third parties. Most CPRA provisions will take effect on January 1, 2023, though the obligations will apply to any personal information collected after January 1, 2022.

In the European Economic Area, or EEA, we are subject to the General Data Protection Regulation, or GDPR, which went into effect in May 2018 and which imposes new obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our partners’ or service providers’ privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill. The GDPR places restrictions on the cross-border transfer of personal data from the EU to countries that have not been found by the European Commission to offer adequate data protection legislation, such as the United States. In July 2020, the CJEU invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimatize the transfer of personal data from the EEA to the U.S. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the U.S. While we were not self-certified under the Privacy Shield, this CJEU decision may lead to increased scrutiny on data transfers from the EEA to the U.S. generally and increase our costs of compliance with data privacy legislation.

Following the withdrawal of the U.K. from the EU, the U.K. Data Protection Act 2018 applies to the processing of personal data that takes place in the U.K. and includes parallel obligations to those set forth by GDPR.

While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

Risks related to employee matters, managing growth and information technology

Our future growth may depend on our ability to identify and acquire businesses or technologies, and if we do not successfully do so, or otherwise fail to integrate any new businesses or technologies into our operations, we may have limited growth opportunities and it could result in significant impairment charges or other adverse financial consequences.

We are continuing to seek to acquire businesses or technologies that we believe are a strategic fit with our business strategy, including our acquisition of Guide Therapeutics, Inc. Future acquisitions, however, may entail numerous operational and financial risks, including:

- a reduction of our current financial resources;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions and in connection with future milestone payment obligations under such acquisition agreements;
- difficulty or inability to secure financing to fund development activities for those acquired or in-licensed technologies;
- higher than expected acquisition and integration costs;
- disruption of our business, customer base and diversion of our management’s time and attention to develop acquired technologies; and
- exposure to unknown liabilities.

We may not have sufficient resources to identify and execute the acquisition businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger biotechnology companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors likely will have access to greater financial resources than we do and may have greater expertise in identifying and evaluating new opportunities. Furthermore, there may be overlap between our product candidates and the companies which we acquire that may create conflicts in relationships or other commitments.
the success of existing or new competitive product candidates or technologies; the timing and results of preclinical studies for any product candidates that we may develop;

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:

- the success of existing or new competitive product candidates or technologies;
- the timing and results of preclinical studies for any product candidates that we may develop;

our financial condition, results of operations, and prospects.

Recruiting and retaining qualified scientific, clinical, manufacturing, and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors, including our scientific co-founders, may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The inability to recruit, or loss of services of certain executives, key employees, consultants, or advisors, may impede the progress of our research, development, and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations, and prospects.

We expect to expand our development, regulatory, and future sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

In connection with the growth and advancement of our pipeline and becoming a public company, we expect to increase the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs, and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

As a growing biotechnology company, we are actively pursuing new platforms and product candidates in many therapeutic areas and across a wide range of diseases. Successfully developing product candidates for and fully understanding the regulatory and manufacturing pathways to all of these therapeutic areas and disease states requires a significant depth of talent, resources and corporate processes in order to allow simultaneous execution across multiple areas. Due to our limited resources, we may not be able to effectively manage this simultaneous execution and the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, legal or regulatory compliance failures, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. Further, in connection with our collaboration and license agreement with Prime Medicine, we are obligated to provide management services to Prime Medicine for up to one year, which could distract our management team from their responsibilities to our own company. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively and commercialize our product candidates, if approved, will depend in part on our ability to effectively manage the future development and expansion of our company.

Risks related to our common stock

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantially losses for purchasers of our common stock and subject us to securities class action litigation.

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:

- the success of existing or new competitive product candidates or technologies;
- the timing and results of preclinical studies for any product candidates that we may develop;
• failure or discontinuation of any of our product development and research programs;
• results of preclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
• developments or changing views regarding the use of genetic medicines, including those that involve gene editing;
• 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, clinical development programs, or product candidates that we may develop;
• the results of our efforts to develop additional product candidates or products;
• actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
• announcement or expectation of additional financing efforts;
• sales of our common stock by us, our insiders or other stockholders;
• expiration of market stand-off or lock-up agreement;
• 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.

Our directors, executive officers and affiliates have significant voting power and may take actions that are not in the best interests of our other stockholders.

As of December 31, 2020, our directors and executive officers and their affiliates beneficially owned shares representing approximately 30% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. To comply with the requirements of being a public company, we have undertaken certain actions, such as documenting, reviewing and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act of 2002, or SOX, which requires annual management assessment of the effectiveness of our internal control over financial reporting.
Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors’ perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our common share price and make it more difficult for us to effectively market and sell our service to new and existing customers.

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

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

As of December 31, 2020, we no longer qualified as a smaller reporting company; however, we are allowed to continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies through our annual report for the year ended December 31, 2020.

We have incurred and expect to continue to incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we have incurred and expect to continue to incur, particularly after we are no longer an “emerging growth company,” significant legal, accounting, and other expenses. 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 have added additional accounting, finance, and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to maintain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. 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.

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

*We do not expect to pay any dividends for the foreseeable future. Investors may never obtain a return on their investment unless they sell our common stock for a price higher than which they paid for it.*

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future credit facility may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment.

**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 authorized our board of directors to make, alter, amend 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 for shares of our common stock, thereby depressing the market price of our common stock.

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

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

**Our amended and restated certificate of incorporation and amended and restated by-laws designate 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 within the State of Delaware will be exclusive forums for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation, our amended and restated by-laws or Delaware law.
incorporation or our amended and restated by-laws, (4) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated by-laws or (5) any other action asserting a claim against us that is governed by the internal affairs doctrine. Furthermore, our amended and restated by-laws also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. 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 and amended and restated by-laws described above. These choice of forum provisions 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 or amended and restated by-laws 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. For example, the Court of Chancery of the State of Delaware recently determined that a provision stating that federal district courts of the United States are the exclusive forum for resolving any complaint asserting a cause of action under the Securities Act is not enforceable. However, this decision may be reviewed and ultimately overturned by the Delaware Supreme Court.

General Risk Factors

Comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, the Tax Act was signed into law. The Tax Act, among other things, contains significant changes to corporate taxation, including (i) reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, (ii) limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), (iii) limitation of the deduction for NOLs to 80% of current year taxable income in respect of NOLs generated during or after 2018 and elimination of NOL carrybacks, (iv) immediate deductions for certain new investments instead of deductions for depreciation expense over time, and (v) modifying or repealing many business deductions and credits. Any federal NOL incurred in 2018 and in future years may now be carried forward indefinitely pursuant to the Tax Act. Similar rules and limitations may apply for state income tax proposes.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn, or additional global financial crises, could result in a variety of risks to our business, including weakened demand for our product candidates, if approved, or our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model or our stock performance, or if our operating results fail to meet the expectations of the investor community, one or more of the analysts who cover our company may change their recommendations regarding our company, and our stock price could decline.

Our internal computer systems, or those of our third-party vendors, collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

Our internal computer systems and those of our current and any future third-party vendors, collaborators and other contractors or consultants are vulnerable to damage or interruption from computer viruses, computer hackers, malicious code, employee theft or misuse, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we seek to protect our information technology systems from system failure, accident and security breach, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other disruptions. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If we were to experience a significant cybersecurity breach of our information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counterparties and data subjects could be material. In addition, our remediation efforts may not be
successful. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our or our third-party vendors’, collaborators’ or other contractors’ or consultants’ data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability including litigation exposure, penalties and fines, we could become the subject of regulatory action or investigation, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. Any of the above could have a material adverse effect on our business, financial condition, results of operations or prospects.

Item 1B. Unresolved Staff Comments.
Not Applicable.

Item 2. Properties.
We occupy approximately 38,203 square feet of office and laboratory space in Cambridge, Massachusetts under a lease that expires in October 2028. We have entered into a lease agreement with the Massachusetts Institute of Technology for approximately 123,209 square feet of office and laboratory space in Cambridge, Massachusetts, which is currently under construction. We currently anticipate commencing this lease at the earliest in late 2021 upon completion of construction. Upon completion of construction and our commencement of our occupancy within the space, the lease will expire in 2034. Additionally, we entered into a lease agreement with Alexandria Real Estate Equities, Inc. to build a 100,000 square foot manufacturing facility in Research Triangle Park, North Carolina intended to support a broad range of clinical programs, which is currently under construction. We expect that the facility will be operational by the first quarter of 2023. Upon completion of construction and our commencement of our occupancy within the space, the lease will expire on the fifteenth anniversary of commencement and we have an option to extend the lease term for two five-year terms. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Item 3. Legal Proceedings.
We are not currently a party to any material legal proceedings. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Regardless of the outcome, litigation can have a material adverse effect on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 4. Mine Safety Disclosures.
Not Applicable.
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market information
Our common stock has been publicly traded on the Nasdaq Global Select Market under the symbol “BEAM” since February 6, 2020. Prior to that time, there was no public market for our common stock.

Holders
As of March 8, 2021, there were approximately 81 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividends
We have not declared or paid any cash dividends on our capital stock since our inception. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends to holders of common stock in the foreseeable future.

Securities authorized for issuance under equity compensation plans
Information about our equity compensation plans is incorporated herein by reference to Item 12, Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters, of this Annual Report on Form 10-K.

Recent sales of unregistered securities
The following list sets forth information regarding all unregistered securities sold by us during the year ended December 31, 2020. No underwriters were involved in the sales and the certificates representing the securities sold and issued contain legends restricting transfer of the securities without registration under the Securities Act or an applicable exemption from registration.

- On July 21, 2020, pursuant to the Bio Palette License Agreement, we issued 175,000 shares of our common stock to Bio Palette Co. Ltd., or Bio Palette, in satisfaction of certain milestone payment obligations pursuant to the Bio Palette License Agreement. We relied on the exemption from the registration requirements of the Securities Act under Section 4(a)(2) thereof, for a transaction by an issuer not involving any public offering.
- On October 6, 2020, pursuant to the license and collaboration agreement between us and Prime Medicine, Inc., or Prime Medicine, we issued 200,307 shares of our common stock to Prime Medicine, in exchange for 5,000,000 shares of Prime Medicine common stock. We relied on the exemption from the registration requirements of the Securities Act under Section 4(a)(2) thereof, for a transaction by an issuer not involving any public offering.

Use of proceeds from registered securities
In February 2020, we closed our IPO in which we issued and sold 12,176,471 shares of our common stock, including 1,588,235 shares of common stock sold pursuant to the underwriters’ full exercise of their option to purchase additional shares, at a public offering price of $17.00 per share, for aggregate gross proceeds of $207.0 million. All of the shares issued and sold in the IPO were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-233985), which was declared effective by the SEC on February 5, 2020, and a Registration Statement on Form S-1 MEF (File No. 333-236284) filed pursuant to Rule 462(b) of the Securities Act. The offering commenced on February 5, 2020 and did not terminate until the sale of all the shares offered.

Our use of the net offering proceeds through the date of the filing of this Annual Report on Form 10-K, is consistent with the use of proceeds described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on February 7, 2020, and there has been no material change in our planned use of the balance of the net proceeds from our IPO described in such prospectus.

Purchases of equity securities by the issuer or affiliated purchasers
Neither we nor any affiliated purchaser or anyone acting on our behalf or on behalf of an affiliated purchaser made any purchases of shares of our common stock during the year ended December 31, 2020.

Not applicable.
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

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

Overview

We are a biotechnology company committed to establishing the leading, fully integrated platform for precision genetic medicines. Our vision is to provide life-long cures to patients suffering from serious diseases. To achieve this vision, we have assembled a platform that includes a suite of gene editing and delivery technologies and are in the process of developing internal manufacturing capabilities. Our suite of gene editing technologies is anchored by our proprietary base editing technology, which potentially enables an entirely new class of precision genetic medicines that target a single base in the genome without making a double-stranded break in the DNA. This approach uses a chemical reaction designed to create precise, predictable and efficient genetic outcomes at the targeted sequence. Our novel base editors have two principal components: (i) a CRISPR protein, bound to a guide RNA, that leverages the established DNA-targeting ability of CRISPR, but modified to not cause a double-stranded break, and (ii) a base editing enzyme, such as a deaminase, which carries out the desired chemical modification of the target DNA base. We believe this design contributes to a more precise and efficient edit compared to traditional gene editing methods, which operate by creating targeted double-stranded breaks in the DNA; these breaks can result in unwanted DNA modifications. We believe that the precision of our editors will dramatically increase the impact of gene editing for a broad range of therapeutic applications.

To unlock the full potential of our base editing technology across a wide range of therapeutic applications, we are pursuing a broad suite of clinically validated and novel delivery modalities. For a given tissue type, we use the delivery modality with the most compelling biodistribution. Our current programs are organized by delivery modality into three distinct pipelines: electroporation for efficient delivery to blood cells and immune cells ex vivo; lipid nanoparticles, or LNPs, for non-viral in vivo delivery to the liver and potentially other organs in the future; and adeno-associated viral vectors, or AAV, for in vivo viral delivery to the eye and central nervous system, or CNS.

The elegance of the base editing approach combined with a tissue specific delivery modality, provides the basis for a targeted efficient, precise, and highly versatile gene editing system, capable of gene correction, gene silencing/gene activation, and or multiplex editing of several genes simultaneously. We are currently advancing a broad, diversified portfolio of base editing programs against distinct editing targets, utilizing the full range of our development capabilities. We believe the flexibility and versatility of our base editors may lead to broad therapeutic applicability and transformational potential for the field of precision genetic medicines.

Recent Developments

In February 2021, we entered into an Agreement and Plan of Merger to acquire Guide Therapeutics, or Guide. Pursuant to the merger agreement, we paid Guide’s former stockholders and optionholders upfront consideration in an aggregate amount of $120.0 million, excluding customary purchase price adjustments, in shares of our common stock, based upon the volume-weighted average price of the common stock over the ten trading day period ending on February 19, 2021. In addition, Guide’s former stockholders and optionholders will be eligible to receive up to an additional $100.0 million in technology adjustments, in shares of our common stock, based upon the volume-weighted average price of the common stock over the ten trading day period ending on February 19, 2021. In addition, Guide’s former stockholders and optionholders will be eligible to receive up to an additional $100.0 million in technology and $220.0 million in product success milestone payments, payable in our common stock.

Manufacturing

In August 2020, we entered into a lease agreement with Alexandria Real Estate Equities, Inc. to build a 100,000 square foot current Good Manufacturing Practice, or cGMP, compliant manufacturing facility in Research Triangle Park, North Carolina intended to support a broad range of clinical programs. We will invest up to $83.0 million over a five-year period and anticipate that the facility will be operational by the first quarter of 2023. The project will be facilitated, in part, by a Job Development Investment Grant approved by the North Carolina Economic Investment Committee, which authorizes potential reimbursements based on new tax revenues generated through the project. The facility will be designed to support manufacturing for our ex vivo cell therapy programs in hematology and oncology and in vivo non-viral delivery programs for liver diseases, with flexibility to support manufacturing of our viral delivery programs, and ultimately, scale-up to support potential commercial supply.

For our initial waves of clinical programs, we will use contract manufacturing organizations, or CMOs, with relevant manufacturing experience in genetic medicines.
COVID-19

With the ongoing concern related to the COVID-19 pandemic, we have maintained and expanded the business continuity plans to address and mitigate the impact of the COVID-19 pandemic on our business. In March 2020, to protect the health of our employees, and their families and communities, we restricted access to our offices to personnel who performed critical activities that must be completed on-site, limited the number of such personnel that can be present at our facilities at any one time, and requested that most of our employees work remotely. In May 2020, as certain states eased restrictions, we established new protocols to better allow our full laboratory staff access to our facilities. These protocols included several shifts working over a seven-day-week protocol. We expect to continue incurring additional costs to ensure we adhere to the guidelines instituted by the CDC and to provide a safe working environment to our onsite employees.

The extent to which the COVID-19 pandemic impacts our business, our corporate development objectives, results of operations and financial condition, including and the value of and market for our common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements, and the effectiveness of actions taken globally to contain and treat the disease. Disruptions to the global economy, disruption of global healthcare systems, and other significant impacts of the COVID-19 pandemic could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

While the COVID-19 pandemic did not significantly impact our business or results of operations during the year ended December 31, 2020, the length and extent of the pandemic, its consequences, and containment efforts will determine the future impact on our operations and financial condition.

Financial operations overview

General

We were incorporated on January 25, 2017 and commenced operations shortly thereafter. Since our inception, we have devoted substantially all of our resources to building our base editing platform and advancing development of our portfolio of programs, establishing and protecting our intellectual property, conducting research and development activities, organizing and staffing our company, business planning, raising capital and providing general and administrative support for these operations. To date, we have financed our operations primarily through the sales of our redeemable convertible preferred stock and proceeds from our IPO and follow on offerings.

We are a development stage company, and all of our programs are at a preclinical stage of development. To date, we have not generated any revenue from product sales and do not expect to generate revenue from the sale of products for the foreseeable future. Since inception we have incurred significant operating losses. Our net losses for the years ended December 31, 2020 and 2019 were $194.6 million and $78.3 million, respectively. As of December 31, 2020, we had an accumulated deficit of $397.6 million. We expect to continue to incur significant expenses and increasing operating losses in connection with ongoing development activities related to our portfolio of programs as we continue our preclinical development of product candidates; advance these product candidates toward clinical development; build and operate our GMP facility in North Carolina, further develop our base editing platform; continue to make investments in delivery technology for our base editors, including in connection with our recent acquisition of Guide Therapeutics; conduct research activities as we seek to discover and develop additional product candidates; maintain, expand, enforce, defend and protect our intellectual property portfolio; and continue to hire research and development, clinical and commercial personnel. In addition, we expect to continue to incur additional costs associated with operating as a public company and implementing controls over financing reporting.

As a result of these anticipated expenditures, we will need additional financing to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances, and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all. Our inability to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We can give no assurance that we will be able to secure such additional sources of funds to support our operations, or, if such funds are available to us, that such additional funding will be sufficient to meet our needs.

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Research and development expenses consist of costs incurred in performing research and development activities, which include:

- Expenses incurred in connection with investments in delivery technology for our base editors, including as a result of our acquisition of Guide Therapeutics;
- the cost to obtain licenses to intellectual property, such as those with Harvard University, or Harvard, Broad Institute of MIT and Harvard, or Broad Institute, and Editas Medicine, Inc, or Editas, and related future payments should certain success, development and regulatory milestones be achieved;
- personnel-related expenses, including salaries, bonuses, benefits and stock-based compensation for employees engaged in research and development functions;
- expenses incurred in connection with the discovery and preclinical development of our research programs, including under agreements with third parties, such as consultants, contractors and contract research organizations;
- expenses incurred in connection with the building of our base editing platform;
- the cost of manufacturing for use in our preclinical studies and future clinical trials;
- laboratory supplies and research materials; and
- facilities, depreciation and other expenses which include direct and allocated expenses.

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

In the early phases of development, our research and development costs are often devoted to product platform and proof-of-concept studies that are not necessarily allocable to a specific target.

We expect that our research and development expenses will increase substantially in connection with our planned preclinical and future clinical development activities.

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, intellectual property, business development, and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters, professional fees for accounting, auditing, tax and consulting services, insurance costs, travel, and direct and allocated facility related expenses and other operating costs.

We anticipate that our general and administrative expenses will increase in the future to support increased research and development activities. We also expect to continue to incur increased costs associated with being a public company and implementing controls over financial reporting, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements, director and officer insurance costs, and investor and public relations costs.

Other income and expenses consist of the following items:

- *Change in fair value of derivative liabilities* consists primarily of remeasurement gains or losses associated with changes in success payment liabilities associated with our license agreement with Harvard, dated as of June 27, 2017, as amended, or the Harvard License Agreement, and the license agreement between Blink and Broad Institute, as amended, dated as of May 9, 2018, or the Broad License Agreement.
- *Interest and other income (expense), net* consists primarily of interest income as well as interest expense related to our equipment financings.
Results of operations

Comparison of the years ended December 31, 2020 and 2019

The following table summarizes our results of operations (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Years Ended December 31,</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2020</td>
<td>2019</td>
</tr>
<tr>
<td>License revenue</td>
<td>$24,000</td>
<td>$18,000</td>
</tr>
<tr>
<td>Operating expenses:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>103,179</td>
<td>54,619</td>
</tr>
<tr>
<td>General and administrative</td>
<td>29,605</td>
<td>20,553</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>132,784</td>
<td>75,172</td>
</tr>
<tr>
<td>Loss from operations</td>
<td>(132,760)</td>
<td>(75,154)</td>
</tr>
<tr>
<td>Other income (expense):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in fair value of derivative liabilities</td>
<td>(63,400)</td>
<td>(5,400)</td>
</tr>
<tr>
<td>Interest and other income (expense), net</td>
<td>1,568</td>
<td>2,228</td>
</tr>
<tr>
<td>Total other income (expense)</td>
<td>(61,832)</td>
<td>(3,172)</td>
</tr>
<tr>
<td>Net loss</td>
<td>$194,592</td>
<td>$78,326</td>
</tr>
</tbody>
</table>

License revenue

License revenue was approximately $24,000 for the year ended December 31, 2020 compared to approximately $18,000 for the year ended December 31, 2019. License revenue represents Verve license revenue recorded under the Collaboration and License Agreement executed in April 2019.

Research and development expenses

Research and development expenses were $103.2 million and $54.6 million for the years ended December 31, 2020 and 2019, respectively. The increase of $48.6 million was primarily due to the following:

- An increase of $20.8 million in outsourced services and lab supplies, driven primarily by external research services such as CMOs, IND enabling studies and sponsored research agreements.
- An increase of $5.9 million in milestone and license expenses, primarily related to our agreement with Prime Medicine. During the year ended December 31, 2020, we recognized $5.5 million of expense, representing the fair value of our common stock issued to Prime Medicine in October 2020.
- Increases of $8.6 million in personnel-related costs and $5.6 million in facility-related costs, including depreciation. These increases were due to the growth in the number of research and development employees from 97 at December 31, 2019 to 149 at December 31, 2020, and their related activities, as well as the expense allocated to research and development related to our leased facilities.
- An increase of $7.0 million in stock compensation from additional stock option and restricted stock awards granted due to the increase in the number of research and development employees, as well as an increase in the value of our common stock.

Research and development expenses will continue to increase as we continue our current research programs, initiate new research programs, continue our preclinical development of product candidates and conduct future clinical trials for any of our product candidates.

General and administrative expenses

General and administrative expenses were $29.6 million and $20.6 million for the years ended December 31, 2020 and 2019, respectively. The increase of $9.1 million was primarily due to the following:

- An increase of $2.9 million in insurance costs due to increased directors and officers insurance costs as a result of our being a public company.
- Increases of $2.7 million in personnel related costs and $1.1 million in other (primarily information technology related) costs due to an increase in general and administrative employees from 21 employees as of December 31, 2019 to 32 employees as of December 31, 2020.
- An increase of $1.5 million in intellectual property costs, offset by a $0.6 million decrease in corporate legal expenses.
- An increase of $1.4 million in stock-based compensation from additional stock options granted due to an increase in the number of general and administrative employees, as well as an increase in the value of our common stock.
Change in fair value of derivative liabilities

During the year ended December 31, 2020, we recorded a $63.4 million change in fair value expense related to the success payment liabilities as compared to a $5.4 million expense for the year ended December 31, 2019, due to a significant increase in the value of our common stock. The success payment obligations are still outstanding as of December 31, 2020 and will continue to be revalued at each reporting period.

Interest and other income (expense), net

Interest and other income (expense), net was $1.6 million for the year ended December 31, 2020 as compared to $2.2 million for the year ended December 31, 2019. The decrease of $0.7 million was primarily due to a decrease in interest income of $1.1 million as a result of decreases in interest rates related to our investment portfolio and an increase in interest expense of $0.4 million due to the occurrence of additional drawdowns on our equipment line in 2020, partially offset by an increase in the fair value of our investment in certain corporate equity securities of $0.5 million, which are accounted for as investments in equity securities.

Liquidity and capital resources

Since our inception in January 2017, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and, if successful, the clinical development of our programs. In February 2020, we completed our IPO in which we issued and sold 12,176,471 shares of our common stock, including 1,588,235 shares of common stock sold pursuant to the underwriters’ full exercise of their option to purchase additional shares, at a public offering price of $17.00 per share. We received net proceeds from our IPO of $188.3 million, after deducting underwriting discounts and offering expenses payable by us. In October 2020, we issued and sold 750,000 shares of our common stock, including 750,000 shares pursuant to the full exercise of the underwriters’ option to purchase additional shares, at a public offering price of $24.25 per share, for aggregate gross proceeds of $18.3 million. We received approximately $1.2 million in net proceeds after deducting applicable underwriting discounts and offering expenses payable by us. To date, we have funded our operations primarily through equity offerings. As of December 31, 2020, we had $299.7 million in cash, cash equivalents, and marketable securities.

In January 2021, we issued and sold 2,795,700 shares of our common stock in a private placement at an offering price of $93.00 per share for aggregate gross proceeds of $260.0 million. We received $252.1 million in net proceeds after deducting estimated offering expenses payable by us.

We are required to make success payments to Harvard and Broad Institute based on increases in the per share fair market value of our Series A-1 Preferred Stock and Series A-2 Preferred Stock or, subsequent to our IPO, our common stock. The first success payment measurement will occur during May of 2021, and any amounts due may be settled in cash or shares of our common stock, at our discretion. We have assessed the liability and several key variables thereto, including probability of event occurrence, timing of event occurrence, as well as the price per share at the time of success payment and have determined that a significant portion of the liability may be coming due within the next twelve months, which could affect our cash resources if not settled in shares of our common stock.

To date, we have not generated any revenue from product sales and do not expect to generate revenue from the sale of products for the foreseeable future. We anticipate the need for additional capital in order to continue to fund our research and development, including our plans for preclinical and clinical trials, building, maintaining, and operating a commercial-scale cGMP manufacturing facility, and new product development, as well as to fund general operations. As and if necessary, we will seek to raise these additional funds through various potential sources, such as equity and debt financings or through corporate collaboration and license agreements. Especially in light of the COVID-19 pandemic, we can give no assurances that we will be able to secure such additional sources of funds to support our operations, or, if such funds are available to us, that such additional financing will be sufficient to meet our needs. For a more detailed discussion of risks related to COVID-19, please see Part II, Item 1A, Risk Factors—Risks related to our relationships with third parties, in this Annual Report on Form 10-K.

Cash flows

The following table summarizes our sources and uses of cash (in thousands):

<table>
<thead>
<tr>
<th>Source/Use of Cash</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net cash used in operating activities</td>
<td>$(95,741)</td>
<td>$(72,003)</td>
</tr>
<tr>
<td>Net cash used in investing activities</td>
<td>(100,123)</td>
<td>(66,659)</td>
</tr>
<tr>
<td>Net cash provided by financing activities</td>
<td>322,322</td>
<td>41,279</td>
</tr>
<tr>
<td>Net increase (decrease) in in cash, cash equivalents and restricted cash</td>
<td>$126,458</td>
<td>$(97,383)</td>
</tr>
</tbody>
</table>

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Operating activities

Net cash used in operating activities for the year ended December 31, 2020 was $95.7 million, consisting primarily of our net loss of $194.6 million and an increase in prepaid expenses and other current assets of $5.7 million, offset by cash provided by increases in accrued expenses of $7.0 million, operating lease liabilities of $3.2 million and long-term liabilities of $1.0 million. Net cash used in operating activities was also offset by non-cash charges consisting primarily of a change in the fair value of derivative liabilities of $63.4 million, stock-based compensation expense of $15.4 million, non-cash license expenses of $5.7 million, depreciation of $4.7 million, and non-cash lease expense of $4.7 million, offset by a $0.5 million non-cash change in the fair value of equity investments.

Net cash used in operating activities for the year ended December 31, 2019 was $72.0 million, consisting primarily of our net loss of $78.3 million, a decrease in financing milestone liabilities of $13.8 million resulting from payment of these liabilities, a decrease in operating lease liabilities of $2.5 million, and an increase in prepaids and other assets of $1.9 million offset by cash provided by increases in accounts payable and accrued expenses of $7.7 million and non-cash charges consisting primarily of stock based compensation expense of $7.0 million, change in fair value of derivative liabilities of $5.4 million, depreciation of $3.5 million, and non-cash lease expense of $1.9 million, offset by amortization of investment premiums of $0.9 million.

Investing activities

For the year ended December 31, 2020, cash used in investing activities was primarily the net result of purchases of marketable securities partially offset by maturities of marketable securities of $83.0 million, in addition to purchases of property and equipment of $16.4 million.

For the year ended December 31, 2019, cash used in investing activities was primarily the net result of purchases of marketable securities partially offset by maturities of marketable securities of $53.7 million, in addition to purchases of property and equipment of $12.5 million.

Financing activities

Net cash provided by financing activities for the year ended December 31, 2020 consisted primarily of proceeds from our IPO and follow on public offering of $319.5 million, net of underwriting discounts, net proceeds of $3.3 million from equipment financing, and proceeds from the exercise of stock options of $3.2 million, offset in part by the payment of equity offering costs of $2.1 million and repayments of equipment financing liabilities of $1.6 million.

Net cash provided by financing activities for the year ended December 31, 2019 consisted primarily of the net proceeds from the issuance of Series B Preferred Stock of $37.9 million, and net proceeds of $5.7 million from equipment financing, offset by the payment of equity issuance costs of $2.5 million.

Funding requirements

Our operating expenses are expected to increase substantially as we continue to advance our portfolio of programs.

Specifically, our expenses will increase if and as we:

- continue our current research programs and our preclinical development of product candidates from our current research programs;
- seek to identify additional research programs and additional product candidates;
- initiate preclinical testing and clinical trials for any product candidates we identify and develop;
- maintain, expand, enforce, defend, and protect our intellectual property portfolio and provide reimbursement of third-party expenses related to our patent portfolio;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials;
- establish a sales, marketing, and distribution infrastructure to commercialize any medicines for which we may obtain marketing approval;
- further develop our base editing platform;
- further develop delivery technology for our base editors, resulting from our acquisition of Guide Therapeutics;
- continue to hire additional personnel including research and development, clinical and commercial personnel;
- add operational, financial, and management information systems and personnel, including personnel to support our product development;
• acquire or in-license products, intellectual property, medicines and technologies; and
• build, maintain, and operate a commercial-scale cGMP manufacturing facility.

We expect that our cash, cash equivalents at December 31, 2020 will enable us to fund our current and planned operating expenses and capital expenditures for at least the next 12 months. We have based these estimates on assumptions that may prove to be imprecise, and we may exhaust our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development our programs, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates.

Our future funding requirements will depend on many factors including:

• the cost of continuing to build our base editing platform;
• the costs of acquiring licenses for the delivery modalities that will be used with our product candidates;
• the scope, progress, results, and costs of discovery, preclinical development, laboratory testing, manufacturing and clinical trials for the product candidates we may develop;
• the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights, and defending intellectual property-related claims;
• the costs, timing, and outcome of regulatory review of the product candidates we may develop;
• the costs of future activities, including product sales, medical affairs, marketing, manufacturing, distribution, coverage and reimbursement for any product candidates for which we receive regulatory approval;
• the success of our license agreements and our collaborations;
• our ability to establish and maintain additional collaborations on favorable terms, if at all;
• the achievement of milestones or occurrence of other developments that trigger payments under any additional collaboration agreements we obtain;
• the payment of success liabilities, should we choose to pay in cash;
• the extent to which we acquire or in-license products, intellectual property, and technologies; and
• the costs of obtaining, building, operating and expanding our manufacturing capacity.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and licensing arrangements. We do not have any committed external source of funds. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends.

If we raise funds through additional collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates, or we may have to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We can give no assurance that we will be able to secure such additional sources of funds to support our operations, or, if such funds are available to us, that such additional funding will be sufficient to meet our needs.

Contractual obligations

The following is a summary of our significant contractual obligations as of December 31, 2020:

<table>
<thead>
<tr>
<th>Contractual obligation</th>
<th>Total (in thousands)</th>
<th>Less than 1 year (in thousands)</th>
<th>More than 1 year and less than 3 years (in thousands)</th>
<th>More than 3 years and less than 5 years (in thousands)</th>
<th>More than 5 years (in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating lease obligations (1)</td>
<td>$169,344</td>
<td>$9,096</td>
<td>$27,774</td>
<td>$29,412</td>
<td>$103,062</td>
</tr>
<tr>
<td>Financing obligations</td>
<td>7,872</td>
<td>2,685</td>
<td>4,676</td>
<td>511</td>
<td>—</td>
</tr>
<tr>
<td>Total</td>
<td>$177,216</td>
<td>$11,781</td>
<td>$32,450</td>
<td>$29,923</td>
<td>$103,062</td>
</tr>
</tbody>
</table>

(1) Represents future minimum lease payments under our operating leases for office and lab space in Cambridge, Massachusetts. The minimum lease payments above do not include any related common area maintenance charges or real estate taxes.
The table above does not include rent payments related to the second phase of our April 2019 lease for office and laboratory space to be built, with the rent payments expected to commence during the first quarter of 2022. The minimum amount of anticipated undiscounted lease payments due under the second phase of this lease is $42.7 million. In addition, the table above does not include our lease agreement with Alexandria Real Estate Equities, Inc. to build a 100,000 square foot manufacturing facility in Research Triangle Park, North Carolina. The initial estimate of minimum amount of undiscounted lease payments due under this lease is $63.9 million, which is expected to be paid over a lease term of 15 years.

The table above also does not include potential milestone and success fees, sublicense fees, royalty fees, licensing maintenance fees, and reimbursement of patent maintenance costs that we may be required to pay under agreements we have entered into with certain institutions to license intellectual property. Our agreements to license intellectual property include potential milestone payments that are dependent upon the development of products using the intellectual property licensed under the agreements and contingent upon the achievement of developmental or regulatory approval milestones, as well as commercial and success payment milestones. We have not included such potential obligations in the table above because they are contingent upon the occurrence of future events and the timing and likelihood of such potential obligations are not known with certainty.

Additionally, we enter into contracts in the normal course of business with contract research organizations and other vendors to assist in the performance of our research and development activities and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore are cancelable contracts and not included in the table of contractual obligations and commitments.

**Off-balance sheet arrangements**

We did not have during the periods presented and do not currently have, any off-balance sheet arrangements, as defined under the applicable regulations of the SEC.

**Critical accounting policies and significant judgements**

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

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

**Stock-based compensation**

We measure stock options and other stock-based awards granted to our employees, directors, consultants or founders based upon their fair value on the date of the grant and recognize stock-based compensation expense over the requisite service period, which is generally the vesting period of the respective award. We recognize forfeitures as they occur.

The majority of our stock-based compensation awards are subject to either service- or performance-based vesting conditions. We apply the straight-line method of expense recognition to all awards with service-based vesting and recognize stock-based compensation for performance-based awards over the service period using the accelerated attribution method to the extent achievement of the performance condition is probable.

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

Prior to our IPO in February 2020, there was no public market for our common stock. As a result, prior to our IPO, the estimated fair value of our common stock was determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuations of common stock and our board of directors’ assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. Following our IPO, the fair value of our common stock is determined based on the quoted market price of our common stock.
Fair value measurements – Success payments

We are required to make success payments to Harvard and Broad Institute based on increases in the per share fair market value of our Series A-1 Preferred Stock and Series A-2 Preferred Stock or, subsequent to our IPO, our common stock. Any amounts due may be settled in cash or shares of our common stock, at our discretion. The success payments are accounted for under Accounting Standards Codification 815, Derivatives and Hedging and were initially recorded at fair value with a corresponding charge to research and development expense. The liabilities are marked to market at each balance sheet date with all changes in value recognized in interest and other income (expense), net in the consolidated statement of operations and other comprehensive loss. We will continue to adjust the liability for changes in fair value until the earlier of the achievement or expiration of the success payment obligation. To determine the estimated fair value of the success payments, we used a Monte Carlo simulation model, which models the value of the liability based on several key variables, including probability of event occurrence, timing of event occurrence, as well as the price per share at the time of success payment.

Accrued research and development costs

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to vendors in connection with preclinical development activities and vendors related to development, manufacturing and distribution of product candidate materials.

We base our expenses related to preclinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple vendors that conduct and manage preclinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period and adjust accordingly.

Leases

On January 1, 2019, we adopted ASU No. 2016-02, Leases (Topic 842), or ASC 842, which requires the recognition of the right-of-use assets and related operating and finance lease liabilities on the balance sheet.

For contracts entered into on or after the effective date, at the inception of a contract, we assess whether the contract is, or contains, a lease. The assessment is based on: (1) whether the contract involves the use of a distinct identified asset, (2) whether we obtain the right to substantially all the economic benefit from the use of the asset throughout the period, and (3) whether we have the right to direct the use of the asset. At inception of a lease, we allocate the consideration in the contract to each lease component based on its relative stand-alone price to determine the lease payments.

Leases are classified as either finance leases or operating leases. A lease is classified as a finance lease if any one of the following criteria are met: the lease transfers ownership of the asset by the end of the lease term, the lease contains an option to purchase the asset that is reasonably certain to be exercised, the lease term is for a major part of the remaining useful life of the asset or the present value of the lease payments equals or exceeds substantially all of the fair value of the asset. A lease is classified as an operating lease if it does not meet any of these criteria.

For all leases at the lease commencement date, a right-of-use asset and a lease liability are recognized. The right-of-use asset represents the right to use the leased asset for the lease term. The lease liability represents the present value of the lease payments under the lease.

The right-of-use asset is initially measured at cost, which primarily comprises the initial amount of the lease liability, plus any initial direct costs incurred if any, less any lease incentives received. All right-of-use assets are reviewed for impairment. The lease liability is initially measured at the present value of the lease payments, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, our secured incremental borrowing rate for the same term as the underlying lease. For real estate leases and other operating leases, we use our secured incremental borrowing rate. For finance leases, we use the rate implicit in the lease or our secured incremental borrowing rate if the implicit lease rate cannot be determined.

Lease payments included in the measurement of the lease liability comprise the following: the fixed noncancelable lease payments, payments for optional renewal periods where it is reasonably certain the renewal period will be exercised, and payments for early termination options unless it is reasonably certain the lease will not be terminated early.

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Lease cost for operating leases consists of the lease payments plus any initial direct costs, primarily brokerage commissions, and is recognized on a straight-line basis over the lease term. Included in lease cost are any variable lease payments incurred in the period that are not included in the initial lease liability and lease payments incurred in the period for any leases with an initial term of 12 months or less. Lease cost for finance leases consists of the amortization of the right-of-use asset on a straight-line basis over the lease term and interest expense determined on an amortized cost basis. The lease payments are allocated between a reduction of the lease liability and interest expense.

Leasehold improvements are not unique and are retained by the lessor at the end of the lease. However, in the case of a space designed to be suitable for our specific real estate needs and if we are responsible for cost overruns, we are the accounting owner of the leasehold improvements.

We made an accounting policy election to not recognize leases with an initial term of 12 months or less within our consolidated balance sheets and to recognize those lease payments on a straight-line basis in our consolidated statements of income over the lease term.

**JOBS Act**

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

We may take advantage of these exemptions until December 31, 2025 or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company earlier if we have more than $1.07 billion in annual revenue, we have more than $700.0 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) or we issue more than $1.0 billion of non-convertible debt securities over a three-year period. We may take advantage of these exemptions 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.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

We are exposed to market risk related to changes in interest rates. As of December 31, 2020, we had cash, cash equivalents and marketable securities of $299.7 million, which consisted of cash, money market funds, commercial paper, corporate notes, U.S. Treasury securities, and government securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term marketable securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, we believe an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio.

We have the ability to hold our investments until maturity, and therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investment portfolio.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we do contract with vendors that are located outside of the United States and may be subject to fluctuations in foreign currency rates. We may enter into additional contracts with vendors located outside of the United States in the future, which may increase our foreign currency exchange risk.
Item 8. Financial Statement

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Item 15, Exhibits and Financial Statement Schedules, of this Annual Report on Form 10-K.


None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on that evaluation of our disclosure controls and procedures as of December 31, 2020, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date were effective at the reasonable assurance level.

Management’s Report on Internal Controls over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers, or persons performing similar functions, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes policies and procedures that:

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We continue to review our internal control over financial reporting and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in “Internal Control — Integrated Framework (2013)” issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”). Based on this assessment, our senior management has concluded that the internal control over financial reporting was effective as of December 31, 2020.
This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for “emerging growth companies”.

Changes in Internal Control over Financial Reporting

We continuously seek to improve the efficiency and effectiveness of our internal controls. This results in refinements to processes throughout our company. There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the year ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. During the year ended December 31, 2020, we have not experienced any material impact in our internal controls over financial reporting despite our employees working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 pandemic to determine any potential impacts on our internal controls over financial reporting including changes to their design and operating effectiveness.

Item 9B. Other Information.

None.
PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the Securities and Exchange Commission, or SEC, with respect to our 2021 Annual Meeting of Stockholders and is incorporated herein by reference.

We have adopted a written code of business conduct and ethics, or Code, that applies to all of 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 available on the investor section of our website at investors.beamtx.com. We intend to disclose on our website any amendments to, or waivers from, our Code that are required to be disclosed pursuant to SEC rules.

Item 11. Executive Compensation.

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


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

Item 13. Certain Relationships and Related Transactions, and Director Independence.

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

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders and is incorporated herein by reference.
## Item 15. Exhibits, Financial Statement Schedules.

### 1. Financial Statements

For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

### 2. Financial Statement Schedules

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

### 3. Exhibits

<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description of Exhibit</th>
<th>Form</th>
<th>File Number</th>
<th>Date of Filing</th>
<th>Exhibit Number</th>
<th>Filed Herewith</th>
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<tr>
<td>2.1#</td>
<td>Agreement and Plan of Merger, dated February 22, 2021, among Beam Therapeutics Inc.,</td>
<td>8-K</td>
<td>001-39208</td>
<td>02/11/2020</td>
<td>3.1</td>
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<td>Fourth Amended Certificate of Incorporation of Beam Therapeutics Inc.</td>
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<td>Specimen stock certificate evidencing shares of common stock</td>
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<td>Amended and Restated Investors’ Rights Agreement, among Beam Therapeutics Inc. and the investors party thereto, dated November 8, 2018</td>
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<td>Description of Registered Securities</td>
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<td>Lease, between UP 26 Landsdowne, LLC and Beam Therapeutics Inc., dated February 21, 2018</td>
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<td>10.2</td>
<td>Indenture of Lease, between Massachusetts Institute of Technology and Beam Therapeutics Inc., dated April 24, 2019</td>
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<td>09/27/2019</td>
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<td>10.3</td>
<td>License Agreement, between MIL 21E, LLC and Beam Therapeutics Inc., dated June 25, 2019</td>
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<td>License Agreement, between the President and Fellows of Harvard College and Beam Therapeutics Inc., dated June 27, 2017</td>
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<td>Amendment No. 1 to License Agreement, between the President and Fellows of Harvard College and Beam Therapeutics Inc., dated December 12, 2017</td>
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<td>License Agreement, between The Broad Institute, Inc. and Blink Therapeutics Inc., dated May 9, 2018</td>
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<td>10.9#</td>
<td>License Agreement, between Editas Medicine, Inc. and Beam Therapeutics Inc., dated May 9, 2018</td>
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<td>Letter Agreement, between Beam Therapeutics Inc., The Broad Institute, Inc., the President and Fellows of Harvard College, and Editas Medicine, Inc., dated September 26, 2018</td>
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<td>Letter Agreement between Beam Therapeutics Inc. and John Evans, dated January 24, 2020</td>
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<td>Beam Therapeutics Inc., Non-Employee Director Compensation Policy, as amended</td>
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<td>10.30</td>
<td>Lease Agreement between Beam Therapeutics Inc. and ARE-NC Region No. 14, LLC</td>
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<td>08/12/2020</td>
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<th>Exhibit Number</th>
<th>Description of Exhibit</th>
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<th>Filed Herewith</th>
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<td>List of Subsidiaries of Beam Therapeutics Inc.</td>
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<td>31.1</td>
<td>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</td>
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<td>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</td>
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<td>Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</td>
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# Portions of this exhibit have been omitted because the Registrant has determined they are not material and are they type that the Registrant treats as private or confidential.
+ Indicates management contract or compensatory plan.
* This certification will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

**Item 16. Form 10-K Summary**

Not applicable.
Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

BEAM THERAPEUTICS INC.

Date: March 15, 2021

By: /s/ John Evans
    John Evans
    Chief Executive Officer

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>/s/ John Evans</td>
<td>Chief Executive Officer and Director</td>
<td>March 15, 2021</td>
</tr>
<tr>
<td></td>
<td>(Principal Executive Officer)</td>
<td></td>
</tr>
<tr>
<td>/s/ Terry-Ann Burrell</td>
<td>Chief Financial Officer and Treasurer</td>
<td>March 15, 2021</td>
</tr>
<tr>
<td></td>
<td>(Principal Financial Officer and Principal Accounting Officer)</td>
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</tr>
<tr>
<td>Terry-Ann Burrell</td>
<td>Director</td>
<td>March 15, 2021</td>
</tr>
<tr>
<td>/s/ Kristina Burow</td>
<td>Director</td>
<td>March 15, 2021</td>
</tr>
<tr>
<td>/s/ Graham Cooper</td>
<td>Director</td>
<td>March 15, 2021</td>
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<tr>
<td></td>
<td></td>
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<tr>
<td>/s/ Mark Fishman</td>
<td>Director</td>
<td>March 15, 2021</td>
</tr>
<tr>
<td>Mark Fishman, M.D.</td>
<td></td>
<td></td>
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<tr>
<td>/s/ Stephen Knight</td>
<td>Director</td>
<td>March 15, 2021</td>
</tr>
<tr>
<td>Stephen Knight, M.D.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Carole Ho</td>
<td>Director</td>
<td>March 15, 2021</td>
</tr>
<tr>
<td>Carole Ho, M.D.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Robert Nelsen</td>
<td>Director</td>
<td>March 15, 2021</td>
</tr>
<tr>
<td>Robert Nelsen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Kathleen Walsh</td>
<td>Director</td>
<td>March 15, 2021</td>
</tr>
<tr>
<td>Kathleen Walsh</td>
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</table>
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Beam Therapeutics Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Beam Therapeutics Inc. and subsidiaries (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations and other comprehensive loss, redeemable convertible preferred stock and stockholders’ equity (deficit), and cash flows, for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ Deloitte & Touche LLP
Boston, Massachusetts
March 15, 2021

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

F-2
## Consolidated Balance Sheets

(in thousands, except share and per share amounts)

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2020</th>
<th>December 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Current assets:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$162,171</td>
<td>$37,221</td>
</tr>
<tr>
<td>Marketable securities</td>
<td>137,500</td>
<td>54,627</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>8,650</td>
<td>2,696</td>
</tr>
<tr>
<td><strong>Total current assets</strong></td>
<td>$308,321</td>
<td>$94,544</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>38,513</td>
<td>24,290</td>
</tr>
<tr>
<td>Restricted cash</td>
<td>14,840</td>
<td>13,332</td>
</tr>
<tr>
<td>Operating lease right-of-use assets</td>
<td>86,859</td>
<td>18,957</td>
</tr>
<tr>
<td>Other assets</td>
<td>3,144</td>
<td>4,976</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td>$451,677</td>
<td>$156,099</td>
</tr>
<tr>
<td><strong>Liabilities, redeemable convertible preferred stock, and stockholders’ equity (deficit)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Current liabilities:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts payable</td>
<td>$6,314</td>
<td>$7,846</td>
</tr>
<tr>
<td>Accrued expenses and other current liabilities</td>
<td>18,487</td>
<td>7,852</td>
</tr>
<tr>
<td>Derivative liabilities</td>
<td>71,200</td>
<td>7,800</td>
</tr>
<tr>
<td>Current portion of lease liability</td>
<td>4,218</td>
<td>4,337</td>
</tr>
<tr>
<td>Current portion of equipment financing liability</td>
<td>2,118</td>
<td>1,303</td>
</tr>
<tr>
<td><strong>Total current liabilities</strong></td>
<td>$102,337</td>
<td>$29,138</td>
</tr>
<tr>
<td>Long-term lease liability</td>
<td>96,014</td>
<td>21,187</td>
</tr>
<tr>
<td>Long-term equipment financing liability</td>
<td>5,294</td>
<td>4,411</td>
</tr>
<tr>
<td>Other liabilities</td>
<td>2,471</td>
<td>418</td>
</tr>
<tr>
<td><strong>Total liabilities</strong></td>
<td>$206,116</td>
<td>$55,154</td>
</tr>
<tr>
<td>Commitments and contingencies (See Note 7, Leases, Note 8, License agreements and Note 9, Collaboration and license agreements)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Redeemable convertible preferred stock (See Note 10, Redeemable convertible preferred stock)</td>
<td>—</td>
<td>302,049</td>
</tr>
<tr>
<td>Stockholders’ equity (deficit):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preferred stock, $0.01 par value; 25,000,000 and no shares authorized, and no shares issued or outstanding at December 31, 2020 and 2019, respectively</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Common stock, $0.01 par value; 250,000,000 and 205,000,000 shares authorized, 58,446,016 and 9,981,991 issued, and 57,254,178 and 7,326,185 outstanding at December 31, 2020 and 2019, respectively</td>
<td>573</td>
<td>73</td>
</tr>
<tr>
<td>Additional paid-in capital</td>
<td>642,633</td>
<td>1,851</td>
</tr>
<tr>
<td>Accumulated other comprehensive (loss) income</td>
<td>(9)</td>
<td>16</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(397,636)</td>
<td>(203,044)</td>
</tr>
<tr>
<td><strong>Total stockholders’ equity (deficit)</strong></td>
<td>245,561</td>
<td>(201,104)</td>
</tr>
<tr>
<td><strong>Total liabilities, redeemable convertible preferred stock, and stockholders’ equity (deficit)</strong></td>
<td>$451,677</td>
<td>$156,099</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these consolidated financial statements.
Beam Therapeutics Inc.
Consolidated Statements of Operations and Other Comprehensive Loss
(in thousands, except share and per share amounts)

<table>
<thead>
<tr>
<th></th>
<th>Years Ended December 31,</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2020</td>
<td>2019</td>
</tr>
<tr>
<td>License revenue</td>
<td>$</td>
<td>24</td>
<td>18</td>
</tr>
<tr>
<td>Operating expenses:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td></td>
<td>103,179</td>
<td>54,619</td>
</tr>
<tr>
<td>General and administrative</td>
<td></td>
<td>29,605</td>
<td>20,553</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td></td>
<td>132,784</td>
<td>75,172</td>
</tr>
<tr>
<td>Loss from operations</td>
<td>(132,760)</td>
<td>(75,154)</td>
<td></td>
</tr>
<tr>
<td>Other income (expense):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in fair value of derivative liabilities</td>
<td>63,400</td>
<td>5,400</td>
<td></td>
</tr>
<tr>
<td>Interest and other income (expense), net</td>
<td>1,568</td>
<td>2,228</td>
<td></td>
</tr>
<tr>
<td>Total other income (expense)</td>
<td></td>
<td>(61,832)</td>
<td>(3,172)</td>
</tr>
<tr>
<td>Net loss</td>
<td>$</td>
<td>(194,592)</td>
<td>(78,326)</td>
</tr>
<tr>
<td>Unrealized (loss) gain on marketable securities</td>
<td>(25)</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Comprehensive loss</td>
<td>$</td>
<td>(194,617)</td>
<td>(78,310)</td>
</tr>
</tbody>
</table>

Reconciliation of net loss to net loss attributable to common stockholders:

<table>
<thead>
<tr>
<th></th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net loss</td>
<td>(194,592)</td>
<td>(78,326)</td>
</tr>
<tr>
<td>Accretion of redeemable convertible preferred stock to redemption value, including dividends on preferred stock</td>
<td>(1,277)</td>
<td>(12,714)</td>
</tr>
<tr>
<td>Net loss attributable to common stockholders</td>
<td>(195,869)</td>
<td>(91,040)</td>
</tr>
<tr>
<td>Net loss per common share attributable to common stockholders, basic and diluted</td>
<td>(4.19)</td>
<td>(14.05)</td>
</tr>
<tr>
<td>Weighted-average common shares used in net loss per share attributable to common stockholders, basic and diluted</td>
<td>46,733,221</td>
<td>6,479,591</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these consolidated financial statements.
## Beam Therapeutics Inc.
### Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders’ Equity (Deficit)
(in thousands, except share amounts)

<table>
<thead>
<tr>
<th>Redeemable Convertible Preferred Stock</th>
<th>Common Stock</th>
<th>Additional Paid-in Capital</th>
<th>Accumulated Other Comprehensive (Loss) Income</th>
<th>Accumulated Deficit</th>
<th>Total Stockholders’ Equity (Deficit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shares</td>
<td>Amount</td>
<td>Shares</td>
<td>Amount</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Balance at December 31, 2018</td>
<td>119,308,387</td>
<td>$ 251,434</td>
<td>5,565,368</td>
<td>$ 56</td>
<td>$ 7,256</td>
</tr>
<tr>
<td>Issuance of Series B redeemable convertible preferred stock, net of issuance costs of $95</td>
<td>11,308,397</td>
<td>37,901</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Accretion of redeemable convertible preferred stock to redemption value</td>
<td>—</td>
<td>12,714</td>
<td>—</td>
<td>—</td>
<td>(12,714)</td>
</tr>
<tr>
<td>Vesting of restricted common stock</td>
<td>—</td>
<td>1,559,126</td>
<td>15</td>
<td>(15)</td>
<td>—</td>
</tr>
<tr>
<td>Exercise of common stock options</td>
<td>—</td>
<td>184,966</td>
<td>2</td>
<td>183</td>
<td>—</td>
</tr>
<tr>
<td>Issuance of common stock related to license agreement</td>
<td>—</td>
<td>16,725</td>
<td>—</td>
<td>113</td>
<td>—</td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>7,028</td>
</tr>
<tr>
<td>Other comprehensive income</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>16</td>
</tr>
<tr>
<td>Net loss</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Balance at December 31, 2019</td>
<td>130,616,784</td>
<td>$ 302,049</td>
<td>7,326,185</td>
<td>$ 73</td>
<td>$ 1,851</td>
</tr>
<tr>
<td>Accretion of redeemable convertible preferred stock to redemption value</td>
<td>—</td>
<td>1,277</td>
<td>—</td>
<td>(1,277)</td>
<td>—</td>
</tr>
<tr>
<td>Conversion of redeemable convertible preferred stock to common stock upon closing of initial public offering</td>
<td>(130,616,784)</td>
<td>(303,326)</td>
<td>29,127,523</td>
<td>291</td>
<td>303,035</td>
</tr>
<tr>
<td>Issuance of common stock from initial public offering, net of issuance costs of $18.7 million</td>
<td>—</td>
<td>—</td>
<td>12,176,471</td>
<td>122</td>
<td>188,201</td>
</tr>
<tr>
<td>Issuance of common stock from October 2020 public offering, net of issuance costs of $8.5 million</td>
<td>—</td>
<td>—</td>
<td>5,750,000</td>
<td>58</td>
<td>126,566</td>
</tr>
<tr>
<td>Issuance of common stock related to license agreements</td>
<td>—</td>
<td>—</td>
<td>375,307</td>
<td>4</td>
<td>5,747</td>
</tr>
<tr>
<td>Vesting of restricted common stock</td>
<td>—</td>
<td>1,638,968</td>
<td>16</td>
<td>(16)</td>
<td>—</td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>15,380</td>
</tr>
<tr>
<td>Exercise of common stock options</td>
<td>—</td>
<td>859,724</td>
<td>9</td>
<td>3,146</td>
<td>—</td>
</tr>
<tr>
<td>Other comprehensive loss</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(25)</td>
</tr>
<tr>
<td>Net loss</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(194,592)</td>
</tr>
<tr>
<td>Balance at December 31, 2020</td>
<td>—</td>
<td>$ 57,254,178</td>
<td>$ 573</td>
<td>$ 642,633</td>
<td>$ (9)</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these consolidated financial statements.
# Beam Therapeutics Inc.
## Consolidated Statements of Cash Flows
(in thousands)

<table>
<thead>
<tr>
<th>Period</th>
<th>Years Ended December 31</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operating activities</strong></td>
<td></td>
<td>$194,592</td>
<td>$(78,326)</td>
</tr>
<tr>
<td>Net loss</td>
<td></td>
<td>(194,592)</td>
<td>$(78,326)</td>
</tr>
<tr>
<td>Adjustments to reconcile net loss to net cash used in operating activities:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation</td>
<td></td>
<td>4,735</td>
<td>3,503</td>
</tr>
<tr>
<td>Amortization of investment discount (premiums)</td>
<td></td>
<td>118</td>
<td>(920)</td>
</tr>
<tr>
<td>Stock-based compensation expense</td>
<td></td>
<td>15,380</td>
<td>7,028</td>
</tr>
<tr>
<td>Change in operating lease right-of-use assets</td>
<td></td>
<td>4,737</td>
<td>1,904</td>
</tr>
<tr>
<td>Non-cash research and development license expense</td>
<td></td>
<td>5,651</td>
<td>113</td>
</tr>
<tr>
<td>Change in fair value of derivative liabilities</td>
<td></td>
<td>63,400</td>
<td>5,400</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>(517)</td>
<td>—</td>
</tr>
<tr>
<td>Changes in operating assets and liabilities:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td></td>
<td>(5,726)</td>
<td>(1,258)</td>
</tr>
<tr>
<td>Other long-term assets</td>
<td></td>
<td>(154)</td>
<td>(634)</td>
</tr>
<tr>
<td>Accounts payable</td>
<td></td>
<td>60</td>
<td>4,092</td>
</tr>
<tr>
<td>Accrued expenses and other liabilities</td>
<td></td>
<td>7,035</td>
<td>3,571</td>
</tr>
<tr>
<td>Operating lease liabilities</td>
<td></td>
<td>3,151</td>
<td>(2,535)</td>
</tr>
<tr>
<td>Financing milestone liabilities</td>
<td></td>
<td>—</td>
<td>(13,750)</td>
</tr>
<tr>
<td>Other long-term liabilities</td>
<td></td>
<td>981</td>
<td>(191)</td>
</tr>
<tr>
<td><strong>Net cash used in operating activities</strong></td>
<td></td>
<td>(95,741)</td>
<td>(72,003)</td>
</tr>
<tr>
<td><strong>Investing activities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchases of property and equipment</td>
<td></td>
<td>(16,357)</td>
<td>(12,518)</td>
</tr>
<tr>
<td>Purchases of marketable securities</td>
<td></td>
<td>(281,612)</td>
<td>(129,760)</td>
</tr>
<tr>
<td>Maturities of marketable securities</td>
<td></td>
<td>198,596</td>
<td>76,069</td>
</tr>
<tr>
<td>Purchase of long-term investment</td>
<td></td>
<td>(750)</td>
<td>(450)</td>
</tr>
<tr>
<td><strong>Net cash used in investing activities</strong></td>
<td></td>
<td>(100,123)</td>
<td>(66,659)</td>
</tr>
<tr>
<td><strong>Financing activities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proceeds from issuance of Series B Preferred Stock, net</td>
<td></td>
<td>—</td>
<td>37,901</td>
</tr>
<tr>
<td>Proceeds from initial public offering, net of underwriting discount</td>
<td></td>
<td>192,510</td>
<td>—</td>
</tr>
<tr>
<td>Proceeds from October 2020 public offering, net of underwriting discount</td>
<td></td>
<td>127,018</td>
<td>—</td>
</tr>
<tr>
<td>Payment of initial and follow-on public offering costs</td>
<td></td>
<td>(2,059)</td>
<td>(2,521)</td>
</tr>
<tr>
<td>Proceeds from equipment financings</td>
<td></td>
<td>3,267</td>
<td>6,178</td>
</tr>
<tr>
<td>Repayment of equipment financings</td>
<td></td>
<td>(1,569)</td>
<td>(464)</td>
</tr>
<tr>
<td>Proceeds from exercise of stock options</td>
<td></td>
<td>3,155</td>
<td>185</td>
</tr>
<tr>
<td><strong>Net cash provided by financing activities</strong></td>
<td></td>
<td>322,322</td>
<td>41,279</td>
</tr>
<tr>
<td><strong>Net increase (decrease) in cash, cash equivalents and restricted cash</strong></td>
<td></td>
<td>126,458</td>
<td>(97,383)</td>
</tr>
<tr>
<td>Cash, cash equivalents and restricted cash—beginning of period</td>
<td></td>
<td>50,553</td>
<td>147,936</td>
</tr>
<tr>
<td>Cash, cash equivalents and restricted cash—end of period</td>
<td></td>
<td>$ 177,011</td>
<td>$ 50,553</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these consolidated financial statements.
## Supplemental disclosure of cash flow information:

<table>
<thead>
<tr>
<th></th>
<th>Years Ended December 31</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash paid for interest</td>
<td>$ 561</td>
<td>$ 187</td>
</tr>
</tbody>
</table>

## Supplemental disclosure of non-cash investing and financing activities:

<table>
<thead>
<tr>
<th></th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conversion of redeemable convertible preferred stock to common stock upon closing of the initial public offering</td>
<td>$303,326</td>
<td>$ —</td>
</tr>
<tr>
<td>Property and equipment additions in accounts payable and accrued expenses</td>
<td>$5,067</td>
<td>$2,465</td>
</tr>
<tr>
<td>Receipt of common stock in exchange for technology license</td>
<td>$100</td>
<td>$460</td>
</tr>
<tr>
<td>Operating lease liabilities arising from obtaining right-of-use assets</td>
<td>$74,723</td>
<td>$6,221</td>
</tr>
<tr>
<td>Issuance of common stock for research and development licenses</td>
<td>$5,751</td>
<td>$113</td>
</tr>
<tr>
<td>Equity issuance costs in accounts payable and accrued expenses</td>
<td>$ —</td>
<td>$593</td>
</tr>
<tr>
<td>Accretion of redeemable convertible preferred stock to redemption value, including dividends on preferred stock</td>
<td>$ 1,277</td>
<td>$12,714</td>
</tr>
</tbody>
</table>

*The accompanying notes are an integral part of these consolidated financial statements*
1. Nature of the business and basis of presentation

Organization

Beam Therapeutics Inc. (the “Company” or “Beam”) is a biotechnology company committed to establishing the leading, fully integrated platform for precision genetic medicines. Beam’s vision is to provide life-long cures to patients suffering from genetic diseases. The Company was incorporated on January 25, 2017 (Inception) as a Delaware corporation and began operations in July 2017. Its principal offices are in Cambridge, Massachusetts.

Liquidity and capital resources

Since its inception, the Company has devoted substantially all of its resources to building its base editing platform and advancing development of its portfolio of programs, establishing and protecting its intellectual property, conducting research and development activities, organizing and staffing the Company, business planning, raising capital and providing general and administrative support for these operations. The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, technical risks associated with the successful research, development and manufacturing of product candidates, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Current and future programs will require significant research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure. Even if the Company’s drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

In connection with the Company’s initial public offering, or IPO, the Company’s board of directors approved a one-for-4.4843 reverse stock split of its issued and outstanding common stock and stock options and a proportional adjustment to the existing conversion ratios for the Company’s redeemable convertible preferred stock effective as of January 24, 2020. Accordingly, all common stock shares, per share amounts, and additional paid in capital amounts for all periods presented in the accompanying financial statements have been retroactively adjusted, where applicable, to reflect the reverse stock split and adjustment to the preferred stock conversion ratios.

In February 2020, the Company completed its IPO in which the Company issued and sold 12,176,471 shares of its common stock, including 1,588,235 shares pursuant to the full exercise of the underwriters’ option to purchase additional shares, at a public offering price of $17.00 per share, for aggregate gross proceeds of $207.0 million. The Company received approximately $188.3 million in net proceeds after deducting underwriting discounts and offering expenses payable by the Company. In connection with the IPO, all outstanding shares of Company’s redeemable convertible preferred stock converted into 29,127,523 shares of its common stock.

In October 2020, the Company issued and sold 5,750,000 shares of its common stock, including 750,000 shares pursuant to the full exercise of the underwriters’ option to purchase additional shares, at a public offering price of $23.50 per share, for aggregate gross proceeds of $135.1 million. The Company received approximately $126.6 million in net proceeds after deducting underwriting discounts and offering expenses payable by the Company. In connection with the IPO, all outstanding shares of Company’s redeemable convertible preferred stock converted into 29,127,523 shares of its common stock.

On January 16, 2021, the Company entered into a Securities Purchase Agreement with certain purchasers, pursuant to which the Company agreed to sell and issue to the Purchasers, in a private placement, shares of common stock of the Company.

The closing of the private placement occurred on January 21, 2021. The Company issued and sold 2,795,700 shares of its common stock at a purchase price of $93.00 per share for aggregate gross proceeds of $260.0 million, before deducting fees to the placement agents and other estimated offering expenses payable by the Company (See Note 11, Preferred stock and common stock). The Company received approximately $252.1 million in net proceeds after deducting estimated offering expenses payable by the Company.

Since its inception, the Company has incurred substantial losses and had an accumulated deficit of $397.6 million as December 31, 2020. The Company expects to generate operating losses and negative operating cash flows for the foreseeable future.

The Company expects that its cash, cash equivalents and marketable securities as of December 31, 2020 of $299.7 million will be sufficient to fund its operations for at least the next twelve months from the date of issuance of these financial statements. The Company will need additional financing to support its continuing operations and pursue its growth strategy. Until such time as the Company can generate significant revenue from product sales, if ever, it expects to finance its operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. The Company may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all. The inability to raise capital as and when needed would have a negative impact on the Company’s financial condition and its ability to pursue its business strategy. The Company will need to generate significant revenue to achieve profitability, and it may never do so.
COVID-19-related significant risks and uncertainties

With the ongoing concern related to the COVID-19 pandemic during 2020, the Company has maintained and expanded its business continuity plans to address and mitigate the impact of the COVID-19 pandemic on its business. In March 2020, to protect the health of its employees, and their families and communities, the Company restricted access to its offices to personnel who performed critical activities that must be completed on-site, limited the number of such personnel that could be present at its facilities at any one time, and requested that most of its employees work remotely. In May 2020, as certain states eased restrictions, the Company established new protocols to better allow its full laboratory staff access to the Company’s facilities. These protocols included several shifts working over a seven-day-week protocol. The Company expects to continue incurring additional costs to ensure it adheres to the guidelines instituted by the Centers for Disease Control and Prevention, or CDC, and to provide a safe working environment to its onsite employees.

The extent to which the COVID-19 pandemic impacts the Company’s business, its corporate development objectives, results of operations and financial condition, and the value of and market for its common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements, and the effectiveness of actions taken globally to contain and treat the disease. Disruptions to the global economy, disruption of global healthcare systems, and other significant impacts of the COVID-19 pandemic could have a material adverse effect on the Company’s business, financial condition, results of operations and growth prospects.

While the COVID-19 pandemic did not significantly impact the Company's business or results of operations during the twelve months ended December 31, 2020, the length and extent of the pandemic, its consequences, and containment efforts will determine the future impact on the Company’s operations and financial condition.

2. Summary of significant accounting policies

Basis of presentation

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

Principles of consolidation

The accompanying consolidated financial statements include the accounts of Beam Therapeutics Inc. and its wholly owned subsidiaries, Blink Therapeutics Inc., or Blink, which is a Delaware subsidiary that holds certain intellectual property related to RNA base editing, and Beam Therapeutics Securities Corporation, which is a Massachusetts subsidiary. All intercompany transactions and balances have been eliminated in consolidation.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses, and the disclosure of contingent assets and liabilities as of and during the reporting period. The Company bases its estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, incremental borrowing rate used in the calculation of lease liabilities, the fair values of common stock, redeemable convertible preferred stock, stock-based compensation, and success payments. Actual results could differ from these estimates.

Cash, and cash equivalents, and restricted cash

Cash and cash equivalents consist of standard checking accounts, money market accounts, and all highly liquid investments with a remaining maturity of three months or less at the date of purchase. Restricted cash represents collateral provided for letters of credit issued as security deposits in connection with the Company’s leases of its corporate and manufacturing facilities.

The following table reconciles cash, cash equivalents, and restricted cash reported within the Company’s consolidated balance sheets to the total of the amounts shown in the consolidated statements of cash flows (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>December 31,</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2020</td>
<td>2019</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$162,171</td>
<td>$37,221</td>
</tr>
<tr>
<td>Restricted cash</td>
<td>14,840</td>
<td>13,332</td>
</tr>
<tr>
<td>Total cash, cash equivalents, and restricted cash</td>
<td>$177,011</td>
<td>$50,553</td>
</tr>
</tbody>
</table>
**Marketable securities**

The Company classifies marketable securities with a remaining maturity when purchased of greater than three months as available-for-sale. Available-for-sale securities are maintained by the Company’s investment managers and consist of commercial paper, high-grade corporate notes, U.S. Treasury securities and government securities. Available-for-sale securities are carried at fair value with the unrealized gains and losses included in accumulated other comprehensive (loss) income as a component of stockholders’ equity until realized. Any premium or discount arising at purchase is amortized and/or accreted to interest income and/or expense over the life of the instrument. Realized gains and losses are determined using the specific identification method and are included in interest and other income (expense), net.

**Concentrations of credit risk**

Financial instruments that are potentially subject to significant concentration of credit risk consist primarily of cash, cash equivalents, marketable securities, and restricted cash. The Company attempts to minimize the risk related to marketable securities by working with highly rated financial institutions that invest in a broad and diverse range of financial instruments as defined the Company. The Company has established guidelines relative to credit ratings and maturities intended to safeguard principal balances and maintain liquidity. The Company maintains its funds in accordance with its investment policy, which defines allowable investments, specifies credit quality standards and is designed to limit credit exposure to any single issuer.

**Guarantees and indemnifications**

As permitted under Delaware law, the Company indemnifies its officers, directors, consultants, and employees for certain events or occurrences that happen by reason of the relationship with, or position held at, the Company. For the twelve months ended December 31, 2020 and 2019, the Company had not experienced any losses related to these indemnification obligations, and no claims were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

**Equity issuance costs**

The Company capitalizes incremental legal, professional, accounting and other third-party fees that were directly associated with its stock offerings as other non-current assets until the offerings are consummated. Upon consummation, these costs are recorded in stockholders’ equity (deficit) as a reduction of additional paid-in-capital generated as a result of the offerings. As of December 31, 2020, there were no deferred offering costs. As of December 31, 2019, equity issuance costs of $3.1 million related to the IPO were included in other assets in the accompanying consolidated balance sheets.

**Fair value of financial instruments**

ASC Topic 820, *Fair Value Measurement*, or ASC 820, establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company’s own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from independent sources. Unobservable inputs are inputs that reflect the Company’s assumptions about the inputs that market participants would use in pricing the assets or liability and are developed based on the best information available in the circumstances. ASC 820 identifies fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tiered value hierarchy that distinguishes between the following:

- **Level 1**—Quoted market prices in active markets for identical assets or liabilities.
- **Level 2**—Inputs other than Level 1 inputs that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.
- **Level 3**—Unobservable inputs for the asset or liability (i.e. supported by little or no market activity). Level 3 inputs include management’s own assumptions about the assumptions that market participants would use in pricing the asset or liability (including assumptions about risk).

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair values requires more judgement. Accordingly, the degree of judgement exercised by the Company in determining fair value is greatest for instruments categorized as Level 3. A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

There have been no changes to the valuation methods utilized during the years ended December 31, 2020 and 2019. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of financial instruments between levels during the years ended December 31, 2020 and 2019.
Property and equipment

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

<table>
<thead>
<tr>
<th>Asset category</th>
<th>Estimated useful life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Computer equipment and software</td>
<td>3 years</td>
</tr>
<tr>
<td>Laboratory equipment and office furniture</td>
<td>5 years</td>
</tr>
<tr>
<td>Leasehold improvements</td>
<td>Shorter of useful life or remaining term</td>
</tr>
</tbody>
</table>

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in interest and other income (expense), net. Expenditures for repairs and maintenance are charged to expense as incurred.

Impairment of long-lived assets

The Company evaluates its long-lived assets, which consist primarily of property and equipment and operating lease right-of-use assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. There were no impairment losses recognized during the years ended December 31, 2020 and 2019.

Freestanding financial instruments and derivatives

Pursuant to a license agreement between the President and Fellows of Harvard College, or Harvard, and the Company, or the Harvard License Agreement, and a license agreement with the Broad Institute of MIT and Harvard, or Broad Institute, and the Company, or the Broad License Agreement, (see Note 8, License Agreements), the Company is required to make success payments to Harvard and Broad Institute based the achievement of specified multiples of the initial weighted average value of the Company’s redeemable convertible Series A-1 Preferred Stock and the Company’s redeemable convertible Series A-2 Preferred Stock, or together the Series A Preferred, at specified valuation dates, payable in cash or Company common stock. Subsequent to the IPO, the amount of the success payments are based on the market value of Beam’s common stock. The success payments are accounted for under ASC 815, Derivatives and Hedging and were initially recorded at fair value with a corresponding charge to research and development expense. The liabilities are marked to market at each balance sheet date with all changes in value recognized in other income (expense) in the consolidated statement of operations and other comprehensive loss. The Company will continue to adjust the liability for changes in fair value until the earlier of the achievement or expiration of the success payment obligation. To determine the estimated fair value of the success payments, the Company used a Monte Carlo simulation model, which models the value of the liability based on several key variables, including probability of event occurrence, timing of event occurrence, as well as the value of the Series A Preferred, prior to the IPO, and the value of the Company’s common stock, subsequent to the IPO.

Leases and rent expense

On January 1, 2019, the Company adopted ASU No. 2016-02, Leases (Topic 842), or ASC 842. Under the standard the Company accounts for leases using a right-of-use, or ROU, model, which recognizes that, at the date of commencement, a lessee has a financial obligation to make lease payments to the lessor for the right to use the underlying asset during the lease term.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as ROU assets and short-term and long-term lease liabilities, as applicable. ROU assets represent the Company’s right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. The Company typically only includes an initial lease term in its assessment of a lease arrangement. It also considers termination options and factors those into the determination of lease payments. Options to renew a lease are not included in the assessment unless there is reasonable certainty that the Company will renew.

Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the ROU asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which it could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. Lease expense for lease payments is recognized on a straight-line basis over the lease term.
The Company is required to pay fees for operating expenses in addition to monthly base rent for certain operating leases (non-lease components). The Company has elected the practical expedient which allows non-lease components to be combined with lease components for all asset classes. Variable non-lease components are not included within the lease right-of-use asset and lease liability on the consolidated balance sheet, and instead are reflected as expense in the period they are paid.

Leasehold improvements are not unique and are retained by the lessor at the end of the lease. However, in the case of a space designed to be suitable for the Company’s specific real estate needs and if the Company is responsible for cost overruns, the Company is the accounting owner of the leasehold improvements.

The Company’s real estate operating leases provide for scheduled annual rent increases throughout the lease terms. The Company recognizes the effects of the scheduled rent increases on a straight-line basis over the full terms of the lease. Tenant improvement allowances, if any, provided by a landlord are recorded as a reduction of the ROU asset related to that lease.

**Redeemable convertible preferred stock**

The Company has classified redeemable convertible preferred stock as temporary equity on the accompanying consolidated balance sheet because it becomes redeemable due to the passage of time or could become redeemable due to certain change in control clauses that are outside of the Company’s control. As a result of becoming redeemable due to the passage of time, the Company records changes in the redemption value and accretes the redeemable convertible preferred stock immediately to redemption value as they occur. These increases are recorded as charges against retained earnings, if any, and then to additional paid-in capital. Then, in the absence of additional paid-in capital, the accretion is charged to the accumulated deficit. All of the Company’s outstanding redeemable convertible preferred stock converted into the Company’s common stock upon the closing of the IPO in February 2020.

**Revenue recognition**

At inception, the Company determines whether contracts are within the scope of ASC 606 or other topics. For contracts that are determined to be within the scope of ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for these goods and services. To achieve this core principle, the Company applies the following five steps (i) identify the contract with the customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when performance obligation is satisfied. The Company only applies the five-step model to contracts when it determines that collection of substantially all consideration for goods and services that are transferred is probable based on the customer’s intent and ability to pay the promised consideration.

Performance obligations promised in a contract are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct and are distinct in the context of the contract. To the extent a contract includes multiple promised goods and services, the Company applies judgment to determine whether promised goods and services are both capable of being distinct and distinct in the context of the contract. If these criteria are not met, the promised goods and services are accounted for as a combined performance obligation.

The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring goods and services to the customer. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing either the expected value method or the most likely amount method, depending on the nature of the variable consideration. Variable consideration is included in the transaction price if, in management’s judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Any estimates, including the effect of the constraint on variable consideration, are evaluated at each reporting period for any changes. Determining the transaction price requires significant judgment.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation on a relative standalone selling price basis unless the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct service that forms part of a single performance obligation. The consideration to be received is allocated among the separate performance obligations based on relative standalone selling prices. The Company typically determines standalone selling prices using an adjusted market assessment approach model.

The Company satisfies performance obligations either over time or at a point in time. Revenue is recognized over time if either (i) the customer simultaneously receives and consumes the benefits provided by the entity’s performance, (ii) the entity’s performance creates or enhances an asset that the customer controls as the asset is created or enhanced, or (iii) the entity’s performance does not create an asset with an alternative use to the entity and the entity has an enforceable right to payment for performance completed to date. If the entity does not satisfy a performance obligation over time, the related performance obligation is satisfied at a point in time by transferring the control of a promised good or service to a customer.
Licensees of intellectual property, or IP: If the license to the Company’s IP is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from consideration allocated to the license when the license is transferred to the customer and the customer can use and benefit from the license. For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. See Note 9, Collaboration and license agreements, for a discussion of Beam’s license agreement with Verve Therapeutics, Inc, or Verve.

Milestone payments: At the inception of each arrangement that includes development or regulatory milestone payments, the Company evaluates the probability of reaching the milestones and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur in the future, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company’s control or the licensee’s, such as regulatory approvals, are not considered probable of being achieved until those approvals are received and therefore revenue recognized is constrained as management is unable to assert that a reversal of revenue would not be possible. The transaction price is then allocated to each performance obligation on a relative standalone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. To date, the Company has not recognized any milestone revenue resulting from any of its agreements.

Commercial Milestone Payments and Royalties: For arrangements that include sales-based royalties, including milestone payments based on levels of sales, if the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its agreements.

When no performance obligations are required of the Company, or following the completion of the performance obligation period, such amounts are recognized as revenue upon transfer of control of the goods or services to the customer. Generally, all amounts received or due other than sales-based milestones and royalties are classified as license fees. Sales-based milestones and royalties will be recognized as royalty revenue at the later of when the related sales occur or when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Deferred revenue arises from amounts received in advance of the culmination of the earnings process and is recognized as revenue in future periods as performance obligations are satisfied. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability. Upfront payment contract liabilities resulting from the Company’s license agreements do not represent a financing component as the payment is not financing the transfer of goods or services, and the technology underlying the licenses granted reflects research and development expenses already incurred by the Company.

Research and development costs

Research and development costs are charged to expense as incurred. Research and development costs consist of costs incurred in performing research and development activities, including salaries and bonuses, stock-based compensation, employee benefits, facilities costs, laboratory supplies, depreciation, manufacturing expenses, preclinical expenses, consulting, and other contracted services. Further, the fair value of the Company’s common stock issued under license agreements, such as those with Bio Palette Co., Ltd., or Bio Palette, and Prime Medicine Inc., or Prime Medicine, are recorded as research and development costs. Additionally, under the terms of the Harvard License Agreement and the Broad License Agreement, the Company is obligated to make future payments should certain development and regulatory milestones be achieved. The Company has included such costs as research and development as the costs incurred related to the license agreements had no alternative future use. Costs for certain research and development activities are recognized based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development costs.

Stock-based compensation

The Company’s stock-based compensation program allows for grants of stock options, restricted stock awards and restricted stock units. Grants are awarded to employees and non-employees, including directors.

The Company accounts for stock-based compensation in accordance with ASC Topic 718, Compensation-Stock Compensation, or ASC 718. ASC 718 requires all stock-based payments to employees, non-employees and directors, to be recognized as expense in the consolidated statements of operations and comprehensive loss based on their fair values. The Company estimates the fair value of options granted using the Black-Scholes option pricing model, or Black-Scholes, for stock option grants to both employees and non-employees. The fair value of the Company’s common stock is used to determine the fair value of restricted stock awards and restricted stock units.
Stock-based compensation awards are subject to either service- or performance-based vesting conditions. Compensation expense related to awards to employees, directors, and non-employees with service-based vesting conditions is recognized on a straight-line basis on the grant date fair value over the associated service period of the award, which is generally the vesting term. Compensation expense related to awards to employees with performance-based vesting conditions is recognized based on grant date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable.

The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate, and (iv) expected dividends. Due to the lack of a public market for the Company’s common stock prior to the IPO and continued lack of sufficient company-specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with expected term assumption. The Company uses the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, Share-Based Payment, to calculate the expected term for options granted to employees and non-employees, whereby, the expected term equals the arithmetic average of the vesting term and the original contractual term of the options due to its lack of sufficient historical data. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock. The Company recognizes forfeitures as they occur.

Due to the absence of an active market for the Company’s common stock prior to the IPO, the Company utilized methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, to estimate the fair value of its common stock. In determining the exercise prices for options granted, the Company considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock has been determined at each grant date based upon a variety of factors, including the illiquid nature of the common stock, arm’s-length sales of the Company’s capital stock (including redeemable convertible preferred stock), the effect of the rights and preferences of the preferred shareholders, and the prospects of a liquidity event. Among other factors are the Company’s financial position and historical financial performance, the status of technological developments within the Company’s research, the composition and ability of the current research and management team, an evaluation or benchmark of the Company’s competition, and the current business climate in the marketplace. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date. Subsequent to the IPO, the Company has used the market value of its common stock on the measurement date.

**Patent costs**

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred. Due to the uncertainty about the recovery of the expenditure, amounts incurred are classified as general and administrative expenses in the accompanying consolidated statements of operations and other comprehensive loss.

**Variable interest entities**

The Company reviews each legal entity in which it has a financial interest to determine whether or not the entity is a variable interest entity, or VIE. If the entity is a VIE, the Company assesses whether or not it is the primary beneficiary of that VIE based on a number of factors, including (i) which party has the power to direct the activities that most significantly affect the VIE’s economic performance, (ii) the parties’ contractual rights and responsibilities pursuant to any contractual agreements and (iii) which party has the obligation to absorb losses or the right to receive benefits from the VIE. If the Company determines that it is the primary beneficiary of a VIE, it consolidates the financial statements of the VIE into its consolidated financial statements at the time that determination is made. On a quarterly basis, the Company evaluates whether it continues to be the primary beneficiary of any consolidated VIEs. If the Company determines that it is no longer the primary beneficiary of a consolidated VIE, or no longer has a variable interest in the VIE, the Company deconsolidates the VIE in the period that the determination is made.

**Income taxes**

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the Company’s financial statements and tax returns. Deferred tax assets and liabilities are determined based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards, using enacted tax rates expected to be in effect in the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that these assets may not be realized. The Company determines whether it is more likely than not that a tax position will be sustained upon examination. If it is not more likely than not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the contingency. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes.

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Comprehensive loss

Comprehensive loss is defined as the change in stockholders’ equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss includes net loss as well as other changes in stockholders’ deficit which includes certain changes in equity that are excluded from net loss. The Company’s only element of other comprehensive loss is unrealized gains and losses on marketable securities.

Net loss per share

The Company follows the two-class method when computing net loss per share, as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

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

For purposes of the dilutive net loss per share calculation, stock options and stock units for which the performance and market vesting conditions have been deemed probable, potential dilutive securities, which include redeemable convertible preferred stock, unvested restricted stock, and common stock options are considered to be common stock equivalents, while stock options and stock units with performance- or market-based vesting conditions that were not deemed probable are not considered to be common stock equivalents.

The Company’s redeemable convertible preferred stock contractually entitled the holders of such shares to participate in dividends but did not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reported a net loss, such losses were not allocated to such participating securities. In periods in which the Company reported a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders was the same as basic net loss per share attributable to common stockholders, since dilutive common shares were not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2020 and 2019.

Segment and geographic information

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or CODM, or decision-making group, in deciding how to allocate resources and in assessing performance. The CODM is the Company’s Chief Executive Officer. The Company views its operations as and manages its business in one operating segment operating exclusively in the United States.

Recent accounting pronouncements

In November 2018, the FASB issued ASU 2018-18, Collaborative Arrangements, or ASC 808, which clarifies certain transactions between collaborative arrangement participants should be accounted for as revenue when the collaborative arrangement participant is a customer in the context of a unit of account and precludes recognizing as revenue consideration received from a collaborative arrangement participant if the participant is not a customer. ASC 808 will be effective for the Company in the first quarter of fiscal 2021, with early adoption permitted. A retrospective adoption to the date the Company adopted ASC 606 is required by recognizing a cumulative-effect adjustment to the opening balance or retained earnings of the earliest period presented. The Company does not expect the adoption of ASU 2018-18 to have a material impact on the Company’s consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, or ASU 2016-13, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes may result in earlier recognition of credit losses. For public entities that are Securities and Exchange Commission filers, excluding entities eligible to be smaller reporting companies, ASU 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. For all other entities, ASU 2016-13 is effective for annual periods beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted. This standard will be effective for the Company on January 1, 2021. The Company does not expect the adoption of ASU 2016-13 to have a material impact on the Company’s consolidated financial statements.

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3. Property and equipment, net

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

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2020</th>
<th></th>
<th>December 31, 2019</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab equipment</td>
<td>$17,201</td>
<td></td>
<td>$12,029</td>
<td></td>
</tr>
<tr>
<td>Leasehold improvements</td>
<td>12,706</td>
<td></td>
<td>12,653</td>
<td></td>
</tr>
<tr>
<td>Furniture and fixtures</td>
<td>1,078</td>
<td></td>
<td>1,040</td>
<td></td>
</tr>
<tr>
<td>Computer equipment</td>
<td>547</td>
<td></td>
<td>547</td>
<td></td>
</tr>
<tr>
<td>Construction in process</td>
<td>15,880</td>
<td></td>
<td>2,185</td>
<td></td>
</tr>
<tr>
<td><strong>Total property and equipment</strong></td>
<td><strong>47,412</strong></td>
<td></td>
<td><strong>28,454</strong></td>
<td></td>
</tr>
<tr>
<td>Less accumulated depreciation</td>
<td>(8,899)</td>
<td></td>
<td>(4,164)</td>
<td></td>
</tr>
<tr>
<td><strong>Property and equipment, net</strong></td>
<td><strong>$38,513</strong></td>
<td></td>
<td><strong>$24,290</strong></td>
<td></td>
</tr>
</tbody>
</table>

The following table summarizes depreciation expense incurred (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Years Ended December 31, 2020</th>
<th></th>
<th>Years Ended December 31, 2019</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Depreciation expense</td>
<td>$4,735</td>
<td></td>
<td>$3,503</td>
<td></td>
</tr>
</tbody>
</table>

4. Fair Value of financial instruments

The Company’s financial instruments that are measured at fair value on a recurring basis consist of cash equivalents, marketable securities, and success payment derivative liabilities pursuant to the Harvard License Agreement and the Broad License Agreement.

The Company also holds investments in privately issued corporate equity securities, which are accounted for as investments in equity securities. These investments do not have readily determinable fair values and the Company values such investments based on the cost of the equity securities adjusted for observable market transactions or impairments, if any. As of December 31, 2020, the Company held $2.6 million of investments in privately issued corporate equity securities. During the year ended December 31, 2020, as a result of an observable market transaction (Level 2), the Company adjusted the value of its investment and recorded an unrealized gain of $0.5 million in interest and other income (expense), net in the Company’s consolidated statements of operations and other comprehensive loss.

The following tables set forth the fair value of the Company’s financial assets and liabilities by level within the fair value hierarchy at December 31, 2020 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Carrying amount</th>
<th>Fair value</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash equivalents:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Money market funds</td>
<td>$88,259</td>
<td>$88,259</td>
<td>$88,259</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Commercial paper</td>
<td>60,494</td>
<td>60,497</td>
<td>—</td>
<td>60,497</td>
<td>—</td>
</tr>
<tr>
<td>Corporate notes</td>
<td>12,314</td>
<td>12,308</td>
<td>—</td>
<td>12,308</td>
<td>—</td>
</tr>
<tr>
<td>Marketable securities:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial paper</td>
<td>113,622</td>
<td>113,622</td>
<td>—</td>
<td>113,622</td>
<td>—</td>
</tr>
<tr>
<td>Corporate notes</td>
<td>7,836</td>
<td>7,836</td>
<td>—</td>
<td>7,836</td>
<td>—</td>
</tr>
<tr>
<td>U.S. Treasury securities</td>
<td>11,009</td>
<td>11,009</td>
<td>—</td>
<td>11,009</td>
<td>—</td>
</tr>
<tr>
<td>Government securities</td>
<td>5,033</td>
<td>5,033</td>
<td>—</td>
<td>5,033</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total Assets</strong></td>
<td><strong>$298,567</strong></td>
<td><strong>$298,564</strong></td>
<td><strong>$88,259</strong></td>
<td><strong>$210,305</strong></td>
<td>—</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Carrying amount</th>
<th>Fair value</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Liabilities</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Success payment liability – Harvard</td>
<td>35,500</td>
<td>35,500</td>
<td>—</td>
<td>—</td>
<td>35,500</td>
</tr>
<tr>
<td>Success payment liability – Broad Institute</td>
<td>35,700</td>
<td>35,700</td>
<td>—</td>
<td>—</td>
<td>35,700</td>
</tr>
<tr>
<td><strong>Total liabilities</strong></td>
<td><strong>$71,200</strong></td>
<td><strong>$71,200</strong></td>
<td>—</td>
<td>—</td>
<td><strong>$71,200</strong></td>
</tr>
</tbody>
</table>

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The following tables set forth the fair value of the Company’s financial assets and liabilities by level within the fair value hierarchy at December 31, 2019 (in thousands):

<table>
<thead>
<tr>
<th>Assets</th>
<th>Carrying amount</th>
<th>Fair value</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash equivalents:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Money market funds</td>
<td>$6,172</td>
<td>$6,172</td>
<td>$6,172</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Commercial paper</td>
<td>3,986</td>
<td>3,986</td>
<td>—</td>
<td>3,986</td>
<td>—</td>
</tr>
<tr>
<td>Marketable securities:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial paper</td>
<td>36,889</td>
<td>36,889</td>
<td>—</td>
<td>36,889</td>
<td>—</td>
</tr>
<tr>
<td>Corporate notes</td>
<td>17,738</td>
<td>17,738</td>
<td>—</td>
<td>17,738</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total Assets</strong></td>
<td><strong>$64,785</strong></td>
<td><strong>$64,785</strong></td>
<td><strong>$6,172</strong></td>
<td><strong>$58,613</strong></td>
<td><strong>—</strong></td>
</tr>
</tbody>
</table>

| Liabilities | | | | | |
| Success payment liability – Harvard | $3,900 | $3,900 | — | — | $3,900 |
| Success payment liability – Broad Institute | 3,900 | 3,900 | — | — | 3,900 |
| **Total liabilities** | **$7,800** | **$7,800** | — | — | **$7,800** |

**Cash equivalents** – Money market funds included within cash equivalents are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets. Commercial paper and corporate notes are classified within Level 2 of the fair value hierarchy because pricing inputs are other than quoted prices in active markets, which are either directly or indirectly observable as of the reporting date, and fair value is determined through the use of models or other valuation methodologies.

**Marketable securities** – The Company measures its marketable securities at fair value on a recurring basis and classify those instruments within Level 2 of the fair value hierarchy. Marketable securities are classified within Level 2 of the fair value hierarchy because pricing inputs are other than quoted prices in active markets, which are either directly or indirectly observable as of the reporting date, and fair value is determined using models or other valuation methodologies.

**Success Payment Liability** – As discussed further in Note 8, License agreements, the Company is required to make payments to Harvard and Broad Institute based upon the achievement of specified multiples of the initial weighted average value of the Company’s Series A Preferred or, subsequent to the IPO, the market value of Beam’s common stock, at specified valuation dates. The Company’s liability for the share-based success payments under the Harvard and Broad License Agreements are carried at fair value. To determine the estimated fair value of the success payment liability, the Company uses a Monte Carlo simulation methodology, which models the future movement of stock prices based on several key variables.

The following variables were incorporated in the calculation of the estimated fair value of the Harvard and Broad Institute success payment liabilities:

<table>
<thead>
<tr>
<th></th>
<th>Harvard</th>
<th>Broad Institute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fair value of Series A Preferred (per share) (1)</td>
<td>December 31, 2020</td>
<td>$</td>
</tr>
<tr>
<td>Fair value of common stock (per share)</td>
<td>81.64</td>
<td>81.64</td>
</tr>
<tr>
<td>Expected volatility</td>
<td>74%</td>
<td>74%</td>
</tr>
<tr>
<td>Expected term (years)</td>
<td>0.35-8.49</td>
<td>0.10-8.01</td>
</tr>
</tbody>
</table>

(1) The effect of the Company’s one-for-4.4843 reverse stock split in January 2020 only applied to its common stock and did not impact its redeemable convertible preferred stock. As such, the Series A Preferred fair value per share as of December 31, 2019 does not show the effect of the reverse stock split. If adjusted for the effect of the reverse stock split, the fair value per share of Series A Preferred would be $16.14 on December 31, 2019. Upon completion of the Company’s IPO, all outstanding shares of redeemable convertible preferred stock converted into shares of the Company’s common stock.

At December 31, 2019, the fair value of the Series A Preferred was determined by management with the assistance of an independent third-party specialist. At December 31, 2020, the fair value of the common stock was the market value of the Company’s common stock. The computation of expected volatility was estimated using available information about the historical volatility of stocks of similar publicly traded companies for a period matching the expected term assumption. In addition, the Company incorporated the estimated number, timing, and probability of valuation measurement dates in the calculation of the success payment liability.
The following table reconciles the change in the fair value of success payment liabilities based on Level 3 inputs (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Harvard</th>
<th>Broad</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance at December 31, 2018</td>
<td>$1,200</td>
<td>$1,200</td>
</tr>
<tr>
<td>Change in fair value</td>
<td>2,700</td>
<td>2,700</td>
</tr>
<tr>
<td>Balance at December 31, 2019</td>
<td>$3,900</td>
<td>$3,900</td>
</tr>
<tr>
<td>Change in fair value</td>
<td>31,600</td>
<td>31,800</td>
</tr>
<tr>
<td>Balance at December 31, 2020</td>
<td>$35,500</td>
<td>$35,700</td>
</tr>
</tbody>
</table>

5. Marketable securities

The following table summarizes the Company’s marketable securities held at December 31, 2020 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Amortized Cost</th>
<th>Gross Unrealized Gains</th>
<th>Gross Unrealized Losses</th>
<th>Fair Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial paper</td>
<td>$113,628</td>
<td>$11</td>
<td>$(17)</td>
<td>$113,622</td>
</tr>
<tr>
<td>Corporate notes</td>
<td>7,839</td>
<td>2</td>
<td>(5)</td>
<td>7,836</td>
</tr>
<tr>
<td>U.S. Treasury securities</td>
<td>11,009</td>
<td>—</td>
<td>—</td>
<td>11,009</td>
</tr>
<tr>
<td>Government securities</td>
<td>5,033</td>
<td>—</td>
<td>—</td>
<td>5,033</td>
</tr>
<tr>
<td>Total</td>
<td>$137,509</td>
<td>$13</td>
<td>$(22)</td>
<td>$137,500</td>
</tr>
</tbody>
</table>

The following table summarizes the Company’s marketable securities held at December 31, 2019 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Amortized Cost</th>
<th>Gross Unrealized Gains</th>
<th>Gross Unrealized Losses</th>
<th>Fair Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial paper</td>
<td>$36,875</td>
<td>$14</td>
<td>—</td>
<td>$36,889</td>
</tr>
<tr>
<td>Corporate notes</td>
<td>17,736</td>
<td>2</td>
<td>—</td>
<td>17,738</td>
</tr>
<tr>
<td>Total</td>
<td>$54,611</td>
<td>$16</td>
<td>—</td>
<td>$54,627</td>
</tr>
</tbody>
</table>

The amortized cost of marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity. At December 31, 2020, the balance in accumulated other comprehensive (loss) income was comprised solely of activity related to marketable securities. There were no realized gains or losses recognized on the sale or maturity of marketable securities for the years ended December 31, 2020 and 2019 and, as a result, the Company did not reclassify any amounts out of accumulated other comprehensive (loss) income for the same periods.

The Company held 21 debt securities in an unrealized loss position at December 31, 2020. The aggregate fair value of securities held by the Company in an unrealized loss position for less than 12 months at December 31, 2020 was $82.8 million, and there were no securities held by the Company in an unrealized loss position for more than 12 months. The Company holds debt securities of companies with high credit quality and has determined that there was no material change in the credit risk of any of its debt securities, and as of December 31, 2020 the Company did not intend to sell, and was more than likely not required to sell, the debt securities in a loss position before recovery of their amortized cost bases. As a result, the Company determined it did not hold any investments with any other-than-temporary impairment at December 31, 2020. The contractual maturity dates of all the investments are less than one year.

6. Accrued expenses and other current liabilities

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

<table>
<thead>
<tr>
<th></th>
<th>December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2020</td>
</tr>
<tr>
<td>Employee compensation and related benefits</td>
<td>7,591</td>
</tr>
<tr>
<td>Process development and manufacturing costs</td>
<td>2,272</td>
</tr>
<tr>
<td>Other research costs</td>
<td>2,423</td>
</tr>
<tr>
<td>Professional fees</td>
<td>1,948</td>
</tr>
<tr>
<td>Other</td>
<td>4,253</td>
</tr>
<tr>
<td>Total</td>
<td>$18,487</td>
</tr>
</tbody>
</table>

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7. Leases

Operating leases

The Company’s operating leases are as follows:

- A February 2018 lease for 38,203 square feet of office and laboratory space, which commenced in March 2018 and terminates in September 2028. The lease is subject to fixed-rate rent escalations and provided for $6.1 million in tenant improvements and a term extension option, which was not reasonably certain of exercise.

- An October 2018 lease for laboratory space, which commenced in April 2019 and was amended in March 2020 and April 2020. The amended lease commenced in April 2020 and terminates in December 2025. The amended lease is subject to fixed-rate rent escalations and provides an option to extend the lease for two additional two-year periods through December 31, 2029, which were not reasonably certain of exercise. Upon commencement of the March 2020 amendment, the Company recorded an operating lease ROU asset and a lease liability of $4.2 million. Upon commencement of the April 2020 amendment, the Company recorded an operating lease ROU asset and a lease liability of $1.8 million.

- Leases in June and July 2019 for office and laboratory space, both of which commenced in October 2019 and terminate in December 2021. The leases are subject to fixed-rate rent escalations.

- An April 2019 lease for office and laboratory space to be built, with the rent payments for the first phase expected to commence at the earliest in late 2021 and the rent payments for the second phase expected to commence at the earliest in the first half of 2022. The lease will terminate 12 years from the second phase rent commencement date. The lease is subject to fixed-rate rent escalations and provides for $23.4 million in tenant improvements and the option to extend the lease for two terms of five years each, which were not reasonably certain of exercise. The Company determined that it is the accounting owner of all tenant improvements. Upon executing the lease, the Company made a security deposit of $11.8 million in the form of a letter of credit, which is included in restricted cash as of December 31, 2020. Upon commencement of the first phase of this lease in October 2020, the Company recorded an operating lease ROU asset of $66.8 million and a lease liability of $68.8 million. As the commencement of the second phase of this lease is expected to occur during the first quarter of 2021, the Company has not recorded an operating lease ROU asset or lease liability for this phase at December 31, 2020. Undiscounted lease payments under the second phase are anticipated to be $42.7 million, which are not included in the tabular disclosure of minimum lease payments below.

The Company identified and assessed the following estimates in recognizing the operating lease right-of-use asset and corresponding liability:

- Expected lease term: The expected lease term includes noncancelable lease periods and, when applicable, periods covered by an option to extend the lease if the Company is reasonably certain to exercise that option, as well as periods covered by an option to terminate the lease if Beam is reasonably certain not to exercise that option.

- Incremental borrowing rate: As the discount rates in the Company’s lease are not implicit, management estimated the incremental borrowing rate based on the rate of interest the Company would have to pay to borrow a similar amount on a collateralized basis over a similar term.

- Lease and non-lease components: The Company is required to pay fees for operating expenses in addition to monthly base rent for certain operating leases (non-lease components). The Company has elected the practical expedient which allows non-lease components to be combined with lease components for all asset classes. Variable non-lease components are not included within the lease right-of-use asset and lease liability on the consolidated balance sheet, and instead are reflected as expense in the period they are paid.
The following table summarizes operating lease costs as well as sublease income (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2020</th>
<th>December 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating lease costs</td>
<td>$8,415</td>
<td>$4,078</td>
</tr>
<tr>
<td>Variable lease costs</td>
<td>929</td>
<td>811</td>
</tr>
<tr>
<td>Short-term lease costs</td>
<td>—</td>
<td>116</td>
</tr>
<tr>
<td>Sublease income</td>
<td>—</td>
<td>(51)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$9,344</strong></td>
<td><strong>$4,954</strong></td>
</tr>
</tbody>
</table>

The following table summarizes the lease term and discount rate for operating leases:

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2020</th>
<th>December 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weighted-average remaining lease term (years)</td>
<td>11.5 years</td>
<td>7.4 years</td>
</tr>
<tr>
<td>Weighted-average discount rate</td>
<td>7.4%</td>
<td>9.8%</td>
</tr>
</tbody>
</table>

The following table summarizes the lease costs included in the measurement of lease liabilities (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Years Ended December 31, 2020</th>
<th>Years Ended December 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating cash flows used for operating leases</td>
<td>$6,911</td>
<td>$4,950</td>
</tr>
<tr>
<td>Operating lease liabilities arising from obtaining ROU assets</td>
<td>74,723</td>
<td>6,221</td>
</tr>
</tbody>
</table>

At December 31, 2020, the future minimum lease payments for the Company’s facility operating leases for each of the next five years and total thereafter were as follows (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
<th>2024</th>
<th>2025</th>
<th>Thereafter</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total undiscounted lease payments</td>
<td>$9,096</td>
<td>13,686</td>
<td>14,088</td>
<td>14,519</td>
<td>14,893</td>
<td>103,062</td>
</tr>
<tr>
<td>Less: imputed interest</td>
<td>(69,112)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total operating lease liabilities</strong></td>
<td>$100,232</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In August 2020, the Company entered into a lease agreement with Alexandria Real Estate Equities, Inc. to build a 100,000 square foot manufacturing facility in Research Triangle Park, North Carolina intended to support a broad range of clinical programs. The lease has a term of fifteen years following the commencement date and provides the Company the option to extend the lease term for two five-year terms. It is subject to fixed rate escalation increases and also provides up to $20.0 million for reimbursement of tenant improvements. As the lease had not commenced as of December 31, 2020, the Company has not recorded an operating lease ROU asset or lease liability for this lease in the accompanying consolidated balance sheets. The lease payments are subject to adjustment following the determination of the total project costs of the landlord. The initial estimate of the minimum amount of undiscounted lease payments due under this lease is $63.9 million. The Company expects to invest up to $83.0 million over a five-year period and anticipates that the facility will be operational by the first quarter of 2023. Further, the tabular disclosure of minimum lease payments above does not include payments due under this lease.

**Financing obligations**

In July 2019, the Company sold certain equipment to a leasing company for a total of $3.8 million, and, concurrently, entered into a lease agreement with the leasing company to lease back the equipment for an annual rent of $1.0 million over a term of four years.

In October 2019, the Company sold additional equipment to the leasing company for a total of $2.4 million and, concurrently, entered into a lease agreement with the leasing company to lease back the equipment for an annual rent of $0.7 million over a term of four years.
In February 2020, the Company sold additional equipment to the leasing company for a total of $1.6 million and, concurrently, entered into a lease agreement with the leasing company to lease back the equipment for an annual rent of $0.5 million over a term of four years.

In December 2020, the Company sold additional equipment to the leasing company for a total of $1.6 million and, concurrently, entered into a lease agreement with the leasing company to lease back the equipment for an annual rent of $0.5 million over a term of four years.

The equipment leases are being accounted for as financings as the lease terms are for substantially all the remaining economic life of the underlying equipment. The Company concluded that control, including the significant risks and rewards of ownership, did not effectively transfer to the buyer-lessee at the inception of the sale and leaseback transactions. As a result, the transactions are accounted for as failed sale and leasebacks and result in the recognition of financing liabilities.

The future minimum payments related to the equipment financing obligations for each of the next five years were as follows (in thousands):

<table>
<thead>
<tr>
<th>Years ending December 31,</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021</td>
<td>$2,685</td>
</tr>
<tr>
<td>2022</td>
<td>2,663</td>
</tr>
<tr>
<td>2023</td>
<td>2,013</td>
</tr>
<tr>
<td>2024</td>
<td>511</td>
</tr>
<tr>
<td>2025</td>
<td>—</td>
</tr>
<tr>
<td>Total</td>
<td>7,872</td>
</tr>
<tr>
<td>Less: amounts representing interest at 8.76%</td>
<td>(1,135)</td>
</tr>
<tr>
<td>Plus: residual values</td>
<td>675</td>
</tr>
<tr>
<td>Financing obligations</td>
<td>$7,412</td>
</tr>
</tbody>
</table>

The following table summarizes the breakdown of the principal and interest portions of the equipment financing payments (in thousands):

<table>
<thead>
<tr>
<th>Years Ended December 31,</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paydown of principal</td>
<td>$1,569</td>
<td>$464</td>
</tr>
<tr>
<td>Payment of interest</td>
<td>561</td>
<td>187</td>
</tr>
</tbody>
</table>

8. License agreements

**Harvard license agreement**

In June 2017, the Company entered into the Harvard License Agreement for certain base editing technology pursuant to which the Company received an exclusive, worldwide, sublicensable, royalty-bearing license under specified patent rights to develop and commercialize licensed products and a nonexclusive, worldwide, sublicensable, royalty-bearing license under certain patent rights to research and develop licensed products. The Company agreed to use commercially reasonable efforts to develop licensed products in accordance with the development plan, to introduce any licensed products that gain regulatory approval into the commercial market, to market licensed products that have gained regulatory approval following such introduction into the market, and to make licensed products that have gained regulatory approval reasonably available to the public. The license term extends until the later of (i) the expiration of (i) the last to expire licensed patent covering a licensed product, (ii) the period of exclusivity associated with a licensed product or (iii) a certain period after the first commercial sale of a licensed product, unless terminated earlier by either party under certain provisions.

As partial consideration for the rights granted under the Harvard License Agreement, the Company issued to Harvard 101,363 shares of the Company’s common stock. Additional consideration under the Harvard License Agreement included an Anti-Dilution Issuance Right, which was settled during the year ended December 31, 2018, Financing Milestone Payments related to Series A Preferred and Series B Preferred financings, which were paid and settled in the year ended December 31, 2019, and Success Payments, which are further described below. The Anti-Dilution Issuance Right and Financing Milestone Payments related to Series A Preferred and Series B Preferred financings were both expensed in the year 2018 and prior.

**Success Payments** – Under the Harvard License Agreement, Harvard is entitled to receive success payments, in cash or shares of Company stock, determined based upon the achievement of specified multiples of the initial weighted average value of the Company’s Series A Preferred at specified valuation dates. The success payments range from $5.0 million to a maximum of $105.0 million and have valuation multiples that range from 5 times to 40 times the initial weighted average value of the Series A Preferred. Subsequent to the Company’s February 2020 IPO, the amount of success payments is based on market value of Beam’s common stock.

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The Company shall make success payments to Harvard during a period of time, or the Harvard Success Payment Period, which has been determined to be the later of (1) the ninth anniversary of the Harvard License Agreement or (2) the earlier of (a) the 12th anniversary of the Harvard License Agreement and (b) the third anniversary of the first date on which a licensed product receives regulatory approval in the United States. During the Harvard Success Payment Period, the Company will perform a calculation of any amounts owed to Harvard on each rolling 90-day period, commencing one year after the Company’s IPO. The first success payment measurement will occur during May 2021.

The following table summarizes the Company’s success payment liability for Harvard (in thousands):

<table>
<thead>
<tr>
<th>Harvard success payment liability</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$35,500</td>
<td>$3,900</td>
</tr>
</tbody>
</table>

The following table summarizes the expense resulting from the change in the fair value of the success payment liability for Harvard (in thousands):

<table>
<thead>
<tr>
<th>Change in fair value of Harvard success payment liability</th>
<th>Years Ended December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2020</td>
</tr>
<tr>
<td></td>
<td>$31,600</td>
</tr>
</tbody>
</table>

**Other Payments** – The Company agreed to pay Harvard an annual license maintenance fee ranging from low-to-mid five figures to low six figures, depending on the calendar year. The Company is responsible for the payment of certain patent prosecution and maintenance costs incurred by Harvard related to licensed patents. To the extent achieved, the Company is obligated to pay up to an aggregate of $75.9 million in product development and regulatory approval milestones, or Harvard Product Milestones. If the Company completes a change of control during the term of the Harvard License Agreement, then certain of the milestone payments would be increased. To the extent there are sales of a licensed product, the Company is required to pay low single digit royalties on net sales. The Company is entitled to certain reductions and offsets on these royalties with respect to a licensed product in a given country. If the Company sublicenses its rights to develop or commercialize a licensed product under the Harvard License Agreement to a third party and the Company receives non-royalty sublicense income, then Harvard is entitled to a percentage of such consideration, ranging from the high single digits to low double digits depending on the date in which such sublicense agreement is executed and the stage of development of the Company’s licensed products at such time.

The annual maintenance fees will be recorded as an expense on an annual basis based on the stated amount for the applicable year. Annual patent costs will be expensed as incurred. Upon determination that a Harvard Product Milestone is probable to occur, the amount due will be recorded as research and development expense. The Company will monitor the Harvard Product Milestone payments for this arrangement on an ongoing basis. The achievement of these milestone payments was not considered probable as of the acquisition date, and no expense has been recorded for these milestones in years ended December 31, 2020 and 2019. Lastly, to the extent products are commercialized under the Harvard License Agreement, the Company will accrue royalty expense and sublicense nonroyalty payments, as applicable, for the amount it is obligated to pay, with adjustments as sales are made.

**Broad license agreement**

In May 2018, the Broad License Agreement was entered into with Broad Institute for certain RNA base editing technology including an RNA editor platform. Under the Broad License Agreement, Broad Institute granted an exclusive and non-exclusive worldwide, sublicensable, royalty-bearing licenses under specified patent rights to develop and commercialize licensed product and a nonexclusive, worldwide, sublicensable, royalty-bearing license under certain patent rights to research and develop licensed products. Under the agreement the Company shall use commercially reasonable efforts to develop licensed products in accordance with the development plan, to introduce any licensed products that gain regulatory approval into the commercial market, to market licensed products that have gained regulatory approval following such introduction into the market, and to make licensed products that have gained regulatory approval reasonably available to the public. The license term extends until the later of the expiration of (i) the last to expire licensed patent covering a licensed product, (ii) the period of regulatory exclusivity associated with a licensed product or (iii) a certain period after the first commercial sale of a licensed product unless terminated earlier by either party under certain provisions.

Additional consideration under the Broad License Agreement included an Anti-Dilution Issuance Right, which was paid and settled during the year ended December 31, 2018, Financing Milestone Payments related to Series A Preferred and Series B Preferred financings, which were settled in the year ended December 31, 2019, and Success Payments, which are further described below. The Anti-Dilution Issuance Right and Financing Milestone Payments related to Series A Preferred and Series B Preferred financings were both expensed in the year 2018 and prior.
Success Payments – Under the Broad License Agreement, Broad Institute is entitled to receive success payments, in cash or shares of Company common stock, determined based upon the achievement of specified multiples of the initial weighted average value of the Series A Preferred at specified valuation dates. Subsequent to the February 2020 IPO, the amount of success payments will be based on market value of Beam’s common stock. The success payments range from $5.0 million to a maximum of $105.0 million and have valuation multiples that range from 5 times to 40 times the initial weighted average value of the Series A Preferred. The Company is required to make success payments to Broad Institute during a period of time, or the Broad Success Payment Period, which has been determined to be the earliest of (1) the twelfth anniversary of the Broad License Agreement or (2) the third anniversary of the first date on which a licensed product receives regulatory approval in the United States. During the Broad Success Payment Period, the Company will perform a calculation of any amounts owed to Broad Institute on each rolling 90-day period, commencing one year after the Company’s IPO. The first success payment measurement will occur during May 2021.

The following table summarizes the Company’s success payment liability for Broad Institute (in thousands):

<table>
<thead>
<tr>
<th>Broad Institute success payment liability</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$35,700</td>
<td>$3,900</td>
</tr>
</tbody>
</table>

The following table summarizes the expense resulting from the change in the fair value of the success payment liability for Broad Institute (in thousands):

<table>
<thead>
<tr>
<th>Change in fair value of Broad Institute success payment liability</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$31,800</td>
<td>$2,700</td>
</tr>
</tbody>
</table>

Other Payments – The Company agreed to pay Broad Institute an annual license maintenance fee ranging from low-to-mid five figures to low six figures, depending on the particular calendar year. The Company is responsible for the payment of certain patent prosecution and maintenance costs incurred by Broad Institute related to licensed patents. To the extent achieved, the Company is obligated to pay up to an aggregate of $75.9 million in product development and regulatory approval milestones, or Broad Product Milestones. If the Company completes a change of control during the term of the Broad License Agreement, then certain of the milestone payments would be increased. To the extent there are commercial sales of a licensed product, the Company is required to pay low single digit royalties on net sales. The Company is entitled to certain reductions and offsets on these royalties with respect to a licensed product in a given country. If the Company sublicenses its rights to develop or commercialize a licensed product under the Broad License Agreement to a third party and the Company receives non-royalty sublicense income, then Broad Institute is entitled to a percentage of such consideration, ranging from the high single digits to low double digits depending on the date on which such sublicense agreement is executed and the stage of development of the Company’s licensed products at such time.

The annual maintenance fees will be recorded as an expense on an annual basis based on the stated amount for the applicable year. Annual patent costs will be expensed as incurred. Upon determination that a Broad Product Milestone is probable to occur, the amount due will be recorded as research and development expense. The Company will monitor the Broad Product Milestone payments for this arrangement on an ongoing basis. The triggering of these milestone payments was not considered probable as of the acquisition date, and no expense has been recorded for these milestones during the years ended December 31, 2020 and 2019. Lastly, to the extent products are commercialized under the Broad License Agreement, the Company will accrue royalty expense and sublicense nonroyalty payments, as applicable, for the amount it is obligated to pay, with adjustments as sales are made.

Editas license agreement

In May 2018, the Company entered into a license agreement, or the Editas License Agreement, with Editas Medicine, Inc., or Editas. Pursuant to the Editas License Agreement, Editas granted to the Company licenses and options to acquire licenses to certain intellectual property rights owned or controlled by Editas, for specified uses. More specifically, Editas granted to the Company a worldwide, exclusive, sublicensable, license (subject to certain exceptions and conditions) under certain intellectual property controlled by Editas for the use of base editing therapies for the treatment of any field of human diseases and conditions, subject to certain exceptions, or the Beam Field, and the licenses granted or to be granted under the Editas License Agreement, or the Editas Development and Commercialization License. Additionally, Editas granted to the Company royalty-free, non-exclusive license under certain intellectual property owned or controlled by Editas to perform research activities in the Beam Field, or the Editas Research License. Editas provided the Company with an exclusive option to obtain an Editas Development and Commercialization License to three additional groups of intellectual property controlled by Editas, for specified uses. More specifically, Editas granted to the Company a worldwide, exclusive, sublicensable, license (subject to certain exceptions and conditions) under certain intellectual property controlled by Editas for the use of base editing therapies for the treatment of any field of human diseases and conditions, subject to certain exceptions, or the Beam Field, and the licenses granted or to be granted under the Editas License Agreement, or the Editas Development and Commercialization License. Additionally, Editas granted to the Company royalty-free, non-exclusive license under certain intellectual property owned or controlled by Editas to perform research activities in the Beam Field, or the Editas Research License. Editas provided the Company with an exclusive option to obtain an Editas Development and Commercialization License to three additional groups of intellectual property owned or controlled by Editas, on a group by group basis, during the specified option period, subject to certain exceptions. Pursuant to the Editas License Agreement, the Company will use commercially reasonable efforts to develop a product that includes the rights licensed to the Company within a specified period of time and to commercialize any such products that have received regulatory approval in certain specified countries.

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Additional consideration will be due to Editas if the Company elects to exercise its option to obtain an Editas Development and Commercialization License to any of the three categories of intellectual property underlying the Editas Research License, for a fee ranging from a mid-teens million dollar amount to a low to mid-eight digit dollar amount per group, depending on the timing of the option exercise. Additionally, the Company is required to reimburse Editas for certain payments Editas may be obligated to make under existing Editas license agreements related to the intellectual property being licensed to the Company, including (i) development, regulatory and commercial milestone payments and certain sublicense income payments due as a result of the Editas License Agreement and (ii) a percentage of the annual maintenance fees and patent fees due to certain of the Editas’ licensors. In addition, to the extent any products are commercialized under an Editas Development and Commercialization License, the Company would be required to make royalty payments equivalent to the royalties that would be due from Editas to any applicable licensors of Editas related to the sales of such licensed products, plus an additional tiered low- to mid-single digit royalty, depending on whether such licensed product is covered by an Editas-owned patent.

The license rights and option rights granted by Editas to the Company are subject to the terms and conditions of the underlying license agreements that Editas is a party to and under which Editas licensed rights or option rights to the Company and the termination of such in-licenses, as applicable. Unless earlier terminated by either party pursuant to the terms of the agreement, the Editas License Agreement will continue in full force and effect and will expire on a licensed product-by licensed product and country-by-country basis upon the later of (i) the last-to-expire royalty term under any applicable institutional license to Editas and (ii) the date at which such product is no longer covered by a valid claim of a licensed Editas-owned patent in such country.

The Company has the right, at its sole discretion, at any time to terminate Editas License Agreement in its entirety or on a group-by-group of intellectual property basis, upon ninety days written notice to Editas. Upon termination of the Editas License Agreement, all rights and licenses granted by the Editas to the Company (including the rights to exercise options and obtain such licenses) will immediately terminate and patents within a group of patents will no longer be deemed licensed patents. Expiration or termination of the Editas License Agreement for any reason does not release either party of any obligation or liability which had accrued, or which is attributable to a period prior to such expiration or termination.

The option exercise fees under the agreement will be recorded as research and development expense, if and when the Company exercises such options. To date, no options have been exercised. The annual maintenance fees are recorded as an expense on an annual basis based on the stated amount for the applicable year. Annual patent costs are expensed as incurred. In addition, the Company is required to make certain development, regulatory and commercial milestone payments to Editas upon the achievement of specified milestones. The triggering of these milestone payments was not considered probable as of the acquisition date, and no expense has been recorded for these milestones during the years ended December 31, 2020 and 2019. To the extent applicable, sublicense income payments will be accrued for the amount the Company is obligated to pay under each applicable in-license as amounts become due. The cost of these milestones payments will be recorded as research and development expense, if and when the Company exercises such options.

Bio Palette license agreement

In March 2019, the Company entered into a license agreement with Bio Palette pursuant to which Beam received an exclusive (even as to Bio Palette), sublicensable license under certain patent rights related to base editing owned or controlled by Bio Palette to exploit products for the treatment of human disease throughout the world, but excluding products in the microbiome field in Asia (the “Bio Palette License Agreement”). In addition, the Company granted Bio Palette an exclusive (even as to Beam) license under certain patent rights related to base editing and gene editing owned or controlled by the Company to exploit products in the microbiome field in Asia. Each party to the agreement retains non-exclusive rights to develop and manufacture products in the microbiome field worldwide for the sole purpose of exploiting those products in its own territory. Each party agrees to certain coordination obligations in the microbiome field if either party determines not to exploit their rights in such field. Unless earlier terminated, the Bio Palette License Agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the expiration of the applicable royalty term for each such licensed product and country.

The Company also agreed to pay a royalty at a fraction of a percent on net sales of products that are covered by the patents licensed by Bio Palette to Beam, and Bio Palette agreed to pay a royalty at a fraction of a percent on net sales of products that are covered by the patents licensed by Beam to Bio Palette. The royalty term for a product in a country will terminate on the later of the expiration of (i) patent-based exclusivity with respect to such licensed product in such country or (ii) regulatory exclusivity with respect to such licensed product in such country.

To the extent achieved, the Company is required to make a certain milestone payment to Bio Palette. The triggering of this milestone was not considered probable at the inception of the Bio Palette License Agreement, and no expense has been recorded as of December 31, 2020 and 2019. To the extent products are commercialized under the Bio Palette License Agreement, the Company will accrue royalty expense for the amount it is obligated to pay, with adjustments as sales are made.
Upon the execution of the Bio Palette License Agreement, the Company paid Bio Palette an upfront fee of $0.5 million and issued to Bio Palette 16,725 shares of its common stock valued at $0.1 million, which were recorded as research and development expense for the year ended December 31, 2020. Upon the issuance of a certain Bio Palette patent in the United States in June 2020, the Company made a milestone payment of $2.0 million and, in July 2020, issued to Bio Palette 175,000 shares of its common stock valued at $0.3 million, which were recognized as research and development expense. The fair value of the common stock issued to Bio Palette under the Bio Palette License Agreement was measured at the inception of arrangement and expensed when the issuance of shares became probable.

Management concluded that the licenses acquired from each transaction above did not meet the accounting definition of a business as inputs, but no processes or outputs were acquired with the licenses, and the licensed technology had not achieved technological feasibility. As the inputs that were acquired along with the licenses do not constitute a “business,” the transactions have been accounted as asset acquisitions. As of the date of each License Agreement, the assets acquired had no alternative future use and the assets had not reached a stage of technological feasibility. As a result, all share-based and cash payment obligations have been recorded as research and development expense in the accompanying consolidated statements of operations and other comprehensive loss.

9. Collaboration and license agreements

Prime Medicine

In September 2019, the Company entered into a collaboration and license agreement with Prime Medicine to research and develop a novel gene editing technology developed by one of Beam’s founders. Under the terms of the agreement, the Company granted Prime Medicine a non-exclusive license to certain of its CRISPR technology (including Cas12b), delivery technology and certain other technology controlled by Beam to develop and commercialize gene editing products for the treatment of human diseases. The Company is not currently using the intellectual property licensed from Prime Medicine in any of its current programs, but it is required to use commercially reasonable efforts to develop new product candidates using the intellectual property licensed from Prime Medicine. Additionally, each party granted to the other party certain exclusive and non-exclusive licenses to certain technology developed after the effective date of the agreement and controlled by the granting party or jointly owned by the parties. Each party has an obligation to assign rights in certain technology developed under the collaboration to the other party.

For products that use technology licensed from Prime Medicine, the Company is required to make milestone payments to Prime Medicine upon the achievement of certain clinical, regulatory and commercial events. It is also required to use commercially reasonable efforts to conduct the activities for which they are responsible under any development plan(s) under the agreement. Prime Medicine has an option to jointly develop and commercialize, and share expenses and revenue for, certain products that use technology licensed from Prime Medicine in the United States. Royalty payments may become due by either party to the other based on the net sales of commercialized products under the agreement. In addition, certain of the rights licensed under the agreement are sublicensed from third parties, and Beam or Prime Medicine may be required to make certain payments to such third parties to the extent the Beam or Prime Medicine develop and commercialize products under such rights.

Beam had an obligation to issue $5.0 million in shares of its common stock to Prime Medicine, and Prime Medicine had an obligation to issue 5,000,000 shares of its common stock to Beam, should Beam elect to extend the collaboration beyond one year. In September 2020, the Company elected to continue the collaboration and, in October 2020, issued 200,307 shares of the Company’s common stock to Prime Medicine. The Company recognized $5.5 million, which represented the fair value of Beam’s common stock issued to Prime Medicine, as research and development expense within the accompanying consolidated statements of operations and other comprehensive loss for the year ended December 31, 2020. Additionally, in October 2020, the Company received 5,000,000 shares of Prime Medicine’s common stock and recognized $0.1 million as an offset to research and development expense within the accompanying consolidated statements of operations and other comprehensive loss for the year ended December 31, 2020.

Additionally, the Company will provide immaterial interim management and startup services to Prime Medicine through March 2021.

As of December 31, 2020, the Company determined that future milestones and royalties under the agreement were not probable of recognition.

Verve

In April 2019, Beam entered into a Collaboration and License Agreement with Verve, or the Verve License Agreement, to investigate gene editing strategies to modify genes associated with an increased risk of coronary diseases. Under the terms of the agreement, the Company granted Verve an exclusive license to certain base editor technology and certain delivery technology and Verve granted Beam a non-exclusive license under certain know-how and patents controlled by Verve, an interest in joint collaboration technology and an exclusive license (except as to Verve) under certain delivery technology. Verve is responsible for all costs associated with the research and development activities under the Verve License agreement. The Company has the option to share in the future...
development of certain products, with no associated fee at the time the right is exercised. Upon exercise of the Company’s option, the profits and expenses of such product will be shared, as defined in the agreement. To date, Beam has not exercised its option.

In connection with the Verve License Agreement, Verve issued Beam 2.6 million shares of its common stock as partial consideration for the licenses granted, having a fair value of $0.5 million. The fair value of the Verve common stock was determined by management with the assistance of a third-party valuation specialist. In addition, to the extent certain clinical, regulatory, and commercial milestones are met with respect to licensed products, Verve will be required to pay to Beam certain amounts, as defined in the agreement. Either party may owe the other party other milestone payments for certain clinical and regulatory events related to the delivery technology products. Royalty payments may become due by either party to the other based on the net sales of any delivery technology products under the agreement. Lastly, to the extent there are sales of a licensed product, Verve is obligated to pay Beam royalties, as defined in the agreement. The term of the agreement commenced in April 2019 and, unless earlier terminated in accordance with the terms of the agreement, will continue until the last to expire royalty term for any licensed product.

Management determined that the performance obligations associated with the Verve License Agreement are the combined licenses and improvements related to the licensed technology. All other items promised to Verve are immaterial in the context of the agreement. The fair value of the shares issued by Verve to Beam were considered a fixed upfront payment of $0.5 million in the form of non-cash consideration. The Company determined that its performance obligations associated with the Verve License Agreement at contract inception were not distinct and represented a single performance obligation, and that the obligations would be completed over the performance period of the agreement. Accordingly, the upfront payment will be recognized as revenue using a time-based proportional performance model over the contract term (April 2019 through 2038) of the collaboration, as license revenue. For the years ended December 31, 2020 and 2019, the Company recognized approximately $24,000 and $18,000, respectively of license revenue and has recorded approximately $0.4 million of deferred revenue at December 31, 2020. To date, no commercial milestone payments or royalties are due. The remaining fees that may be paid under the agreement are considered variable consideration and will be constrained until it is probable that a significant revenue reversal would not occur. To date, the Company has not exercised its option to opt-in to a licensed product and no milestones or royalties have been achieved.

10. Redeemable convertible preferred stock

In February 2019, the Company authorized the sale of an additional 2,980,000 shares of Series B Preferred stock. In January and February 2019, the Company issued 11,308,397 shares of Series B Preferred stock at a price of $3.36 per share, resulting in gross cash proceeds of $38.0 million, and incurred issuance costs of $0.1 million.

In January 2020, the Company’s board of directors approved a one-for-4.4843 reverse stock split of its common stock and stock options and a proportional adjustment to the existing conversion ratios for the Company’s redeemable convertible preferred stock.

In February 2020, upon the closing of the IPO, all outstanding shares of Preferred Stock converted into 29,127,523 shares of the Company’s common stock. There is no Preferred Stock outstanding as of December 31, 2020.

During the years ended December 31, 2020 and 2019, the Company recorded accretion of redeemable convertible preferred stock to redemption value, including dividends on preferred stock of $1.3 million and $12.7 million, respectively.

At December 31, 2019, Preferred Stock consisted of the following (in thousands, except for share data):

<table>
<thead>
<tr>
<th>Preferred stock authorized</th>
<th>Preferred stock issued and outstanding</th>
<th>Carrying value</th>
<th>Liquidation preference</th>
<th>Common stock issuable upon conversion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Series A-1 Preferred</td>
<td>26,833,324</td>
<td>26,833,324</td>
<td>$30,877</td>
<td>$30,877</td>
</tr>
<tr>
<td>Series A-2 Preferred</td>
<td>63,604,886</td>
<td>63,604,886</td>
<td>125,647</td>
<td>105,620</td>
</tr>
<tr>
<td>Series B Preferred</td>
<td>40,230,000</td>
<td>40,178,574</td>
<td>145,525</td>
<td>145,525</td>
</tr>
</tbody>
</table>

|                                 | 130,668,210                          | 130,616,784    | $302,049               | $282,022                            | 29,127,523                         |

11. Preferred stock and common stock

In January 2020, the Company authorized the issuance of 25,000,000 shares of preferred stock and increased its authorized common stock issuable to 250,000,000 shares, both with a $0.01 par value per share.

The holders of common stock are entitled to one vote for each share of common stock. Subject to the payment in full of all preferential dividends to which the holders of the Preferred Stock are entitled, the holders of common stock shall be entitled to receive dividends out of funds legally available. In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, after the payment or provision for payment of all debts and liabilities of the Company and all preferential amounts to which the holders of Preferred Stock are entitled with respect to the distribution of assets in liquidation, the holders of common stock shall be entitled to share ratably in the remaining assets of the Company available for distribution.

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As noted previously, the Company’s board of directors approved a one-for-4.4843 reverse stock split of its common stock and stock options and a proportional adjustment to the existing conversion ratios for the Company’s redeemable convertible preferred stock effective as of January 24, 2020. Accordingly, all common stock shares, per share amounts, and additional paid-in capital amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split.

In February 2020, the Company completed its IPO in which the Company issued and sold 12,176,471 shares of its common stock, including 1,588,235 shares pursuant to the full exercise of the underwriters’ option to purchase additional shares, at a public offering price of $17.00 per share, for aggregate gross proceeds of $207.0 million. The Company received approximately $188.3 million in net proceeds after deducting underwriting discounts and offering expenses payable by the Company. In connection with this financing, all outstanding shares of Preferred Stock converted into 29,127,523 shares of the Company’s common stock.

In July 2020, upon the issuance of a certain Bio Palette patent in the United States in June 2020, the Company issued to Bio Palette 175,000 shares of its common stock.

In October 2020, the Company issued and sold 5,750,000 shares of its common stock, including 750,000 shares pursuant to the full exercise of the underwriters’ option to purchase additional shares, at a public offering price of $23.50 per share, for aggregate gross proceeds of $135.1 million. The Company received approximately $126.6 million in net proceeds after deducting underwriting discounts and offering expenses payable by the Company.

In October 2020, due to the Company’s election to continue the collaboration agreement between Beam and Prime Medicine, the Company issued 200,307 shares of the Company’s common stock to Prime Medicine.

In January 2021, the Company issued and sold 2,795,700 shares of its common stock in a private placement at an offering price of $93.00 per share for aggregate gross proceeds of $260.0 million. The Company received $252.1 million in net proceeds after deducting estimated offering expenses payable by the Company.

12. Stock option and grant plan

2017 stock option and grant plan

In June 2017, the Company’s board of directors adopted the Beam Therapeutics Inc. 2017 Stock Option and Grant Plan, or the 2017 Plan, which provided for the grant of qualified incentive stock options and nonqualified stock options, restricted stock or other awards to the Company’s employees, officers, directors, advisors, and outside consultants for the issuance or purchase of shares of the Company’s common stock. In May 2019, the 2017 Plan was amended to provide up to 8,078,681 shares of common stock for the issuance of stock options and restricted stock.

The 2017 Plan is administered by the board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the common stock on the date of grant. Stock options awarded under the 2017 Plan expire 10 years after the grant date, unless the board of directors sets a shorter term. Vesting periods for awards under the 2017 Plan are determined at the discretion of the board of directors. Incentive stock options granted to employees and shares of restricted stock granted to officers, founders and consultants of the Company typically vest over four years. Certain options provide for accelerated vesting if there is a change in control, as defined in the 2017 Plan. Non-statutory options granted to employees, officers, members of the board of directors and consultants of the Company typically vest over four years.

2019 incentive plan

In October 2019, the Company’s board of directors adopted the Beam Therapeutics Inc. 2019 Equity Incentive Plan, or the 2019 Plan, and, following the IPO, all equity-based awards are granted under the 2019 Plan. The 2019 Plan provides for grant of qualified and nonqualified stock options, stock appreciation rights, restricted and unrestricted stock and stock units, performance awards, and other share-based awards to the Company’s employees, officers, directors, advisors, and outside consultants.

The maximum number of shares of the Company’s common stock that may be issued under the 2019 Plan is 3,700,000 shares, or the Share Pool, plus the number of shares of the Company’s common stock underlying awards under the 2017 Plan, not to exceed 5,639,818 shares, that become available again for grant under the 2017 Plan in accordance with its terms. The Share Pool will automatically increase on January 1st of each year from 2021 to 2029 by the lesser of (i) four percent of the number of shares of the Company’s common stock outstanding as of the close of business on the immediately preceding December 31st and (ii) the number of shares determined by the Company’s board of directors on or prior to such date for such year.

As of December 31, 2020, the Company had 7,456,317 shares reserved and 2,036,376 shares available for future issuance under the 2019 Plan.
Stock-based compensation expense recorded as research and development and general and administrative expenses in the consolidated statements of operations and other comprehensive loss is as follows (in thousands):

<table>
<thead>
<tr>
<th>Years Ended December 31</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and development</td>
<td>$11,199</td>
<td>$4,236</td>
</tr>
<tr>
<td>General and administrative</td>
<td>4,181</td>
<td>2,792</td>
</tr>
<tr>
<td><strong>Total stock-based compensation expense</strong></td>
<td><strong>$15,380</strong></td>
<td><strong>$7,028</strong></td>
</tr>
</tbody>
</table>

**Stock options**

The assumptions used in the Black-Scholes option-pricing model for stock options granted were:

<table>
<thead>
<tr>
<th>Years Ended December 31</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expected volatility</td>
<td>75.6-82.6%</td>
<td>86.4-87.6%</td>
</tr>
<tr>
<td>Weighted-average risk-free interest rate</td>
<td>1.07%</td>
<td>2.17%</td>
</tr>
<tr>
<td>Expected dividend yield</td>
<td>0.00%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Expected term (in years)</td>
<td>6.24</td>
<td>6.25</td>
</tr>
</tbody>
</table>

A summary of option activity under the Company’s equity award plans:

<table>
<thead>
<tr>
<th></th>
<th>Number of options</th>
<th>Weighted average exercise price</th>
<th>Weighted remaining contractual life (years)</th>
<th>Aggregate intrinsic value (1) (in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding as of December 31, 2019</td>
<td>4,791,047</td>
<td>$4.72</td>
<td>9.0</td>
<td>$43,394</td>
</tr>
<tr>
<td>Granted</td>
<td>1,487,096</td>
<td>22.47</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercised</td>
<td>(859,724)</td>
<td>3.67</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forfeitures</td>
<td>(81,978)</td>
<td>7.27</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outstanding as of December 31, 2020</td>
<td>5,336,441</td>
<td>9.70</td>
<td>8.3</td>
<td>383,901</td>
</tr>
<tr>
<td>Exercisable as of December 31, 2020</td>
<td>1,432,552</td>
<td>4.38</td>
<td>7.9</td>
<td>110,678</td>
</tr>
</tbody>
</table>

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the estimated fair value of the common stock for the options that were in the money as of December 31, 2020 and 2019.

The Company has granted stock options to certain employees to purchase shares of common stock that contain certain performance-based vesting criteria, primarily related to the achievement of certain development milestones related to editing applications, and the closing price of the Company’s common stock following an IPO. Recognition of stock-based compensation expense associated with these performance-based stock options commences when the performance condition is considered probable of achievement, using management’s best estimates, which consider the inherent risk and uncertainty regarding the future outcomes of the milestones. The expense related to performance-based stock options was immaterial for the year ended December 31, 2020 and no expense was recognized for the year ended December 31, 2019.

As of December 31, 2020, there was $29.3 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 2.5 years.

**Restricted stock**

The Company issued shares of restricted common stock during the year ended December 31, 2020, including both restricted stock units and restricted stock awards. The Company did not issue any shares of restricted common stock during the year ended December 31, 2019. Restricted common stock issued generally vests over a period of two to four years.

Under the 2017 Plan, the Company granted restricted common stock awards with service conditions. In 2018, the Company issued shares of restricted common stock to certain of the Company’s scientific founders and a portion of these issued shares are subject to vesting over a period of four years, with the commencement of vesting of the remaining shares upon the achievement of certain financing milestones, and in certain instances continued service after the milestones are achieved.

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If the holders of restricted common stock cease to have a business relationship with the Company, the Company may reacquire any unvested shares of common stock held by these individuals for the original purchase price, and in certain instances for no consideration. The amounts received to date for the purchase price of restricted stock are immaterial. The unvested shares of restricted common stock are not considered outstanding shares for accounting purposes until the shares vest.

The following summarizes the Company’s restricted stock activity:

<table>
<thead>
<tr>
<th>Shares</th>
<th>Weighted-average grant date fair value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unvested as of December 31, 2019</td>
<td>2,655,806 $ 2.73</td>
</tr>
<tr>
<td>Issued</td>
<td>258,500 52.29</td>
</tr>
<tr>
<td>Vested</td>
<td>(1,638,968) 4.24</td>
</tr>
<tr>
<td>Unvested as of December 31, 2020</td>
<td>1,275,338 $ 10.95</td>
</tr>
</tbody>
</table>

The aggregate fair value of restricted shares that vested during the years ended December 31, 2020 and 2019, was $6.9 million, and $3.6 million, respectively.

At December 31, 2020, there was approximately $13.8 million of unrecognized stock-based compensation expense related to restricted stock that is expected to vest. These costs are expected to be recognized over a weighted-average remaining vesting period of 0.87 years.

### 2019 Employee Stock Purchase Plan

In January 2020, the Beam Therapeutics Inc. 2019 Employee Stock Purchase Plan, or the 2019 ESPP, was adopted by the Company’s board of directors and approved by the Company’s stockholders. The purpose of the 2019 ESPP is to provide eligible employees of the Company with opportunities to purchase shares of the Company’s common stock at a discount of up to 15% based on the lower of the price at the start of the offering period and at the end of the relevant purchase period within such offering period. 465,000 shares of common stock in the aggregate have been approved and reserved for this purpose. On January 1, 2021 and each January 1 thereafter until January 1, 2029, the number of shares of the Company’s common stock reserved and available for issuance under the 2019 ESPP shall be cumulatively increased by the lesser of (i) one percent of the number of shares of the Company’s common stock outstanding as of the close of business on the immediately preceding December 31st and (ii) the number of shares of stock determined by the Company’s board of directors on or prior to such date for such year up to a maximum of 5,083,204 shares in the aggregate. As of December 31, 2020, the Company has not yet implemented the 2019 ESPP.

### 13. Net loss per share attributable to common stockholders

As noted above, for periods in which the Company reports a net loss attributable to common stockholders, potentially dilutive securities have been excluded from the computation of diluted net loss per share as their effects would be anti-dilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at period end, from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect:

<table>
<thead>
<tr>
<th>Shares</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Redeemable convertible preferred stock</td>
<td>—</td>
<td>29,127,523</td>
</tr>
<tr>
<td>Unvested restricted stock</td>
<td>1,275,338</td>
<td>2,655,806</td>
</tr>
<tr>
<td>Outstanding options to purchase common stock</td>
<td>5,336,441</td>
<td>4,791,047</td>
</tr>
<tr>
<td>Total</td>
<td>6,611,779</td>
<td>36,574,376</td>
</tr>
</tbody>
</table>

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The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company (in thousands, except share and per share amounts):

<table>
<thead>
<tr>
<th>Years Ended December 31</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Numerator:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td>$(194,592)</td>
<td>$(78,326)</td>
</tr>
<tr>
<td>Accretion of redeemable convertible preferred stock to redemption value, including dividends on preferred stock</td>
<td>$(1,277)</td>
<td>$(12,714)</td>
</tr>
<tr>
<td>Net loss attributable to common stockholders</td>
<td>$(195,869)</td>
<td>$(91,040)</td>
</tr>
<tr>
<td><strong>Denominator:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weighted average number of common shares, basic and diluted</td>
<td>46,733,221</td>
<td>6,479,591</td>
</tr>
<tr>
<td>Net loss per common share attributable to common stockholders, basic and diluted</td>
<td>$(4.19)</td>
<td>$(14.05)</td>
</tr>
</tbody>
</table>

14. Income taxes

A reconciliation of the income tax expense computed using the federal statutory income tax rate to the Company’s effective income tax rate is as follows:

<table>
<thead>
<tr>
<th>Years Ended December 31</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal statutory rate</td>
<td>21.0%</td>
<td>21.0%</td>
</tr>
<tr>
<td>State income taxes, net of federal benefit</td>
<td>7.2</td>
<td>7.4</td>
</tr>
<tr>
<td>Research and development tax credits</td>
<td>2.1</td>
<td>3.1</td>
</tr>
<tr>
<td>Nondeductible/ nontaxable permanent items</td>
<td>0.8</td>
<td>(1.8)</td>
</tr>
<tr>
<td>Change in valuation allowance</td>
<td>(31.1)</td>
<td>(29.7)</td>
</tr>
<tr>
<td>Total</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

The components of the Company’s deferred taxes are as follows (in thousands):

<table>
<thead>
<tr>
<th>December 31</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Deferred tax assets:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net operating loss carryforwards</td>
<td>$58,338</td>
<td>$26,767</td>
</tr>
<tr>
<td>Research and development tax credits</td>
<td>8,756</td>
<td>4,876</td>
</tr>
<tr>
<td>Accrued expenses and other</td>
<td>1,445</td>
<td>1,106</td>
</tr>
<tr>
<td>Derivative liabilities</td>
<td>19,421</td>
<td>2,131</td>
</tr>
<tr>
<td>Stock options</td>
<td>1,975</td>
<td>123</td>
</tr>
<tr>
<td>Amortization</td>
<td>2,079</td>
<td>11</td>
</tr>
<tr>
<td>Lease liability</td>
<td>27,340</td>
<td>6,973</td>
</tr>
<tr>
<td>Total deferred tax assets</td>
<td>119,354</td>
<td>41,987</td>
</tr>
<tr>
<td>ROU asset</td>
<td>(23,692)</td>
<td>(5,179)</td>
</tr>
<tr>
<td>Property and equipment</td>
<td>(558)</td>
<td>(373)</td>
</tr>
<tr>
<td>Other</td>
<td>(141)</td>
<td>—</td>
</tr>
<tr>
<td>Less: valuation allowance</td>
<td>(94,963)</td>
<td>(36,435)</td>
</tr>
<tr>
<td>Deferred tax assets, net</td>
<td>$—</td>
<td>$—</td>
</tr>
</tbody>
</table>

The Company had no income tax expense due to the operating loss incurred for the years ended December 31, 2020 and 2019. Management has evaluated the positive and negative evidence bearing upon the realizability of the Company’s net deferred tax assets and has determined that it is more likely than not that the Company will not recognize the benefits of the net deferred tax assets. As a result, the Company has recorded a full valuation allowance at December 31, 2020 and 2019. The valuation allowance increased by $58.5 million in 2020, due to the increase in deferred tax assets, primarily due to net operating loss carryforwards, and research and development tax credits, amortization expenses and the fair value of the derivative liability. The valuation allowance increased by $21.4 million in 2019.
As of December 31, 2020, the Company had $215.2 million of federal and $208.0 million of state net operating loss carryforwards. If not utilized, both the federal and state net operating loss carryforwards expire starting in 2037. Included in the $215.2 million federal net operating loss carryforwards is $211.9 million of net operating loss generated in 2018, 2019 and 2020 that will not expire. Additionally, as of December 31, 2020, the Company had $7.1 million of federal and $2.0 million of Massachusetts tax credits that expire starting in 2038 and 2033, respectively.

As of December 31, 2020, and 2019, the Company had no uncertain tax positions. The Company recognizes both interest and penalties associated with unrecognized tax benefits as a component of income tax expense. The Company has not recorded any interest or penalties for unrecognized tax benefits since its inception.

The Company filed income tax returns in the United States and the Commonwealth of Massachusetts in all tax years since inception. The tax year 2017 remains open to examination by these jurisdictions, as carryforward attributes generated in past years may be adjusted in a future period. The Company’s 2018 tax return is currently under audit by the IRS. The IRS has not made any assessments as of December 31, 2020.

15. Related party transactions

Founders

For the years ended December 31, 2020 and 2019, the Company made payments of $0.5 million and $0.5 million, respectively, to its three founder shareholders for scientific consulting and other expenses.

Verve

The Company and Verve are parties to a collaboration and license agreement and have a common board member. During the years ended December 31, 2020 and 2019, the Company purchased shares of Verve series A preferred stock valued at $0.8 million and $0.4 million, respectively. During the year ended December 31, 2020, the Company recognized unrealized gains of $0.5 million on its investment in Verve preferred stock.

The Company purchased certain materials from Verve amounting to $0.4 million, which is recorded as research and development expenses within the accompanying consolidated statements of operations and other comprehensive loss for the year ended December 31, 2020. The Company also sold certain materials to Verve amounting to $0.2 million, which is recorded as interest and other income (expense), net within the accompanying consolidated statements of operations and other comprehensive loss for the year ended December 31, 2020.

Prime Medicine

The Company and Prime Medicine are parties to a collaboration and license agreement and have a common founder and several common board members. In September 2020, the Company elected to continue its collaboration with Prime Medicine and, in October 2020, as required by the terms under its collaboration and license agreement with Prime Medicine, issued 200,307 shares of the Company’s common stock to Prime Medicine. The Company recognized $5.5 million, which represents the fair value of Beam’s common stock issued to Prime Medicine, as research and development expense within the accompanying consolidated statements of operations and other comprehensive loss for the year ended December 31, 2020. Additionally, in October 2020, the Company received 5,000,000 shares of Prime Medicine’s common stock and recognized $0.1 million as an offset to research and development expense within the accompanying consolidated statements of operations and other comprehensive loss for the year ended December 31, 2020. Management services provided to the Company by Prime Medicine were immaterial for the year ended December 31, 2020.

Additionally, in September 2019, in connection with the Company’s collaboration and license agreement with Prime Medicine, the Company executed a letter agreement, as amended, to provide certain interim management and startup services to Prime Medicine through March 2021. Prime Medicine is obligated to reimburse the Company’s out-of-pocket costs incurred in connection with performing the services and, beginning in October 2020, will pay the Company a $30,000 monthly service fee. For the year ended December 31, 2020, the Company recognized $0.1 million for performing such services in interest and other income (expense), net, within the accompanying consolidated statements of operations and other comprehensive loss.

16. Employee benefits

In 2018, the Company established a defined-contribution plan under Section 401(k) of the Internal Revenue Code, or the 401(k) Plan. The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Beginning January 1, 2020, the Company made matching contributions equal to 50% of the employee’s contributions, subject to a maximum of 6% of eligible compensation. The Company made matching contributions of $0.6 million for the year ended December 31, 2020.
17. Subsequent events

Private Placement
In January 2021, the Company issued and sold 2,795,700 shares of its common stock in a private placement at an offering price of $93.00 per share for aggregate gross proceeds of $260.0 million. The Company received $252.1 million in net proceeds after deducting estimated offering expenses payable by the Company.

Merger Agreement
In February 2021, the Company entered into an Agreement and Plan of Merger with Guide Therapeutics, Inc., or Guide.

The Company paid Guide’s former stockholders and optionholders upfront consideration in an aggregate amount of $120.0 million, excluding customary purchase price adjustments, in shares of the Company’s common stock, based upon the volume-weighted average price of the Company’s common stock over the ten trading day period ending on February 19, 2021.

In addition, Guide’s former stockholders and optionholders will be eligible to receive up to an additional $100.0 million in technology and $220.0 million in product success milestone payments, payable in the Company’s common stock valued using the volume-weighted average price of the Company’s common stock over the ten trading day period ending two trading days prior to the date on which the applicable milestone is achieved.
AGREEMENT AND PLAN OF MERGER

BY AND AMONG

BEAM THERAPEUTICS INC.,

GALILEO MERGER SUB I, INC.,

GALILEO MERGER SUB II, LLC,

GUIDE THERAPEUTICS, INC.,

SHAREHOLDER REPRESENTATIVE SERVICES LLC, AS SHAREHOLDERS’ REPRESENTATIVE,

AND

THE COMPANY HOLDERS SIGNATORY HERETO

(solely for purposes of Section 2.12)

DATED AS OF FEBRUARY 22, 2021
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AGREEMENT AND PLAN OF MERGER

This Agreement and Plan of Merger (this “Agreement”) dated as of February 22, 2021, is made by and among Beam Therapeutics Inc., a Delaware corporation (“Buyer”), Galileo Merger Sub I, Inc., a Delaware corporation, and a wholly-owned direct subsidiary of Buyer (“Merger Sub”), Galileo Merger Sub II, LLC, a Delaware limited liability company, and a wholly-owned direct subsidiary of Buyer (“Merger Sub II”), Guide Therapeutics, Inc., a Delaware corporation (the “Company”), each Company Holder (as defined below) signatory hereto (solely for purposes of Section 2.12), and Shareholder Representative Services LLC, a Colorado limited liability company, solely in its capacity as the Shareholders’ Representative.

RECITALS

WHEREAS, the board of directors of the Company and Merger Sub have each (i) determined that the merger of Merger Sub with and into the Company (the “Merger”) with the Company surviving on the terms and subject to the conditions set forth in this Agreement and the Delaware General Corporation Law (the “DGCL”) is advisable and in the best interest of their respective stockholders to consummate; and (ii) approved the Merger on the terms and subject to the conditions set forth in this Agreement;

WHEREAS, Buyer as the sole member of Merger Sub II and the board of directors of the Company and Merger Sub have each (i) determined that, immediately following the Merger, the merger of the Surviving Corporation (as defined below) with and into Merger Sub II (the “Subsequent Merger” and, together with the Merger, the “Mergers”), with Merger Sub II surviving on the terms and subject to the conditions set forth in this Agreement, the DGCL and the Delaware Limited Liability Company Act (the “DLLCA”) is advisable and in the best interest of their respective members and stockholders, as applicable, to consummate; and (ii) approved the Subsequent Merger on the terms and subject to the conditions set forth in this Agreement;

WHEREAS, promptly following the execution of this Agreement, the Company will distribute an action by written consent in lieu of a meeting pursuant to which stockholders of the Company representing the affirmative vote of the Company Capital Stock required to approve and authorize the Company’s execution and delivery of this Agreement and the Mergers will be asked to adopt this Agreement and approve the Mergers;

WHEREAS, it is intended that for U.S. federal income Tax purposes the Mergers contemplated herein shall together be treated as an integrated transaction and qualify as a “reorganization” within the meaning of Section 368(a) of the Code and the parties hereby adopt this agreement as a “plan of reorganization” within the meaning of Treasury Regulations Section 1.368-2(g); and

WHEREAS, the consideration payable to the securityholders of the Company as a result of the Mergers shall be allocated among the holders of securities of the Company in accordance with the provisions of this Agreement and the Charter (as defined below).

NOW, THEREFORE, in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth herein, the Parties (as defined below) agree as follows:
ARTICLE 1

DEFINED TERMS

Definitions. For purposes of this Agreement, the capitalized terms set forth in this ARTICLE 1 shall have the meanings set forth herein.

Section 1.1. “Accounting Firm” is defined in Section 2.17(e).

Section 1.2. “Accounting Principles” means GAAP as in effect on the Most Recent Balance Sheet Date and, to the extent consistent with GAAP, using the same accounting methods, principles, practices, procedures and estimation methodologies as those utilized in the preparation of the Most Recent Balance Sheet.

Section 1.3. [**]

Section 1.4. “Action” means any claim, controversy, action, cause of action or suit, litigation, assessment, arbitration, mediation, investigation, audit, dispute, hearing, charge, complaint, demand, notice, opposition, interference or proceeding (in each case, whether in contract, tort or otherwise, whether at law or in equity, and whether civil or criminal) that is commenced, brought, conducted, tried or heard by or before, or otherwise involving, any Governmental Entity, but (except as used in Section 4.6) excluding the review and response to compliance filings and review and processing of applications for Permits.

Section 1.5. “Additional Filing Date” is defined in Section 2.8(a)(iii).

Section 1.6. “Additional Registration Statement” is defined in Section 2.8(a)(iii).

Section 1.7. “Additional Merger Consideration” means:

(i) Any cash disbursements made to Company Holders by the Shareholders’ Representative in accordance with Section 2.12(h);

(ii) any cash disbursements made to Company Holders in accordance with Section 2.17; and

(iii) Milestone Payments (if any) payable pursuant to Section 2.18.

Section 1.8. “Additional Merger Consideration Per Share Amount” means, with respect to any Additional Merger Consideration, an amount equal to the quotient of (a) such Additional Merger Consideration divided by (b) the Fully Diluted Share Number.

Section 1.9. “Additional Registration Statement” is defined in Section 2.8(a)(iii).

Section 1.10. “Adjustment Escrow Account” means an escrow account for the purposes of securing the payment of the Company Holders’ obligations pursuant to the Closing Payment adjustment in Section 2.17(f) (if applicable).
Section 1.11. "Adjustment Escrow Amount" means $400,000.

Section 1.12. "Affiliate" means, with respect to a Person, another Person (a) that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, such Person; provided, that, for purposes of this definition, "control" means, with respect to a Person, the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of such Person, whether through the ownership of voting securities, by Contract, by board of director membership or representation, or otherwise, or (b) that is a direct or indirect beneficial holder of at least 10% of any class of Capital Stock of such Person.

Section 1.13. "Agreement" is defined in the preamble of this Agreement.

Section 1.14. "Annex I" means a statement delivered to Buyer by the Company prior to the Closing Date with the following information:

(a) the name, email address (to the extent available) and address of record of each Company Holder;
(b) the number of shares of each class or series of Company Capital Stock held by each Company Holder as of immediately prior to the Effective Time, including the number of shares that are Restricted Company Common Stock and whether a Section 83(b) election was properly made with respect to any shares that are Restricted Company Common Stock;
(c) the number of Company Options held by each Company Optionholder and the number of shares of Company Common Stock into which such Company Options are exercisable, in each case, as of immediately prior to the Effective Time (without regard to whether the Company Options are then vested) together with the exercise price of each such Company Option;
(d) the Company’s good faith estimate of the amount of any Tax to be withheld from each Company Optionholder’s Optionholder Merger Consideration; and
(e) each Company Holder’s Pro Rata Percentage.

Section 1.15. "Annex II" is defined in Section 2.3(a)(ii).

Section 1.16. "Annex III" is defined in Section 2.3(a)(iii).

Section 1.17. "Annex IV" means the cost basis of each issuance of Company Capital Stock.

Section 1.18. "BLA" means a biologics license application filed with the applicable Regulatory Authority in a country or other regulatory jurisdiction, which application is required under Law to be approved in order to commercially market or sell a pharmaceutical or biologic product in such country or jurisdiction (and any amendments thereto).

Section 1.19. "Business" means the businesses conducted by the Company as of the date hereof.
Section 1.20. “Business Day” means a day other than Saturday, Sunday or any other day on which commercial banks located in the Commonwealth of Massachusetts and the State of Georgia are authorized or obligated by applicable Laws to close.

Section 1.21. “Buyer” is defined in the preamble of this Agreement.

Section 1.22. “Buyer [**]” is defined in Section 10.2.

Section 1.23. “Buyer Common Stock” means the common stock, par value $0.01 per share, of Buyer.

Section 1.24. “Buyer Common Stock Average VWAP Price” means, with respect to a certain date, the average of the volume weighted average price of the Buyer Common Stock, as reported by Bloomberg L.P., over the ten (10) trading-day period ending on the last trading day immediately prior to such date.

Section 1.25. “Capital Stock” means any capital stock or share capital of, other voting securities of, other equity interest in, or right to receive profits, losses or distributions of, any Person.

Section 1.26. “Capital Stock Merger Consideration” is defined in Section 2.7(c).

Section 1.27. “CARES Act” means the Coronavirus Aid, Relief, and Economic Security Act (H.R. 748) and any similar or successor Law or executive order or executive memo (including the Memorandum on Deferring Payroll Tax Obligations in Light of the Ongoing Covid-19 Disaster, dated August 8, 2020, Notice 2020-65, and Notice 2021-11) in any jurisdiction, and any subsequent Law intended to address the consequences of COVID-19, including the Health and Economic Recovery Omnibus Emergency Solutions Act and Consolidated Appropriations Act 2021.

Section 1.28. “Cash” means, as of the applicable date of determination, all cash and cash equivalents of the Company, determined in accordance with GAAP.


Section 1.30. “Certificate of Merger” is defined in Section 2.3(b).

Section 1.31. “Change of Control Payments” means (a) any transaction, retention, change in control or other bonus, severance or other payment or other form of compensation that is created, accelerated, accrues or becomes payable by the Company to any Company Personnel or other Persons, including pursuant to any employment agreement, benefit plan or any other Contract, except (A) for accelerated vesting of Company Options and (B) with respect to any Company Personnel who is employed by Buyer or a Subsidiary of Buyer following the Closing, to the extent dependent on post-Closing service or another post-Closing vesting condition (e.g., “double-trigger” payments), including the employer portion of any Taxes payable on or triggered by any such payment (for the avoidance of doubt, without regard to any ability to defer any payroll)
or other Tax amounts under the CARES Act or other applicable Law and excluding any payments with respect to the Company Options, (b) without duplication of any other amounts included within the definition of Seller Transaction Expenses, any other payment, expense or fee that accrues or becomes payable by the Company to any Governmental Entity or other Person under any Legal Requirement or Contract, including in connection with the making of any filings, the giving of any notices or the obtaining of any consents, authorizations or approvals, in the case of each of (a) and (b), as a result of or in connection with the execution and delivery of this Agreement, the consummation of the Merger or the transactions contemplated thereby (alone or together with any other event), including those listed in Annex III and (c) without duplication, any payroll or other Tax amounts payable by the Company in connection with the payments in respect of the Company Options pursuant to Section 2.9 of this Agreement or otherwise in connection with the consummation of the transactions contemplated hereby (whether or not deferred or deferrable under the CARES Act); provided, however, that any payroll or other Tax amounts with respect to payments that become payable to Company Optionholders after the Closing Date (including, for the avoidance of doubt, any Milestone Stock Consideration or payment in lieu thereof) shall not be Change of Control Payments.

Section 1.32. “Charter” means the Company’s Certificate of Incorporation, as amended, in effect immediately prior to the Effective Time.

Section 1.33. “Clinical Trial” means a clinical trial in humans that is designed to generate data regarding a pharmaceutical or biologic product to obtain, support or maintain a BLA (or its equivalent) with the FDA or other applicable Regulatory Authority.

Section 1.34. “Closing” is defined in Section 2.2.

Section 1.35. “Closing Cash Amount” means, as of immediately prior to the consummation of the Closing, the aggregate amount of Cash of the Company.

Section 1.36. “Closing Date” means the date on which the Closing occurs.

Section 1.37. “Closing Liability Amount” means all Liabilities of the Company reflected on the Estimated Closing Balance Sheet, to be calculated as of immediately prior to the consummation of the Closing; provided, that (a) “Closing Liability Amount” shall not include any amounts taken into account in Seller Transaction Expenses and (b) any Taxes shall be calculated as of the end of the day on the Closing Date.

Section 1.38. “Closing Payment” means the amount that is equal to:

(a) the Upfront Purchase Price; plus

(b) the Closing Cash Amount (as finally determined in accordance with Section 2.17); minus

(c) the Closing Liability Amount (as finally determined in accordance with Section 2.17); minus

(d) the Adjustment Escrow Amount; minus
any Seller Transaction Expenses (as finally determined in accordance with Section 2.17); minus
the Shareholders’ Representative Reserve.

Section 1.39. “Closing Stock Consideration” means a number of shares of Buyer Common Stock equal
to the aggregate of all Per Share Closing Stock Consideration payable pursuant to Section 2.7(c) plus the aggregate of all
Optionholder Closing Stock Consideration payable pursuant to Section 2.9(a)(i).

Section 1.40. “Code” means the Internal Revenue Code of 1986, as amended, including the rules and
regulations thereunder and any substitute or successor provisions.

Section 1.41. “Commercially Reasonable Efforts” means with respect to the performing Party under
this Agreement, the carrying out of obligations of such Party with efforts that are consistent with the efforts used by such Party in
the exercise of its commercially reasonable business practices relating to the research, development and commercialization of a
pharmaceutical or biologic compound or product, as applicable, [**].

Section 1.42. “Company” is defined in the preamble of this Agreement.

Section 1.43. “Company Benefit Plan” is defined in Section 4.19(a).

Section 1.44. “Company Capital Stock” means the Capital Stock of the Company.

Section 1.45. “Company Common Stock” means the common stock, $0.00001 par value per share, of
the Company.

Section 1.46. “Company Equity Plan” means the Guide Therapeutics, Inc. 2019 Stock Incentive Plan.

Section 1.47. “Company Holders” means the holders of Company Capital Stock or Company Options
as of immediately prior to the Effective Time (other than holders of Dissenting Shares).

Section 1.48. “Company Intellectual Property” means all Intellectual Property that is (a) owned by or
purported to be owned by the Company or (b) licensed or purported to be licensed to the Company.

Section 1.49. “Company LNP Discovery Platform” means the Company’s in vivo screening platform,
as described in [**] and [**], in which a [**].

Section 1.50. “Company Optionholder” means a Person that holds Company Options.

Section 1.51. “Company Option” means an option to purchase shares of Company Common Stock
granted under the Company Equity Plan.
Section 1.52. "Company Partner" is defined in Section 4.5(e).

Section 1.53. "Company Personnel" means any former or current director, manager, officer, employee, independent contractor or consultant of the Company.

Section 1.54. "Company Product" means any product or technology (1) that is or was researched, developed, tested, labeled, manufactured, stored, imported, exported, marketed or distributed by or on behalf of the Company on or before the date of this Agreement or at any time thereafter prior to the Closing Date, (2) that uses, incorporates, or is developed using any Company Intellectual Property or (3) the research, development, testing, labeling, manufacturing, storage, importation, exportation, marketing or distribution of which would, without a license or ownership under the relevant Patent, infringe a claim in any issued Patent, or infringe a claim in any pending Patent application (if such patent application were to issue as a patent) (i) in the Company Intellectual Property or (ii) filed on any Know-How that is included in or derived from any Company Intellectual Property, whether such claim is in the form of such claim as of the date hereof, as of the Closing Date or at any time thereafter, including in each case any LNP structure listed in Section 1.54 of the Disclosure Schedule.

Section 1.55. "Company Registered IP" is defined in Section 4.13(a).

Section 1.56. "Company's Knowledge," “to the Knowledge of the Company” or variations thereof means, with respect to the Company, the actual knowledge, after reasonable investigation, of one or more of the following: (i) James Dahlman (ii) Cory Sago, and (iii) Julie Sunderland.

Section 1.57. "Constitutive Documents" means, with respect to any Person (other than an individual), (a) the certificate or articles of incorporation or organization and any joint venture, limited liability company, operating or partnership agreement and other similar documents adopted or filed in connection with the creation, formation or organization of such Person and (b) all bylaws, voting agreements and similar documents, instruments or agreements relating to the organization or governance of such Person, in each case, as amended or supplemented.

Section 1.58. "Continuing Employee" is defined in Section 6.10(a).

Section 1.59. "Contract" means any loan or credit agreement, bond, debenture, note, mortgage, deed, indenture, guarantee, security agreement, license, sublicense, lease, sublease or other contract, commitment, agreement, instrument, obligation, undertaking, engagement letter, concession, franchise, license, evidence of Indebtedness or other legally binding arrangement or understanding, whether written or oral.

Section 1.60. "Contractor" is defined in Section 4.18(d).

Section 1.61. "Copyrights" means copyrights and any other legally recognized proprietary right or interest in any work of authorship, including moral rights, fixed in a medium of expression, whether or not registered, including all registrations and applications therefor and renewals, extensions and reversions, and all common law rights, statutory rights, administrative rights and contractual rights relating to the foregoing.
Section 1.62. “Cover” means, with respect to a given compound, product, material or activity and a given Patent Right, that the manufacture, use, sale, offer for sale, or importation of such compound, product, material or activity would infringe one or more claims of such Patent Right absent ownership of or a license under such Patent Right.

Section 1.63. “Cut Back Shares” is defined in Section 2.8(b).

Section 1.64. “D&O Indemnified Parties” is defined in Section 6.2(a).

Section 1.65. “D&O Insurance Policy” is defined in Section 6.2(b).

Section 1.66. “Data Handling” is defined in Section 4.14(a).

Section 1.67. “Data Privacy Requirements” means any applicable Laws and any rules, standards, regulatory guidance, policies and procedures of any applicable Governmental Entity or industry associations, including payment card associations, with respect to data privacy and data security, the Company’s internal and external privacy policies and statements, and contractual requirements relating to the access, use and disclosure of Sensitive Data.

Section 1.68. “Data Room” means the electronic data room made available to Buyer by the Company in connection with the negotiation of this Agreement, as constituted on or prior to the date that is one Business Day prior to the date hereof.

Section 1.69. “DGCL” is defined in the Recitals.

Section 1.70. “Disclosure Schedule” means the disclosure schedule delivered by the Company to Buyer contemporaneously with this Agreement. The Disclosure Schedule shall be arranged in sections and subsections corresponding to the numbered and lettered sections and subsections contained in this Agreement.

Section 1.71. “Dispute Notice” is defined in Section 2.17(d).

Section 1.72. “Dispute Submission Notice” is defined in Section 2.17(e).

Section 1.73. “Dissent Statute” means Section 262 of the DGCL.

Section 1.74. “Dissenting Shares” is defined in Section 2.14(a).

Section 1.75. “DLLCA” is defined in the Recitals.

Section 1.76. “DTC” is defined in Section 2.10(b).

Section 1.77. “Effect” is defined in Section 1.128.

Section 1.78. “Effective Time” means the time when the Merger becomes effective, which shall be the acceptance of the filing of the Certificate of Merger with respect to the Merger by the Secretary of State of the State of Delaware.

Section 1.79. “Effectiveness Deadline” is defined in Section 2.8(a)(ii).
Section 1.80. “EMA” means the European Medicines Agency or any successor agency or authority having substantially the same function.

Section 1.81. “Environmental Law” means any Law relating to: (a) the manufacture, processing, use, labeling, distribution, treatment, storage, discharge, disposal, recycling, generation or transportation of Hazardous Materials; (b) pollution of air (including indoor air), soil, surface, subsurface or groundwater; (c) Releases or threatened Releases of Hazardous Materials; (d) protection of wildlife, endangered species, wetlands or natural resources; (e) underground storage tanks (USTs); (f) above-ground storage tanks (ASTs); (g) health and safety of employees (with respect to exposure to Hazardous Materials).

Section 1.82. “ERISA” means the Employee Retirement Income Security Act of 1974, as amended.

Section 1.83. “ERISA Affiliate” means any Person, trade or business which, together with the Company, is treated as a single employer under Section 4001(b)(1) of ERISA or Section 414(b), (c), (m) or (o) of the Code.

Section 1.84. “Escrow Agent” means Computershare Trust Company, N.A.

Section 1.85. “Escrow Agreement” means that certain escrow agreement, dated as of the date hereof, by and among the Buyer, the Escrow Agent and the Shareholders’ Representative, under which the Escrow Agent shall act as escrow agent with respect to the Adjustment Escrow Account, in the form attached as Exhibit B.

Section 1.86. “Estimated Closing Balance Sheet” is defined in Section 2.17(a).

Section 1.87. “Estimated Closing Cash Amount” is defined in Section 2.17(a).

Section 1.88. “Estimated Closing Liability Amount” is defined in Section 2.17(a).

Section 1.89. “Estimated Closing Payment” means the amount that is equal to:

(a) the Upfront Purchase Price; plus
(b) the Estimated Closing Cash Amount; minus
(c) the Estimated Closing Liability Amount; minus
(d) the Adjustment Escrow Amount; minus
(e) any Estimated Seller Transaction Expenses; minus
(f) the Shareholders’ Representative Reserve.

Section 1.90. “Estimated Closing Statement” is defined in Section 2.17(a).

Section 1.91. “Estimated Seller Transaction Expenses” is defined in Section 2.17(a).

Section 1.93. "Filing Date" is defined in Section 2.8.

Section 1.94. "FDA" means the U.S. Food and Drug Administration or any successor agency or authority thereto.

Section 1.95. "Final Closing Balance Sheet" is defined in Section 2.17(e).

Section 1.96. "Final Closing Statement" is defined in Section 2.17(e).

Section 1.97. "Financial Statements" is defined in Section 4.7.

Section 1.98. "FIRPTA Certificate" is defined in Section 3.1(a).


Section 1.100. "Fully Diluted Share Number" means the sum (without duplication) of (a) the aggregate number of shares of Company Common Stock issued and outstanding as of immediately prior to the Effective Time (other than the shares to be cancelled and retired pursuant to Section 2.7(b)), plus (b) the aggregate number of shares of Company Common Stock into which the shares of Preferred Stock issued and outstanding immediately prior to the Effective Time are convertible, plus (c) the aggregate number of shares of Company Common Stock into which the Company Options that are outstanding immediately prior to the Effective Time are then exercisable (without regard to whether the Company Options are then vested).

Section 1.101. "GAAP" means U.S. generally accepted accounting principles, in effect from time to time, consistently applied.

Section 1.102. [**].

Section 1.103. "Governmental Entity" means any instrumentality, subdivision, court, administrative agency, commission, bureau, department, official or other authority of any country, state, province, prefect, municipality, locality or other government or political subdivision thereof, or any multinational organization or authority, or any quasi-governmental, private body, mediator, arbitrator or arbitral body exercising any executive, legislative, judicial, quasi-judicial, regulatory, taxing, importing, administrative or other governmental or quasi-governmental authority, or stock exchange.

Section 1.104. "Hazardous Material" means any chemical, pollutant, contaminant, pesticide, fungicide, rodenticide, petroleum or petroleum product, radioactive substance, wastes that are regulated as hazardous, extremely hazardous, special, dangerous, or toxic, any substance, chemical or material regulated, listed, limited or defined as hazardous or toxic under any Environmental Law, including: (a) any by-products, derivatives, or combinations of such material; (b) lead, asbestos, asbestos-containing material, presumed asbestos-containing material, poly-chlorinated biphenyls, solvents and waste oil, and mold or other indoor air contaminants; (c) any
“hazardous substance,” “pollutant,” “toxic pollutant” or “contaminant” as defined under Environmental Laws; and (d) any “hazardous waste” as defined under RCRA.

Section 1.105. “HHS” means the U.S. Department of Health and Human Services, or any successor agency or authority thereto.

Section 1.106. [**].

Section 1.107. “IND” means an Investigational New Drug Application filed with the FDA, together with all amendments and supplements thereto.

Section 1.108. “IND Acceptance” means, with respect to an IND filed with the FDA, the thirtieth (30th) day following such filing if no hold has been placed on such IND by the FDA during such thirty- (30)-day period or, if such a hold has been placed on the IND during such thirty- (30)-day period, the date that such hold is lifted by the FDA.

Section 1.109. “Indebtedness” of any Person means, without duplication, (a) all indebtedness of such Person for borrowed money or indebtedness issued or incurred in substitution or exchange for indebtedness for borrowed money, with respect to deposits or advances of any kind or for the deferred purchase price of property or services (other than current trade liabilities incurred in the Ordinary Course of Business and payable in accordance with customary practices and not more than ninety (90) days past due), (b) all obligations of such Person evidenced by bonds, debentures, notes, mortgages or similar instruments, (c) all obligations of such Person under conditional sale or other title retention agreements relating to any assets and properties purchased by such Person, (d) all indebtedness of others secured by (or for which the holder of such indebtedness has an existing right, contingent or otherwise, to be secured by) any Lien or other claim on any assets and properties owned or acquired by such Person, whether or not the obligations secured thereby have been assumed, (e) all guarantees by such Person or contingent liabilities of such Person with respect to the indebtedness of others, (f) all capital lease obligations of such Person, (g) all outstanding obligations of such Person as an account party in respect of letters of credit and banker’s acceptances, (h) all outstanding and current obligations of such Person consisting of overdrafts (e.g., cash float reflected as a negative on the cash line), (i) all Liabilities or obligations to any Person pursuant to any deferred compensation arrangement, severance or other termination-related payments or benefits (including the employer portion of any Taxes payable on or triggered by any such payment), (j) all Liabilities with respect to accrued but unpaid bonus and commission payments, including the employer portion of any Taxes payable on or triggered by any such payment, (k) obligations under any interest rate, currency or other hedging agreement, (l) any amounts owed by the Company under settlement agreements, (m) unpaid Tax Liabilities of the Company for any Pre-Closing Tax Period (determined in accordance with the principles of Section 6.1(c) (taking into account any estimated or advance Tax payments by the Company that will offset such unpaid Tax Liabilities of the Company on a jurisdiction by jurisdiction basis, provided that such unpaid Tax Liabilities shall never be less than zero in any jurisdiction), (n) all Liabilities for payroll Taxes that were or are deferred under the CARES Act from a Pre-Closing Tax Period to a Post-Closing Tax Period, and that would have been accrued Taxes of the Company or any of its Subsidiaries for a Pre-Closing Tax Period but for such deferral.
Section 1.110. “Intellectual Property” means all rights, title, and interests in and to all intellectual property and proprietary or similar rights of every kind and nature however denominated, whether protected, created or arising under the laws of the United States or any other jurisdiction or under any international convention, including (a) Patent Rights, (b) Marks, (c) Copyrights, (d) Know-How, (e) rights of privacy and publicity and (f) any and all registrations, applications, recordings, licenses, common-law rights, statutory rights, administrative rights, and contractual rights relating to any of the foregoing.

Section 1.111. “Intended Tax Treatment” is defined in Section 6.1(e).

Section 1.112. “IRS” means the Internal Revenue Service of the United States of America.

Section 1.113. “IT Systems” is defined in Section 4.13(l).

Section 1.114. “Judgment” means any writ, judgment, injunction, order, decree, stipulation, ruling, decision, verdict, determination or award, or of or by, or any settlement under the jurisdiction of, any Governmental Entity.

Section 1.115. “Know-How” means trade secrets and information, know-how, ideas, information, data, inventions, discoveries, research and development, works, innovations, compositions, formulations, formulas, practices, procedures, processes, methods, schematics, knowledge, data, databases, data collection, technology, techniques, designs, drawings, product configurations, prototypes, models, improvements, proposals, graphics, illustrations, artwork, manuals, industrial designs, correspondence, algorithms, mask works, circuit designs, documents, apparatus, results and strategies, including regulatory documentation and submissions, information pertaining to, or made in association with, filings with any Regulatory Authority or patent office, pharmacological, toxicological, non-clinical, pre-clinical and clinical data, analytical and quality control data, manufacturing data and descriptions, market data, financial data or descriptions, reports, descriptions, laboratory notebooks, devices, assays, specifications, physical, chemical and biological materials and compounds, cost and pricing information, business and marketing plans and proposals, manufacturing techniques, business methods, customer, supplier, distributor and provider lists, and the like, in each case, in written, electronic, oral or other tangible or intangible form, now known or hereafter developed, whether or not patentable, and all rights thereto.

Section 1.116. “Law” means any federal, state, territorial, foreign or local law, statute, ordinance, decision, rule, regulation or code of any Governmental Entity.

Section 1.117. “Leased Property” is defined in Section 4.11(b).

Section 1.118. “Legal Requirement” means any Law, or any Judgment, or any license, franchise, Permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law.

Section 1.119. “Letter of Transmittal” is defined in Section 2.11(a).

Section 1.120. “Liabilities” or “Liability” means, with respect to any Person, any and all Indebtedness, damages, debts, liabilities and obligations (except for those pursuant to
Section 1.121. “Lien” means any lien, security interest, mortgage, pledge, lease, license, claim, levy, restriction on transfer or other encumbrance or restriction of any kind, whether arising by Contract or by operation of Law, or any conditional sale Contract, title retention Contract or other Contract to grant any of the foregoing.

Section 1.122. “LLC Agreement” means, with respect to a limited liability company, its limited liability company agreement, as amended.

Section 1.123. “LNP” means a lipid nanoparticle used as a pharmaceutical drug delivery system.

Section 1.124. “LNP Product” means any Company Product that (i) Targets [**] utilizing LNPs generated by use of the Company LNP Discovery Platform [**] Covered by a Valid Claim in the Patents included within the Company Registered IP or (ii) Targets (A) [**] or (B) [**] utilizing, in each case, LNPs generated by use of the Company LNP Discovery Platform [**] Covered by a Valid Claim in the Patents included within the Company Registered IP.

Section 1.125. “LOT Materials” is defined in Section 2.11(a).

Section 1.126. “Mandatory Registration Statement” is defined in Section 2.8(a)(i).

Section 1.127. “Mark” means any trademark, trade name, trade dress, service mark, service name, logo, brand, community design, domain name, website and social media user name, account or handle, metatag, keyword and other website search term, uniform resource locator, geographical identifier or other brand or source identifier and the reputation and goodwill associated therewith, including any and all registrations and applications therefor and all common law rights, statutory rights, administrative rights and contractual rights relating to the foregoing.

Section 1.128. “Material Adverse Effect” means any change, effect, event, occurrence, state of facts or development (each an “Effect”) which individually or in the aggregate would reasonably be expected to result in, or has resulted in, any change or effect, that (a) is materially adverse to the Company’s business, and other Company Products, the Company’s condition (financial or otherwise) or results of operations of the Company or (b) would reasonably be expected to prevent or materially impede, materially interfere with, materially hinder or materially delay the consummation of the Merger or the other transactions contemplated by this Agreement; provided, that none of the following shall be deemed, either alone or in combination, to constitute, and none of the following shall be taken into account in determining whether there
has been or will be, a Material Adverse Effect: (i) any Effect relating to or reasonably attributable to (A) the economy in general in the United States or in any other jurisdiction in which the Company has operations or conducts business, (B) any outbreak or escalation of hostilities or declared or undeclared acts of war or terrorism, (C) any floods, earthquakes, fires, storms, or other acts of God, natural disasters, or outbreak, pandemic, or epidemic (including the Coronavirus), so long as the Effects, in each case, do not disproportionately impact the Company relative to other participants in its industry, (ii) any Effect reasonably attributable to conditions affecting the industry in which the Company participates, so long as the Effects do not disproportionately impact the Company relative to other participants in its industry, (iii) any failure, in and of itself, by the Company to meet any internal projections, forecasts or revenue or earnings predictions for any period ending on or after the date of this Agreement (it being understood that the facts or occurrences giving rise to or contributing to such failure may be deemed to constitute, or be taken into account in determining whether there has been or will be, a Material Adverse Effect), (iv) changes or proposed changes in GAAP (or interpretations thereof), or (v) any Effect resulting from the announcement or the existence of, or compliance with, Legal Requirements, this Agreement, the Merger or the other transactions contemplated by this Agreement, or the identity of Buyer or its Affiliates.

Section 1.129. “Material Contract” is defined in Section 4.12(a).

Section 1.130. “Materials” means all inventions, works, discoveries, innovations, Know-How, information (including ideas, research and development, formulas, algorithms, compositions, processes and techniques, data, designs, drawings, specifications, customer and supplier lists, pricing and cost information, business and marketing plans and proposals, graphics, illustrations, artwork, documentation, and manuals), systems, equipment, and all other forms of technology and business materials, whether tangible or intangible, embodied in any form, whether or not protectable or protected by patent, copyright, mask work right, trade secret law, or otherwise, and all documents and other materials recording any of the foregoing.

Section 1.131. “Merger” is defined in the Recitals.

Section 1.132. “Mergers” is defined in the Recitals.

Section 1.133. “Merger Consideration” is defined in Section 2.9.

Section 1.134. “Merger Sub” is defined in the preamble of this Agreement.

Section 1.135. “Merger Sub II” is defined in the preamble of this Agreement.

Section 1.136. “Merger Sub Common Stock” means the common stock, par value $0.0001 per share, of Merger Sub.

Section 1.137. “Milestone Events” means the Technology Success Milestone Events and the Product Milestone Events.

Section 1.138. “Milestone Payments” means the Technology Success Milestone Payments and the Product Milestone Payments.
Section 1.139. “Milestone Stock Consideration” means, with respect to any Milestone Event, a number of shares of Buyer Common Stock, rounded down to the nearest whole share, equal to the quotient of (i) the value of the corresponding Milestone Payment to be paid in Buyer Common Stock divided by (ii) the Buyer Common Stock Average VWAP Price calculated as of the day immediately prior to the date on which such Milestone Event is achieved.

Section 1.140. “Milestones” means the milestones set forth in Section 2.18(a).

Section 1.141. “Most Recent Balance Sheet” is defined in Section 4.7.

Section 1.142. “Most Recent Balance Sheet Date” is defined in Section 4.7.

Section 1.143. [**].

Section 1.144. “Off-the-Shelf Software Licenses” means licenses in respect of generally commercially available, “off-the-shelf” software from third parties on general commercial terms used by the Company that (i) is not material to the business, (ii) is not redistributed by or in connection with the Company’s business or incorporated in or necessary for the development of any Company Product, (iii) continues to be widely available on such commercial terms as of the Closing Date, (iv) involves license, maintenance, support, or other fee, royalty or other consideration of less than $25,000 per year in the aggregate and (v) is not Open Source Software.

Section 1.145. “Open Source Software” means any software that is distributed (i) as “free software” (as defined by the Free Software Foundation), (ii) as “open source software” or pursuant to any license identified as an “open source license” by the Open Source Initiative (www.opensource.org/licenses) or other license that substantially conforms to the Open Source Definition (opensource.org/osd), or (iii) is distributed under any similar licensing or distribution model, or (iv) requires code disclosure, is freely relicensable, and allows creation of derivative works.

Section 1.146. “Optionholder Merger Consideration” is defined in Section 2.9.

Section 1.147. “Ordinary Course of Business” means the ordinary course of business of the Company, consistent with past practice.

Section 1.148. [**].

Section 1.149. “Outstanding Shares” means the sum of the total number of shares of Company Capital Stock issued and outstanding immediately prior to the Effective Time, calculated on an as converted to Common Stock basis.

Section 1.150. “Overpayment Amount” is defined in Section 2.17(f)(ii).

Section 1.151. “Party” or “Parties” means Buyer, Merger Sub, Merger Sub II, the Company and the Shareholders’ Representative.
Section 1.152. "Patent Rights" means patents and patent applications and all priority applications, international applications, substitutions, divisions, continuations, continuations-in-part, any patent issued with respect to any such patent applications, any reissue, reexamination, utility models or designs, renewal or Patent Term Extension of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all counterparts thereof in any country.

Section 1.153. "Patent Term Extension" means any patent term extension under 35 U.S.C. §156 or any non-U.S. counterpart or equivalent of the foregoing, including supplemental protection certificates and any other extensions that are available as of the Effective Time or become available in the future.

Section 1.154. "Patents" means all United States and foreign patents and utility models and applications therefor and all reissues, divisions, re-examinations, revisions, renewals, extensions, provisionals, continuations and continuations-in-part thereof, and equivalent or similar rights anywhere in the world in inventions and discoveries, including invention disclosures.

Section 1.155. "Per Share Amount" means an amount equal to the quotient of (a) the sum of the Estimated Closing Payment plus the aggregate exercise price of all Company Options divided by (b) the Fully Diluted Share Number.

Section 1.156. "Per Share Closing Stock Consideration" means a number of shares of Buyer Common Stock equal to the quotient of (i) the Per Share Amount divided by (ii) the Buyer Common Stock Average VWAP Price calculated as of the day immediately prior to the Closing Date.

Section 1.157. "Permit" means any consent, approval, order, authorization, certificate, filing, notice, permit, concession, registration, franchise, license or right issued by, or required under Law to be obtained from, any Governmental Entity.

Section 1.158. "Permitted Liens" means the following: (a) statutory Liens for Taxes not yet due and payable and not otherwise in default; (b) Liens for assessments and other governmental charges or Liens of landlords, carriers, warehousemen, mechanics and repairmen incurred in the Ordinary Course of Business, in each case for sums not yet due and payable and not otherwise in default; (c) Liens incurred in the Ordinary Course of Business in connection with workers’ compensation, unemployment insurance and other types of social security; and (d) encumbrances in the nature of zoning restrictions, easements, rights or restrictions of record on the use of real property if the same do not materially detract from the value of the property encumbered thereby, in each case of clauses (a) through (d), none of which are material to the business, operations or financial condition of the Company so encumbered, either individually or in the aggregate.

Section 1.159. "Person" means an individual, corporation, company, partnership, limited liability company, joint venture, association, trust, business trust, Governmental Entity, unincorporated organization, a division or operating group of any of the foregoing or any other entity or organization.
Section 1.160. “Phase III Clinical Trial” means any Clinical Trial that would satisfy the requirements for a Phase 3 study as defined in 21 C.F.R. 312.21(c) (or any amended or successor regulation), or a Phase III study as defined in the ICH E8 Guideline (or any amended or successor regulations), or an equivalent study as defined in comparable regulations in any country or jurisdiction outside the U.S. (or any amended or successor regulations).

Section 1.161. “PIPE Agreement” means the Securities Purchase Agreement, dated as of January 16, 2021, among Buyer and the purchasers party thereto, relating to sale by Buyer of 2,795,700 shares of Buyer Common Stock.

Section 1.162. “Post-Closing Tax Period” means any Tax Period beginning after the Closing Date, and the portion of any Straddle Period that begins after the Closing Date.

Section 1.163. “Pivotal Clinical Trial” means any Clinical Trial that the FDA confirms in writing will be considered a pivotal study to support an application for Regulatory Approval.

Section 1.164. “Pre-Closing Tax Period” means any Tax Period ending on or before the Closing Date, and the portion of any Straddle Period through the end of the Closing Date.

Section 1.165. “Preferred Stock” means the preferred stock, $0.00001 par value per share of the Company, comprised of the Series Seed Preferred Stock and the Series Seed-1 Preferred Stock (each as defined in the Charter).

Section 1.166. “Pro Rata Percentage” means, with respect to each Company Holder, the quotient of (a) the sum of (1) the aggregate number of shares of Company Common Stock held by such Company Holder as of immediately prior to the Effective Time (other than the shares to be cancelled and retired pursuant to Section 2.7(b)), plus (2) the aggregate number of shares of Common Stock into which the shares of Preferred Stock held by such Company Holder immediately prior to the Effective Time are convertible plus (3) the aggregate number of shares of Common Stock into which the Company Options held by such Company Holder immediately prior to the Effective Time are then exercisable (without regard to whether the Company Options are then vested), divided by (b) the Fully Diluted Share Number.

Section 1.167. “Product Milestone Event” is defined in Section 2.18(b).

Section 1.168. “Product Milestone Payment” is defined in Section 2.18(b).

Section 1.169. “Proposed Final Closing Balance Sheet” is defined in Section 2.17(c).

Section 1.170. “Proposed Final Closing Statement” is defined in Section 2.17(c).

Section 1.171. “PTO” is defined in Section 4.13(n).

“Registration Statement” means any registration statement or a prospectus or prospectus supplement relating to a previously filed registration statement, and shall include any preliminary prospectus, final prospectus, exhibit or amendment included in or relating to such registration statements.

“Regulatory Approval” means all approvals necessary for the manufacture, marketing, importation and sale of a Company Product for one or more indications in a country or regulatory jurisdiction, which may include satisfaction of all applicable regulatory and notification requirements, including any pricing and reimbursement approvals.

“Regulatory Authority” means the FDA, the EMA, or any other national, supranational, regional, state or local regulatory agency, department, bureau, commission, council or other Governmental Entity granting any approval required by applicable Laws to promote, market and sell pharmaceutical products.

“Regulatory Authorizations” is defined in Section 4.5(b).

“Regulatory Materials” means regulatory applications, submissions, reports, notifications, certifications, analyses, registrations, Regulatory Approvals, or other information regarding any Company Product filed or delivered by or on behalf of the Company to any Regulatory Authority or received by the Company from any Regulatory Authority, including any written correspondence or meeting minutes, made to, made with, or received from a Regulatory Authority relating to any Company Product in a particular country or jurisdiction in the Territory.

“Related Product” means with respect to an LNP Product (the “Reference LNP Product”), any LNP Product (i) [**].

“Release” or “Released” means any spill, discharge, leak, migration, emission, escape, injection, dumping, leaching, or other release of any Hazardous Material into the indoor or outdoor environment, whether or not intentional, and whether or not notification or reporting to any Governmental Entity was or is required at the time it initially occurred or continued to occur. Without limiting the above, Release includes the meaning of “Release” as defined under CERCLA.

“Representative Losses” is defined in Section 2.12(d).

“Representatives” means with respect to a Person, such Person’s legal, financial, internal and independent accounting and other advisors and representatives.

“Resale Registration Statement” is defined in Section 2.8(a)(iii).

“Restricted Company Common Stock” means Company Common Stock that is subject to a substantial risk of forfeiture within the meaning of Section 83 of the Code.

“Restriction Termination Date” is defined in Section 2.8(h).
Section 1.185. “Rights Transfer Event” means any transaction consummated in which Buyer or an Affiliate of Buyer (or its direct or indirect Rights Transferee in a previous Rights Transfer Event) transfers, assigns, sells, licenses, sub-licenses, or otherwise grants a Third Party the exclusive right, under the Intellectual Property related to the Company Products, to market and sell any Company Product either throughout the world or in any particular country or region, whether by way of merger, sale of stock, sale of assets, license or other disposition (other than pursuant to a distribution agreement with a Third Party Distributor).

Section 1.186. “Rights Transferee” means a Third Party transferee, assignee, purchaser, licensee, or sublicensee in a Rights Transfer Event.

Section 1.187. “Rule 5635” is defined in Section 2.18(a)(ii).

Section 1.188. “[**].”

Section 1.189. “SEC” means the U.S. Securities and Exchange Commission.

Section 1.190. “SEC Restrictions” is defined in Section 2.8(b).

Section 1.191. “Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

Section 1.192. “Seller Transaction Expenses” means all costs, fees and expenses incurred in connection with or in anticipation of the negotiation, execution and delivery of this Agreement and the transactions contemplated by this Agreement or in connection with or in anticipation of any alternative transactions considered by the Company to the extent such costs, fees and expenses are payable or reimbursable by the Company and unpaid or unreimbursed as of immediately prior to the consummation of the Closing, including (i) all fees and expenses payable to the Company’s financial advisor(s) and all other brokerage fees, commissions, finders’ fees or financial advisory fees so incurred, (ii) the fees and expenses of the Company’s legal and accounting advisors and all other fees and expenses of legal counsel, accountants, consultants and other experts and advisors so incurred (iii) all Change of Control Payments; (iv) 50% of the premium for the [**], and (v) 50% of the premium for the D&O Insurance Policy, all without duplication.

Section 1.193. “Sensitive Data” means any data or information that alone, or in combination with other information, may be used to identify a natural person or is linked to the identity of a particular individual (including any customers, prospective customers, employees, health care providers and other third parties), including any information defined as “personal data”, “personally identifiable information”, “individually identifiable health information”, “protected health information”, “personal information”, “nonpublic personal information,” or a similar term, each as defined under applicable Law.

Section 1.194. “Shareholder Approval” is defined in Section 4.2(b).

Section 1.195. “Shareholders’ Registration Representative” means Julie Sunderland.
Section 1.196. “Shareholders’ Representative” is defined in Section 2.12(a).

Section 1.197. “Shareholders’ Representative Reserve” means an amount equal to $200,000.

Section 1.198. “Staff” is defined in Section 2.8(b).

Section 1.199. “Stock Consideration Cap” means an amount of shares of Buyer Common Stock equal to 20% of all of the issued and outstanding shares of Buyer Common Stock immediately prior to the Closing.

Section 1.200. “Straddle Period” means any Tax Period that includes (but does not end on) the Closing Date.

Section 1.201. “Subsequent Acquiror” is defined in Section 2.18(d).

Section 1.202. “Subsequent Merger” is defined in the Recitals.

Section 1.203. “Subsequent Merger Certificate of Merger” is defined in Section 2.3(b).

Section 1.204. “Subsidiary” means, with respect to any Person, (a) any corporation more than fifty percent (50%) of whose stock of any class or classes is owned by such Person directly or indirectly through one or more Subsidiaries of such Person and (b) any partnership, association, joint venture or other entity in which such Person directly or indirectly through one or more Subsidiaries of such Person has more than a fifty percent (50%) equity interest.

Section 1.205. “Successful Demonstration” means that a given result is repeated in at least [**] experiments, as reported in writing in accordance with Section 2.18(a)(ii) upon completion of the final study report for the [**] experiment.

Section 1.206. “Surviving Corporation” is defined in Section 2.1(a).

Section 1.207. “Surviving Corporation Common Stock” is defined in Section 2.7(a).

Section 1.208. “Surviving LLC” is defined in Section 2.1(b).

Section 1.209. [**].

Section 1.210. [**].

Section 1.211. “Tax” (and, with correlative meaning, “Taxes” and “Taxable”) means: (a) any federal, state, local, foreign and other income, capital gains, branch profits, alternative or add-on minimum, estimated, gross income, gross receipts, sales, use, excise, value added, ad valorem, franchise, capital stock or other equity securities, profits, license, registration, withholding, employment, unemployment, disability, severance, occupation, social security (or similar including FICA), payroll, transfer, conveyance, documentary, stamp, property (real, tangible or intangible), premium, escheat and unclaimed property obligation, environmental,
windfall profits, customs duties, or other taxes of any kind or any fees, charges, levies, excises, duties or assessments of any kind in the nature of (or similar to) taxes whatsoever, together with any interest, penalties or addition thereto, whether disputed or not; (b) any Liability for the payment of any amount of any type described in clause (a) of this sentence as a result of being or having been a member of an affiliated, consolidated, combined, unitary or aggregate group for any Tax Period; and (c) any Liability for the payment of any amounts of the type described in clause (a) or (b) of this sentence as a result of being a transferee of or successor to any Person or as a result of any express or implied obligation to assume such Taxes or to indemnify any other Person, or otherwise.

Section 1.212. “Tax Law” means all currently applicable Laws relating to or regulating the assessment, determination, collection or imposition of Taxes.

Section 1.213. “Tax Period” means any period prescribed by any Taxing Authority for which a Tax Return is required to be filed or a Tax is required to be paid.

Section 1.214. “Tax Return” means any report, return, declaration, claim for refund, information return, statement, designation, election, notice or certificate filed or required to be filed with any Taxing Authority in connection with the determination, assessment, collection or payment of any Taxes, including any schedule or attachment thereto and including any amendment thereof.

Section 1.215. “Taxing Authority” means any Governmental Entity having jurisdiction over the assessment, determination, collection, or imposition of any Taxes (domestic or foreign).

Section 1.216. “Technology Success Milestone Event” is defined in Section 2.18(a).

Section 1.217. “Technology Success Milestone Payment” is defined in Section 2.18(a).

Section 1.218. “Territory” means all countries, jurisdictions and territories worldwide.

Section 1.219. “Third Party” means any Person other than Buyer or the Company or their respective Affiliates.

Section 1.220. “Third Party Distributor” means any Third Party appointed by the Buyer or its Affiliates to a Third Party Buyer to distribute, market, and sell a Product, with or without packaging rights, in one or more countries in the Territory, in circumstances where such Third Party purchases its requirements of the Product from the Buyer or its Affiliates for resale and takes title to such Product, but does not make any royalty payment to the Buyer or its Affiliates with respect to its resale of such Product.

Section 1.221. “Trading Day” means a day on which the Buyer Common Stock is traded on Nasdaq.
Section 1.222. “Transfer Agent” means Computershare Trust Company, N.A., as transfer agent and registrar for the Buyer Common Stock and as paying agent for any Merger Consideration payable in cash (other than for any compensatory payments).

Section 1.223. “Transfer Taxes” means all transfer, sale and use, registration, documentary or mortgage recording, value added, stamp and similar Taxes and fees (including any penalties and interest) incurred, imposed, assessed or payable in connection with or as a result of this Agreement or any transactions contemplated hereby.

Section 1.224. “Underpayment Amount” is defined in Section 2.17(f)(i).

Section 1.225. “Union Contract” is defined in Section 4.12(a)(ii).

Section 1.226. “United States” or “U.S.” means the United States of America, its territories and possessions, including Puerto Rico.

Section 1.227. “Upfront Purchase Price” means $120,000,000.

Section 1.228. “Valid Claim” means a claim of (a) an issued and unexpired patent, which claim has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction which is not appealable or has not been appealed within the time allowed for appeal, and which has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination, inter-partes review, post-grant review, opposition procedure, nullity suit or otherwise, or (b) a patent application for a patent that has been pending less than [**] years from the earliest date on which such patent application claims priority and which claim has not been cancelled, withdrawn, abandoned or finally rejected by an administrative agency action from which no appeal can be taken.

Section 1.229. “Withholding Person” is defined in Section 2.19.

Section 1.230. “Written Consent” means the written consent of the stockholders of the Company adopting this Agreement, approving the consummation of the Merger and waiving any appraisal or dissenters’ rights, in each case in accordance with this Agreement and the DGCL.

Section 1.231. Descriptive Headings; Certain Interpretations.

(a) Headings. The table of contents and headings contained in this Agreement are for reference purposes only and shall not control or affect the meaning or construction of this Agreement.

(b) Interpretations. Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement:

(i) “or” has the inclusive meaning represented by the phrase “and/or”;

(ii) “include”, “includes” and “including” are not limiting;
“hereof”, “hereto”, “hereby”, “herein” and “hereunder” and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement;

“date hereof” refers to the date of this Agreement set forth in the preamble;

“extent” in the phrase “to the extent” means the degree to which a subject or other thing extends, and such phrase does not mean simply “if”;

definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms;

references to an agreement or instrument mean such agreement or instrument as from time to time amended, modified or supplemented;

references to a Person are also to its permitted successors and assigns;

references to an “Article”, “Section”, “Subsection”, “Exhibit” or “Schedule” refer to an Article of, a Section or Subsection of, or an Exhibit or Schedule to, this Agreement;

words importing the masculine gender include the feminine or neuter and, in each case, vice versa;

“day” or “days” refers to calendar days;

references to a Law include any amendment or modification to such Law and any rules or regulations issued thereunder, whether such amendment or modification is made, or issuance of such rules or regulations occurs, before or, only with respect to events or developments occurring or actions taken or conditions existing after the date of such amendment, modification or issuance, after the date of this Agreement, but only to the extent such amendment or modification, to the extent it occurs after the date hereof, does not have a retroactive effect;

references to “employees” will be deemed to include employees of any professional employer organization that are or have been provided to the Company or any of its Affiliates, and for purposes of Section 4.18 and Section 4.19, references to the “Company” will be deemed to include any such professional employer organization, solely with respect to the employees who are or have been provided to the Company or its Affiliates;

the language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party; and
Section 1.232. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

ARTICLE 2
THE MERGER

Section 2.1. The Mergers.

(a) At the Effective Time and subject to and upon the terms and conditions of this Agreement, Merger Sub shall be merged with and into the Company in accordance with the DGCL. Following the Merger, the separate corporate existence of Merger Sub shall cease and the Company shall continue as the surviving corporation (the “Surviving Corporation”) and a wholly owned Subsidiary of Buyer.

(b) On the Closing Date, immediately following the Effective Time and subject to and upon the terms and conditions of this Agreement, the Surviving Corporation shall be merged with and into Merger Sub II in accordance with the DGCL and the DLLCA. Following the Subsequent Merger, the separate corporate existence of the Surviving Corporation shall cease and Merger Sub II shall continue on as the surviving entity (the “Surviving LLC”) and a wholly owned Subsidiary of Buyer.

Section 2.2. Closing of the Mergers. The closing of the Mergers (the “Closing”) will take place by electronic delivery of documents (by “portable document format,” email, or other form of electronic communication), all of which will be deemed to be originals, as promptly as practicable following the satisfaction or, if permissible by the express terms of this Agreement, waiver of the conditions set forth in Article 7 on the Business Day following the date hereof (the “Closing Date”).

Section 2.3. Certain Actions.

(a) Prior to the date hereof, the Company has delivered to Buyer the following:

(i) Annex I;

(ii) an annex setting forth all Seller Transaction Expenses payable in connection with Closing (other than the Change of Control Payments), including the recipient of such Seller Transaction Expenses and wire transfer instructions or a mailing address for payment to be made (“Annex II”);

(iii) an annex setting forth all Change of Control Payments, including each recipient of such Change of Control Payments, the amounts to be paid to such
recipient (before any applicable Tax withholding), the applicable payroll process, and the wire transfer instructions or mailing address for payment to be made (“Annex III”); and

(iv) Annex IV.

(b) On the Closing Date, the Parties shall cause the Merger to be consummated by filing with the Secretary of State of the State of Delaware a certificate of merger (the “Certificate of Merger”) executed in accordance with the relevant provisions of the DGCL. Immediately following the Effective Time, the Surviving Corporation and Merger Sub II shall cause the Subsequent Merger to be consummated by filing with the Secretary of State of the State of Delaware a certificate of merger (the “Subsequent Merger Certificate of Merger”) with respect to the Subsequent Merger executed in accordance with the relevant provisions of the DGCL and the DLLCA.

(c) Immediately following the Effective Time on the Closing Date, Buyer shall pay or cause to be paid

(i) the Seller Transaction Expenses as set forth on Annex II to the applicable recipients thereof at the wire instructions or mailing address as set forth on Annex II;

(ii) the Change of Control Payments to the applicable recipients thereof through the applicable procedures as set forth on Annex III; and

(iii) the Shareholders’ Representative Reserve to the Shareholders’ Representative in accordance with Section 2.12(h).

(d) Immediately following the Effective Time on the Closing Date, Buyer shall deposit with the Escrow Agent the Adjustment Escrow Amount, which the Escrow Agent shall promptly deposit into the Adjustment Escrow Account to be held in trust by the Escrow Agent pursuant to the Escrow Agreement.

Section 2.4. Effects of the Mergers. The Mergers shall have the effects set forth in this Agreement and the applicable provisions of the DGCL and the DLLCA.

Section 2.5. Certificate of Incorporation and Bylaws; LLC Agreement.

(a) At the Effective Time, the certificate of incorporation of the Surviving Corporation shall be amended and restated to be in the form of the certificate of incorporation of Merger Sub as in effect immediately prior to the Effective Time, except that the name of the Surviving Corporation shall be “Guide Therapeutics, Inc.” and the bylaws of the Surviving Corporation shall be amended to be in the form of the bylaws of Merger Sub as in effect immediately prior to the Effective Time, except that the name of the Surviving Corporation shall be “Guide Therapeutics, Inc.”.

(b) Upon acceptance by the Secretary of State of Delaware of the Subsequent Merger Certificate of Merger, the LLC Agreement of the Surviving LLC shall be amended and restated to be in the form of the LLC Agreement of Merger Sub II as in effect immediately prior
to the Effective Time, except that the name of the Surviving LLC shall be “Guide Therapeutics, LLC”.

Section 2.6. **Directors and Officers of Surviving Corporation and Surviving LLC.**

(a) The directors of Merger Sub immediately prior to the Effective Time shall be appointed as the directors of the Surviving Corporation immediately following the Effective Time, until the earlier of their resignation or removal or until their successors are duly elected and qualified. The officers of Merger Sub immediately prior to the Effective Time shall be appointed as the officers of the Surviving Corporation immediately following the Effective Time, until the earlier of their resignation or removal or until their successors are duly elected and qualified.

(b) The Surviving LLC shall not have any directors. The officers of Merger Sub II immediately prior to the Effective Time shall be appointed as the officers of the Surviving LLC immediately following acceptance by the Secretary of State of Delaware of the Subsequent Merger Certificate of Merger, until the earlier of their resignation or removal or until their successors are duly elected and qualified.

Section 2.7. **Conversion of Capital Stock.** On the terms and subject to the conditions set forth in this Agreement, at the Effective Time, by virtue of the Merger and without any action on the part of Buyer, the Company, Merger Sub or any Company Holder:

(a) each issued and outstanding share of Merger Sub Common Stock shall be converted into and shall become one share of common stock, par value $0.00001 per share, of the Surviving Corporation (“Surviving Corporation Common Stock”);

(b) each share of Company Capital Stock that is held by the Company as treasury stock or owned by the Company shall be canceled and retired and shall cease to exist and no consideration shall be delivered in exchange therefor;

(c) except as provided in Section 2.7(b), each share of Company Capital Stock outstanding immediately prior to the Effective Time (other than the Dissenting Shares) shall be converted into the right to receive, without interest and subject to Section 2.11 and Section 2.12, the following payments (collectively, the “Capital Stock Merger Consideration”):

(i) on the Closing Date, the Per Share Closing Stock Consideration; and

(ii) an amount equal to the Additional Merger Consideration Per Share Amount with respect to any Additional Merger Consideration, payable in cash or Milestone Stock Consideration, as applicable, pursuant to terms of this Agreement.

(d) The shares of Company Capital Stock converted into the right to receive a portion of the Merger Consideration in accordance with this Section 2.7 shall no longer be outstanding and shall automatically be canceled and retired and shall cease to exist, and each holder of Company Capital Stock immediately prior to the Effective Time shall cease to have any rights with respect thereto, except the right to receive such holder’s applicable portion of the Merger Consideration.
Upon acceptance by the Secretary of State of Delaware of the Subsequent Merger Certificate of Merger, by virtue of the Subsequent Merger and without any action on the part of Buyer, the Surviving Corporation or Merger Sub II, each then issued and outstanding share of Surviving Corporation Common Stock shall be converted into and become one membership unit of the Surviving LLC and the shares of the Surviving Corporation Common Stock shall no longer be outstanding and shall automatically be cancelled and retired and shall cease to exist.

The shares of Buyer Common Stock comprising the Closing Stock Consideration and Milestone Stock Consideration (if any) to be issued to the Company Holders in consideration for the Company Capital Stock pursuant to this Agreement will be issued from Buyer to the Company Holders in a private placement transaction, pursuant to the exemption from registration set forth in Section 4(a)(2) of the Securities Act. The offering and issuance of the shares of Buyer Common Stock hereunder will not be registered with the SEC, and accordingly, the shares of Buyer Common Stock will be “restricted securities” under the Securities Act. Any subsequent offer, sale or disposition of the shares of Buyer Common Stock by a Company Holder must be either registered under the Securities Act and applicable state securities laws or exempt from such registration requirements (including pursuant to the safe harbor provided by Rule 144 promulgated under the Securities Act). Except as set forth in Section 2.8, Buyer has no obligation to register the offering or issuance of the shares of Buyer Common Stock with the SEC or the securities regulatory authority of any other state or jurisdiction.

Section 2.8. Registration of Closing Stock Consideration.

(a) Procedures and Expenses.

(i) Buyer will file a Registration Statement (the “Mandatory Registration Statement”) with the SEC on April 1, 2021 (the “Filing Date”) to register all of the shares of Closing Stock Consideration on Form S-3 under the Securities Act (providing for shelf registration of such shares under SEC Rule 415). In the event that Form S-3 is not available for the registration of the shares of Closing Stock Consideration, Buyer will register the resale of the shares of Closing Stock Consideration on such other form as is available to the Company.

(ii) Buyer will use its commercially reasonable efforts to cause the Mandatory Registration Statement to be declared effective as soon as practicable and in any event within the earlier of: (i) thirty (30) days following the Filing Date and (ii) four (4) Business Days after the date the Company receives written notification from the SEC that the Mandatory Registration Statement will not be reviewed (or, in the event the staff of the SEC reviews and has written comments to the Mandatory Registration Statement, within ninety (90) days following the Filing Date) (the earlier of the foregoing or the applicable date set forth in Section 2.8(a)(ix), the “Effectiveness Deadline”), such efforts to include, without limiting the generality of the foregoing, preparing and filing with the SEC any financial statements or other information that is required to be filed prior to the effectiveness of such Mandatory Registration Statement.

(iii) Notwithstanding anything contained in this Agreement to the contrary, in the event that the SEC limits the amount of shares of Closing Stock
Consideration or otherwise requires a reduction in the number of shares of Closing Stock Consideration that may be included and sold by the Company Holders in the Mandatory Registration Statement (in each case, subject to Section 2.8(e)), then Buyer shall prepare and file (i) within ten (10) Trading Days of the first date or time that such excluded shares of Closing Stock Consideration may then be included in a Resale Registration Statement if the SEC shall have notified Buyer that certain shares of Closing Stock Consideration were not eligible for inclusion in the Resale Registration Statement or (ii) in all other cases, within twenty (20) days following the date that Buyer becomes aware that such additional Resale Registration Statement is required (the “Additional Filing Date”), a Resale Registration Statement (any such Resale Registration Statement registering such excluded shares of Closing Stock Consideration, an “Additional Registration Statement” and, together with the Mandatory Registration Statement, a “Resale Registration Statement”) to register any shares of Closing Stock Consideration that have been excluded (or, if applicable, the maximum number of such excluded shares of Closing Stock Consideration that Buyer is permitted to register for resale on such Additional Registration Statement consistent with SEC guidance), if any, from being registered on the Mandatory Registration Statement.

(iv) Not less than two (2) Trading Days prior to the filing of a Resale Registration Statement or any related prospectus or any amendment or supplement thereto, Buyer will furnish via email to the Shareholders’ Registration Representative copies of all such documents proposed to be filed, which documents (other than any document that is incorporated or deemed to be incorporated by reference therein) will be subject to the review of the Shareholders’ Registration Representative. Buyer shall reflect in each such document when so filed with the SEC such comments regarding the Company Holders and the plan of distribution as the Shareholders’ Registration Representative may reasonably and promptly propose no later than two (2) Trading Days after the Shareholders’ Registration Representative has been so furnished with copies of such documents as aforesaid.

(v) Buyer will use its commercially reasonable efforts to cause any such Additional Registration Statement to be declared effective as promptly as practicable following the Additional Filing Date, such efforts to include, without limiting the generality of the foregoing, preparing and filing with the SEC any financial statements or other information that is required to be filed prior to the effectiveness of any such Additional Registration Statement.

(vi) Buyer will promptly prepare and file with the SEC such amendments and supplements to such Resale Registration Statements and the prospectus used in connection therewith as may be necessary to keep such Resale Registration Statements continuously effective and free from any material misstatement or omission to state a material fact therein until termination of such obligation as provided in Section 2.8(d) below, subject to Buyer’s right to suspend pursuant to Section 2.8(c).

(vii) Buyer will furnish to the Company Holders such number of copies of prospectuses in conformity with the requirements of the Securities Act and such other documents as the Company Holders may reasonably request, in order to facilitate the public
sale or other disposition of all or any of the shares of Closing Stock Consideration by the Company Holders.

(viii) Buyer will file such documents as may be required of Buyer for normal securities law clearance for the resale of the shares of Closing Stock Consideration in such states of the United States as may be reasonably requested by the Company Holders and use its commercially reasonable efforts to maintain such blue sky qualifications during the period Buyer is required to maintain effectiveness of the Resale Registration Statements; provided, however, that Buyer shall not be required in connection with this Section 2.8(q)(viii) to qualify as a foreign corporation or execute a general consent to service of process in any jurisdiction in which it is not now so qualified or has not so consented.

(ix) Upon notification by the SEC that the Resale Registration Statement will not be reviewed or is not subject to further review by the SEC, Buyer shall within three (3) Trading Days following the date of such notification request acceleration of such Resale Registration Statement (with the requested effectiveness date to be not more than two (2) Trading Days later).

(x) Upon notification by the SEC that that the Resale Registration Statement has been declared effective by the SEC, Buyer shall file the final prospectus under Rule 424 of the Securities Act within the applicable time period prescribed by Rule 424.

(xi) Buyer will advise the Shareholders’ Representative promptly (and in any event within two (2) Trading Days thereof):

(A) of the effectiveness of the Resale Registration Statement or any post-effective amendments thereto;

(B) of any request by the SEC for amendments to the Resale Registration Statement or amendments to the prospectus or for additional information relating thereto;

(C) of the issuance by the SEC of any stop order suspending the effectiveness of the Resale Registration Statement under the Securities Act or of the suspension by any state securities SEC of the qualification of the shares of Closing Stock Consideration for offering or sale in any jurisdiction, or the initiation of any proceeding for any of the preceding purposes; and

(D) of the existence of any fact and the happening of any event that makes any statement of a material fact made in the Resale Registration Statement, the prospectus and amendment or supplement thereto, or any document incorporated by reference therein, untrue, or that requires the making of any additions to or changes in the Resale Registration Statement or the prospectus in order to make the statements therein not misleading.

(xii) Buyer will cause all shares of Closing Stock Consideration to be listed on each securities exchange, if any, on which equity securities by Buyer are then listed.
Buyer will bear all expenses in connection with the procedures in paragraphs (i) through (xii) of this Section 2.8(a) and the registration of the shares of Closing Stock Consideration on such Resale Registration Statement and the satisfaction of the blue sky laws of such states.

(b) Rule 415; Cutback. If at any time the staff of the SEC ("Staff") takes the position that the offering of some or all of the shares of Closing Stock Consideration in a Registration Statement is not eligible to be made on a delayed or continuous basis under the provisions of Rule 415 under the Securities Act or requires any Company Holder to be named as an "underwriter," Buyer shall use its commercially reasonable efforts to persuade the SEC that the offering contemplated by the Registration Statement is a valid secondary offering and not an offering "by or on behalf of the issuer" as defined in Rule 415 and that none of the Company Holders is an "underwriter." In the event that, despite Buyer's commercially reasonable efforts and compliance with the terms of this Section 2.8(b), the Staff refuses to alter its position, Buyer shall (i) remove from the Registration Statement such portion of the shares of Closing Stock Consideration (the "Cut Back Shares") and/or (ii) agree to such restrictions and limitations on the registration and resale of the shares of Closing Stock Consideration as the Staff may require to assure Buyer's compliance with the requirements of Rule 415 (collectively, the "SEC Restrictions"); provided, however, that Buyer shall not agree to name any Company Holder as an "underwriter" in such Registration Statement without the prior written consent of such Company Holder. Any cutback imposed on the Company Holders pursuant to this Section 2.8(b) shall be allocated among the Company Holders on a pro rata basis, unless the SEC Restrictions otherwise require or provide or the Shareholders' Representative otherwise agrees. No liquidated damages shall accrue as to any Cut Back Shares until such date as Buyer is able to effect the registration of such Cut Back Shares in accordance with any SEC Restrictions (such date, the "Restriction Termination Date" of such Cut Back Shares). From and after the Restriction Termination Date applicable to any Cut Back Shares, all of the provisions of this Section 2.8 shall again be applicable to such Cut Back Shares; provided, however, that (x) the Filing Deadline for the Registration Statement including such Cut Back Shares shall be ten (10) Trading Days after such Restriction Termination Date, and (y) the Effectiveness Deadline with respect to such Cut Back Shares shall be the 90th day immediately after the Restriction Termination Date or the 120th day if the Staff reviews such Registration Statement (but in any event no later than three (3) Trading Days from the Staff indicating it has no further comments on such Registration Statement).

(c) Prospectus Suspension. Each Company Holder acknowledges that there may be times when Buyer must suspend the use of the prospectus forming a part of the Resale Registration Statement until such time as an amendment to the Resale Registration Statement has been filed by Buyer and declared effective by the SEC, or until such time as Buyer has filed an appropriate report with the SEC pursuant to the Exchange Act. Each Company Holder hereby covenants that it will not sell any shares of Closing Stock Consideration pursuant to said prospectus during the period commencing at the time at which Buyer gives the Company Holders notice of the suspension of the use of said prospectus and ending at the time Buyer gives the Company Holders notice that the Company Holders may thereafter effect sales pursuant to said prospectus; provided, that such suspension periods shall in no event exceed 30 days in any 12 month period and that, in the good faith judgment of Buyer's board of directors, Buyer would, in the absence of such delay or suspension hereunder, be required under state or federal securities laws to disclose any corporate development, a potentially significant transaction or event involving Buyer, or any
negotiations, discussions, or proposals directly relating thereto, in either case the disclosure of which would reasonably be expected to have a material adverse effect upon Buyer or its stockholders.

(d) **Termination of Obligations.** The obligations of Buyer pursuant to Section 2.8(a) hereof shall cease and terminate, with respect to any shares of Closing Stock Consideration, upon the earlier to occur of (a) such time such shares of Closing Stock Consideration have been resold; (b) such time as such shares of Closing Stock Consideration are eligible to be sold pursuant to Rule 144 under the Securities Act without condition or restriction, including without any limitation as to volume of sales, and without the Company Holder needing to comply with any method of sale requirements or notice requirements under Rule 144, or (c) such time as such shares of Closing Stock Consideration shall cease to be outstanding following their issuance.

(e) **Effect of Failure to File and Obtain and Maintain Effectiveness of Registration Statement.** If a Mandatory Registration Statement covering all of the shares of Closing Stock Consideration required to be covered thereby and required to be filed by Buyer pursuant to this Agreement is not filed with the SEC on or before the Filing Date (the “**Filing Failure**”), then, as partial relief for the damages to any Company Holder by reason of any such delay in or reduction of its ability to sell the underlying shares of Buyer Common Stock (which remedy shall not be exclusive of any other remedies available at law or in equity), Buyer shall pay to each Company Holder an amount in cash equal to one percent (1%) of the amount of the Merger Consideration paid on the Closing Date to such Company Holder pursuant to this Agreement (which amount of the Merger Consideration shall be valued based upon the Buyer Common Stock Average VWAP Price calculated as of the day immediately prior to the Closing Date). Buyer shall pay, or cause such amounts to be paid, such amounts to each Company Holder no later than the third Trading Day after the Filing Date.

Section 2.9. **Treatment of Company Options.**

(a) Immediately prior to the Effective Time, the Company shall cause each Company Option that is then outstanding (whether such Company Option is vested or unvested, but not to the extent it has theretofore been exercised) to become fully vested and exercisable in full. At the Effective Time, each Company Option, to the extent then outstanding and unexercised, will be automatically cancelled and extinguished and converted at the Effective Time into the right to receive the following consideration (such consideration, the “**Optionholder Merger Consideration**” and, together with the Capital Stock Merger Consideration, the “**Merger Consideration**”):

(i) within three (3) Business Days following the next regular payroll period of the Company following the Closing Date, a number of shares of Buyer Common Stock, rounded down to the nearest whole share, equal to the quotient of (i) (A) the Per Share Amount multiplied by the number of shares of Company Common Stock that were covered by the unexercised portion of such Company Option immediately prior to the Effective Time, minus (B) the aggregate exercise price of the unexercised portion of such Company Option, divided by (ii) the Buyer Common Stock Average VWAP Price calculated as of the day immediately prior to the Closing Date (such shares, “**Optionholder Closing Stock Consideration**”);
(ii) an amount equal to the Additional Merger Consideration Per Share Amount with respect to any Additional Merger Consideration, payable in cash or Milestone Stock Consideration, as applicable, pursuant to terms of this Agreement; and

(iii) notwithstanding the foregoing or anything to the contrary herein, to the extent a Withholding Person is required pursuant to Section 2.19 to deduct and withhold any Tax from the Optionholder Merger Consideration or Additional Merger Consideration Per Share Amount, as applicable, the number of shares of Buyer Common Stock that would otherwise have been delivered in respect of such Optionholder Merger Consideration or Additional Merger Consideration Per Share Amount, respectively, under the terms of this Agreement shall be reduced by a number of shares having a fair market value approximately equal to such Tax.

(b) Prior to the Effective Time, the Company shall adopt all resolutions and take all actions that were necessary or desirable to effectuate the provisions of this Section 2.9 and terminated all Company Options and other rights outstanding under the Company Equity Plan and the Company Equity Plan, in each case contingent on and effective as of the Closing and with no Liability to Buyer other than the obligation to deliver the amounts described in this Section 2.9.

Section 2.10. Legends on Share Consideration.

(a) The shares of Buyer Common Stock to be issued as Closing Stock Consideration and Milestone Stock Consideration (if any) shall be characterized as “restricted securities” for purposes of Rule 144 under the Securities Act, and each certificate representing any such shares shall, until such time that such shares are not so restricted under the Securities Act, bear a legend identical or similar in effect to the following legend (together with any other legend or legends required by applicable state securities Laws or otherwise, if any):

“THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE OF THE UNITED STATES OR IN ANY OTHER JURISDICTION. THE SECURITIES REPRESENTED HEREBY MAY NOT BE OFFERED, SOLD OR TRANSFERRED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT FOR THE SECURITIES UNDER APPLICABLE SECURITIES LAWS UNLESS OFFERED, SOLD OR TRANSFERRED PURSUANT TO AN AVAILABLE EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THOSE LAWS.”

(b) Buyer shall, at its sole expense, upon appropriate notice from any Company Holder stating that shares of Closing Stock Consideration have been sold pursuant to an effective Resale Registration Statement, timely prepare and deliver certificates or book-entry shares representing the shares to be delivered to a transferee pursuant to the Resale Registration Statement, which certificates or book-entry shares shall be free of any restrictive legends and in such denominations and registered in such names as such Company Holder may request. Further, Buyer shall, at its sole expense, cause its legal counsel or other counsel satisfactory to the transfer agent:
(i) while the Resale Registration Statement is effective, to issue to the transfer agent a “blanket” legal opinion to allow (A) the legend on such shares to be removed, or (B) sales without restriction pursuant to the effective Resale Registration Statement, and (ii) provide all other opinions as may reasonably be required by the transfer agent in connection with the removal of legends. A Company Holder may request that Buyer remove, and Buyer agrees to authorize the removal of, any legend from such shares of Closing Stock Consideration or Milestone Stock Consideration, following the delivery by a Company Holder to Buyer or Buyer’s transfer agent of a legended certificate representing such shares: (i) following any sale of such shares pursuant to Rule 144, (ii) if such shares are eligible for sale under Rule 144(b)(1), or (iii) following the time that the Resale Registration Statement is declared effective. If a legend removal request is made pursuant to the foregoing, Buyer will, no later than three (3) Trading Days following the delivery by a Company Holder to Buyer or Buyer’s transfer agent of a legended certificate representing such shares of Closing Stock Consideration or Milestone Stock Consideration or a request for legend removal, in the case of shares issued in book-entry form), instruct Buyer’s transfer agent to deliver or cause to be delivered to such Company Holder a certificate representing such shares that is free from all restrictive legends or an equivalent book-entry position, as requested by the Company Holder. Certificates for shares free from all restrictive legends may be transmitted by Buyer’s transfer agent to the Company Holders by crediting the account of Buyer’s prime broker with the Depository Trust Company (“DTC”) as directed by such Company Holder. Subject to each Company Holder’s compliance with applicable securities laws, Buyer warrants that the shares of Closing Stock Consideration and Milestone Stock Consideration shall otherwise be freely transferable on the books and records of Buyer as and to the extent provided in this Agreement. If a Company Holder effects a transfer of shares of Closing Stock Consideration or Milestone Stock Consideration in accordance with this Section 2.10(b), Buyer shall permit the transfer and shall promptly instruct its transfer agent to issue one or more certificates or credit shares to the applicable balance accounts at DTC in such name and in such denominations as specified by such Company Holder to effect such transfer. Such Company Holder hereby agrees that the removal of the restrictive legend pursuant to this Section 2.10(b) is predicated upon Buyer’s reliance that such Company Holder will sell any such shares pursuant to either the registration requirements of the Securities Act, including any applicable prospectus delivery requirements, or an exemption therefrom, and such Company Holder shall, if requested by Buyer, deliver to Buyer or its legal counsel or other counsel delivering an opinion referred to in this Section 2.10(b), a customary representation letter as may be reasonably requested in order to deliver an opinion referred to in this Section 2.10(b).

Section 2.11. Exchange Procedures.

(a) Payment Procedures. Promptly following the execution of this Agreement, the Company will send to each Company Holder (i) a letter of transmittal, in the form attached as Exhibit A (the “Letter of Transmittal”), and (ii) instructions for effecting the delivery of the Merger Consideration payable to such Company Holder. Such payment is conditioned upon (i) the due execution and delivery of such Letter of Transmittal, and (ii) a properly executed Form W-9 or Form W-8BEN (or W-8BEN-E) or other applicable Form W-8 (the “LOT Materials”), as applicable, from such holder in form and substance reasonably acceptable to Buyer and the Transfer Agent. After the Effective Time (or with respect to Company Optionholders, after the date of the next regular payroll period of the Company following the Closing Date), within five (5) Business Days after receipt by Buyer or the Surviving LLC of a duly executed LOT Materials.
from a Company Holder, Buyer will cause the Transfer Agent to deliver to such Company Holder the applicable portion of the Closing Stock Consideration set forth in Section 2.7(c)(i) and Section 2.9(a)(i), without interest and subject to applicable Tax withholding.

(b) If payment of any portion of the applicable Merger Consideration is to be made to a Person other than the Person in whose name the applicable shares of Company Capital Stock or Company Options, as applicable, are registered, it will be a condition of payment that the Person requesting such payment (A) will have paid any Taxes required by reason of the payment of those amounts to a Person other than such registered holder, and will have established to the satisfaction of the Buyer that such Taxes have been paid, or (B) will have established to the reasonable satisfaction of the Buyer that such Taxes are not applicable.

(c) **Transfer Books; No Further Ownership Rights.** At the Closing, the transfer books of the Company will be closed, and thereafter there will be no further registration of transfers of Company Capital Stock on the records of the Company.

Section 2.12. **Company Holder Representations; Shareholders’ Representative.**

(a) Each Company Holder represents that such Company Holder (i) is a sophisticated investor with respect to the transactions described herein and, either alone or with a representative, has such knowledge and experience in financial and business matters sufficient to evaluate the merits and risks of owning and investing in securities similar to the Buyer Common Stock, making an informed decision with respect thereto, and evaluating properly the terms and conditions of this Agreement, and he, she or it has made its own analysis and decision to adopt this Agreement and approve the Merger, (ii) acknowledges the availability of the Buyer SEC Reports, (iii) has obtained all information it deems necessary or appropriate in order to adopt this Agreement and approve the Merger, (iv) understands that the shares of Buyer Common Stock to be issued pursuant to this Agreement have not been registered under the Securities Act or under any comparable securities act of any jurisdiction and are being sold in reliance upon an exemption from the registration requirements thereof, (v) will acquire the shares of Buyer Common Stock issued pursuant to this Agreement for such Company Holder’s own account for investment and not with a view to, or for resale in connection with, the distribution thereof and (vi) acknowledges that he, she or it has had an opportunity to review the terms of this Agreement and all schedules and exhibits hereto and has received or has had access to all the information relating to the Buyer that such Company Holder has requested and considers necessary and relevant to making an informed investment decision with respect to the shares of Buyer Common Stock.

(b) By voting in favor of or consenting to the Merger, or by delivering to the Buyer or the Company (or its designee payroll service provider), as applicable, an executed Letter of Transmittal in exchange for the consideration to be paid in accordance with this Agreement, each Company Holder irrevocably approves the depositing of the funds held in the Shareholders’ Representative Reserve and the constitution and appointment of, and hereby irrevocably constitutes and appoints Shareholder Representative Services LLC as of the Closing as the sole, exclusive, true and lawful agent, representative and attorney-in-fact of all Company Holders and each of them (the “Shareholders’ Representative”) with respect to any and all matters relating to, arising out of, or in connection with, this Agreement, or the agreements ancillary hereto, including
for purposes of taking any action or omitting to take any action on behalf of each Company Holder hereunder to:

(i) act for each Company Holder to defend, compromise, or settle any claims and to otherwise prosecute or pursue any litigation claims in connection with the enforcement of this Agreement;

(ii) execute and deliver all amendments, waivers, ancillary agreements, certificates and documents that the Shareholders’ Representative deems necessary or appropriate in connection with the consummation of the transactions contemplated by this Agreement or the agreements ancillary hereto;

(iii) receive funds, make payments of funds and give receipts for funds;

(iv) do or refrain from doing any further act or deed on behalf of the Company Holders that the Shareholders’ Representative deems necessary or appropriate in its discretion relating to the subject matter of this Agreement as fully and completely as the Company Holders could do if personally present;

(v) administer the defense and/or settlement of any disputes regarding the Closing Payment adjustment pursuant to Section 2.17 and agreeing to or negotiating the Final Closing Balance Sheet, the final Closing Payment, and the payment or non-payment of any of the Adjustment Escrow Amount;

(vi) administer the defense and/or settlement of any disputes regarding any Milestone Payments pursuant to Section 2.18;

(vii) give any written direction to the Escrow Agent or the Transfer Agent;

(viii) give or receive notices to be given or received by the Company Holders under this Agreement or the Escrow Agreement (except to the extent that this Agreement or the Escrow Agreement expressly contemplates that any such notice shall be given or received by each Company Holder individually); and

(ix) receive service of process in connection with any claims under this Agreement or the Escrow Agreement.

After the Closing, all actions, notices, communications and determinations by or on behalf of the Company Holders shall be given or made by the Shareholders’ Representative and all such actions, notices, communications and determinations by the Shareholders’ Representative shall conclusively be deemed to have been authorized by, and shall be binding upon, any of and all Company Holders, and no Company Holder shall have the right to object, dissent, protest or otherwise contest the same. Without limiting the rights and obligations of the Company, Buyer, Merger Sub and Merger Sub II under this Agreement, the Shareholders’ Representative shall be entitled to: (i) rely upon Annex I, Annex II, Annex III and Annex IV, (ii) rely upon any signature believed by it to be genuine, and (iii) reasonably assume that a signatory has proper authorization to sign on behalf of the applicable Company Holder.
(c) The Shareholders’ Representative may resign at any time. If the Shareholders’ Representative resigns, dies or becomes legally incapacitated, then a majority of the Company Holders, based on their respective Pro Rata Percentages, shall promptly designate in writing to Buyer a single Person to fill the Shareholders’ Representative vacancy as the successor Shareholders’ Representative hereunder. If at any time there shall not be a Shareholders’ Representative or the Company Holders fail to designate a successor Shareholders’ Representative, then Buyer may have a court of competent jurisdiction appoint a Shareholders’ Representative hereunder. A majority of the Company Holders, based on their respective Pro Rata Percentages, may also replace the Person serving as the Shareholders’ Representative from time to time and for any reason upon at least ten (10) days’ prior written notice to Buyer.

(d) The Shareholders’ Representative shall act for the Company Holders on all of the matters set forth in this Agreement in the manner the Shareholders’ Representative believes to be in the best interest of the Company Holders. The Shareholders’ Representative is authorized to act on behalf of the Company Holders notwithstanding any dispute or disagreement among the Company Holders. In taking any actions as Shareholders’ Representative, the Shareholders’ Representative may rely conclusively, without any further inquiry or investigation, upon any certification or confirmation, oral or written, given by any Person the Shareholders’ Representative believes to be authorized thereunto. The Shareholders’ Representative may, in all questions arising hereunder, rely on the advice of counsel, and the Shareholders’ Representative shall not be liable to any Company Holder for anything done, omitted or suffered in good faith by the Shareholders’ Representative based on such advice. The Shareholders’ Representative undertakes to perform such duties and only such duties as are specifically set forth in this Agreement and no implied covenants or obligations shall be read into this Agreement against the Shareholders’ Representative. The Shareholders’ Representative shall not have any liability to the Company Holders for any act done or omitted hereunder as Shareholders’ Representative while acting in good faith and without gross negligence or willful misconduct. The Company Holders shall indemnify, defend and hold harmless the Shareholders’ Representative from and against any and all losses, liabilities, damages, claims, penalties, fines, forfeitures, actions, fees, costs and expenses (including the fees and expenses of counsel and experts and their staffs and all expense of document location, duplication and shipment) (collectively, “Representative Losses”) arising out of or in connection with the Shareholders’ Representative’s execution and performance of this Agreement and any agreements ancillary hereto, in each case as such Representative Loss is suffered or incurred; provided, that in the event that any such Representative Loss is finally adjudicated to have been directly caused by the gross negligence or willful misconduct of the Shareholders’ Representative, the Shareholders’ Representative will reimburse the Company Holders the amount of such indemnified Representative Loss to the extent attributable to such gross negligence or willful misconduct. If not paid directly to the Shareholders’ Representative by the Company Holders, any such Representative Losses may be recovered by the Shareholders’ Representative from (i) the funds in the Shareholders’ Representative Reserve and (ii) any other funds that become payable to the Company Holders under this Agreement at such time as such amounts would otherwise be distributable to the Company Holders; provided, that while this section allows the Shareholders’ Representative to be paid from the aforementioned sources of funds, this does not relieve the Company Holders from their obligation to promptly pay such Representative Losses as they are suffered or incurred, nor does it prevent the Shareholders’ Representative from seeking any remedies available to it at law or otherwise. In no event will the Shareholders’ Representative be required to advance its own funds on behalf of the Company.
Holders or otherwise. Notwithstanding anything in this Agreement to the contrary, any restrictions or limitations on liability or indemnification obligations of, or provisions limiting the recourse against non-parties otherwise applicable to, the Company Holders set forth elsewhere in this Agreement are not intended to be applicable to the indemnities provided to the Shareholders’ Representative under this section. The foregoing indemnities will survive the Closing, the resignation or removal of the Shareholders’ Representative or the termination of this Agreement.

(e) The Shareholders’ Representative shall treat confidentially any nonpublic information disclosed to it pursuant to this Agreement and shall not use such nonpublic information other than in the performance of its duties as the Shareholders’ Representative. In addition, the Shareholders’ Representative shall not disclose any nonpublic information disclosed to it pursuant to this Agreement to anyone except as required by Law; provided, that (i) the Shareholders’ Representative may disclose such nonpublic information to legal counsel and other advisors under an obligation of confidentiality and non-use in its capacity as such, (ii) the Shareholders’ Representative (or legal counsel or other advisor to whom information is disclosed pursuant to clause (i) above) may disclose such nonpublic information disclosed to the Shareholders’ Representative pursuant to this Agreement in any Action relating to this Agreement or the transactions contemplated hereby (or, in either case, discussion in preparation therefor) and (iii) the Shareholders’ Representative may disclose to any Company Holder on a need-to-know basis any such nonpublic information disclosed to the Shareholders’ Representative pursuant to this Agreement in any Action relating to this Agreement or the transactions contemplated hereby (or, in either case, discussion in preparation therefor) and (iii) the Shareholders’ Representative may disclose to any Company Holder on a need-to-know basis any such nonpublic information disclosed to the Shareholders’ Representative pursuant to this Agreement.

(f) Buyer shall be entitled to rely on the authority of the Shareholders’ Representative as the agent, representative and attorney-in-fact of the Company Holders for all purposes under this Agreement and shall have no Liability for any such reliance. No Company Holder may revoke the authority of the Shareholders’ Representative. Each Company Holder, by voting in favor of or consenting to the Merger or by delivering an executed Letter of Transmittal to Buyer hereby ratifies and confirms, and hereby agrees to ratify and confirm, any action taken by the Shareholders’ Representative in the exercise of the power-of-attorney granted to the Shareholders’ Representative pursuant to this Section 2.12, which power-of-attorney, being coupled with an interest, is irrevocable and shall survive the death, incapacity or incompetence of such Company Holder.

(g) At the Closing, the Buyer shall wire the Shareholders’ Representative Reserve to the Shareholders’ Representative, which shall be maintained by the Shareholders’ Representative in a segregated account. The Shareholders’ Representative will hold these funds separate from its funds, will not use these funds for its operating expenses or any other corporate purposes and will not voluntarily make these funds available to its creditors in the event of bankruptcy. The Company Holders shall not receive interest or other earnings on the Shareholders’ Representative Reserve and the Company Holders irrevocably transfer and assign to the Shareholders’ Representative any ownership right that they may otherwise have had in any interest or earnings that may accrue on funds held in the Shareholders’ Representative Reserve. The Company Holders acknowledge that the Shareholders’ Representative is not providing any investment supervision, recommendations or advice. The Shareholders’ Representative shall have no responsibility or liability for any loss of principal of the Shareholders’ Representative Reserve.
other than as a result of its bad faith, gross negligence or willful misconduct. For Tax purposes, the Shareholders’ Representative Reserve shall be treated in accordance with Section 6.1(d).

(h) Upon the determination of the Shareholders’ Representative that the Shareholders’ Representative Reserve is no longer necessary in connection with post-Closing matters pursuant to this Section 2.12, the Shareholders’ Representative shall deposit such amount with the Transfer Agent and shall calculate the amount to be distributed to each Company Holder according to each Company Holder’s respective Pro Rata Percentage after payment of all of the Shareholders’ Representative’s out-of-pocket expenses incurred in connection with its services as Shareholders’ Representative. The Transfer Agent shall make payments to the Company Holders and the Surviving LLC in accordance with the Pro Rata Percentages set forth on Annex I. Any portion of the Shareholders’ Representative Reserve that remains undeliverable or unclaimed after eighteen (18) months of the initial delivery attempt (or such earlier date, immediately prior to such time when the amounts would otherwise escheat to or become property of any Governmental Entity by Law) shall become, to the extent permitted by Law, including any abandoned property, escheat or similar Law, the property of Buyer, free and clear of any claims or interest of any Person previously entitled thereto. The Shareholders’ Representative Reserve shall not be available to Buyer to satisfy any claims in connection with this Agreement or the transactions contemplated hereby. Any payments as may be required by the Shareholders’ Representative to be made directly to it by any Company Holder pursuant to this Agreement or any other agreement shall be paid in accordance with such Company Holder’s Pro Rata Percentage.

Section 2.13. Close of Stock Transfer Books. At the Effective Time, the stock transfer books of the Company shall be closed and thereafter there shall be no further registration of transfers of shares of Company Capital Stock on the records of the Company. From and after the Effective Time, no shares of Company Capital Stock shall be deemed to be outstanding, and the holders of shares of Company Capital Stock immediately prior to the Effective Time shall cease to have any rights with respect to such shares, except as otherwise provided herein or by applicable Law.


(a) Notwithstanding anything in this Agreement to the contrary, any shares of Company Capital Stock outstanding immediately prior to the Effective Time and held by a holder who (i) voted against the Merger (if submitted for approval at a meeting of shareholders); (ii) did not consent in writing to the Merger (if submitted for approval by written consent in lieu of a meeting); or (iii) has not otherwise contractually waived its rights of dissent and appraisal, and, in each case, who has exercised and perfected its rights of dissent and appraisal for such shares in accordance with the Dissent Statute and has not effectively withdrawn or lost such rights of dissent and appraisal (collectively, the “Dissenting Shares”) shall not be converted into or represent the right to consideration for Company Capital Stock set forth in Section 2.7 and the holder or holders of such Dissenting Shares shall be entitled only to such rights as may be granted to such holder or holders under the Dissent Statute. At the Effective Time, the Dissenting Shares shall no longer be outstanding and shall automatically be cancelled and shall cease to exist, and each holder of Dissenting Shares shall cease to have any rights with respect thereto, except the right to receive the appraised value of such shares in accordance with the relevant provisions of the Dissent Statute.
The holders of any Dissenting Shares shall instead be entitled to receive payment of the fair value of such Dissenting Shares held by them in accordance with the Dissent Statute.

(b) Notwithstanding the provisions of Section 2.14(a), if any holder of Dissenting Shares shall effectively withdraw or lose (through failure to perfect or otherwise) such holder’s rights to dissent and appraisal under the Dissent Statute, or a court of competent jurisdiction shall determine that such holder is not entitled to relief provided under the Dissent Statute, then, as of the later of the Effective Time and the occurrence of such event, such holder’s shares of Company Capital Stock shall automatically be converted into and represent only the right to receive the consideration for Company Capital Stock set forth in Section 2.7, without interest.

(c) After the Effective Time, the Surviving LLC shall give the Shareholders’ Representative prompt notice of any written demands for appraisal, negotiations between the Surviving LLC and any holders of Dissenting Shares, withdrawals of demands for appraisal and any other related instruments served on or by the Surviving LLC. Notwithstanding the foregoing, Buyer shall have the right to participate in and direct all negotiations and proceedings with respect to such demands; provided, however, that neither Party shall voluntarily make any payment with respect to any demand for appraisal or settle or offer to settle any such demand without the written consent of the other Party, which consent shall not be unreasonably conditioned, withheld or delayed, except for payments required to be made by the Surviving LLC pursuant to the Dissent Statute, for which the Shareholders’ Representative’s written consent shall not be required.

Section 2.15. No Fractional Shares. No fractional shares of Buyer Common Stock shall be issued in connection with the Merger, no certificates or scrip representing fractional shares of Buyer Common Stock shall be delivered upon the conversion of Company Common Stock pursuant to Section 2.7, and such fractional share interests shall not entitle the owner thereof to vote or to any other rights of a holder of shares of Buyer Common Stock. The number of shares of Buyer Common Stock to be issued to a Company Holder will be rounded down to the nearest whole share after aggregating all shares of Buyer Common Stock to be received by such Company Holder as Closing Stock Consideration or Milestone Stock Consideration, as applicable. No such holder shall be entitled to dividends, voting rights or any other rights in respect of any fractional share of Buyer Common Stock.

Section 2.16. Certain Adjustments. If the outstanding shares of Buyer Common Stock shall change into a different number of shares or a different class of shares by reason of any stock dividend, subdivision, reclassification, stock split, reverse stock split, combination or exchange of shares, or any similar event shall have occurred (other than in connection with the Merger) between the date of calculation and payment, as applicable, pursuant to this Agreement, then the Merger Consideration or the Milestone Payments, as applicable, shall be equitably adjusted, without duplication, to proportionally reflect such change; provided, that nothing in this Section 2.16 shall be construed to permit the Company to take any of the foregoing actions with respect to its securities to the extent otherwise prohibited by the terms of this Agreement.

Section 2.17. Closing Payment Adjustment.

(a) Estimated Closing Balance Sheet and Estimated Closing Statement. Prior to the date hereof, the Company prepared in good faith and provided to Buyer an estimated balance
sheet of the Company as of the Closing Date (the “Estimated Closing Balance Sheet”), together with a statement setting forth in reasonable detail its good faith estimate of the estimated Closing Liability Amount (the “Estimated Closing Liability Amount”), the estimated Closing Cash Amount (the “Estimated Closing Cash Amount”), and the estimated Seller Transaction Expenses (the “Estimated Seller Transactions Expenses”, and such statement, the “Estimated Closing Statement”). The Estimated Closing Balance Sheet and the Estimated Closing Statement were prepared in accordance with the Accounting Principles.

(b) Estimated Closing Payment. The amount of the Estimated Closing Payment has been calculated using the Estimated Closing Liability Amount, the Estimated Closing Cash Amount, and the Estimated Seller Transaction Expenses set forth in the Estimated Closing Statement, which shall be subject to a “true-up” adjustment after the Closing pursuant to Section 2.17(f).

(c) Proposed Final Closing Balance Sheet and Proposed Final Closing Statement. Not later than ninety (90) days after the Closing Date, Buyer shall prepare or cause to be prepared, and deliver to the Shareholders’ Representative, a balance sheet of the Company as of the close of business on the date immediately preceding the Closing Date, (the “Proposed Final Closing Balance Sheet”), together with a statement setting forth in reasonable detail its proposed final determination of the Closing Liability Amount, the Closing Cash Amount, and the Seller Transaction Expenses (the “Proposed Final Closing Statement”). The Proposed Final Closing Balance Sheet and the Proposed Final Closing Statement will be prepared in accordance with the Accounting Principles. Notwithstanding anything to the contrary in this Agreement, any calculations with respect to Taxes in the Estimated Closing Statement and the Final Closing Statement shall be calculated as of the end of the day on the Closing Date taking into account the effect of the transactions contemplated by this Agreement. The Shareholders’ Representative and its Representatives shall have reasonable access to the work papers and other books and records of the Surviving LLC for purposes of assisting the Shareholders’ Representative and its Representatives in their review of the Proposed Final Closing Balance Sheet and the Proposed Final Closing Statement.

(d) Dispute Notice. The Proposed Final Closing Balance Sheet and the Proposed Final Closing Statement will be final, conclusive and binding on the Parties unless the Shareholders’ Representative provides a written notice (a “Dispute Notice”) to Buyer no later than the thirtieth (30th) Business Day after the delivery to the Shareholders’ Representative of the Proposed Final Closing Balance Sheet and the Proposed Final Closing Statement. Any Dispute Notice must set forth in reasonable detail (i) any item on the Proposed Final Closing Balance Sheet which the Shareholders’ Representative believes has not been prepared in accordance with this Agreement and the correct amount of such item and (ii) the Shareholders’ Representative’s alternative calculation of the Closing Liability Amount, the Closing Cash Amount, and the Seller Transaction Expenses, as applicable. For the avoidance of doubt, any item not included in the Dispute Notice shall be considered final and binding.

(e) Resolution of Disputes. Buyer and Shareholders’ Representative will attempt to promptly resolve the matters raised in any Dispute Notice in good faith. If the Parties have not resolved the matters raised in any Dispute Notice, within ten (10) Business Days after the date of delivery of any Dispute Notice pursuant to Section 2.17(d) either Buyer or Shareholders’
Representative may provide written notice to the other (the "Dispute Submission Notice") that it elects to submit the disputed items to a nationally recognized independent accounting firm chosen jointly by Buyer and the Shareholders’ Representative (the “Accounting Firm”). In the event that such firm has not agreed to act as the Accounting Firm and an alternative Accounting Firm has not been selected by mutual agreement of Buyer and the Shareholders’ Representative within ten (10) Business Days following the giving of the Dispute Submission Notice, each of Buyer and the Shareholders’ Representative shall promptly select an accounting firm and promptly cause such two (2) accounting firms to mutually select a third independent accounting firm to act as the Accounting Firm within twenty (20) Business Days of the giving of the Dispute Submission Notice. The Accounting Firm will promptly, in accordance with the rules set forth in the Accounting Firm’s engagement letter and its customary practices review only those unresolved items and amounts specifically set forth and objected to in the Dispute Notice and resolve the dispute with respect to each such specific unresolved item and amount in accordance with this Agreement. In any such case, a single partner of the Accounting Firm selected by such Accounting Firm in accordance with its normal procedures and having expertise with respect to settlement of such disputes and the industry in which the Surviving LLC operates shall act for the Accounting Firm in the determination proceeding, and the Accounting Firm shall render a written decision as to each disputed matter, including a statement in reasonable detail of the basis for its decision. In no event shall the decision of the Accounting Firm provide for a calculation of the Closing Liability Amount, the Closing Cash Amount or the Seller Transaction Expenses that is less than the calculation thereof shown in the Proposed Final Closing Statement or greater than the Shareholders’ Representative’s alternative calculation thereof shown in the Dispute Notice. The fees and expenses of the Accounting Firm shall be borne equally by Buyer and the Shareholders’ Representative (on behalf of the Company Holders). The decision of the Accounting Firm with respect to the disputed items of the Proposed Final Closing Balance Sheet and the Proposed Final Closing Statement submitted to it will be final, conclusive and binding on the Parties. As used herein, the Proposed Final Closing Balance Sheet and the Proposed Final Closing Statement, as adjusted to reflect any changes agreed to by the Parties and the decision of the Accounting Firm, in each case, pursuant to this Section 2.17(e), are referred to herein as the “Final Closing Balance Sheet” and the “Final Closing Statement”, respectively. Each of the Parties agrees to use its commercially reasonable efforts to cooperate with the Accounting Firm (including by executing a customary engagement letter reasonably acceptable to it) and to cause the Accounting Firm to resolve any such dispute as soon as practicable after the commencement of the Accounting Firm’s engagement.

(f) Closing Payment Adjustment. If any of the Closing Liability Amount, the Closing Cash Amount or the Seller Transaction Expenses (as finally determined pursuant to this Section 2.17 and as set forth in the Final Closing Statement) differs from the Estimated Closing Liability Amount, the Estimated Closing Cash Amount or the Estimated Seller Transaction Expenses, respectively, set forth in the Estimated Closing Statement, the following shall occur:

(i) if the recalculated final Closing Payment equals or exceeds the Estimated Closing Payment (such excess, if any, the “Underpayment Amount”), then within two (2) Business Days of the date such recalculation is finally determined in accordance with this Section 2.16, (A) Buyer shall deliver or cause to be delivered to the Transfer Agent and the Surviving LLC (for any compensatory payments) by wire transfer of immediately available funds, an amount equal to the Underpayment Amount, if any, for
further disbursement to the Company Holders (pro rata in accordance with their respective Pro Rata Percentages), and (B) Buyer and the Shareholders’ Representative shall jointly instruct the Escrow Agent to deliver to the Transfer Agent and the Surviving LLC (for any compensatory payments) by wire transfer of immediately available funds, any funds in the Adjustment Escrow Account for further disbursement to the Company Holders (pro rata in accordance with their respective Pro Rata Percentages); or

(ii) if the Estimated Closing Payment exceeds the recalculated final Closing Payment (such excess, if any, the “Overpayment Amount”), then within two (2) Business Days of the date such recalculation is finally determined in accordance with this Section 2.16, Buyer and the Shareholders’ Representative shall jointly instruct the Escrow Agent to deliver (A) to Buyer by wire transfer of immediately available funds, an amount equal to the Overpayment Amount from the Adjustment Escrow Account, and (B) to the Transfer Agent and the Surviving LLC (for any compensatory payments) by wire transfer of immediately available funds, any funds remaining in the Adjustment Escrow Account following the disbursement to Buyer pursuant to clause (A) above for further disbursement to the Company Holders (pro rata in accordance with their respective Pro Rata Percentages). In no event shall the Company Holders be responsible for any Overpayment Amount in excess of the funds then-remaining in the Adjustment Escrow Account, which funds shall be Buyer’s sole source of recovery to satisfy any Overpayment Amount.

Section 2.18. Milestone Payments.

(a) Technology Success Milestones. Buyer shall make the payments described in Table 1 below (each, a “Technology Success Milestone Payment”), following first achievement or first occurrence of the corresponding event with respect to a Company Product developed by the Company or Buyer, its Affiliates or a Rights Transferee or any Affiliate thereof (each, a “Technology Success Milestone Event”) described in the row to the left of such payment in Table 1.

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(i) Notwithstanding anything to the contrary, in no event shall any of the Technology Success Milestone Payments be paid more than once or be subject to setoff or offset by Buyer or any other Person.
With respect to the documentation of the Successful Demonstration of [**] for purposes of the Technology Success Milestone Events, Buyer shall use Commercially Reasonable Efforts to conduct and achieve Successful Demonstration of the Technology Success Milestone Events as soon as possible and to complete study reports on a timely basis. The Buyer shall provide written notice to the Shareholders’ Representative of the achievement of any Technology Success Milestone Event no later than [**] days after the occurrence thereof, and the Buyer shall pay to the Transfer Agent or the Surviving LLC, as applicable, for further disbursement to the Company Holders (pro rata in accordance with their respective Pro Rata Percentages) the applicable Technology Success Milestone Payment within [**] days after achievement. Each such payment will be made by issuing the applicable Milestone Stock Consideration; provided, that in no event will Buyer be obligated to issue Buyer Common Stock with respect to any Milestone Payment, if the Milestone Stock Consideration to be issued in connection with such payment, when combined with the Closing Stock Consideration and all previously issued Milestone Stock Consideration, would equal or exceed the Stock Consideration Cap, unless Buyer has obtained stockholder consent for such issuance in satisfaction of Nasdaq Marketplace Rule IM 5635 (“Rule 5635”), or otherwise complied with Rule 5635 or any successor rule, and Buyer will use commercially reasonable efforts to obtain stockholder consent for such issuance in satisfaction of Rule 5635 or to otherwise comply with Rule 5635 or any successor rule, and, if such stockholder consent has not been obtained and such issuance cannot otherwise be made in compliance with Rule 5635 or any successor rule, then Buyer will issue Buyer Common Stock with respect to any such Milestone Payment to the extent permitted in accordance with Nasdaq Marketplace Rules and will make all payments owed pursuant to this Section 2.18(a) that cannot be satisfied by the issuance of Buyer Common Stock in cash.

(b) **Product Milestones.** Buyer shall make the payments described in Table 2 below (each, a “Product Milestone Payment”), following first achievement or first occurrence of the corresponding event with respect to LNP Products developed by the Company or Buyer, its
Affiliates or a Rights Transferee or any Affiliate thereof (each a “Product Milestone Event”) described in the row to the left of such payment in Table 2.

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(i) In no event shall any of the Product Milestone Payments be paid more than once or be subject to setoff or offset by Buyer or any other Person.

(ii) The Product Milestone Payments set forth in this Section 2.18(b) shall not be payable with respect to a subsequent achievement of the same Product Milestone Event by any LNP Product that is a replacement for another LNP Product for the same targeted disease state, the development of which has been discontinued after achievement of such same Product Milestone Event. In addition, an LNP Product and all Related Products to such LNP Product shall be treated as the same LNP Product for purposes of determining the achievement of a Product Milestone Event.

(iii) The Buyer shall provide written notice to the Shareholders’ Representative of the achievement of any Product Milestone Event no later than [**] days after the occurrence thereof, and the Buyer shall pay to the Transfer Agent or the Surviving LLC, as applicable, for further disbursement to the Company Holders (pro rata in accordance with their respective Pro Rata Percentages) the applicable Product Milestone Payment within [**] days after achievement. Each such payment will be made by issuing the applicable Milestone Stock Consideration; provided, that in no event will Buyer be obligated to issue Buyer Common Stock with respect to any Milestone Payment, if the Milestone Stock Consideration to be issued in connection with such payment, when combined with the Closing Stock Consideration and all previously issued Milestone Stock Consideration, would equal or exceed the Stock Consideration Cap, unless Buyer has obtained stockholder consent for such issuance in satisfaction of Rule 5635, or otherwise complied with Rule 5635 or any successor rule, and Buyer will use commercially reasonable efforts to obtain stockholder consent for such issuance in satisfaction of Rule 5635 or to otherwise comply with Rule 5635 or any successor rule, and, if such stockholder
consent has not been obtained and such issuance cannot otherwise be made in compliance with Rule 5635 or any successor rule, then Buyer will issue Buyer Common Stock with respect to any such Milestone Payment to the extent permitted in accordance with Nasdaq Marketplace Rules and will make all payments owed pursuant to this Section 2.18(b) that cannot be satisfied by the issuance of Buyer Common Stock in cash.

(c) Notwithstanding anything contained herein to the contrary, Buyer agrees that it will, and will cause its subsidiaries and require any Rights Transferees to, (i) use Commercially Reasonable Efforts to achieve the Milestone Events, and (ii) provide at least [**].

(d) Notwithstanding anything contained herein to the contrary, Buyer may not transfer, sell, or assign, to any Person, any rights pertaining to the LNP Products or Company LNP Discovery Platform (excluding as a part of a sale that includes all or substantially all of the assets of Buyer or all or substantially all of the equity interests of Buyer, including by way of a merger or consolidation) unless [**] under this Section 2.18, excluding payment of the Milestone Payments (any such permitted transferee, or assignee, a “Subsequent Acquiror”); provided, that in the event of any such permitted transfer, sale, or assignment, Buyer shall notify the Shareholders’ Representative of any such transfer, sale, or assignment within two (2) Business Days thereof.

Section 2.19. Withholding. Notwithstanding anything in this Agreement to the contrary, each of Buyer, the Surviving Corporation, the Surviving LLC, the Escrow Agent, the Transfer Agent and any other applicable withholding agent (each, a “Withholding Person”), will be entitled to deduct and withhold, or cause to be deducted and withheld, from any amount payable or consideration otherwise deliverable pursuant to or as contemplated by this Agreement to any Company Holders, recipients of Change of Control Payments, the Shareholders’ Representative on the Company Holders’ behalf, or any other Person, such amounts as may be required to be deducted and withheld therefrom under the Law. Any such Tax deducted and withheld on amounts payable or consideration otherwise deliverable under this Agreement shall be timely paid to the appropriate Taxing Authority when required by Law and treated for all purposes of this Agreement as having been paid to any such Company Holder or other recipient. Notwithstanding anything to the contrary in this Agreement, all compensatory amounts subject to payroll reporting and withholding payable pursuant to or as contemplated by this Agreement shall be payable in accordance with applicable payroll procedures.

ARTICLE 3
CLOSING DELIVERIES

Section 3.1. Company Deliverables. At the Closing, the Company shall deliver to Buyer the following:

(a) A certificate (and accompanying notice to the IRS) in form and substance reasonably satisfactory to Buyer, dated as of the Closing Date, pursuant to Treasury Regulations 1.897-2(h) (as described in Treasury Regulations 1.1445-2(c)(3)) stating that the Company is not as of the Closing Date and was not during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code, a “United States real property holding corporation” as defined in Section 897 of the Code (the “FIRPTA Certificate”);
a non-compete and restrictive covenant agreement, duly executed by the Company and Cory Sago, in a form attached as Exhibit C;

(c) a consulting agreement, duly executed by Buyer and James Dahlman, in a form attached as Exhibit D; and

(d) the Escrow Agreement, duly executed by the Shareholders’ Representative.

Section 3.2. **Buyer Deliverables.** At the Closing, Buyer shall deliver to the Company the following:

(a) the Escrow Agreement, duly executed by Buyer.

**ARTICLE 4**

**REPRESENTATIONS AND WARRANTIES OF THE COMPANY**

The Company represents and warrants to Buyer that, except as disclosed by the Company in the Disclosure Schedule delivered on the date hereof, the following statements are true and correct as of the date hereof, provided, that any exception set forth in a section or subsection of the Disclosure Schedule shall be deemed to be disclosed solely for purposes of, and shall solely qualify, such section or subsection of this Agreement and any other section or subsection of this Agreement where it is readily apparent on the face of such exception that such exception would be applicable to such other section or subsection:

**Section 4.1. Organization and Standing; No Subsidiaries.**

(a) The Company (i) is a corporation duly organized, validly existing and in good standing under the Laws of the jurisdiction of its incorporation; (ii) has all requisite corporate power and authority and possesses all material Permits necessary to enable it to use its corporate or other name and to own or lease or otherwise hold and operate its assets and properties and to carry on the Business; and (iii) is duly qualified, licensed or registered to do business and is in good standing in each jurisdiction in which the nature of its business or the ownership, leasing or operation of its properties makes such qualification, licensing or registration necessary, which jurisdictions are listed in Section 4.1(a) of the Disclosure Schedule. The Company has made available in the Data Room to Buyer and its Representatives true, complete and correct copies of its Constitutive Documents, as amended. The Company has made available in the Data Room to Buyer and its Representatives copies of the transfer books and the minute books of the Company, each of which is true and complete and has been maintained in accordance with applicable Law and sound and prudent business practices. The Company has never issued any stock certificates representing shares of Company Capital Stock.

(b) The Company has no, and has never had any, Subsidiaries.

(c) Power and Authority; Binding Agreement. Subject to obtaining Shareholder Approval, the Company has all requisite corporate power and authority to execute and deliver this Agreement and to consummate the Merger and the other transactions contemplated hereby and to perform its obligations hereunder. The execution and delivery by the Company of
this Agreement and the consummation by the Company of the Merger and the other transactions contemplated hereby have been duly authorized by all necessary corporate action on the part of the Company, and no other proceedings on the part of the Company are necessary to authorize this Agreement or to consummate the Merger and the other transactions contemplated hereby other than the (a) the Shareholder Approval and (b) the filing of the Certificate of Merger and Subsequent Merger Certificate of Merger with the offices of the Secretary of State of the State of Delaware. This Agreement has been duly executed and delivered by the Company and, assuming due authorization, execution and delivery by the other Parties, constitutes a valid, legal and binding obligation of the Company, enforceable against the Company in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, fraudulent transfer, moratorium or similar Laws affecting creditors’ rights generally and general principles of equity (regardless of whether enforcement is sought in a proceeding at law or in equity).

Section 4.2. Authorization.

(a) The board of directors of the Company, at a meeting duly called and held at which all directors of the Company were present or pursuant to an action by written consent, duly and unanimously adopted resolutions: (i) approving and declaring advisable the Merger, this Agreement and the other transactions contemplated hereby; (ii) determining that the Merger Consideration is fair to the Company Holders and declaring that the Merger, this Agreement and the other transactions contemplated hereby are in the best interests of the Company Holders; (iii) adopting this Agreement; (iv) authorizing the Company to enter into this Agreement and to consummate the Merger and the other transactions contemplated hereby, on the terms and subject to the conditions set forth in this Agreement; (v) directing that the Merger and this Agreement be submitted to the Company Holders at a meeting or by written consent in lieu of a meeting for a vote for adopting this Agreement and approving the Merger; and (vi) recommending that the Company Holders vote to approve and adopt this Agreement and approve the Merger.

(b) The only vote or consent of holders of any class or series of Company Capital Stock necessary to adopt this Agreement and approve the principal terms of the Merger under the DGCL and the Company’s Constitutive Documents, each as in effect at the time of such adoption and approval, is the affirmative vote or written consent of (i) at least a majority of the outstanding Preferred Stock and (ii) at least a majority of the Outstanding Shares (the “Shareholder Approval”).

Section 4.3. Capitalization.

(a) Section 4.3(a) of the Disclosure Schedule sets forth the number of (i) authorized and (ii) issued and outstanding shares of each of the Common Stock and the Preferred Stock. The rights, preferences, privileges and restrictions of the Preferred Stock are as stated in the Charter.

(b) Section 4.3(b) of the Disclosure Schedule sets forth a true, complete and accurate list of (i) the name, email address and address of record of all holders of Company Capital Stock, showing the number of shares of such Capital Stock, and the class or series of such shares, held by each such Company Holder and (ii) the name, email address and address of each Company Optionholder and holder of Restricted Company Common Stock, showing, as applicable, the
number of Company Options held by each such Company Holder and the number of shares of Company Common Stock subject thereto or the number of shares of Restricted Company Common Stock held by such Company Holder, the grant or issuance date, the exercise price, the vesting schedule and the extent to which such Company Option or Restricted Company Common Stock is vested, status as an incentive stock option within the meaning of Section 422 of the Code and the expiration date. All of the issued and outstanding shares of Company Capital Stock and Company Options have been offered, issued and sold by the Company in compliance with all applicable federal and state securities Laws. Each share of Restricted Company Common Stock is subject to a valid election under Section 83(b) of the Code. The Company has made available to Buyer complete and accurate copies of the Company Stock Plan and all Contracts evidencing Company Stock Options and Restricted Company Common Stock awards. The only plan, program or arrangement under which the Company has granted options to purchase Company Common Stock is the Company Stock Plan. Each Company Stock Option and shares of Restricted Company Common Stock was granted in compliance with all applicable Laws and all terms and conditions of the Company Stock Plan and each Company Stock Option has an exercise price per share of Company Common Stock equal to or greater than the fair market value of a share of Company Common Stock, as determined by the board of directors in accordance with Section 409A of the Code, on the date of such grant.

(c) Except as set forth in Section 4.3(b) of the Disclosure Schedule, there are no outstanding options, restricted stock, restricted stock units, profits interests, equity appreciation rights, phantom equity interests, warrants, rights or other convertible securities (including conversion rights, preemptive rights, co-sale rights, rights of first refusal or other similar rights) or agreements for the purchase or acquisition from the Company of any shares of Company Capital Stock.

(d) All of the outstanding shares of Company Capital Stock have been duly authorized and validly issued, and are fully paid and nonassessable. All of the shares of Company Capital Stock underlying Company Options have been duly authorized and when issued pursuant to exercise of the Company Option will be validly issued, fully paid and nonassessable.

(e) None of the shares of Company Capital Stock or Company Options have been issued in violation of any subscription, option, call, commitment, right of first refusal, preemptive right, conversion right, option, convertible security or other similar right, or any Contract to which the Company is subject, bound or a party. None of the shares of Company Capital Stock are subject to any subscription, warrant, option, call, commitment, right of first refusal, preemptive right, conversion right or other similar right under any Law, the Constitutive Documents of the Company, or any Contract to which the Company is subject, bound or a party thereto. The Company has no obligation (contingent or otherwise) to issue, grant or otherwise sell any subscription, warrant, option, call, commitment, right of first refusal, preemptive right, convertible security, “phantom” stock right or other such right, or to issue, distribute or otherwise sell to holders of any shares of its Capital Stock any evidences of Indebtedness or assets of the Company. The Company has no obligation (contingent or otherwise) to purchase, redeem or otherwise acquire any shares of Capital Stock, or other equity or voting interest in, the Company or any other Person or to pay any dividend or to make any other distribution in respect of its Capital Stock. The Company has no obligation (contingent or otherwise) to vote to dispose of any shares of its Capital Stock or other equity or voting interest. There are no outstanding or authorized stock
appreciation rights, phantom stock awards or other rights that are linked in any way to the price of the Common Stock or the value of the Company or any part thereof. There are no equity securities of the Company reserved for issuance for any purpose, except Common Stock issuable upon conversion of outstanding Preferred Stock.

(f) There is no Contract between the Company and any holder of its securities, or, to the Knowledge of the Company, among any holders of its securities, relating to the sale or transfer (including agreements relating to rights of first refusal, co-sale rights or “drag-along” rights), registration under the Securities Act, or voting, of any Company Capital Stock.

(g) The Company does not directly or indirectly own any equity or similar interest in, or any interest convertible into or exchangeable or exercisable for any equity or similar interest in, any Person. There is no Indebtedness that provides its holder with the right to vote on any matters on which Company Holders may vote.

(h) As of the Closing Date, the information in Annex I, Annex II, Annex III and Annex IV provided in accordance with Section 2.3(a) is true, correct and complete.

Section 4.4. Noncontravention.

(a) The execution and delivery by the Company of this Agreement, the consummation of the Merger and the other transactions contemplated hereunder and the compliance by the Company with the provisions of this Agreement, do not and will not conflict with, or result in any violation or breach of, or default (with or without notice or lapse of time or both) under, or give rise to a right of, or result in, termination, cancellation or acceleration of any obligation or to a loss of a material benefit under, or result in the creation of any Lien in or upon any of the properties or assets of the Company under, or give rise to any payment under or any increased, additional, accelerated or guaranteed rights or entitlements under, or require any action by or notice to any Person under, any provision of (i) the Constitutive Documents of the Company, (ii) any Contract to which the Company is a party or bound by or by which its assets or properties are bound or under which the Company has rights or benefits, except where such violation, breach, conflict, default, termination, cancellation, acceleration, loss of material benefit, creation of a Lien, payment, or increased, additional accelerated or guaranteed right or entitlement, or action or notice would not impair in any material respect the ability of the Company to perform its obligations under this Agreement or prevent or materially impede or delay the consummation of the Merger or any of the other transactions contemplated under this Agreement, or (iii) any Law or Judgment applicable to the Company or its assets or properties.

(b) No consent, approval, qualification, order or authorization of, registration, declaration or filing with, or notice to, any Governmental Entity is necessary or required by or with respect to the Company in connection with the execution and delivery by the Company of this Agreement, the consummation by the Company of the Merger and the other transactions contemplated by this Agreement or the compliance by the Company with the provisions of this Agreement, except for (i) the filing of the Certificate of Merger and Subsequent Merger Certificate of Merger with the office of the Secretary of State of the State of Delaware and appropriate documents with the relevant authorities of other states in which the Company is qualified to do business, and (ii) such other consents, approvals, orders, authorizations, registrations, declarations,
Section 4.5. Compliance with Laws; Regulatory Matters.

(a) The Company is not and has not been in breach or in violation of, or default under, its Constitutive Documents. The Company is and has been in material compliance with all applicable Laws and Judgments of any Governmental Entity applicable to it or to the conduct by the Company of its business, or the ownership or use of any of its assets and properties, including the Leased Properties. The Company has not received any written, or to the Knowledge of the Company oral, notice or other communication alleging a possible material violation by the Company of any applicable Law or Judgment of any Governmental Entity applicable to its businesses or operations. The Company is not, and has not been, subject to a deferred prosecution agreement, non-prosecution agreement, corporate integrity agreement, consent decree, monitoring agreement, settlement agreement or similar agreement or order mandating or prohibiting future or post activities.

(b) Regulatory Authorizations. To the extent required for the lawful operation of the Company’s business, the Company is and has at all times been in possession of, and in compliance with all approvals, clearances, licenses and Permits reasonably necessary for the Company to engage in the testing, development, processing, marketing, distribution and provision of the Company Products, including any FDA clearance and any other international equivalent thereof (the “Regulatory Authorizations”), a true, complete and correct list of which for the Business as of the date that this representation is made is set forth in Section 4.5(b) of the Disclosure Schedule. To the extent required, each such Regulatory Authorization is valid and in full force and effect and the Company is in material compliance with the terms of such Regulatory Authorizations. The Company has not received any written notice of, and there has not occurred, and, to the Knowledge of the Company, there is no pending or threatened, suspension, cancellation, modification, termination, revocation, or nonrenewal of any required Regulatory Authorization.

(c) Actions and Investigations. The Company has not received or been subject to (i) any written, or to the Knowledge of the Company oral, notice, warning, administrative proceeding order, complaint, or other written communication of any actual or threatened enforcement Action or investigation or allegation that the Company has violated any applicable Law by the FDA, HHS, EMA, FTC or other Regulatory Authority, including any FDA Form 483, warning letter or untitled letter, and, to the Knowledge of the Company, neither the FDA, HHS, EMA, FTC, nor any other Regulatory Authority either in or outside the United States, is considering such Action, investigation or allegation, and (ii) any written, or to the Knowledge of the Company oral, notice, correspondence, or communication from any health care professional, customer, competitor, or current or former officer, director, employee or contractor of the Company alleging or asserting noncompliance with Laws. To the Company’s Knowledge, no Person has filed or has threatened to file against the Company any Action under any federal or state whistleblower statute or equivalent law in the applicable jurisdiction, including under the federal False Claims Act, 21 U.S.C. §§ 3729-3733.
(d) **Regulatory Materials.** Neither the Company nor any Person on behalf of the Company has ever submitted any Regulatory Materials to any Regulatory Authority. The Company has not received notice from any Regulatory Authority indicating or suggesting that any Company Product may not be commercialized in a jurisdiction.

(e) **Records and Reports.** All reports, documents, forms, claims, applications for Regulatory Authorizations, records submissions, supplements, amendments, and notices, including all design history files and technical files concerning the Company Products, required to be filed with, maintained for or furnished to any other Regulatory Authority with respect to the Company Products by the Company or any Person that manufactures, develops, packages, processes, labels, markets, tests or distributes Company Products pursuant to a development, distribution, commercialization, manufacturing, supply, testing or other arrangement with the Company (each, a “Company Partner”) have been so filed, maintained or furnished by the Company and the Company Partners, as applicable. All such reports, documents, forms, claims, applications for Regulatory Authorizations, records submissions, supplements, amendments, and notices were complete, true and accurate in all material respects on the date filed or furnished (or were corrected in or supplemented by a subsequent filing) and remain complete, true and accurate in all material respects as required by applicable Law. Neither the Company nor, to the Knowledge of the Company, any officer, director, employee or agent of the Company has made any material false statement or material omission in any report, document, form, claim, application for Regulatory Authorization, application, records submission, supplement, amendment, or notice relating to the Company Products to or any Regulatory Authority.

Section 4.6. **Permits.** The Company validly holds and has in full force and effect all material Permits necessary for it to own, lease or operate its assets and properties and to carry on the Business, and there has occurred no material violation of, or material default (with or without notice or lapse of time or both) under, or, to the Knowledge of the Company, event giving to any Governmental Entity any right of termination, amendment or cancellation of, any such Permit. The Company has complied in all material respects with the terms and conditions of all Permits issued to or held by the Company, and such Permits will not be subject to suspension, modification, revocation or nonrenewal as a result of the execution and delivery of this Agreement or the consummation of the Merger or the other transactions contemplated hereunder. No Action is pending or, to the Knowledge of the Company, threatened seeking the revocation or limitation of any Permit. Section 4.6 of the Disclosure Schedule lists each Permit issued or granted to or held by the Company, true and complete copies of which have been made available in the Data Room to Buyer and its Representatives. All of the Permits listed on Section 4.6 of the Disclosure Schedule are held in the name of the Company, and none are held in the name of any Company Personnel or agent or otherwise on behalf of the Company.

Section 4.7. **Financial Matters.** Section 4.7 of the Disclosure Schedule sets forth (i) the unaudited balance sheet of the Company as of December 31, 2020 (such date, the “Most Recent Balance Sheet Date” and such financials the “Most Recent Balance Sheet”) and (ii) the unaudited statement of profit and loss of the Company for the twelve-month period ended on December 31, 2020 (together with the Most Recent Balance Sheet, the “Financial Statements”). The Financial Statements have been prepared from the books and records of the Company and are consistent with the books and records of the Company and fairly present, in all material respects, the financial condition and results of operations of the Company as of the dates indicated, and have
been prepared in accordance with GAAP, with the exception that the Company’s unaudited financial statements remain subject to changes resulting from normal year-end adjustments and lack footnotes.

Section 4.8. Absence of Changes or Events. Since January 1, 2020, (a) the Company has not conducted any business operations outside the Ordinary Course of Business, (b) there has occurred no Material Adverse Effect, nor any change, circumstance, development, state of facts, event or effect that would reasonably be expected to result in a Material Adverse Effect, and (c) the Company has not taken any of the following actions:

(a) declared, set aside or paid any dividends on, or made any other distribution (whether in cash, stock or property) in respect of, any Company Capital Stock to holders of Company Capital Stock from time to time outstanding;

(b) with respect to Intellectual Property, other than as necessary or in the Ordinary Course of Business, (A) sold, assigned, licensed, sublicensed, encumbered, impaired, abandoned, transferred or otherwise disposed of any Intellectual Property, (B) failed to use commercially reasonable efforts to file and prosecute any pending Patent Right applications or (C) disclosed or otherwise made available or accessible any material confidential Know-How to any Person who is not subject to a written agreement to maintain the confidentiality of such Know-How;

(c) (A) materially increased the amount of any compensation payable or paid, whether conditionally or otherwise, to any Company Personnel, (B) entered into any employment, severance, retention or any other similar agreement with any Company Personnel, (C) terminated, established, adopted, entered into or amended any Company Benefit Plan, (D) granted any Company Stock Options or Restricted Company Common Stock or (E) materially increased the benefits under any Company Benefit Plan;

(d) sold, licensed, mortgaged, transferred, encumbered, subjected to any Lien other than a Permitted Lien, or otherwise disposed of (A) any properties or assets, including the Leased Properties, which are material, individually or in the aggregate, to the Company (excluding any sale of furniture, fixtures or equipment that does not materially impact the conduct of the Company’s business) or (B) in any case, any Company Intellectual Property (or otherwise abandon, cancel or allow to lapse any Company Intellectual Property); or

(e) (A) created, incurred or assumed any Indebtedness, or issued or sold, or amended, modified or changed any term of, any debt securities or options, warrants, calls or other rights to acquire any debt securities of the Company, (B) guaranteed or endorsed any Indebtedness of another Person, (C) made any loans, advances or capital contributions to, or investments in, any Person other than the Company, or (D) entered into any Contract having the economic effect of any of the foregoing subsections (A) through (C).

Section 4.9. Undisclosed Liabilities. The Company does not have any Indebtedness or other Liabilities, except for such Liabilities (a) set forth on the face of the Most Recent Balance Sheet or the Estimated Closing Balance Sheet or that are Seller Transaction Expenses, and (b) Liabilities which have arisen since the date of the Balance Sheet in the ordinary
course of business and which are, in nature and amount, consistent with those incurred historically and are not material to the Company.

Section 4.10. **Assets.** The Company is the true and lawful owner and has good and valid title to all assets reflected on the Most Recent Balance Sheet or thereafter acquired (whether real or personal and whether tangible or intangible), except those sold or otherwise disposed of for fair value or consumed in the Ordinary Course of Business since January 1, 2020 and not in violation of this Agreement, in each case, free and clear of all Liens, other than Permitted Liens.

Section 4.11. **Real Property.**

(a) The Company does not own fee title to real property.

(b) Section 4.11(b) of the Disclosure Schedule lists all real property leased by the Company (each, a “Leased Property”), including the address of the property and the name and address of the landlord. The Company has made available to Buyer and its Representatives in the Data Room true, complete and accurate copies of all leases, subleases, lease guarantees, subordinations, non-disturbance, and attornment agreements with respect to each Leased Property. With respect to the Leased Property, (i) the Company has good and valid title to the leasehold estate relating thereto arising under the applicable lease, free and clear of all options, rights of first refusal, Liens, easements, rights of way, restrictions on use, encroachments, licenses to third parties, leases to third parties or irregularities in title thereto, including any Liens or conditions imposed by any Environmental Laws (other than Permitted Liens), (ii) the lease relating to such Leased Property is in writing and is valid and binding, in full force and effect and enforceable against the Company and, to the Knowledge of the Company, the other parties thereto, in accordance with its terms, (iii) the lease relating to such Leased Property will, immediately following the Effective Time, continue to be legal, valid, binding, in full force and effect and enforceable against the Company and, to the Knowledge of the Company, the other parties thereto, in accordance with its terms as in effect on the date hereof, (iv) neither the Company nor, to the Knowledge of the Company, any other party to the lease relating to such Leased Property is in material breach or violation of, or material default under, such lease in any material respect, (v) no event, occurrence, condition or act has occurred, is pending or, to the Knowledge of the Company, is threatened, which, with the giving of notice or the lapse of time would constitute a material breach or material default by the Company or, to the Knowledge of the Company, any other party to such lease, under such lease, or give rise to a right of termination, cancellation or to loss of a material benefit under, or to increased, additional, accelerated or guaranteed rights or entitlements of any Person under any such leases, (vi) there are no disputes, oral agreements or forbearance programs in effect between the Company and the lessor as to the lease relating to such Leased Property, (vii) all rents and additional rents due and payable on the lease relating to such Leased Property have been paid, (viii) all facilities included in such Leased Property are supplied with utilities and other services adequate for the operation of such facilities in their current use, (ix) there is no Lien, easement, covenant or other restriction applicable to such Leased Property which would reasonably be expected to materially impair the current uses or the occupancy by the Company of such Leased Property, (x) the current use by the Company of the facilities located on such Leased Property does not violate any local zoning or similar land use requirement, including any Environmental Law or other Law in any material respect and (xi) all of the buildings, structures
and appurtenances situated on the Leased Property are in good operating condition and in a state of good maintenance and repair (ordinary wear and tear excepted), are adequate and suitable for the purposes for which they are presently being used and all necessary Permits for the occupancy and use of such Leased Property have been obtained and are in full force and effect and, with respect to each, the Company has adequate rights of ingress and egress for operation of the Company’s business and operations.

Section 4.12. Contracts.

(a) Section 4.12(a) of the Disclosure Schedule lists all of the following Contracts that are in effect and to which the Company is a party or to which it, or any of its assets and properties, is bound (each such Contract, excluding any Company Benefit Plan, a “Material Contract”):

(i) employment, independent contractor, consulting or services Contracts, in each case with Company Personnel requiring or otherwise involving payments by or to the company of more than an aggregate of $50,000 in the previous or upcoming fiscal year;

(ii) collective bargaining agreements or other Contracts with any labor union or other employee representative body (each such Contract, a “Union Contract”);

(iii) Contracts containing any restriction on the Company’s solicitation, hiring or engagement of any Person;

(iv) any Contracts with or involving (A) any current or former holder of Company Capital Stock or its Affiliate (other than the Company); (B) any Affiliate of the Company; (C) any Company Personnel or their Affiliate (other than the Company) thereof; (D) any family member of any current or former holder of Company Capital Stock or its Affiliate; or (E) any family member of any Company Personnel.

(v) Contracts under which the Company or the Surviving LLC is, or may become, obligated to incur payment that would become payable by reason of this Agreement or the transactions contemplated hereby;

(vi) Contracts that (A) grant any exclusive rights (including exclusive rights in Company Intellectual Property) to any Person, (B) limit the freedom of the Company to compete with any Person or engage in any line of business or geographic area, (C) restrict the research, development, manufacture, marketing, distribution, sale, supply, license or marketing of the products and services of the Company or that the Company or any Affiliate currently plans to develop or (D) limit the freedom of the Company to use any Company Intellectual Property after the Closing Date;

(vii) Contracts (or substantially related Contracts) for the purchase or sale of products or the furnishing or receipt of services (A) requiring or otherwise involving payment by or to the Company of more than an aggregate of $50,000 in a twelve (12) month period, (B) in which the Company has granted manufacturing rights, (C) in which the Company has granted “most favored nation” pricing provisions relating to any products

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or territory or (D) in which the Company has agreed to purchase a minimum quantity of goods or services with a value greater than $50,000 or has agreed to purchase certain goods or services exclusively from a certain party;

(viii) Contracts relating to capital expenditures or other purchases of materials, supplies, equipment or other assets or properties (other than purchase orders for inventory or supplies entered in the Ordinary Course of Business) (A) in excess of $50,000 in a twelve (12) month period; or (B) that include minimum purchase requirements;

(ix) any option, warrant, purchase right, or other Contract (other than this Agreement) that could require the Company to sell, transfer, or otherwise dispose of any assets of the Company other than the sale of the Company Products to customers in the Ordinary Course of Business;

(x) Contracts (or letters of intent) involving the disposition or acquisition of any product line, business or significant portion of the assets, properties or business of the Company, or any merger, consolidation or similar business combination transaction, whether or not enforceable;

(xi) Contracts for any limited liability company, joint venture, partnership, joint product development, strategic alliance or co-marketing arrangement;

(xii) Contracts for the purchase or sale of any Company Intellectual Property or pursuant to which the Company has acquired ownership of material Intellectual Property owned by any other Person;

(xiii) Contracts (A) granting to a third party any rights, title, interests, license or sublicense to any Company Intellectual Property, or (B) pursuant to which the Company uses or licenses any third party Intellectual Property or has been granted by a third party any rights, title, interests, license or sublicense to any Intellectual Property or owes any royalties or other payments to any Person for the use of any Intellectual Property, or (C) any other license, sublicense, option or other Contract relating in whole or in part to the Company Intellectual Property, or the Company’s rights to use the Company Intellectual Property, or the Intellectual Property of any other Person (including any other interest, title or right, including covenants not to sue, use or enforce), except, in each case, for Off-the-Shelf Software Licenses;

(xiv) Contracts providing that the Company or any Company Personnel maintain the confidentiality of any information, or providing for any Person to maintain the confidentiality of any Know-How or other information material to the Company, other than mutual confidentiality provisions entered into in the Ordinary Course of Business;

(xv) any Contracts containing any covenant not to sue, concurrent use agreement, settlement agreement, pre-rights declarations, co-existence agreement or other consent with respect to the Company Intellectual Property or Contracts under which the Company has agreed to or has an obligation to indemnify any Person for or against any interference, infringement, dilution, misappropriation or other violation with respect to any Intellectual Property;
(xvi) Contracts (other than trade debt incurred in the Ordinary Course of Business) under which the Company has borrowed (or may borrow) any money from, or issued (or may issue) any note, bond, debenture or other evidence of Indebtedness to, any Person;

(xvii) Contracts granting a Lien (other than Permitted Liens) upon any property or asset (including Intellectual Property) of the Company;

(xviii) Contracts involving any resolution or settlement of any Action;

(xix) Contracts under which the consequences of a default or termination could reasonably be expected to result in a Material Adverse Effect;

(xx) Contracts relating to the Leased Properties; and

(xxi) Any other Contracts involving future payments by or to the Company in excess of $50,000 in a twelve (12) month period.

(b) Each Material Contract is in full force and effect, and is valid and binding and enforceable in accordance with its terms against the Company and, to the Knowledge of the Company, the other parties thereto, subject to applicable bankruptcy, insolvency, reorganization, fraudulent transfer, moratorium or similar Laws affecting creditors’ rights generally and general principles of equity, and has been negotiated in good faith on an “arms length” transaction basis. A true, correct and complete copy of each written Material Contract has been made available in the Data Room to Buyer and its Representatives. There is no material violation, breach (including anticipatory breach) or default under any Material Contract by the Company or, to the Knowledge of the Company, by any other party thereto, and no event has occurred or condition exists that with the lapse of time or the giving of notice or both would constitute a material default thereunder by the Company or, to the Knowledge of the Company, any other party thereto, and the Company has not received or given notice of any default or claimed or purported or alleged default or state of facts which, with notice or lapse of time or both, would constitute a material default on the part of any party in the performance or payment of any Material Contract. No notice, waiver, consent or approval is required (or the lack of which would give rise to a right of termination, cancellation or acceleration of, or entitle any party to accelerate, whether after the giving of notice or lapse of time or both, any obligation under the Material Contracts) under or relating to any Material Contract in connection with the execution, delivery and performance of this Agreement or the consummation of the Merger or any of the other transactions contemplated hereby. Immediately following the Effective Time, each Material Contract will continue to be in full force and effect, and valid, binding and enforceable in accordance with its terms.


(a) Section 4.13(a) of the Disclosure Schedule sets forth a true and complete list of all Patent Right, Marks, Copyrights and domain names and all other Company Intellectual Property that is the subject of: (A) an application, certificate, filing, draft filing, registration or other document issued, filed with or recorded with any Governmental Entity or (B) a registration or filing with a private registrar, such as a domain name registrar (collectively, “Company Registered IP”). For purposes of this Agreement, all items listed on Section 4.13(a) of the
Disclosure Schedule shall be called “Scheduled Intellectual Property.” Section 4.13(a) of the Disclosure Schedule specifically identifies those items of Scheduled Intellectual Property that are exclusively licensed to the Company, including the identification of the Contract pursuant to which each such Intellectual Property right is licensed. For each applicable item of Company Registered IP, Section 4.13(a) of the Disclosure Schedule includes the following information: the relevant registration or application, number, the owner of record, the country or jurisdiction and the filing date or registration date. To the Knowledge of the Company, all Company Registered IP is valid, subsisting and enforceable. The Company is the sole owner of each item of Company Registered IP except the Company Registered IP exclusively licensed to the Company identified as exclusively licensed to the Company in Section 4.13(a) of the Disclosure Schedule.

(b) The Company has not taken any action, or failed to take any action, that could reasonably be expected to result in the forfeiture, relinquishment, invalidation or unenforceability of any Company Intellectual Property. All Company Registered IP has been duly registered, and/or filed with, or duly issued by each appropriate Governmental Entity, all necessary affidavits of continuing use with respect to the Company Registered IP have been timely filed, all fees necessary to maintain the Company Registered IP have been timely paid to continue all such rights in effect and, with respect to any applications for Company Registered IP, has diligently pursued such applications (including by timely filing fees and responses). The Company Registered IP is currently in compliance with all Legal Requirements necessary to record and perfect the Company’s interest in, and the chain of title of, the Company Registered IP. As of the date of this Agreement, there are no filings, payments or other actions that must be made or taken on or before the three (3)-month anniversary of the Closing Date for the purposes of obtaining, maintaining, perfecting, preserving or renewing any Company Registered IP, including the payment of any registration, maintenance or renewal fees or the filing of any responses to office actions or documents, for the purposes of obtaining, maintaining, preserving or renewing any Company Registered IP.

(c) The Company owns and possesses all worldwide rights, title and interests in and to each item of Company Intellectual Property, free and clear of any Lien other than Permitted Liens or licenses granted to third parties identified in Section 4.12(a)(xiii) of the Disclosure Schedule. The Company is the sole owner of all Company Registered IP except those IP exclusively licensed to the Company identified in Section 4.13(a) of the Disclosure Schedule, no Company Registered IP is subject to any outstanding order by a Governmental Entity, and no Action (including any opposition, cancellation, interference, inter partes review, post grant review, derivation proceedings or re-examination) is pending or threatened, that challenges the legality, patentability, validity and enforceability, use, scope, or ownership of any Company Registered IP. Each of the Patent Rights included in the Company Registered IP is owned or controlled by the Company or any of its Affiliates. All other Company Registered IP, properly identifies each and every inventor of the claims thereof as determined in accordance with the Laws of the jurisdiction in which such Patent Right is issued or pending.

(d) The Company owns or has adequate rights to use all Materials and Intellectual Property used or proposed to be used in connection with the Business without any infringement (without relying on the safe harbor exemption under 35 U.S.C. 271(e)), misappropriation or violation of the Intellectual Property of others.
(e) The Company has taken all commercially reasonable steps necessary to protect its rights, including perfecting its ownership in the Company Intellectual Property and maintain the confidentiality, secrecy and value of all confidential Know-How of the Company. To the Company’s Knowledge, neither the Company nor any of its Affiliates has disclosed or otherwise made available or accessible any of its Know-How intended to be maintained as confidential to any Person who is not subject to a written agreement to maintain the confidentiality of such Know-How and there has not been any disclosure of or access to any Know-How of the Company or its Affiliates (including any such information of any other Person disclosed in confidence to the Company or any of its Affiliates) to any Person in a manner that has resulted or is likely to result in the loss of trade secret or other rights in and to such information.

(f) Except pursuant to Off-the-Shelf Software Licenses, the Company does not pay or receive any royalty or other payment or compensation to or from anyone with respect to any Company Intellectual Property, nor has the Company licensed to any Person any Company Intellectual Property.

(g) The Company is not subject to any Judgment with respect to, nor has it entered into or is it a party to any Contract that restricts or impairs the use of, any Company Intellectual Property.

(h) As of the date of this Agreement, (i) the Company, the Company Products and the conduct of the Business has not and do not interfere with, infringe (without relying on the safe harbor exemption under 35 U.S.C. 271(e)), misappropriate, dilute, violate or constitute the unauthorized use of, any Intellectual Property of any third party or constitute unfair competition or trade practices under the Laws of any jurisdiction in which the Business operates. The commercial manufacture, use or sale of the Company Products do not infringe, misappropriate or violate the Intellectual Property of others. The Company has not received or made any notice, charge, complaint, demand, or claim (including an invitation to take a license or request or demand to refrain from using any Intellectual Property of any Person in connection with the conduct of the Business, the use of Materials or the manufacture and sales of Company Products) asserting or alleging, that any interference, infringement, misappropriation, derivation, violation or unauthorized use of the Intellectual Property of any Person is or may be occurring or has or may have occurred, nor are there any facts that would support a reasonable claim in that regard. To the Knowledge of the Company, no Person has interfered with, misappropriated, infringed, derived, diluted or violated, is interfering with, misappropriating, infringing, deriving, diluting or violating any Company Intellectual Property. No third party has made any disclosure of any trade secrets or proprietary or protected data or information included in the Company Intellectual Property that has had, or would be reasonably expected to have, a Material Adverse Effect. The Company has not sent any notice to any Person concerning any actual or potential infringement, misappropriation, derivation or unauthorized use of any Company Intellectual Property.

(i) The Company has not entered into any consent, indemnification, forbearance to sue, settlement agreement or similar Contract with respect to Intellectual Property, and no claims have been asserted in writing against the Company by any Person, and the Company has not received any notice or claim, that challenges the validity or enforceability of, or the Company’s ownership of or right to use, the Company Intellectual Property or alleging any misuse of the Company Intellectual Property.
Neither the Company nor any of its Affiliates has received any opinion of counsel that the conduct of the Business, or the use, practice or other exploitation of any Company Intellectual Property, has infringed, misappropriated or otherwise violated, or will infringe, misappropriate or otherwise violate, any Intellectual Property rights of any other Person.

To the Company’s Knowledge, all prior art and information known to the Company and its Affiliates and material to the patentability of the Patent Rights included in the Company Registered IP has been disclosed to Buyer in writing prior to the date hereof, and was disclosed to the relevant Governmental Entity during the prosecution of such Patent Rights in accordance with applicable Laws. Neither the Company nor any of its Affiliates nor, to the Company’s Knowledge, any other Person, has made any untrue statement of a material fact or fraudulent statement or omission to any applicable Governmental Entity regarding any pending or issued Patent claims included in the Company Intellectual Property owned or controlled by the Company or any of its Affiliates and to the Company’s Knowledge, any other Company Registered IP.

The Company (i) lawfully owns, licenses, or leases all software, hardware, firmware, computer systems, network connectivity, electronics, platforms, servers, interfaces, applications, websites, communication equipment, and other related information technology necessary for or used in the operations of its business, including any outsourced systems and processes that are owned or used by the Company (the “IT Systems”) and (ii) will continue to have such rights immediately after the Closing. Since the inception of the Company, there has been no failure or other material substandard performance of any IT Systems that has caused any material disruption to the Company’s business. The Company has taken commercially reasonable steps to provide for the back-up and recovery of data and information and commercially reasonable disaster recovery and business continuity plans, procedures and facilities and, as applicable, has taken commercially reasonable steps to implement such plans and procedures and tests such plans and procedures on a regular basis, and such plans and procedures have been proven effective in all material respects upon such testing.

All Company Personnel, and any personnel of a third party who have contributed to any Company Intellectual Property, have executed and delivered to the Company a valid, written confidentiality agreement, present assignment of all present and future rights in inventions or employment agreement with (i) customary confidentiality restrictions restricting such Person’s right to use or disclose the proprietary information or other Know-How of the Company only for the benefit of the Company and (ii) provisions assigning to the Company and waiving all moral rights in all such Person’s rights in any Intellectual Property developed, conceived, created or modified on behalf of, or during his or her employment or engagement (as applicable) with, the Company. To the Knowledge of the Company, no Company Personnel or personnel of a third party have any claim against the Company in connection with such Person’s involvement in the conception or development of any Intellectual Property, and no such claim has been asserted or threatened. To the Knowledge of the Company, none of the Company Personnel or personnel of a third party own any Intellectual Property in or to any composition of matter, process, method of use or invention of any kind now used or needed by the Company in the furtherance of its business operations or commercialization of any Company Product, which Intellectual Property has not been assigned to the Company, with such assignment, if applicable, duly filed for recordation in the United States Patent and Trademark Office (“PTO”), or the
applicable patent or trademark office, if outside the United States. To the Knowledge of the Company, at no time during the development, conception of or reduction to practice of any Company Intellectual Property, or during any employment or engagement of any Company Personnel with the Company, was any developer, inventor or other contributor to such Intellectual Property operating under any grants from any Governmental Entity or private source, performing research sponsored by any Governmental Entity or private source or subject to any employment agreement or invention assignment or nondisclosure agreement or other obligation with any third party or Governmental Entity, in each case that reasonably could be expected to impair or limit the Company’s rights in or to such Intellectual Property.

(n) The execution, delivery and performance by the Company of this Agreement, and the consummation of the transactions contemplated hereby, will not result in the breach, loss or impairment of, or give rise to any right of any third party to terminate or re-price or otherwise modify any of the Company’s rights or obligations relating to Intellectual Property under any Material Contract, nor entitle any Person to impose any restriction upon, obtain any rights to, or receive any compensation based on, the Company Intellectual Property, nor alter or impair the Company’s rights in or to any Company Intellectual Property, or IT Systems. The Company will continue to own or have after the Closing, valid rights or licenses as are sufficient to use all of the Company Intellectual Property and Materials to the same extent as prior to the Closing. The consummation of the transactions contemplated by this Agreement will not result in the loss or impairment of the Company’s rights in any Company Intellectual Property or Materials and will not result in the breach of, or create on behalf of any third party, the right to terminate or modify any agreement as to which the Company is a party and pursuant to which the Company is authorized or licensed to use any third party Intellectual Property, in either case that would, or might reasonably be expected to, have a Material Adverse Effect. All milestones, payment obligations and other conditions set forth in any Contracts under which any Intellectual Property is licensed to the Company that are required to be satisfied in order for the Company to retain any exclusive rights granted under such Contracts have been timely satisfied.


(a) The collection, storage, processing, use, access, transfer or transmission (including in each case across jurisdictional borders), disclosure, securing and otherwise handling (“Data Handling”) of Sensitive Data by the Company complies with all applicable Laws (including all federal and state privacy and data protection Laws), industry requirements, Contracts of the Company, policies of the Company and codes of conduct to which the Company is a party. The Company has taken steps, including implementing and monitoring compliance with policies, procedures and practices (including with respect to administrative safeguards and technical and physical security), to protect all Sensitive Data against loss or corruption and against unauthorized access, use, modification, disclosure or other misuse that (i) comply with all applicable Laws, industry requirements, Contracts of the Company, policies of the Company and codes of conduct to which the Company is a party, (ii) are consistent with industry standards and best practices, (iii) are consistently enforced and followed in the conduct of the business of the Company and (iv) are the subject of routine training administered by the Company to its officers, directors, employees, subcontractors, and agents. The Company has promptly investigated and documented any deviations from such policies, procedures and practices, and has taken corrective and mitigating actions to prevent the recurrence of any such deviations.
On each website and online service operated by the Company, the Company has posted a privacy policy or privacy statement, in conformance in all material respects with all applicable Data Privacy Requirements, with respect to the Data Handling of Sensitive Data by it or on its behalf. The Company’s written public-facing privacy policies fully and accurately disclose the Data Handling by the Company of Sensitive Data, and provide a point of contact responsible for Data Handling by the Company.

The Company has contractually obligated all third party service providers, outsourcers, processors, or other third parties which engage in the Data Handling of Sensitive Data, in each case on behalf of the Company to (i) comply with applicable Data Privacy Requirements, (ii) take reasonable steps to adequately protect and secure Sensitive Data from loss, theft, unauthorized access, use, modification, disclosure or other misuse, (iii) maintain a written information privacy and security program that establishes reasonable and appropriate measures to protect the privacy, operation, confidentiality, integrity and security of all Sensitive Data against any unauthorized acquisition of, access to, loss of, Data Handling, sale, rental or misuse (by any means) of Sensitive Data or other act or omission that compromises the security, integrity, or confidentiality of Sensitive Data and (iv) maintain a written public-facing privacy policy that fully and accurately discloses the Data Handling of the Company of Sensitive Data, and provides a point of contact responsible for responding to inquiries regarding the Data Handling practices.

No Sensitive Data subject to Data Handling by the Company has been lost, inappropriately accessed, misappropriated or misused or unlawfully disclosed. There have been no breaches of or lapses compromising or otherwise involving any Sensitive Data or in the security of any IT Systems or facilities of the Company or of any communications means or interface with the IT Systems. The Company is and at all times has been in compliance in all material respects with all Laws relating to notification obligations with respect to data loss, theft and breach. Neither the Company nor any Company Personnel has received any claim or notice from any Governmental Entity alleging or referencing the investigation of any breach, violation of the IT Systems or the improper use, disclosure of or access to any Sensitive Data (including protected health information, as defined under HIPAA) in its possession, custody or control. There has been no unlawful disclosure of electronic communications, including Sensitive Data, to any third party, including any Governmental Entity.

Section 4.15. Taxes.

(a) All Tax Returns with respect to the Company that are required to have been filed have been duly and timely filed with the appropriate Taxing Authority and such Tax Returns are and were true, correct and complete in all material respects. All Taxes owed by the Company (whether or not shown as due and payable on any Tax Returns) have been timely paid in full.

(b) All Taxes that the Company has been required to deduct, collect or withhold in connection with amounts paid or owing to any Company Personnel, creditor, stockholder or other Person, have been duly deducted, collected or withheld and have been duly and timely paid to the appropriate Taxing Authority, and in all material respects, the Company has complied with all associated or related reporting and record keeping requirements.
(c) No dispute, audit, investigation, proceeding, claim or other Action concerning any Liability for Taxes or Tax Returns of the Company is pending, being conducted or claimed, and no such dispute, audit, investigation, proceeding, claim or other Action has been raised or threatened in writing by a Taxing Authority or other Governmental Entity in writing. The Company has made available to Buyer and its Representatives in the Data Room true, correct and complete, in all material respects, copies of all Tax Returns, examination reports, and statements of deficiencies filed, assessed against, or agreed to by the Company since its formation.

(d) There are no Liens for Taxes (other than statutory Liens for current Taxes not yet due and payable) on the assets or properties of the Company.

(e) No written claim has ever been made by a Taxing Authority, in a jurisdiction where the Company does not file Tax Returns or does not pay Taxes, that the Company is (or may be) required to file Tax Returns in or be subject to Tax by that jurisdiction.

(f) No agreement or arrangement extending, or having the effect of extending, the period of assessment or collection of any Taxes payable by the Company is in effect and the Company is not the beneficiary of any extension of time within which to file any Tax Return other than extensions validly obtained in the Ordinary Course of Business. There is no power of attorney given by or binding upon the Company with respect to Taxes or Tax Returns currently in force. No closing agreements, private letter rulings, technical advice memoranda or similar agreements or rulings relating to Taxes have been entered into or issued by any Taxing Authority with or in respect of the Company.

(g) The Company has not, since the Most Recent Balance Sheet Date, made, changed or revoked any Tax election, elected or changed any method of accounting for Tax purposes, changed any Tax accounting period, amended any Tax Return, surrendered any material right to claim a refund of Taxes, settled or compromise any Action in respect of material Taxes, consented to any extension or waiver of the statutory period of limitations applicable to any Action in respect of Taxes, entered into any contractual obligation in respect of Taxes with any Taxing Authority or other party, filed any material Tax Return inconsistent with past practice, failed to pay material Taxes (including estimated Taxes) in the Ordinary Course of Business, or incurred material Taxes outside of the Ordinary Course of Business, in each case, that could materially increase the Taxes of the Company for any period ending after the Closing Date or materially decrease any Tax attribute of the Company existing on the Closing Date;

(h) The Company is not and has not been required to make any material adjustment pursuant to Section 481(a) of the Code (or any predecessor provision) or any similar provision of state, local or foreign Tax law by reason of any change in any accounting methods, and there is no application pending with any Taxing Authority requesting permission for any such changes in any of the Company’s accounting methods for Tax purposes. No Taxing Authority or Governmental Entity has proposed in writing any such material adjustment or change in accounting method.

(i) The unpaid Taxes of the Company (i) did not as of the Most Recent Balance Sheet Date exceed the liability for Taxes (excluding any reserve for deferred Taxes established to reflect timing differences between book and Tax income) set forth thereon, (ii) will not, as of the
Closing Date, exceed that reserve as adjusted for the passage of time through the Closing Date in accordance with the past custom and practice of the Company and (iii) will not materially exceed the amount of accrued but unpaid Taxes taken into account as an item of Indebtedness in calculating the Closing Payment, as finally determined pursuant to Section 2.15.

(j) The Company will not be required to include any material item of income or gain in, or exclude any material item of deduction or loss from, Taxable income for any Post-Closing Tax Period as a result of any (i) “closing agreement” as described in Section 7121 of the Code (or any corresponding or similar provision of state, local or foreign income Tax Law) executed on or prior to the Closing Date, (ii) installment sale or open transaction disposition made prior to the Closing, (iv) prepaid amount received or paid or deferred revenue prior to the Closing, or (v) deferred intercompany gain or excess loss account described in Treasury Regulations under Section 1502 of the Code (or any corresponding or similar provision of Law).

(k) The Company is not, and has not been, a “United States real property holding corporation” within the meaning of Section 897 of the Code.

(l) The Company is not, and has not been, a member of an affiliated group of corporations filing a consolidated federal income Tax Return. The Company has never had any Subsidiaries. The Company does not have Liability for the Taxes of any Person under Treasury Regulations Section 1.1502-6 (or comparable provision of domestic or foreign Tax Law), as a transferee or successor, by contract, or otherwise.

(m) The Company has not constituted a “distributing corporation” or a “controlled corporation” in a distribution qualifying or purported to qualify for Tax-free treatment (in whole or in part) under Section 355(a) or Section 361 of the Code or under analogous provisions of domestic or foreign Tax Law.

(n) The Company is not a party to, or otherwise bound by or subject to, any Tax sharing, allocation or indemnification or similar agreement, or arrangement, other than any Contract or arrangement entered into in the Ordinary Course of Business the purpose of which is not primarily related to Taxes.

(o) The Company is not a party to any joint venture, partnership or other arrangement or Contract which could be treated as a partnership for Tax purposes.

(p) The Company does not own any property of a character, the indirect transfer of which, pursuant to the transactions contemplated in this Agreement, would give rise to any material Transfer Taxes.

(q) The Company has not been a party to a transaction that is or is substantially similar to a “reportable transaction” as such term is defined in Treasury Regulations Section 1.6011-4(b) or any “tax shelter” within the meaning of Section 6662 of the Code, or any other transaction requiring disclosure under analogous provisions of domestic or foreign Tax Law.

(r) The Company is, and has been since its formation, treated as a C corporation for U.S. federal income tax purposes.
The Company has not (i) made any election to defer any payroll Taxes under the CARES Act, (ii) taken, claimed, or applied for an employee retention tax credit under the CARES Act, or (iii) taken out any loan, received any loan assistance or received any other financial assistance, or requested any of the foregoing, in each case under the CARES Act, including pursuant to the Paycheck Protection Program or the Economic Injury Disaster Loan Program.

Section 4.16. Litigation. There is no Action that is pending or, to the Knowledge of the Company, threatened against the Company (or Company Holders or Company Personnel, to the extent such Actions relate to the Company) or any assets or properties of the Company. There are no Judgments outstanding against the Company (or any Company Holders or Company Personnel, to the extent such Judgments relate to the Company) or any assets or properties of the Company. There has not been any Action in respect of the Company that (a) resulted in a Judgment against or settlement by the Company (whether or not such Judgment or settlement was paid, in whole or in part, by an insurer of the Company or other third party), (b) resulted in any equitable relief or (c) relates to the Merger and the other transactions contemplated by this Agreement. There is no Action pending by the Company, or which the Company intends to initiate, against any other Person. To the Knowledge of the Company, there is no fact or circumstance that would reasonably be expected to serve as a basis for an Action that would be material to the Company.

Section 4.17. Insurance. Section 4.17 of the Disclosure Schedule contains a complete and accurate list of all policies of fire, liability, workers’ compensation, title and other forms of insurance owned, held by or otherwise applicable to the assets, properties or operations of the Company, and the Company has heretofore made available in the Data Room to Buyer and its Representatives a complete and accurate copy of all such policies, including all occurrence based policies applicable to the assets, properties or operations of the Company for all periods prior to the Closing Date. All such policies (or substitute policies with substantially similar terms and underwritten by insurance carriers with substantially similar or higher ratings) are valid and subsisting and in full force and effect in accordance with their terms in all material respects, all premiums with respect thereto covering all periods up to and including the Closing Date have been paid to the extent due and payable, and no notice of cancellation or termination (or any other threatened termination) has been received with respect to any such policy. Such policies are sufficient for material compliance by the Company with (i) all requirements of applicable Law and (ii) all Contracts to which the Company is a party, and the Company has complied in all material respects with the provisions of each such policy under which it is an insured party. The Company is not in default under any of such insurance policies, and, to the Company’s Knowledge, there exists no event, occurrence, condition or act which, with the giving of notice, the lapse of time or the happening of any other event or condition, would reasonably be likely to become a default thereunder. The Company has not been refused any insurance or suffered the cancellation of any insurance with respect to the assets, properties or operations of the Company by any insurance carrier to which it has applied for any such insurance or with which it has carried insurance during the last five (5) years. There are no pending or, to the Knowledge of the Company, threatened claims under any insurance policy of the Company.
Section 4.18.  Employees and Consultants.

(a) Each Company Personnel has executed a nondisclosure and assignment-of-rights agreement for the benefit of the Company vesting all rights in work product created by the individual during the individual’s employment or affiliation with the Company.

(b) The Company is not, and has not at any relevant period been, a government contractor.

(c) Section 4.18(c) of the Disclosure Schedule contains a complete and accurate listing of each individual who is an employee of the Company as of the Effective Time and with respect to each such individual: (i) such individual’s name, (ii) title or position (including whether full- or part-time), (iii) hire date, (iv) work location, (v) current annual base compensation rate, (vi) commission, bonus or other incentive-based compensation, (vii) classification for overtime pay purposes, (viii) leave status, (ix) visa status (if applicable), and (x) whether such individual is covered by a Union Contract.

(d) Section 4.18(d) of the Disclosure Schedule contains a complete and accurate listing of the name (if an entity, including the name of the individuals employed by or providing service on behalf of such entity) and contact information of each independent contractor, consultant, freelancer and other service provider (collectively, “Contractors”) used by the Company as of the date hereof. A copy of each Contract relating to the services each Contractor provides or has provided to the Company has been made available in the Data Room to Buyer and its Representatives prior to the date hereof. To the Knowledge of the Company, no Contractor used by the Company is a party to, or is otherwise bound by, any agreement or arrangement with any third party, including any confidentiality or non-competition agreement, that in any way adversely affects or restricts the performance of such Contractor’s duties for the Company. Each Contractor retained by the Company that developed or contributed Intellectual Property owned or purported to be owned by the Company has executed a nondisclosure and assignment-of-rights agreement for the benefit of the Company and the Company is the owner of all rights in and to all such Intellectual Property created by each Contractor in performing services for the Company. To the Knowledge of the Company, no current Contractor used by the Company intends to terminate his or her or its relationship with the Company.

(e) Except as set forth in Section 4.18(e) of the Disclosure Schedule, (i) the Company is not party to, or bound by, any Union Contract, and no Union Contract is being negotiated by the Company, (ii) no employee of the Company is represented by a union or other similar representative body, (iii) since January 1, 2018, no petition has been filed or proceedings instituted by or on behalf of an employee or group of employees of the Company with any labor relations board or other Governmental Entity seeking recognition of a bargaining representative, (iv) since January 1, 2018, no demand for recognition of any employees of the Company has been made by, or on behalf of, any union or other similar representative body, and (v) to the Company’s Knowledge, there is no effort currently being made or threatened by, or on behalf of, any union or other similar representative body to organize any employees of the Company or any of its Subsidiaries, and there have been no such efforts since January 1, 2018.
The Company is, and in the past three (3) years has been, in material compliance with all applicable Laws with respect to labor, employment, employment practices, terms and conditions of employment, wages and hours (including minimum wages and overtime pay), classification and compensation of employees and independent contractors, labor relations, employment discrimination, harassment and retaliation, plant closings and mass layoffs, immigration, workers’ compensation, labor relations, withholdings and deductions, workers’ compensation, occupational health and safety (including any guidance published by any Governmental Authority related to the COVID-19 pandemic), immigration, disability and unemployment insurance. The Company maintains, and has maintained for each of the past three (3) years, a valid Form I-9 for each of its employees.

The Company has not, in any relevant period, incurred any obligations or liabilities that remain unsatisfied under the federal Worker Adjustment and Retraining Notification Act or any similar state or local law.

To the Company’s Knowledge, no current executive or group of employees has given notice of termination of employment or otherwise disclosed plans to terminate employment with the Company within the twelve (12) month period following the date hereof. Since January 1, 2018, no director, manager, officer or executive of the Company has been the subject of any allegation of sex-based discrimination, sexual harassment or sexual misconduct.

There is not, and for the past three (3) years there has not been, any Action pending (or to the Company’s Knowledge, threatened) by or before any Governmental Entity against or affecting the Company concerning employment-related matters or brought by or on behalf any Company Personnel.

Section 4.19. **Company Benefit Plans**

(a) Section 4.19(a) of the Disclosure Schedule sets forth a correct and complete list of each Company Benefit Plan. For purposes of this Agreement, “Company Benefit Plan” means any employee benefit plan within the meaning of Section 3(3) of ERISA (whether or not subject to ERISA), or any stock bonus, stock purchase, stock ownership, equity or equity-based award, cash incentive or commission, employment, individual independent contractor, severance, termination, separation, deferred-compensation, change-in-control, retention, transaction, retirement, pension, profit sharing, health or welfare, employee loan, vacation or paid time off, fringe benefit, or other employee benefit plan, agreement, program, policy or arrangement, in each case, whether written or unwritten, that is sponsored, maintained, contributed (or required to be contributed) to by the Company or under which the Company has any Liability. With respect to each Company Benefit Plan, the Company has made available to Buyer complete and correct copies (to the extent applicable) of (i) the plan (or in the case of an unwritten Company Benefit Plan, a written description of the material terms thereof) and trust documents (with all amendments thereto), and any custodial agreements, insurance policies or contracts, and administrative and similar agreements, (ii) the most recent summary plan description and any amendments or summaries of material modifications with respect thereto, (iii) the most recent annual report on Form 5500 (with all schedules and attachments, including financial statements), (iv) the most recent IRS determination, advisory or opinion letter, and (v) all material notices, letters, filings, and material correspondence with all Governmental Entities in the past six (6) years.
(b) Each Company Benefit Plan and each related trust has been established, maintained, operated, administered and funded in all material respects in compliance with its terms, ERISA, the Code and all other applicable Laws. Each Company Benefit Plan intended to be qualified under Section 401(a) of the Code, and the trust (if any) forming a part thereof, has received (or is a prototype plan entitled to rely upon) a current, favorable determination or opinion letter from the IRS upon which it can rely and, to the Company’s Knowledge, there are no existing circumstances or events that would reasonably be expected to result in any revocation of, or a change to, such determination letter or result in material Liability to the Company. Other than routine claims for benefits, there are no pending or, to the Company’s Knowledge, threatened claims by or on behalf of any participant in any of the Company Benefit Plans, or otherwise involving any Company Benefit Plan or the assets of any Company Benefit Plan.

(c) Neither the Company nor any of its ERISA Affiliates maintains, sponsors or contributes (or is required to contribute) to, or has any Liability with respect to any Company Benefit Plan that is, a (i) multiemployer plan, as defined in Section 3(37) of ERISA, (ii) employee benefit plan that is subject to Title IV of ERISA, Section 302 of ERISA, or Section 412 of the Code, (iii) “multiple employer plan” (within the meaning of Section 413 of the Code) or (iv) “multiple employer welfare arrangement” (within the meaning of Section 3(40) of ERISA). No Company Benefit Plan provides health or welfare benefits following retirement or other termination of employment, other than as required under Section 4980B of the Code or as required under applicable Law at the sole expense of the participant.

(d) Neither the execution, delivery or performance of this Agreement by the Company nor the consummation of the transactions contemplated by this Agreement will not (alone or in combination with any other event) (i) result in an increase in the amount of compensation or benefits or the acceleration of the vesting or timing of payment of any compensation or benefits payable to or in respect of any Company Personnel, (ii) result in any increased or accelerated funding obligation with respect to any Company Benefit Plan, (iii) entitle any Company Personnel to severance pay, unemployment compensation, termination pay or any other payment, (iv) result in any limitation or restriction in respect of the right of Buyer or any of its Affiliates to, after the consummation of the transactions contemplated hereby, merge, amend or terminate any Company Benefit Plan, or (v) result in any forgiveness of indebtedness of any Person.

(e) Neither the Company nor any of its Affiliates has made any payments, or has been or is a party to any Contract that could result in it making payments, that have resulted or would result, separately or in the aggregate, in the payment of any “excess parachute payment” as defined in Section 280G(b)(1) of the Code or in the imposition of an excise Tax under Section 4999 of the Code (or any corresponding provisions of state, local or foreign Tax law). The Company does not have any obligation or commitment to “gross up” any Person with respect to Taxes under Section 280G, 4999 or 409A of the Code or otherwise.

Section 4.20. Environmental Matters. The Company is not subject to any pending material liability for the presence of, Release of, or arranging for the disposal of Hazardous Material on any property and no such liability could reasonably be expected to be incurred by the Company. The Company has not Released any Hazardous Material into the environment except (i) in compliance with Law or (ii) in an amount or concentration that would not reasonably be expected to give rise to any material liability or obligation to investigate or remediate such
Hazardous Material under any Environmental Law. To the Company's Knowledge, there have been no Hazardous Materials generated by the Company that have been disposed of or come to rest at any site that has been included in any published U.S. federal, state or local “superfund” site list or any other similar list of hazardous or toxic waste sites published by any Governmental Entity in the U.S. The Company has not received any written notice, demand, letter, claim or request for information from any Governmental Entity or other Person indicating that it may be in violation of, or subject to liability under, any Environmental Law or regarding any actual, alleged, possible or potential liability arising from or relating to the presence, generation, manufacture, production, transportation, importation, use, treatment, refinement, processing, handling, storage, discharge, release, emission or disposal of any Hazardous Material used by the Company. No Lien or “superlien” has been placed on any site owned or to Company’s Knowledge, operated by the Company pursuant to CERCLA or any similar state, local or federal Law.

Section 4.21. State Takeover Statutes. The board of directors of the Company has unanimously approved the terms of this Agreement and the consummation of the Merger and the other transactions contemplated by this Agreement, and such approval represents all the actions necessary to render inapplicable to this Agreement and to the Merger and the other transactions contemplated by this Agreement, the restrictions on “business combinations” set forth in the DGCL to the extent such restrictions would otherwise be applicable to this Agreement, the Merger and the other transactions contemplated by this Agreement. No other state takeover statute or similar statute or regulation applies to this Agreement, the Merger or the other transactions contemplated by this Agreement.

Section 4.22. Corporate Records. The minute books of the Company made available in the Data Room to Buyer and its Representatives accurately and adequately reflect in all material respects all action previously taken by the shareholders, the board of directors of the Company and the committees of the board of directors of the Company. The copies of the stock book records of the Company made available in the Data Room to Buyer and its Representatives are true and complete, and accurately reflect all transactions effected in Company Capital Stock through and including the date hereof.

Section 4.23. Bank Accounts. Section 4.23 of the Disclosure Schedule contains a true, correct and complete list of all bank accounts maintained by the Company, including each account number and the name and address of each bank and the name of each Person who has signature power with respect to each such account.

Section 4.24. Transactions with Affiliates. Section 4.24 of the Disclosure Schedule describes any transaction between the Company, on the one hand, and any Company Holder or Affiliate of the Company, on the other hand, other than any employment Contract, Contract entered into in respect of and in connection with the issuance or grant of Company Capital Stock, Contract to maintain the confidential information of the Company, or Contract assigning Intellectual Property rights to the Company, in each case, listed in Section 4.12(a) of the Disclosure Schedule. No Affiliate of the Company (a) owns or has any interest in any (i) Company Intellectual Property, (ii) other material property (real or personal, tangible or intangible) of the Company or (iii) Material Contract used in or pertaining to the business of the Company, (b) to the Knowledge of the Company, has any claim or cause of action against the Company or (c) owes any money to, or is owed any money by (other than, with respect to any Affiliate who is an employee of the
Company, wages or benefits payable in the Ordinary Course of Business or a Change of Control Payment), the Company.

Section 4.25. **Brokers.** The Company does not have Liability to any investment banker, broker, finder, consultant or intermediary in connection with the Merger or the other transactions contemplated hereunder.

Section 4.26. **HSR Thresholds.** The Company represents and warrants that it is not a “person” (as defined in 16 C.F.R. § 801.1(a)(1)) with $18.8 million or more of total assets or annual net sales, in each case as determined in accordance with 16 C.F.R. § 801.11.

**ARTICLE 5**

**REPRESENTATIONS AND WARRANTIES OF BUYER, MERGER SUB AND MERGER SUB II**

Buyer, Merger Sub and Merger Sub II represent and warrant to the Company, as of the date hereof, as follows:

Section 5.1. **Organization and Standing.** Each of Buyer, Merger Sub and Merger Sub II is a corporation duly organized, validly existing and in good standing under the Laws of its jurisdiction of incorporation.

Section 5.2. **Power and Authority; Binding Agreement.** Each of Buyer, Merger Sub and Merger Sub II has all requisite corporate power and authority to execute and deliver this Agreement, to consummate the Mergers and the other transactions contemplated hereunder, and to perform its obligations hereunder. The execution and delivery by Buyer, Merger Sub and Merger Sub II of this Agreement, and the consummation by Buyer, Merger Sub and Merger Sub II of the Mergers and the other transactions contemplated hereunder, have been duly authorized by all necessary corporate action on the part of Buyer, Merger Sub and Merger Sub II, and no other proceedings on the part of Buyer or Merger Sub are necessary to authorize this Agreement or to consummate the Merger and the other transactions contemplated hereunder other than the filing of the Certificate of Merger and Subsequent Merger Certificate of Merger with the office of the Secretary of State of the State of Delaware. This Agreement has been duly executed and delivered by Buyer, Merger Sub and Merger Sub II and, assuming the due execution of this Agreement by the other Parties, constitutes a valid and binding obligation of Buyer, Merger Sub and Merger Sub II, enforceable against Buyer, Merger Sub and Merger Sub II in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, fraudulent transfer, moratorium or similar Laws affecting creditors’ rights generally and general principles of equity (regardless of whether enforcement is sought in a proceeding at law or in equity).

Section 5.3. **Noncontravention.**

(a) The execution and delivery by Buyer, Merger Sub and Merger Sub II of this Agreement, the consummation of the Mergers and the other transactions contemplated hereunder and the compliance by Buyer, Merger Sub and Merger Sub II with the provisions of this Agreement will not (i) result in the breach of any of the terms or conditions of, or constitute a default under or violate, as the case may be, the Constitutive Documents of Buyer, Merger Sub or Merger Sub II
or (ii) violate any Law or Judgment applicable to, or Contract of, Buyer, Merger Sub or Merger Sub II, other than any such breaches, defaults or violations that individually or in the aggregate would not impair in any material respect the ability of each of Buyer, Merger Sub and Merger Sub II to perform its obligations under this Agreement, or prevent or materially impede or delay the consummation of the Mergers or any of the other transactions contemplated hereunder.

(b) No consent, approval, order or authorization of, registration, declaration or filing with, or notice to, any Governmental Entity is required by or with respect to Buyer, Merger Sub or Merger Sub II in connection with the execution and delivery by Buyer, Merger Sub and Merger Sub II of this Agreement, the consummation by Buyer, Merger Sub and Merger Sub II of the Mergers and the other transactions contemplated by this Agreement or the compliance by Buyer, Merger Sub and Merger Sub II with the provisions of this Agreement, except for (i) filing of the Certificate of Merger and Subsequent Merger Certificate of Merger with the office of the Secretary of State of the State of Delaware and appropriate documents with the relevant authorities of other states in which the Company is qualified to do business and (ii) such other consents, approvals, orders, authorizations, registrations, declarations, filings and notices, the failure of which to be obtained or made individually or in the aggregate would not impair in any material respect the ability of each of Buyer, Merger Sub and Merger Sub II to perform its obligations under this Agreement, or prevent or materially impede or delay the consummation of the Mergers or any of the other transactions contemplated hereunder.

Section 5.4. Brokers. Buyer has not employed or entered into any Contract with any investment banker, broker, finder, consultant or intermediary in connection with the transactions contemplated by this Agreement, pursuant to which the Company Holders could be liable for the fee or commission of such investment banker, broker, finder, consultant or intermediary, or for any similar fee or commission in connection with the Mergers, this Agreement or the other transactions contemplated hereunder.

Section 5.5. Buyer SEC Filings. The periodic reports required to be made by the Buyer since February 5, 2020 under the Exchange Act have been filed with the SEC, and such filings complied, as of their respective dates or, if applicable, as of the date of any subsequent amendment to such filing, in all material respects with applicable requirements of the Exchange Act and the rules and regulations of the SEC thereunder (collectively, the “Buyer SEC Reports”). None of the Buyer SEC Reports, as of their respective dates, after giving effect to any amendments thereto filed prior to the date hereof, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements made therein not misleading.

Section 5.6. Buyer Financial Statements. The consolidated financial statements of the Buyer and its subsidiaries included in the Buyer SEC Reports complied, as of the dates thereof, as to form in all material respects with the applicable rules and regulations of the SEC with respect thereto. The consolidated financial statements of the Buyer and its subsidiaries included in the Buyer SEC Reports present fairly, in all material respects, the financial position of the Buyer and its subsidiaries as of the dates thereof, and the results of operations and cash flows for the periods set forth therein (subject, in the case of unaudited statements, to the absence of notes and normal year-end audit adjustments), in each case in conformity with U.S. GAAP, except as may be noted therein.

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Section 5.7. **Valid Issuance; Sufficient Cash on Hand.**

(a) The Buyer Common Stock to be issued pursuant to this Agreement will, when issued, be duly authorized, validly issued, fully paid, and non-assessable, and will not be subject to any preemptive rights or rights of first refusal, or other similar rights of any Buyer securityholder.

(b) Buyer or Merger Sub will have on the Closing Date funds sufficient to pay the Seller Transaction Expenses, the Change of Control Payments, the Shareholders’ Representative Reserve, the D&O Insurance Policy premium, and the Adjustment Escrow Amount, and any other amounts required to be paid in connection with the consummation of the Transactions, including all related fees and expenses. Buyer need not borrow or raise financing for purposes of paying, directly or indirectly, such amounts.

Section 5.8. **Litigation.** There are no Actions pending or threatened against or affecting Buyer, Merger Sub or Merger Sub II seeking to prevent, enjoin, or otherwise delay the transactions contemplated by this Agreement.

Section 5.9. **No Order.** There is no order issued or made by any Governmental Entity having the effect of ceasing or suspending the distribution or trading of Buyer Common Stock or ceasing or suspending the trading of any other securities of Buyer, and no proceedings have been initiated or are pending or threatened by any Governmental Entity in relation thereto.

**ARTICLE 6**

**CERTAIN COVENANTS**

Section 6.1. **Tax Matters.**

(a) All Transfer Taxes, if any, incurred in connection with the consummation of the Mergers and the other transactions contemplated by this Agreement shall be borne 50% by the Company Holders, and 50% by the Buyer. The party responsible under applicable Law for filing any Tax Return with respect to such Transfer Taxes shall timely file such Tax Return and, if required by applicable Law, the other party will join in the execution of any such Tax Returns and other documentation.

(b) To the maximum extent permitted by applicable Law, the taxable year of the Company shall terminate as of the end of the day on the Closing Date.

(c) For purposes of allocating Taxes in this Agreement for a Straddle Period, the portion of such Tax which relates to the portion of such Straddle Period ending on the Closing Date shall (x) in the case of any Taxes other than Taxes based upon or measured by income or receipts, sales or use Taxes, transfer or transaction-based Taxes, employment or payroll Taxes, or withholding Taxes of the Company be deemed to be the amount of such Tax for the entire Tax Period multiplied by a fraction the numerator of which is the number of days in the portion of the Straddle Period ending on the Closing Date and the denominator of which is the number of days in the entire Straddle Period, and (y) in the case of any Tax based upon or measured by income or receipts, sales or use Taxes, transfer or transaction-based Taxes, employment or payroll Taxes, or
withholding Taxes of the Company, be deemed equal to the amount which would be payable if the relevant Tax Period ended on the Closing Date based on an interim closing of the books as of the close of business on the Closing Date (and for such purpose, the Tax Period of any partnership or other pass-through entity or any “controlled foreign corporation” (within the meaning of Section 957 of the Code) or “passive foreign investment company” (within the meaning of Section 1297 of the Code) in which the Company holds a beneficial interest shall be deemed to terminate at such time). Exemptions, allowances or deductions that are calculated on an annual basis, such as the deduction for depreciation, shall be apportioned on a daily basis and Taxes that are computed on a periodic basis, such as property Taxes, shall also be apportioned on a daily basis. Notwithstanding anything in this Agreement to the contrary, Taxes attributable to actions taken by Buyer on the Closing Date after the Closing that are not contemplated by this Agreement and that are outside the Ordinary Course of Business shall be allocated to the Post-Closing Tax Period.

(d) **Shareholders’ Representative Reserve.** The Shareholders’ Representative Reserve shall be treated as having been received and voluntarily set aside by the Company Holders at the time of Closing (and, for the avoidance of doubt, Tax withholding with respect to such deemed contribution by any Company Holder shall be satisfied from such Company Holder’s share of the Closing Payment and shall not reduce the Shareholders’ Representative Reserve).

(e) **Certain Tax Matters.**

(i) Buyer, Merger Sub, Merger Sub II, and the Company each intend for U.S. federal income Tax purposes that (i) the Mergers shall be treated as an integrated transaction and a reorganization within the meaning of Section 368(a) of the Code and (ii) neither the Milestone Stock Consideration payable to the holders of Company Capital Stock (nor the right to receive the Milestone Stock Consideration by the holders of Company Capital Stock) shall be treated as taxable “boot” for purposes of Section 354, 356 and 368 of the Code (the “**Intended Tax Treatment**”). The Parties shall (and the Letter of Transmittal shall instruct the holders of Company Capital Stock to) file, and use commercially reasonable efforts to cause their agents (including the Transfer Agent) to file, their Tax Returns consistent with such Intended Tax Treatment, and shall not take, and use commercially reasonable efforts to cause their agents (including the Transfer Agent) not to take, a position inconsistent with such Intended Tax Treatment (including in connection with any audit or administrative appeal), [**]. For the avoidance of doubt, it is inconsistent with the Intended Tax Treatment for Buyer or its agents (including the Transfer Agent) to report the Closing Stock Consideration and Milestone Stock Consideration (if any) on IRS Form 1099-B with respect to the holders of Company Capital Stock.

(ii) Buyer will provide any factual information reasonably requested by the Shareholders’ Representative that is reasonably necessary to support the Intended Tax Treatment (provided that, for the avoidance of doubt, Buyer shall not be required to provide any factual representations or other certifications of fact).

(iii) The Parties (other than the Shareholders’ Representative) represent that, to their knowledge, as of the date hereof and the Closing, no facts or circumstances not set forth in this Agreement exist that could reasonably be expected to prevent the Mergers from qualifying for the Intended Tax Treatment (provided that, for the avoidance
of doubt, the foregoing shall not be construed as providing any assurances as to the impact of the terms of this Agreement on the validity of the Intended Tax Treatment).

(iv) Buyer represents that:

(A) Merger Sub and Merger Sub II were each formed solely for the purpose of engaging in the Mergers, have at all times been, and will be through the Closing, wholly and directly owned by Buyer, and neither Merger Sub nor Merger Sub II have engaged, and will not prior to the Closing engage, in any business activities or conducted any operations or incurred any obligation or liability, other than, in each case, in connection with or incidental to the Mergers and this Agreement. Merger Sub II is as of the date hereof, and has been since the date of its formation, treated as a disregarded entity for U.S. federal income Tax purposes, and there is no current plan or intention to elect to treat Merger Sub II as a corporation for U.S. federal income Tax purposes; and

(B) Following the Mergers, as of the date hereof and the Closing, Buyer plans and intends to cause Buyer to directly or indirectly (through Merger Sub II, one or more members of Buyer’s “qualified group” (within the meaning of Treasury Regulations Section 1.368-1(d)(4)(ii)), or a partnership meeting the requirements set forth in Treasury Regulations Section 1.368-1(d)(4)(iii)) to continue the Company’s historic business by pursuing the Milestone Events contemplated in this Agreement in the manner required by this Agreement (provided that, for the avoidance of doubt, nothing in this paragraph shall be construed as limiting or expanding the rights and obligations of the Parties relating to the Milestone Events).

(v) Solely to the extent any of the foregoing could reasonably be expected to cause the Mergers to fail to qualify for the Intended Tax Treatment, unless otherwise consented to by the Shareholders’ Representative (with such consent not to be unreasonably withheld, conditioned, or delayed):

(A) Buyer shall not cause Merger Sub II to elect to be treated as a corporation for U.S. federal income Tax purposes for a period of one (1) year following the date hereof;

(B) Buyer will not directly redeem or directly purchase from any Company Holder who holds Company Capital Stock any of the Buyer Common Stock issued to holders of Company Capital Stock pursuant to this Agreement; and

(C) [**].

(f) Designation of Stock. Unless a holder of Company Capital Stock makes an express designation to the contrary in its Letter of Transmittal, and to the extent permitted by applicable Law, for purposes of this Agreement and in accordance with Treasury Regulation Section 1.358-2(a)(2), any cash consideration and Closing Stock Consideration that such Holder is entitled to receive pursuant to this Agreement shall be treated as received for its Company Capital Stock exchanged in the Merger in the following order of priority (with the cash consideration allocated first): (i) to the Company Capital Stock held by such holder for more than one year before the Merger within the meaning of Section 1223 of the Code, if any, allocated first to such Company Capital Stock with the highest federal income tax basis and then in descending tax basis order; and (ii) any remaining amount to all other Company Capital Stock held by such holder, allocated first to such Company Capital Stock with the highest federal income tax basis and then in descending order
tax basis order. The Shareholders’ Representative shall use commercially reasonably efforts to request from Company Holders any information reasonably requested in connection with this Section 6.1(f) and to provide Buyer with any such information in its possession.

Section 6.2. Indemnification of Officers and Directors.

(a) From and after the Effective Time, Buyer shall cause the Surviving LLC to fulfill and honor in all respects the obligations of the Company pursuant to any indemnification provisions under the certificate of formation and bylaws of the Company as in effect on the date of this Agreement, and pursuant to any agreements between the Company and any Person providing for rights to indemnification or exculpation in favor of such Person, as in effect on the date of this Agreement and set forth on the Disclosure Schedule (the Persons entitled to be indemnified pursuant to such provisions, and all other current and former directors and officers of the Company, being referred to collectively as the “D&O Indemnified Parties”).

(b) Subject to Section 6.4, the Company shall obtain, at or prior to the Effective Time, a prepaid (or “tail”) directors’ and officers’ liability insurance policy in respect of events occurring prior to the Effective Time (the “D&O Insurance Policy”) for a period of six (6) years from the Effective Time, on terms with respect to such coverage and amounts no less favorable than the Company’s existing policy or, if insurance coverage that is no less favorable is unavailable, the best available coverage; provided, that the premium for such D&O Insurance Policy may not be in excess of three hundred percent (300%) of the last annual premium paid prior to the Closing.

(c) In the event Buyer or the Surviving LLC or any of their respective Subsidiaries (i) consolidates with or merges into any other Person and shall not be the continuing or surviving corporation or entity of such consolidation or merger, or (ii) transfers or conveys all or substantially all of its properties and assets to any Person, then, and in each such case, proper provision shall be made so that the successors and assigns of Buyer or the Surviving LLC or any of their respective Subsidiaries assume the obligations set forth in this Section 6.2.

(d) This Section 6.2 shall survive the consummation of the Mergers and the Effective Time, is intended to benefit and may be enforced by the D&O Indemnified Parties, and shall be binding on all successors and assigns of Buyer and the Surviving LLC.

Section 6.3. Publicity. No Party shall, and each Party shall cause its Affiliates, officers, directors, employees, advisors and other Representatives not to, issue a press release or public announcement or otherwise make any public disclosure concerning the subject matter of this Agreement without the prior written approval of the other Party; provided, however, that any Party may make any public disclosure it believes in good faith is required by applicable Law or stock market rule and in such case such Party must, prior to making such disclosure, (a) use commercially reasonable efforts to advise the other Party of such disclosure (including a copy thereof) as far in advance of such disclosure as is reasonably practicable and (b) consult with the other Party with respect to the content of such disclosure.

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Section 6.4. Expenses. Except as otherwise set forth in this Agreement, each of the Company, Buyer, Merger Sub and Merger Sub II shall bear its own fees and expenses incurred or owed in connection with the Mergers, this Agreement and the other transactions contemplated hereby; provided, that (a) Buyer, on the one hand, and the Company Holders, on the other hand, shall each bear 50% of the fees and expenses of the Escrow Agent, and, for the avoidance of doubt, the 50% paid by the Company Holders at Closing for the fees and expense of the Escrow Agent shall be considered “Seller Transaction Expenses” under this Agreement; (b) Buyer, on the one hand, and the Company Holders, on the other hand, shall each bear 50% of the premium for the [*]; (c) Buyer, on the one hand, and the Company Holders, on the other hand, shall each bear 50% of the premium for the D&O Insurance Policy; and (d) the Company Holders shall bear (severally, and not jointly, in accordance with their respective Pro Rata Percentages) the fees and expenses of the Shareholders’ Representative in accordance with the terms of Section 2.12; and (d) Buyer shall bear all fees and expenses of the Transfer Agent.

Section 6.5. Further Assurances and Approvals. From time to time, as and when requested by any Party, the Parties shall execute and deliver, or cause to be executed and delivered, all such documents and instruments and shall take, or cause to be taken, all such further or other actions as reasonably necessary to carry out the intent and accomplish the purposes of this Agreement and, subject to the conditions of this Agreement, the consummation of the transactions contemplated hereunder.

Section 6.6. Data Room Record. Not later than three (3) Business Days after the date hereof, the Company shall deliver to each of Buyer and Buyer’s counsel, Ropes & Gray LLP, a DVD ROM disc (or similar media) containing a digital copy of all of the materials included in the Data Room.

Section 6.7. Stockholder Consent. Immediately following the execution of this Agreement, the Company shall obtain the Written Consent executed by stockholders of the Company holding 100% of the Outstanding Shares as of the date hereof (the “Stockholder Consent”) and deliver the Stockholder Consent to Buyer prior to 5:00 p.m. Eastern Standard Time on the date hereof.

Section 6.8. Operation of the Business. From the date of this Agreement until the Closing or the earlier termination of this Agreement in accordance with ARTICLE 8, without the prior written consent of Buyer, the Company shall conduct its business only in the Ordinary Course of Business and in all material respects in accordance with all applicable Legal Requirements and shall preserve intact its business organization and relationships with third parties and employees.

Section 6.9. Buyer Periodic Reports. If the Registration Statement has not been declared effective by the SEC before September 30, 2021, from September 30, 2021 until the September 30, 2022, Buyer shall file with the SEC, within the time periods specified therefor in the SEC’s rules and regulations applicable to Buyer, all required periodic reports under Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended (other than reports on Form 8-K), including electronically submitting any interactive data files required to be submitted by Buyer.
Section 6.10. Employee Matters.

(a) Through December 31, 2021 (or such shorter period of the Continuing Employee’s employment, as applicable), Buyer shall cause the Surviving LLC to provide each employee of the Company who is employed by the Company as of the Closing and who continues to be employed by the Surviving LLC immediately following the Closing (each, a “Continuing Employee”) with (i) a base salary or hourly wage rate no less favorable than that provided to such Continuing Employee immediately prior to the Effective Time; (ii) except as otherwise agreed between Buyer and a Continuing Employee, a target cash incentive compensation opportunity (excluding any equity-based compensation) no less favorable than that provided to such Continuing Employee immediately prior to the Effective Time; and (iii) other employee benefits (excluding any equity-based compensation), substantially comparable in the aggregate to either (y) those benefits provided to such Continuing Employee immediately prior to the Effective Time and made available in the Data Room to Buyer and its Representatives or (z) those benefits provided by Buyer to similarly situated employees of Buyer.

(b) To the extent that service is relevant for eligibility, vesting or allowances (including paid time off but excluding for purposes of any equity-based compensation) under any severance, health or welfare benefit plan, 401(k) plan or other benefit plan of Buyer or the Surviving LLC, Buyer shall use commercially reasonable efforts to cause such plan to, for purposes of eligibility vesting and allowances (including paid time off), credit Continuing Employees for service with the Company prior to the Closing to the same extent that such service was recognized prior to the Closing under a corresponding Company Benefit Plan; provided, that the foregoing shall not apply to the extent that its application would result in a duplication of benefits; provided, further, that the foregoing shall not apply for benefit accrual purposes under any defined benefit pension plan or retiree medical plan.

(c) With respect to each health or welfare benefit plan of Buyer or the Surviving LLC made available to Continuing Employees in the plan year in which the Closing occurs, Buyer or the Surviving LLC shall use commercially reasonable efforts to cause to be waived any pre-existing condition or eligibility limitations and give effect, in determining any deductibles and maximum out of pocket limitations, to claims incurred, amounts paid by, and amounts reimbursed to, Continuing Employees under similar Company Benefit Plans as in effect prior to the Closing.

(d) Nothing in this Section 6.10 shall (i) create any right in any Continuing Employee to continued employment by Buyer or the Surviving LLC or terms or conditions of employment or (ii) require Buyer or the Surviving LLC to continue any Company Benefit Plan or prevent the establishment, adoption, amendment, modification or termination of any Company Benefit Plan or any other employee benefit or compensatory plan, program, policy, arrangement or agreement after the Closing. Nothing in this Section 6.10 shall be construed to create a right in any employee to employment with Buyer or the Surviving LLC. Nothing in this Section 6.10, or elsewhere in this Agreement, shall confer upon any employee or other service provider to the Company or the Surviving LLC or any of their Affiliates, or any legal representative or beneficiary of any such Person, any rights or remedies of any nature or kind whatsoever under or by reason of this Agreement.
ARTICLE 7

CLOSING CONDITIONS

Section 7.1.  Conditions to the Obligations of Buyer at Closing. The obligations of Buyer, Merger Sub and Merger Sub II to consummate the Mergers are subject to the fulfillment, or, to the extent permitted by Law, waiver by Buyer, Merger Sub and Merger Sub II, of each of the following conditions:

(a) The Stockholder Consent will have been received and delivered to Buyer.

(b) The deliverables listed in Section 3.1 will have been delivered to Buyer.

(c) The Company will have performed and complied with, in all material respects, all agreements, obligations and covenants contained in this Agreement that are required to be performed or complied with by it at or prior to the Closing.

(d) No temporary restraining order, preliminary or permanent injunction, or other order or judgment preventing the consummation of the Mergers or the other transactions contemplated by this Agreement shall have been issued by any court of competent jurisdiction and remain in effect.

(e) Since the date of this Agreement, there will not have occurred or arisen any events, changes, facts, conditions or circumstances, nor will there exist any events, changes, facts, conditions or circumstances, which individually or in the aggregate have resulted in or would reasonably be expected to result in a Material Adverse Effect.

Section 7.2.  Conditions to the Obligations of the Company at Closing. The obligations of the Company to consummate the Mergers is subject to the fulfillment, or, to the extent permitted by Law, waiver by the Company, of each of the following conditions:

(a) The deliverables listed in Section 3.2 will have been delivered to Buyer.

(b) Buyer will have performed and complied with, in all material respects, all agreements, obligations and covenants contained in this Agreement that are required to be performed or complied with by it at or prior to the Closing.

(c) No temporary restraining order, preliminary or permanent injunction, or other order or judgment preventing the consummation of the Mergers or the other transactions contemplated by this Agreement shall have been issued by any court of competent jurisdiction and remain in effect.
ARTICLE 8
TERMINATION

Section 8.1. **Termination of Agreement.** This Agreement may be terminated and the Mergers and the other transactions contemplated by this Agreement may be abandoned at any time prior to the Closing:

(a) by mutual written consent of Buyer and the Company;

(b) by Buyer, if the Stockholder Consent is not received and delivered to Buyer prior to 5:00 p.m. Eastern Standard Time on the date hereof; or

(c) by either Buyer or the Company, if the Closing has not occurred before 5:00 p.m. Eastern Standard Time on the Business Day following the date hereof; provided that, a Party may not terminate this Agreement pursuant to this Section 8.1(c) if the Closing has not occurred on such Business Day as a result of any breach of any provision of this Agreement by such Party.

Section 8.2. **Effect of Termination.** In the event of a termination of this Agreement pursuant to Section 8.1, this Agreement (other than the provisions of this ARTICLE 8 and Section 6.3 (Publicity), Section 6.4 (Expenses), Section 10.4 (Enforcement) and Section 10.10 (Governing Law), which shall survive termination) shall then be null and void and have no further force and effect and all other rights and liabilities of the parties hereunder will terminate without any liability of any Party to any other Party, except for liabilities arising in respect of intentional or willful breaches under this Agreement by any Party prior to such termination.

ARTICLE 9
NO SURVIVAL

Section 9.1. **No Survival of Representations and Warranties.** Except in the case of fraud, (a) all representations and warranties of the parties set forth in this Agreement, and (b) the covenants and agreements of the parties required to be performed or fulfilled at or prior to the Effective Time contained in this Agreement shall, in each case, terminate, expire, and cease to have any further force or effect at the Effective Time. For the avoidance of doubt, nothing in this Agreement (including this Section 9.1) shall preclude recovery by Buyer under the [**].

ARTICLE 10
MISCELLANEOUS

Section 10.1. **Notices.** All notices, requests, claims, demands, waivers and other communications under this Agreement shall be in writing and shall be delivered by (a) electronic mail in .pdf or similar format (with confirmation of transmission), (b) a nationally recognized overnight courier (with confirmation of delivery) or (c) personal delivery, in each case to the
following addresses, or to such other addresses as shall be designated from time to time by a Party in accordance with this Section 10.1:

(a) if to Buyer, Merger Sub or Merger Sub II:
    Beam Therapeutics Inc.
    26 Lansdowne Street
    Cambridge, MA 02139
    Attention: John Evans, Chief Executive Officer
    Tel: [**]
    Email: [**]

    with a copy to (which shall not constitute notice):
    Ropes & Gray LLP
    Attention: Marc A. Rubenstein, Esq.
    Prudential Tower
    800 Boylston Street
    Boston, MA 02199
    Tel: [**]
    Email: [**]

if to the Company:
    Guide Therapeutics, Inc.
    Attention: Cory Sago, Chief Technology Officer
    1860 Montreal Rd
    Tucker, GA 30084
    Email: [**]

    with a copy to (which shall not constitute notice):
    Orrick Herrington & Sutcliffe LLP
    Columbia Center
    1152 15th Street, N.W.
    Washington, D.C. 20005-1706
    United States
    Attn: David Schulman
    Email: [**]

if to the Shareholders’ Representative:
    Shareholder Representative Services LLC
    950 17th Street, Suite 1400
    Denver, CO 80202
    Attention: Managing Director
    Email: [**]
    Facsimile: [**]
    Telephone: [**]
Section 10.2. Assignment. Neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned, in whole or in part, by operation of Law or otherwise by any of the Parties prior to the Closing without the prior written consent of the other Parties, except that (a) each of Merger Sub and Merger Sub II may assign, in its sole discretion, any of or all its rights, interests and obligations under this Agreement to Buyer or to any Affiliate of Buyer, and (b) Buyer may assign, in its sole discretion, any or all of its rights, interests and obligations under this Agreement to any Affiliate of Buyer; provided, that in each case no such assignment shall release the assigning Party of its obligations under this Agreement. Subject to Section 2.18(d) and Section 6.1(e)(v)(C), any of the rights, interests or obligations hereunder may be assigned, in whole or in part, by operation of Law or otherwise following the Closing by any of the Parties without the prior written consent of the other Parties. Subject to the preceding two sentences, this Agreement shall be binding upon, inure to the benefit of and be enforceable by, the Parties and their respective successors and assigns.

Section 10.4. Enforcement; Specific Performance.

(a) Each Party irrevocably submits to the exclusive jurisdiction of the Delaware Chancery Court, and any federal court of the United States of America sitting in the State of Delaware, for the purposes of any suit, action or other proceeding arising out of this Agreement or any transaction contemplated hereby. Each Party agrees to commence any such action, suit or proceeding either in the Delaware Chancery Court or if such suit, action or other proceeding may not be brought in such court for jurisdictional reasons, in any federal court of the United States of America sitting in the State of Delaware. Each Party further agrees that service of any process, summons, notice or document by the U.S. registered mail to such Party’s respective address set forth above shall be effective service of process for any action, suit or proceeding in Delaware with respect to any matters to which it has submitted to jurisdiction in this Section 10.4. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in (i) the Delaware Chancery Court, and (ii) any federal court of the United States of America sitting in the State of Delaware, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. This Section 10.4 shall not apply to any dispute under Section 2.17 that is required to be decided by the Accounting Firm.

(b) EACH PARTY HERETO WAIVES ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY. Each Party hereto (i) certifies that no Representative of any other Party has represented, expressly or otherwise, that such Party would not, in the event of any action, suit or proceeding, seek to enforce the foregoing waiver and (ii) acknowledges that it and the other Parties hereto have been induced to enter into this Agreement, by, among other things, the mutual waiver and certifications in this Section 10.4.
The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. Accordingly, each of the parties shall be entitled to specific performance of the terms of this Agreement, including an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement, this being in addition to any other remedy to which they are entitled at law or in equity. Each of the Parties further waives (i) any defense in any action for specific performance that a remedy at law would be adequate, and (ii) any requirement under any Law to post security as a prerequisite to obtaining equitable relief.

Section 10.5. Amendment and Waiver.

(a) No failure or delay on the part of any Party in exercising any right, power or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy preclude any other or further exercise thereof or the exercise of any other right, power or remedy. The remedies provided for herein are cumulative and are not exclusive of any remedies that may be available to any Party at Law, in equity or otherwise.

(b) Except as otherwise specifically set forth in this Agreement, this Agreement may be amended by the Parties at any time, whether before or after the Shareholder Approval has been obtained; provided, however, that, after the Shareholder Approval has been obtained, there shall be made no amendment that by Law requires further approval by shareholders of either Party, without the further approval of such shareholders. This Agreement may not be amended, supplemented or modified except by an instrument in writing signed on behalf of each of the Parties; provided that, to the extent permitted by applicable Law, Buyer and the Shareholders’ Representative may cause this Agreement to be amended at any time after the Closing by execution of an instrument in writing signed on behalf of Buyer and the Shareholders’ Representative. In the case of a waiver, such waiver shall be effective only if it is made or given in writing and signed by the party granting the waiver and shall be effective only in the specific instance and for the specific purpose for which made or given.

Section 10.6. No Additional Representations and Warranties.

(a) The parties hereto acknowledge and agree that (a) each such party is an informed and sophisticated Person, has engaged expert advisors experienced in the evaluation and acquisition of companies such as the Company as contemplated under this Agreement, (b) has undertaken such investigation and has been provided with and has evaluated such documents and information as it has deemed necessary to enable it to make an informed and intelligent decision with respect to the execution, delivery, and performance of this Agreement and all the transactions contemplated hereby and (c) they are relying exclusively on the representations set forth in Article 4 and Article 5 and their own examination and investigation of the Company and that they are not relying on any other statements or documents. Without limiting the generality of the
foregoing, the parties hereto each acknowledge that the neither party makes any representation or warranty with respect to (i) any projections, estimates, or budgets delivered to or made available to the other party of future revenues, future results of operations (or any component thereof), future cash flows, or future financial condition (or any component thereof) of the Surviving LLC or the future business and operations of the Surviving LLC, or (ii) any other written information or documents made available to the other party or their counsel, accountants, or advisors with respect to the Company, Buyer or any of their businesses, assets, Liabilities or operations, except as expressly set forth in this Agreement.

Section 10.7. **Entire Agreement.** This Agreement, together with all annexes, schedules (including the Disclosure Schedule) and exhibits and all ancillary agreements, documents or instruments to be delivered in connection herewith and therewith, contain the entire agreement and understanding between the Parties with respect to the subject matter hereof and thereof and supersede all prior discussions, negotiations, commitments, agreements and understandings, both written and oral, relating to such subject matter.

Section 10.8. **No Third-Party Beneficiaries.** Except as otherwise provided in this Agreement, this Agreement is for the sole benefit of the Parties and their permitted successors and assigns and nothing herein expressed or implied shall give or be construed to give to any Person, other than the Parties and such successors and assigns, any legal or equitable rights hereunder (except that Section 6.2 is intended to benefit the D&O Indemnified Parties).

Section 10.9. **Counterparts.** This Agreement may be executed in any number of counterparts and by the Parties in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. This Agreement may be executed by .pdf or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were the original signatures.

Section 10.10. **Governing Law.** This Agreement and all matters relating to or arising out of this Agreement (whether sounding in contract, tort or otherwise) shall be governed by, and construed in accordance with, the substantive Laws of the State of Delaware, regardless of the Laws that might otherwise govern under applicable principles of conflict of laws thereof.

Section 10.11. **Severability.** If any term or other provision of this Agreement is invalid, illegal or incapable of being enforced by any rule of law or public policy, all other conditions and provisions of this Agreement shall nevertheless remain in full force and effect. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the Parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the Parties as closely as possible to the fullest extent permitted by applicable Law in an acceptable manner to the end that the transactions contemplated hereby are fulfilled to the extent possible.

[Signature pages follow.]
IN WITNESS WHEREOF, the Parties have caused this Agreement to be signed by their duly authorized representatives as of the date first written above.

BEAM THERAPEUTICS INC.

By: /s/ John Evans
Name: John Evans
Title: Chief Executive Officer

GALILEO MERGER SUB I, INC.

By: /s/ John Evans
Name: John Evans
Title: Chief Executive Officer

GALILEO MERGER SUB II, LLC

By: /s/ John Evans
Name: John Evans
Title: Chief Executive Officer
SHAREHOLDER REPRESENTATIVE
SERVICES LLC, solely in its capacity as the Shareholders' Representative

By: /s/ Sam Riffe
    Name: Sam Riffe
    Title: Managing Director
COMPANY HOLDER
(solely for purposes of Section 2.12)

By: /s/ Brandon Krupczak
COMPANY HOLDER
(solely for purposes of Section 2.12)

By: /s/ Cory Sago
COMPANY HOLDER
(solely for purposes of Section 2.12)

By: /s/ Thomas Reese Saylor

--------------------------------------------------
COMPANY HOLDER
(solely for purposes of Section 2.12)

GreatPoint Ventures Innovation Fund II, L.P.,
a Delaware Limited Partnership

By: GreatPoint Investment Partners II, LLC
Its: General Partner

By: /s/ Andrew Perlman
Name: Andrew Perlman
Title: Managing Partner
COMPANY HOLDER
(solely for purposes of Section 2.12)

By: GV 2019 GP, L.P., its General Partner
BY: GV 2019 GP, L.L.C., its General Partner

By: /s/ Daphne Chang
Name: Daphne Chang
Title: Authorized Signatory
COMPANY HOLDER
(solely for purposes of Section 2.12)

Biomatics Capital Partners II, L.P.

By: Biomatics Capital Management II, L.L.C.
Its: General Partner

By: /s/ Julie Sunderland
Name: Julie Sunderland
Title: Managing Director
COMPANY HOLDER
(solely for purposes of Section 2.12)

By:  /s/ James Dahlman
COMPANY HOLDER
(solely for purposes of Section 2.12)

The Dahlman Cattie New Hampshire Trust

By:  /s/ Steve Burke
Name: Steve Burke
Title: Trustee
Exhibit A

Form of Letter of Transmittal
Exhibit B

Form of Escrow Agreement
Exhibit C

Form of Non-Compete and Restrictive Covenant Agreement
Exhibit D

Form of Consulting Agreement
Exhibit E

[**]
Annex I

Company Holder Information

[Attached]
Annex II
Seller Transaction Expenses

[Attached]
Annex III

Change of Control Payments

[Attached]
Annex IV
Cost Basis Information

[Attached]
AMENDMENT NO. 1 TO LICENSE AGREEMENT

Harvard Case Nos: [**]; [**]

This Amendment No. 1 to License Agreement (this “Amendment No. 1”) is entered into as of December 12, 2017 (the “Amendment No. 1 Effective Date”), by and between Beam Therapeutics Inc., a corporation existing under the laws of the State of Delaware, having a place of business at c/o Mass Innovation Labs, 675 W Kendall St., Cambridge, MA 02142 (“Licensee”) and President and Fellows of Harvard College, an educational and charitable corporation existing under the laws and the constitution of the Commonwealth of Massachusetts, having a place of business at Richard A. and Susan F. Smith Campus Center, Suite 727E, 1350 Massachusetts Avenue, Cambridge, Massachusetts 02138 (“Harvard”). Capitalized terms used but not defined herein shall have the same meanings ascribed to such terms in the Agreement, as such term is defined in the Recitals.

RECITALS

WHEREAS, Harvard and Licensee entered into a License Agreement dated as of June 27, 2017 (the “Agreement”); and

WHEREAS, pursuant to Section 11.12 of the Agreement, Harvard and Licensee wish to execute this Amendment No. 1 to add Harvard Case Nos. [**] and [**] to the Patent Rights set forth on Exhibit 1.70 of the Agreement, and to provide for an additional payment to Harvard as consideration for the amendment of such Patent Rights.

NOW, THEREFORE, for good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties agree to amend the Agreement as follows:

TERMS

1. Amendment to Exhibit 1.70. Exhibit 1.70 of the Agreement is hereby deleted and replaced in its entirety with Exhibit 1.70 attached hereto.

2. Payment. As consideration for the amendment of the Patent Rights as set forth herein, Licensee shall pay to Harvard the amount of [**] U.S. dollars ($[**] USD) within thirty (30) days of the Amendment No. 1 Effective Date. In addition, within [**] days after the Amendment No. 1 Effective Date, Licensee shall [**]. All documented, out-of-pocket expenses incurred by Harvard pursuant to Article 6 of the Agreement will be reimbursed by Licensee in accordance with Section 6.2 of the Agreement.

3. Miscellaneous.

3.1 Except as amended hereby, all other terms of the Agreement shall remain unchanged and in full force and effect.

3.2 This Amendment No. 1 shall be deemed incorporated into, and part of the Agreement.

3.3 This Amendment No. 1 will be governed by, and construed in accordance with, the substantive laws of the Commonwealth of Massachusetts, without giving effect to any choice or conflict of law provision.
IN WITNESS WHEREOF, the parties hereto have caused this Amendment No. 1 to be executed by their duly authorized representatives as of the Amendment No. 1 Effective Date.

**President and Fellows of Harvard College**  
By: /s/ Isaac T. Kohlberg  
Title: Senior Associate Provost  
Chief Technology Development Officer  
Office of Technology Development  
Harvard University

**Beam Therapeutics Inc.**  
By: /s/ John Evans  
Title: CEO
AMENDMENT NO. 2 TO LICENSE AGREEMENT

This Amendment ("Amendment No. 2"), effective as of March 27, 2020 ("Amendment No. 2 Effective Date"), is entered into by and between Beam Therapeutics, Inc., a corporation existing under the laws of the State of Delaware, having a place of business at 26 Landsdowne Street, Cambridge, Massachusetts 02139 ("Licensee"), and President and Fellows of Harvard College, an educational and charitable corporation existing under the laws and the constitution of the Commonwealth of Massachusetts, having a place of business at Richard A. and Susan F. Smith Campus Center, Suite 727, 1350 Massachusetts Avenue, Cambridge, Massachusetts 02138 ("Harvard"). Each of Harvard and Licensee are a "Party" hereunder and collectively, the "Parties".

WHEREAS, Licensee and Harvard have entered into that certain License Agreement dated as of June 27, 2017, as amended by that certain Amendment No. 1 to License Agreement, dated as of December 12, 2017 (the "Agreement"); and

WHEREAS, Licensee and Harvard desire to amend the Agreement to revise the definition of "Non-Royalty Sublicense Income".

NOW THEREFORE, for valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

ARTICLE 1. AGREEMENT TO AMEND

1.1 Capitalized terms used but not defined herein shall have the meaning given to them in the Agreement.

1.2 Section 1.65 of the Agreement is hereby amended and restated in its entirety to read as follows:

"Non-Royalty Sublicense Income" means all consideration received by Licensee or its Affiliates for a Sublicense such as license or distribution fees, milestone or option payments, or license maintenance fees, including any consideration received by Licensee under a Sublicense, but excluding reimbursement of future research and development by or for the Licensee at Licensee’s fully burdened cost, reimbursement for patent expenses (including prosecution and enforcement expenses) paid to third parties at out-of-pocket cost to Licensee, reimbursement of commercialization expenses of Licensee under a co-promotion arrangement at Licensee’s cost (determined in accordance with U.S. generally accepted accounting principles consistently applied), reimbursement of license, option, or other fees paid to third parties at out-of-pocket cost to Licensee, proceeds from equity investments to the extent at fair market value, principal amount of loans to the extent not forgiven, the [**] of any [**] that is received by Licensee or its Affiliates under such Sublicense, based on [**], to the extent such [**] of such [**] does not exceed Licensee’s and its Affiliates’ [**] following the effective date of the Sublicense (taking into consideration the [**]), provided that with respect to [**] on which such [**] is based, [**], and royalties on Net Sales of Licensed Products. To avoid doubt as to the calculation of Non-Royalty Sublicense Income, “equity investments to the extent at fair market value” means that only a premium over the fair market value of the security received for the equity investment (such fair market value being determined by reference to the price paid by a non-Sublicensee Third Party for the equivalent Licensee security (equal to such price wherever available) or by a reasonable methodology where such non-Sublicensee Third Party price is not available) would be included in Non-Royalty Sublicense Income, and if a loan is partially forgiven, then only the forgiven portion of
the loan would be included in the Non-Royalty Sublicense Income. In the event that non-cash consideration is received as Sublicense Income, Sublicense Income shall be calculated based on the fair market value of such non-cash consideration, or, at Licensee’s election, Licensee may distribute Harvard’s share to Harvard in kind; provided that Licensee may only elect to make such a distribution if such non-cash consideration is a freely transferable security (except for such restrictions on transfer imposed by law). For clarity, a license of intellectual property rights that are necessary for Licensee to make, have made use, have used, sell, offer for sale, have sold, export and import Licensed Products, and other routine contractual covenants that do not involve the payment of any monetary consideration and are customary in the type of deal that the Sublicense is included in (including covenants providing for the research, development, supply, and commercialization responsibilities of the Sublicensee, confidentiality provisions, licenses or other rights or forbearances with respect to improvements and other technologies and intellectual property, retention of co-promotion rights or options to obtain co-promotion rights to the Licensed Product(s) covered by such Sublicense, and indemnification) shall not be deemed non-cash consideration. For purposes of this Section, “all consideration received by Licensee or its Affiliates for a Sublicense” shall include all consideration received by Licensee or its Affiliates for any option, license, sublicense, standstill, covenant not to sue or other right granted under any other rights owned or controlled (for example, by virtue of a license granted by a third party) by Licensee or its Affiliate, or other agreement or arrangement entered into by Licensee or its Affiliate, in connection with a Sublicense. All rights relevant to making, using, selling, offering to sell or importing particular Licensed Products or Enabled Products to which a Sublicense relates shall be included in or deemed to be granted in connection with the Sublicense under which the rights granted to Licensee hereunder are sublicensed with respect to such Licensed Products or Enabled Products. In addition, to the extent that Licensee enters into a cross-license with a Third Party to achieve freedom-to-operate for Licensed Products while providing the Third Party with freedom-to-operate with respect to all or some portion of the Licensed Patents, the value of the licenses to Licensee as part of such cross-license, and the other routine contractual covenants by other parties to such cross-license, shall not be deemed to give rise to Non-Royalty Sublicense Income for purposes of this Agreement. In addition, no Change of Control transaction or other transaction giving rise to potential payments under Section 4.7 of this Agreement shall be deemed to be a Sublicense nor to give rise to Non-Royalty Sublicense Income.”

1.3 Section 5.1.1.4 of the Agreement is hereby amended and restated in its entirety to read as follows:

“5.1.1.4 a detailed accounting of all Non-Royalty Sublicense Income received during the applicable Calendar Quarter, which shall include, without limitation, a [**].”
2.1 Except as specifically set forth in this Amendment, the terms and conditions of the Agreement (including all exhibits thereto) shall remain unchanged and in full force and effect. Licensee and Harvard hereby agree to be bound by provisions substantially identical to Sections 11.5 through 11.17 of the Agreement with respect to this Amendment, mutatis mutandis (which are incorporated herein by reference as they so apply); provided that references to the Agreement provided in Section 11.5 shall be read to apply to the Agreement as amended by this Amendment.
IN WITNESS WHEREOF, the parties hereto have caused this Amendment No. 2 to be executed by their duly authorized representatives as of the Amendment No. 2 Effective Date.

President and Fellows of Harvard College

By: /s/ Isaac T. Kohlberg
Title: Senior Associate Provost
Chief Technology Development Officer
Office of Technology Development
Harvard University

Beam Therapeutics Inc.

By: /s/ John Evans
Title: CEO
First Amendment to License Agreement

This First Amendment ("Amendment"), effective as of September 4, 2018, is entered into by and between Blink Therapeutics Inc., a corporation existing under the laws of the State of Delaware, having a place of business at 325 Vassar St., Suite 2A, Cambridge, Massachusetts 02139 ("Licensee"), and the Broad Institute, Inc., a non-profit corporation existing under the laws of Massachusetts, having a place of business at 415 Main Street, Cambridge, MA 02142 ("Broad").

WHEREAS, Licensee and Broad have entered into that certain License Agreement dated May 9, 2018 (the "Agreement");

WHEREAS, Licensee and Broad desire to amend the Agreement to include an additional patent case as a incorporate (a) certain provisions applicable only to the TIDE Research Project and (b) one generally applicable provision as set forth herein.

NOW THEREFORE, for valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereby agree as follows:

Capitalized terms used but not defined herein shall have the meaning given to them in the Agreement.

1. Amendment to Exhibit 1.117 (Patent Rights). Exhibit 1.117 (Patent Rights) of the Agreement is hereby amended by adding the Patent Right set forth on Exhibit A (the "Added Patent Right") to this Amendment as a DNA Cleaving Patent Right.

2. Expenses. Solely with respect to the Added Patent Right: Notwithstanding the first sentence of Section 6.3 (Expenses) of the Agreement, Licensee shall reimburse Broad for all **, documented, out-of-pocket expenses incurred by Broad [**] with respect to the Prosecution of the Added Patent Right, which Broad estimates as equal to [**], in seven (7) equal installments with the first installment due within on or before September 30, 2018 and each of the subsequent installments due before the end of each full Calendar Quarter thereafter (so that the second installment would be due on or before December 31, 2018).

3. No Other Modifications. Except as specifically set forth in this Amendment, the terms and conditions of the Agreement (including all exhibits thereto) shall remain in full force and effect. Licensee and Broad hereby agree to be bound by provisions substantially identical to Article 11 with respect to this Amendment, mutatis mutandis (which are incorporated herein by reference as they so apply); provided that references to the Agreement provided in Section 11.6 shall be read to apply to the Agreement as amended by this Amendment.

[Signatures Follow]
IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed by their duly authorized representatives as of the date first written above.

THE BROAD INSTITUTE, INC.  

By: /s/ Issi Rozen  
Name: Issi Rozen  
Title: Chief Business Officer  
The Broad Institute, Inc.

BLINK THERAPEUTICS INC.  

By: /s/ John Evans  
Name: John Evans  
Title: CEO
Exhibit A – Added Patent Right

[**]**
Re: Certain Agreements Related to that certain License Agreement between Beam and Editas

Ladies and Gentlemen:

As you are aware, Beam Therapeutics Inc. ("Beam") and Editas Medicine, Inc. ("Editas") entered into a License Agreement as of May 9, 2018 (as may be amended from time to time in accordance with its terms, the "Beam-Editas Agreement") under which Editas granted Beam a sublicense of some or all of the rights granted to Editas (a) by The Broad Institute, Inc. ("Broad") and President and Fellows of Harvard College ("Harvard") under the Amended and Restated Cas9-I License Agreement by and between Broad, Harvard and Editas dated as of December 16, 2016, as amended (as such may be amended from time to time in accordance with its terms, the “Cas9-I Agreement”), (b) by Broad under the Cas9-II License Agreement by and between Broad and Editas dated as of December 16, 2016 (as such may be amended from time to time in accordance with its terms, the “Cas9-II Agreement”) and (c) by Broad under the Cpf1 License Agreement by and between Broad and Editas dated as of December 16, 2016 (as such may be amended from time to time in accordance with its terms, the “Cpf1 License Agreement” and, collectively with the Cas9-I Agreement and Cas9-II Agreement, the “Editas In-Licenses”). Beam and Harvard are parties to that certain License Agreement dated as of June 27, 2017 (as such may be amended from time to time in accordance with its terms, the “Beam-Harvard Agreement”. An affiliate of Beam and Broad entered into a License Agreement as of May 9, 2018 (as such may be amended from time to time in accordance with its terms, the “Beam-Broad Agreement” and, together with the Beam-Harvard Agreement, the “Beam-Institution Agreements”). In consideration of the execution of the Beam-Editas Agreement and Beam’s agreement to exploit the technology to which it receives a sublicense under the Beam-Editas Agreement, Beam, Editas, Broad and Harvard (the “Parties” and each a “Party”) are entering into this letter agreement (the “Letter Agreement”) and, intending to be legally bound, hereby agree as follows:

__________________________________________________________________________________________________________________________
(1) **Right to Further Sublicense under Cas9-I Agreement.** Each of Broad and Harvard hereby agrees, pursuant to Section 2.5.2.6 of the Cas9-I Agreement, to the grant by Beam of further Sublicenses (as defined in the Cas9-I Agreement as of the date hereof) of the rights sublicensed to Beam pursuant to the Beam-Edistas Agreement, subject to the other conditions of the Cas9-I Agreement, provided, that Beam complies with all requirements of Section 2.5.2 of the Cas9-I Agreement as if Beam were Edistas and Beam’s sublicensee were a Sublicensee, including, without limitation, by (i) providing a fully-executed, unredacted copy of such sublicense to Edistas, Broad and Harvard promptly following execution of such sublicense, (ii) including a [*]**, (iii) including a provision that the sublicensee agrees to the obligations applicable to a Sublicensee under the Cas9-I Agreement, including all such obligations under Section 2.5.2 thereof, (iv) naming the Institutions (as defined in the Cas9-I Agreement) and Edistas as third party beneficiaries under any sublicense arrangement and (v) requiring Sublicensee to indemnify, defend and hold the Edistas Indemnity (as defined in the Beam-Edistas Agreement) and each of the Indemnity and HHMI Indemnity (each as defined in the Cas9-I Agreement) harmless, and carry insurance, under the same terms, as set forth in Article 9 of the Cas9-I Agreement and Article 8 of the Beam-Edistas Agreement.

(2) **Right to Further Sublicense under Other Edistas In-Licenses.** Broad hereby agrees, pursuant to Section 2.5.2.6 of the Cas9-II Agreement and Section 2.5.2.6 of the Cpf1 Agreement, to the grant by Beam of further Sublicenses (as defined in the Cas9-II Agreement or Cpf1 Agreement, as applicable) of the rights sublicensed to Beam pursuant to the Beam-Edistas Agreement, subject to the other conditions of the Cas9-II Agreement or Cpf1 Agreement, as applicable, provided, that Beam complies with all requirements of Section 2.5.2 of the Cas9-II or Cpf1 Agreement, as applicable, as if Beam were Edistas and Beam’s sublicensee were a Sublicensee, including, without limitation, by (i) providing a fully-executed, unredacted copy of such sublicense to Edistas and Broad promptly following execution of such sublicense, (ii) including a [*]**, (iii) including a provision that the sublicensee agrees to the obligations applicable to a Sublicensee under the Cas9-II Agreement or the Cpf1 Agreement, as applicable, as third party beneficiaries under any sublicense arrangement and (v) requiring Sublicensee to indemnify, defend and hold the Edistas Indemnity (as defined in the Cas9-II Agreement or the Cpf1 Agreement, as applicable) and the Edistas Indemnity harmless, and carry insurance, under the same terms, as set forth in Article 9 of the Cas9-II Agreement or the Cpf1 Agreement, as applicable, and Article 8 of the Beam-Edistas Agreement.

(3) **Sublicense/Sublicensee Clarification.** For the avoidance of doubt, with respect to an Edistas In-License and this Letter Agreement, as between the Institutions (as defined in such Edistas In-License) on the one hand and Edistas and Beam on the other, any third party to which Beam, pursuant to the Beam-Edistas Agreement, grants further sublicenses of the rights granted to Edistas under such Edistas In-License shall be considered a Sublicensee of Edistas and the agreements pursuant to which such further sublicenses are granted shall be considered Sublicenses of Edistas, in each case under such Edistas In-License(s) for all purposes thereunder. Solely as between Edistas and Beam, (i) Edistas and Beam may allocate responsibility therefor amongst Edistas and Beam and (ii) Edistas and Beam hereby agree that Beam shall assume full responsibility, and shall remain primarily liable, for causing the performance of all obligations of each Sublicensee to which it grants a sublicense in accordance with the terms of Section 2.4 of the Beam-Edistas Agreement. For avoidance of doubt, with respect to an Edistas In-License, any payments or other consideration paid or transferred to Beam by a sublicensee of Beam under a further sublicense of the rights granted to Edistas under such Edistas In-License shall not be considered Sublicense Income (as defined...
in such Editas In-License) for purposes of the applicable Editas In-License(s) or result in any amounts owed to Broad or Harvard by Beam or Editas under such Editas In-License solely as a result of such payment to Beam by a sublicensee of Beam. For further clarity, and notwithstanding the terms above, Editas’s obligations under the Editas In-Licenses to make payments to the Institutions in relation to any Sublicense Income (as defined in the applicable Editas In-License) received by Editas shall not be abrogated by any of the terms of this Letter Agreement, and the obligations of Beam under the Beam-Institution Agreements to make payments to any Institution in relation to any sublicense income derived under any sublicense of rights granted in any Beam-Institution Agreement shall not be abrogated by any of the terms of this Letter Agreement.

(4) Royalty Offsets Under Editas In-Licenses.

a. It is the intention of all the Parties to this Letter Agreement that the “anti-stacking” provision of each of the Editas In-Licenses will, in addition to permitting the offset of certain portions of third party royalties paid by Editas as described in the applicable Editas In-License against Royalties (as defined in the applicable Editas In-License) owed to Harvard and/or Broad, as applicable, permit the offset against such Royalties owed by Editas to the relevant licensor based on Net Sales (as defined in the applicable Editas In-License) of Beam or any of its controlled Affiliates (as defined in the Beam-Editas Agreement) of a portion of payments of third party royalties made by Beam to a third party (as outlined below) on net sales of Licensed Products or Enabled Products (each as defined in the applicable Editas In-License) for a license under or the use of patent rights held by such third party that Cover (as defined in the applicable Editas In-License) such Licensed Products or Enabled Products and that are [**] for the commercialization of such Licensed Products or Enabled Products. As a result of this ability to offset third party royalties paid by Beam against royalties owed by Editas under the Editas In-Licenses, the amount of royalties based on the Institutional Royalty Rate (as defined in the Beam-Editas Agreement) owed by Beam to Editas under the Beam-Editas Agreement may be reduced solely to the extent permitted pursuant to the terms of this Letter Agreement and, for purposes of clarity, in no event shall the amount of royalties based on the Institutional Royalty Rate be reduced to an amount less than what is owed by Editas to the Institutions under any of the Editas In-Licenses or to the General Hospital Corporation, d/b/a Massachusetts General Hospital (“MGH”) under any license agreement by and between Editas and MGH.

b. To effect such intention, with respect to each Editas In-License, Broad and, with respect to the Cas9-I Agreement, Harvard, hereby agree that, notwithstanding anything to the contrary in Section 4.5.2.2 of the Cas9-I Agreement and Section 4.4.2.2 of the Cpf1 Agreement, on a product-by-product basis and solely with respect to Licensed Products or Enabled Products sold by or on behalf of Beam or any of its controlled Affiliates (as defined in the Beam-Editas Agreement) and subject to clause c. below, any portion of payments of running royalties made by Beam or any of its controlled Affiliates (as defined in the Beam-Editas Agreement) to a third party other than Editas, Harvard or Broad (an “Other Party”) that would be, if paid by Editas, creditable against Royalties payable by Editas under such Editas In-License pursuant to Section 4.5.2.2 of the Cas9-I Agreement and Cas9-II Agreement and Section 4.4.2.2 of the Cpf1 Agreement, as the case may be, shall be deemed, under the relevant provisions of Editas In-License(s), as payments made by Editas for the purposes of determining the permitted offsets to
Royalties owed by Editas to the Institutions in connection with the Beam-Editas Agreement, subject to the limitations in Section 4.5.2 of the Cas9-I Agreement and the Cas9-II Agreement and Section 4.4.2 of the Cpf1 Agreement.

c. Notwithstanding the foregoing, or anything to the contrary in Section 4.4.4. of the Beam-Broad Agreement or Section 4.4.3 of the Beam-Harvard Agreement, where a portion of payments of running royalties made by Beam to an Other Party would be eligible for offset under more than one of the Beam-Editas Agreement, the Beam-Harvard Agreement or the Beam-Broad Agreement, the total offset that Beam may take under each such applicable agreement may not exceed the total of such amount eligible for offset under such applicable Other Party license (e.g., [**]% of such running royalties payable under such Other Party license) in the applicable reporting period, and shall be applied to the offset under all of the applicable Beam Institution Agreements and Beam-Editas Agreement, on a proportional basis based on the applicable royalty rate under each such agreement. For example, if a payment under an Other Party license was eligible for offset under the Beam-Editas Agreement and the Beam-Harvard Agreement, but not the Beam-Broad Agreement, and if the applicable royalty rate under the Beam-Editas Agreement was [**]% the applicable royalty rate under the Beam-Harvard Agreement of [**]%, such offset based on such eligible payments under the Beam-Editas Agreement shall be allocated double to what is allocated to the Beam-Harvard Agreement, and will not be allocated to the Beam-Broad Agreement.

d. Beam hereby agrees (i) that the Beam-Editas Agreement is excluded from the applicability of the royalty offset provisions under each of the Beam-Institution Agreements, and that any amounts due under the Beam-Editas Agreement are not eligible for offset of the royalties owed under either of the Beam-Institution Agreements; and (ii) that each of the Beam Institution Agreements are excluded from the applicability of the royalty offset provisions under each of the other Beam-Institution Agreements and the Beam-Editas Agreement.

(5) **Termination for Patent Challenge.** Each of Broad and Harvard hereby agree that, in the event of a Patent Challenge (as defined in the applicable Editas In-License(s) to which such is a party) by a sublicensee of Beam with respect to rights granted to Beam pursuant to the Beam-Editas Agreement, if Beam terminates its sublicense with such challenging sublicensee within [**] from the date of notice by Broad or Harvard, as applicable, to Editas and to Beam that Broad or Harvard, as applicable, intend to terminate the applicable Editas In-License or the rights sublicensed to Beam thereunder, either directly or indirectly (e.g. through the termination of the relevant Editas In-License), due to the relevant Patent Challenge, the Beam-Editas Agreement (or the rights sublicensed to Beam thereunder) and the Editas In-Licenses will no longer be subject to termination as a result of the relevant Patent Challenge.

(6) **Confidentiality.** The terms of this Letter Agreement shall be deemed the Confidential Information of each Party under the Editas In-Licenses to which such Party is party, if applicable. In addition, the terms of this Letter Agreement shall be deemed the Confidential Information of each of Editas and Beam under the Editas-Beam Agreement.

(7) **Amendment.** This Letter Agreement may not be amended without the written agreement of each Party.
Term. This Letter Agreement shall terminate in its entirety upon the termination or expiration of the Beam-Editas Agreement and in part with respect to a given Editas In-License or Beam-Institution Agreement upon the termination or expiration of such Editas In-License or Beam-Institution Agreement, provided that, any payment obligations of Beam that have accrued under Beam-Editas Agreement and this Letter Agreement as of the termination thereof and Sections 3 and 4 of this Letter Agreement hereof shall survive such termination.

Notices. Unless otherwise specifically provided, all notices required or permitted by this Letter Agreement shall be in writing and may be delivered personally, or may be sent by expedited delivery or certified mail, return receipt requested, to the Parties’ addresses set forth above, unless the Parties are subsequently notified of any change of address by a Party in writing. Any notice shall be deemed to have been received as follows: (a) by personal delivery or expedited delivery, upon receipt; (b) by certified mail, as evidenced by the return receipt.

Governing Law and Jurisdiction. This Letter Agreement shall be governed by, and construed in accordance with, the substantive laws of the Commonwealth of Massachusetts, without giving effect to any choice or conflict of law provision, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted. Any action, suit or other proceeding arising under or relating to this Agreement (a “Suit”) shall be brought in a court of competent jurisdiction in the Commonwealth of Massachusetts, and the Parties hereby consent to the sole jurisdiction of the state and federal courts sitting in the Commonwealth of Massachusetts. Each Party agrees not to raise any objection at any time to the laying or maintaining of the venue of any Suit in any of the specified courts, irrevocably waives any claim that Suit has been brought in any inconvenient forum and further irrevocably waives the right to object, with respect to any Suit, that such court does not have any jurisdiction over such Party. Notwithstanding the foregoing, each of Editas, Broad and Harvard, and any applicable Institution under an Editas In-License, may enforce their rights under any Sublicense, including under the Editas-Beam Agreement, in accordance with the terms of such Sublicense, and seek any preliminary equitable relief, in each case in any court of competent jurisdiction.

Binding Effect. This Letter Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors and permitted assigns.

Headings. Section and subsection headings are inserted for convenience of reference only and do not form a part of this Letter Agreement. The word “including” shall be read to have the non-limiting construction of the phrase “including, without limitation”).

Counterparts. The Parties may execute this Letter Agreement in two or more counterparts (including by .pdf electronic copy), each of which shall be deemed an original.

Assignment. This Letter Agreement may not be assigned by Beam, whether by operation of law or otherwise, without the consent of each of the other Parties except that Beam may assign or transfer this Letter Agreement without the consent of any Party to a party to which it has assigned the Editas-Beam Agreement, provided, that Beam shall remain liable for the performance by such assignee of all of Beam’s financial obligations hereunder. This Letter Agreement may not be assigned by Editas, whether by operation of law or otherwise, without the consent of the other Parties except that Editas may, and shall, assign or transfer this Letter Agreement to a party to which it has assigned both an Editas In-License in accordance with
the terms thereof and the Beam-Editas Agreement (to the extent it relates to the assigned Editas In-License). This Letter Agreement may not be assigned by Harvard or Broad except that (a) Harvard may, and shall, assign or transfer this Letter Agreement to a party to whom it has assigned the Cas9-1 Agreement and (b) Broad may, and shall, assign or transfer this Letter Agreement to a party to whom it has assigned an Editas In-License; provided that such assignment of this Letter Agreement shall solely be to the extent this Letter Agreement relates to the assigned Editas In-License. Any assignment of this Letter Agreement, in whole or in part, by a Party shall be promptly notified by the assigning Party to the other Parties. Any assignee of this Letter Agreement shall agree in writing to be bound by the terms of this Letter Agreement. Any attempted assignment in contravention of this Section 14 shall be null and void.

(15) **Severability.** If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the Parties that the remainder of this Letter Agreement shall not be affected.

(16) **Agreement.** To indicate your agreement with the foregoing, please execute and return a signed copy of this Letter Agreement whereupon this Letter Agreement shall be effective as of the date first written above.
Regards,

BEAM THERAPEUTICS INC.

By: /s/ John Evans
Title: CEO

Agreed and Acknowledged by:

THE BROAD INSTITUTE, INC.

By: /s/ Issi Rozen
Title: Chief Business Officer
       The Broad Institute, Inc.

Agreed and Acknowledged by:

PRESIDENT AND FELLOWS OF HARVARD COLLEGE

By: /s/ Isaac T. Kolberg
Name: Isaac T. Kolberg
Title: Senior Associate Provost, Chief Technology Development Officer
       Office of Technology Development
       Harvard University

EDITAS MEDICINE, INC.

By: /s/ Andrew Hack
Name: Andrew Hack
Title: CFO
January 7, 2021

Office of Technology Development
Harvard University
Richard A. and Susan F. Smith Campus Center,
Suite 727
1350 Massachusetts Avenue
Cambridge, Massachusetts 02138
Facsimile: [**]
Attn: Chief Technology Development Officer

The Broad Institute, Inc.
415 Main Street
Cambridge, MA 02142
Attn: Chief Business Officer

Re: Third Amendment to Beam-Harvard Agreement; Second Amendment to Beam-Broad Agreement; Other Agreements

Ladies and Gentlemen:

As you are aware, (i) Beam Therapeutics Inc. (“Beam”) and President and Fellows of Harvard College (“Harvard”) are parties to the License Agreement dated as of June 27, 2017 and amended by Amendment No. 1 to License Agreement dated as of December 12, 2017, and Amendment No. 2 to License Agreement dated as of March 27, 2020 (as may be further amended from time to time in accordance with its terms, the “Beam-Harvard Agreement”), and (ii) a wholly-owned subsidiary of Beam and The Broad Institute, Inc. (“Broad”, together with Harvard, the “Institutions”) are parties to the License Agreement dated as of May 9, 2018 and amended under the First Amendment to License Agreement between such Beam subsidiary and Broad effective as of September 4, 2018, as may be further amended from time to time in accordance with its terms (the “Beam-Broad Agreement” and, collectively with the Beam-Harvard Agreement, the “Beam-Institution Agreements”), and (iii) Beam, Editas Medicine, Inc. (“Editas”), Harvard and Broad are parties to the letter agreement dated September 26, 2018 (the “Four-Party Letter Agreement”).

To facilitate, and in consideration of, Beam’s continued agreement to exploit the technology under which it receives a license under the Beam-Institution Agreements in accordance with the terms of the respective Beam-Institution Agreement, Beam, Harvard and Broad (the “Parties” and each, a “Party”) are entering into this letter agreement (the “Letter Agreement”) and, intending to be legally bound, hereby agree as follows:

1) Section 4.4.3 of the Beam-Harvard Agreement shall be amended and restated as follows:

“Third Party Royalty Set-Off. If Licensee, its Affiliates or a Sublicensee obtains a license from a third party after arm’s length negotiations to patent application(s) and/or patent(s) that Licensee, its Affiliates or a Sublicensee believes in good faith Cover a Licensed Product, then Licensee may offset [**] percent ([**]% of any running royalty payments due under such third-party license with respect to such patent application(s) and/or patent(s) with respect to sales of Licensed Products against the royalty payments that are due to Harvard with respect to Net Sales of such Licensed Products in such country; provided
that (a) in no event shall the royalty payments to Harvard with respect to such Licensed Products be reduced by more than [**] percent ([**]%) of the amount otherwise due, (b) with respect to royalties paid to the third party solely on the basis of claims of pending patent applications of the third party (and no issued patent claim of the third party covers the applicable Licensed Product), such amounts shall only be offsettable in accordance with the foregoing in this Section 4.4.3 if the Covering pending claim of the third party's pending application would meet the definition of Valid Claim set forth in this Agreement were such pending claim within the Patent Rights as of the Effective Date, and (c) the royalty offset provided in this Section 4.4.3 may be applied to any combination product for which an adjustment to Net Sales has been made in accordance with Section 4.4.5, but to avoid doubt only as relates to royalties on patent applications and patents that would apply in the absence of the Other Active Components (third party patent royalties due solely because of the presence of the Other Active Components shall not be offsettable against adjusted Net Sales of a Combination Product)."

2) Section 4.4.4 of the Beam-Broad Agreement shall be amended and restated as follows:

"Third Party Royalty Set-Off. On a Licensed Product-by-Licensed Product basis, if Licensee, an Affiliate of Licensee or a Sublicensee is legally required by a future court order, settlement agreement, contract, or other legally binding written commitment to make payments to a Third Party for a license under or the use of patent rights held by such Third Party that (i) Cover such Licensed Product in a country in the Territory and (ii) are necessary for the commercialization of such Licensed Product in a country in the Territory, then Licensee may offset [**] percent ([**]%) of any running royalty payments on net sales actually paid by Licensee, an Affiliate of Licensee or a Sublicensee to such Third Party under such third-party license with respect to such patent application(s) or patent(s) with respect to sales of Licensed Products against the running royalty payments that are due to Broad with respect to Net Sales of such Licensed Products in such country; provided that (a) in no event shall the running royalty payments to Broad with respect to such Licensed Products be reduced by more than [**] percent ([**]%) of the amount otherwise due under Section 4.4.1 (Rate for Licensed Products), as may be reduced by Section 4.4.3 (Royalty Term), and (b) with respect to royalties paid to the Third Party solely on the basis of claims of pending patent applications of the third party (and no issued patent claim of the third party covers the applicable Licensed Product), such amounts shall only be offsettable in accordance with the foregoing in this Section 4.4.4 (Third Party Royalty Set-Off) if the Covering pending claim of the third party’s pending application would meet the definition of Valid Claim set forth in this Agreement were such pending claim within the Patent Rights as of the Effective Date and (c) the royalty offset provided in this Section 4.4.4 (Third Party Royalty Set-Off) may be applied to any Combination Product for which an adjustment to Net Sales has been made in accordance with Section 4.4.7 (Combination Products), but to avoid doubt only as relates to royalties on patent applications and patents that would apply in the absence of the Other Active Components (third party patent royalties due because of the presence of the Other Active Components shall not be offsettable against adjusted Net Sales of a Combination Product)."

3) With respect to royalties payable for a Licensed Product (as such term is defined in the Beam-Broad Agreement) under the Beam-Broad Agreement, in the event that such Licensed Product is Covered by at least one Valid Claim of a Patent Right within each of (a) the DNA Cleaving Patent Rights (as such term is defined in the Beam-Broad Agreement), (b) the Base Editor Patent Rights (as such term is defined in the Beam-Harvard Agreement) (c) the CRISPR Patent Rights (as such term is defined in the Cas9-I Agreement), then the royalty rate for such Licensed Product set forth in Section 4.4.1 of the Beam-Broad Agreement shall be reduced from [**] percent ([**]%) of Net Sales of such Licensed Product to a rate of [**] percent ([**]%) of Net Sales of such Licensed Product, calculated in accordance with and subject to the remainder of Section 4.4 of the Beam-Broad Agreement.
The Parties acknowledge and agree that (a) Harvard and Broad are parties to the Amended and Restated Cas9-I License Agreement by and between Broad, Harvard and Editas dated as of December 16, 2016 (as such may have been or may be amended from time to time in accordance with its terms, the “Cas9-I Agreement”) and (b) Broad is a party to the Cas9-II License Agreement by and between Broad and Editas dated as of December 16, 2016 (as such may have been or may be amended from time to time in accordance with its terms, the “Cas9-II Agreement” and, collectively with the Cas9-I Agreement, the “Cas9 Agreements”) and, pursuant to that certain License Agreement, dated as of May 9, 2018, by and between Beam and Editas (as such may have been or may be amended from time to time in accordance with its terms, the “Beam-Editas Agreement”), Beam is a Sublicensee (as defined in the Cas9 Agreements) under the Cas9 Agreements. Notwithstanding anything to the contrary in the Cas9 Agreements or the Four-Party Letter Agreement, the Institutions hereby agree to the following with respect to amounts payable to the Institutions under the Cas9 Agreements as a result of the exercise of Beam’s rights as a Sublicensee thereunder pursuant to the Beam-Editas Agreement:

a. In the event that to the extent Beam, its Affiliates (as defined in the Beam-Editas Agreement), or any of its or their licensees or sublicensees is the party that achieves the Milestone Event triggering such Milestone Payment under the Cas9-I Agreement or Cas9-II Agreement. Harvard and Broad hereby expressly , pursuant to Section 11.12 of the Cas9-I Agreement, and Broad hereby expressly , pursuant Section 11.12 of the Cas9-II Agreement, to any such Milestone Payment under the Cas9-I Agreement or Cas9-II Agreement.

b. Running royalties actually paid by Beam, its Affiliates (as defined in the Beam-Editas Agreement), or any of its or their licensees or sublicensees to third parties other than Editas, Harvard or Broad (“Other Parties”) on net sales of Licensed Products or Enabled Products for a license under or the use of patent rights held by such other Party that Cover such Licensed Products or Enabled Products shall be of Beam, its Affiliates (as defined in the Beam-Editas Agreement), licensees or sublicensees and otherwise treated in the same manner as amounts actually paid by Beam as , and subject to the restrictions in , for purposes of determining the to the Institutions under the Cas9 Agreements. Each of Harvard and Broad hereby acknowledges that, under the Cas9 Agreements and the Beam-Editas Agreement, it does not have the right to receive any amounts of royalties on Net Sales in excess of those that would be owed by Beam , as applicable, pursuant to the Cas9 Agreements and the Beam-Editas Agreement, , either from Beam , as a result of the Net Sales of Beam, its Affiliates (as defined in the Beam-Editas Agreement), licensees or sublicensees.

For clarity, and notwithstanding anything in this Letter Agreement to the contrary, as between and among the Beam-Editas Agreement and the Beam-Institution Agreements, and the in each of the Beam-Institution Agreements, remains as provided in the applicable agreement and in all cases subject to the restrictions and limitations of the Four-Party Letter Agreement.

For the purposes of this paragraph 4, the definitions of “Milestone Payment”, “Milestone Event”, “Net Sales,” “Licensed Product”, “Enabled Product” and shall have the definitions set forth in the Cas9-I Agreement or Cas9-II Agreement, as applicable. The Parties agree that the intent of this paragraph 4 is to to Harvard and/or Broad, as applicable, under the Cas9-I Agreement or Cas9-II Agreement. The Parties acknowledge and agree that .

5) Confidentiality. The terms of this Letter Agreement shall be deemed the Confidential Information of each of Beam and Harvard under the Beam-Harvard Agreement and each of Beam and Broad under the Beam-Broad Agreement.
6) **Amendment.** This Letter Agreement may not be amended without the written agreement of each Party.

7) **Term.** This Letter Agreement shall terminate in its entirety upon the mutual agreement of the Parties; **provided** that any amendment to the Beam-Harvard Agreement effected by this Letter Agreement shall terminate upon the termination or expiration of the Beam-Harvard Agreement and any amendment to the Beam-Broad Agreement effected by this Letter Agreement shall terminate upon the termination or expiration of the Beam-Broad Agreement.

8) **Notices.** Unless otherwise specifically provided, all notices required or permitted by this Letter Agreement shall be delivered pursuant to Section 11.6 of the Beam-Harvard Agreement or 11.7 of the Beam-Broad Agreement, as applicable.

9) **Governing Law and Jurisdiction.** This Letter Agreement shall be governed by, and construed in accordance with, the substantive laws of the Commonwealth of Massachusetts, without giving effect to any choice or conflict of law provision, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted. Any action, suit or other proceeding arising under or relating to this Agreement (a "Suit") shall be brought in a court of competent jurisdiction in the Commonwealth of Massachusetts, and the Parties hereby consent to the sole jurisdiction of the state and federal courts sitting in the Commonwealth of Massachusetts. Each Party agrees not to raise any objection at any time to the laying or maintaining of the venue of any Suit in any of the specified courts, irrevocably waives any claim that Suit has been brought in any inconvenient forum and further irrevocably waives the right to object, with respect to any Suit, that such court does not have any jurisdiction over such Party. Notwithstanding the foregoing, each of Harvard and Broad may enforce their rights under their respective Beam-Institution Agreements in accordance with the terms of such Beam-Institution Agreement, and seek any preliminary equitable relief, in each case in any court of competent jurisdiction.

10) **Binding Effect.** This Letter Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors and permitted assigns.

11) **Headings.** Section and subsection headings are inserted for convenience of reference only and do not form a part of this Letter Agreement. The word “including” shall be read to have the non-limiting construction of the phrase “including, without limitation” and the term “or” will be interpreted in the inclusive sense commonly associated with the term “and/or”.

12) **Counterparts.** The Parties may execute this Letter Agreement in two or more counterparts (including by .pdf electronic copy), each of which shall be deemed an original.

13) **Assignment.** This Letter Agreement may not be assigned by Beam, whether by operation of law or otherwise, without the consent of the Institutions except that Beam may assign or transfer this Letter Agreement without the consent of the Institutions to a party to which it has validly assigned the Beam-Institution Agreements. This Letter Agreement may not be assigned by an Institution except that each Institution may, and shall, assign or transfer this Letter Agreement to a party to whom it has assigned the applicable Beam-Institution Agreement, Cas9-I Agreement or Cas9-II Agreement; **provided** that such assignment of this Letter Agreement shall solely be to the extent this Letter Agreement relates to the assigned agreement. Any assignment of this Letter Agreement, in whole or in part, by a Party shall be promptly notified by the assigning Party to the other Parties. Any assignee of this Letter Agreement shall agree in writing to be bound by the terms of this Letter Agreement. Any attempted assignment in contravention of this paragraph 13 shall be null and void.
14) **Severability.** If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the Parties that the remainder of this Letter Agreement shall not be affected.

15) **Ratification.** Except as specifically set forth in this Letter Agreement, the terms and conditions of each of the Beam-Institution Agreements (including all exhibits thereto) shall remain in full force and effect.

16) **Agreement.** To indicate your agreement with the foregoing, please execute and return a signed copy of this Letter Agreement whereupon this Letter Agreement shall be effective as of the date first written above.
Regards,

BEAM THERAPEUTICS INC.

By:  /s/ John Evans  
Name:  John Evans  
Title:  CEO
Agreed and Acknowledged by:

PRESIDENT AND FELLOWS OF HARVARD COLLEGE

By: /s/ Isaac Kohlberg
Name: Isaac Kohlberg
Title: Senior Associate Provost, Chief Technology Development Officer

THE BROAD INSTITUTE, INC.

By: /s/ Issi Rozen
Name: Issi Rozen
Title: CBO
### Name:

### Number of Restricted Stock Units subject to Award: 

### Date of Grant: 

### Vesting Commencement Date: 

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**BEAM THERAPEUTICS INC.**

**2019 EQUITY INCENTIVE PLAN**

**RESTRICTED STOCK UNIT AWARD AGREEMENT**

This agreement (this “Agreement”) evidences an award (this “Award”) of restricted stock units granted by Beam Therapeutics Inc. (the “Company”) to the individual named above (the “Participant”), pursuant to and subject to the terms of the Beam Therapeutics Inc. 2019 Equity Incentive Plan (as from time to time amended and in effect, the “Plan”). Except as otherwise defined herein, all capitalized terms used herein have the same meaning as in the Plan.

1. **Grant of Restricted Stock Unit Award.** The Company grants to the Participant on the date set forth above (the “Date of Grant”) the number of restricted stock units (the “Restricted Stock Units”) set forth above giving the Participant the conditional right to receive, without payment and pursuant to and subject to the terms and conditions set forth in this Agreement and in the Plan, one share of Stock (a “Share”) with respect to each Restricted Stock Unit forming part of this Award, subject to adjustment pursuant to Section 7 of the Plan in respect of transactions occurring after the date hereof.

2. **Vesting; Cessation of Employment.**

   (a) **Vesting.** Unless earlier terminated, forfeited, relinquished or expired, the Restricted Stock Units will vest in [] substantially equal annual installments on each of the first [] anniversaries of the Vesting Commencement Date set forth above (with the number of Restricted Stock Units that vest on any date being rounded down to the nearest whole share and the Award becoming vested as to 100% of the Restricted Stock Units on the [] anniversary of the Vesting Commencement Date), subject to the Participant remaining in continuous Employment from the Date of Grant through such vesting date.

   (b) **Cessation of Employment.** If the Participant’s Employment ceases, except as expressly provided for in an employment agreement between the Participant and the Company that is in effect at the time of such termination, (i) the unvested portion of this Award will terminate and be immediately forfeited for no consideration, and (ii) the vested portion of this Award, if any, will terminate and be immediately forfeited for no consideration if the Participant’s Employment is terminated for Cause or occurs in circumstances that in the determination of the Administrator would have constituted grounds for the Participant’s Employment to be terminated for Cause (in each case, without regard to the lapsing of any required notice or cure periods in connection therewith).
3. **Delivery of Shares.** Subject to Section 4 below, the Company shall, as soon as practicable upon the vesting of any portion of this Award (but in no event later than thirty (30) days following the date on which such Restricted Stock Units vest), effect delivery of the Shares with respect to such vested Restricted Stock Units to the Participant (or, in the event of the Participant’s death, to the person to whom this Award has passed by will or the laws of descent and distribution). No Shares will be issued pursuant to this Award unless and until all legal requirements applicable to the issuance or transfer of such Shares have been complied with to the satisfaction of the Administrator.

4. **Forfeiture; Recovery of Compensation.** By accepting, or being deemed to have accepted, this Award, the Participant expressly acknowledges and agrees that his or her rights, and those of any permitted transferee, with respect to this Award, including the right to any Shares acquired under this Award or proceeds from the disposition thereof, are subject to Section 6(a)(5) of the Plan (including any successor provision). The Participant further agrees to be bound by the terms of any clawback or recoupment policy of the Company that applies to incentive compensation that includes Awards such as the Restricted Stock Units. Nothing in the preceding sentence will be construed as limiting the general application of Section 8 of this Agreement.

5. **Dividends; Other Rights.** This Award shall not bestow upon the Participant any equity interest or ownership in the Company or any subsidiary prior to the date on which the Company delivers Shares to the Participant. The Participant is not entitled to vote any Shares by reason of the granting of this Award or to receive or be credited with any dividends declared and payable on any Share prior to the date on which any such Share is delivered to the Participant hereunder. The Participant will have the rights of a shareholder only as to those Shares, if any, that are actually delivered under this Award.

6. **Nontransferability.** This Award may not be transferred except as expressly permitted under Section 6(a)(3) of the Plan.

7. **Taxes.**

   (a) The Participant acknowledges and agrees that the vesting or settlement of the Restricted Stock Units acquired hereunder may give rise to “wages” subject to withholding. No Shares will be delivered pursuant to this Award unless and until the Participant has remitted to the Company an amount sufficient to satisfy all taxes required to be withheld in connection with such vesting or settlement. The Participant authorizes the Company and its subsidiaries to withhold any amounts due in respect of any required tax withholdings or payments from any amounts otherwise owed to the Participant, but nothing in this sentence may be construed as relieving the Participant of any liability for satisfying his or her obligation under the preceding provisions of this Section 7.

   (b) By accepting this Award, the Participant hereby acknowledges and agrees that he or she shall be required to sell Shares issued on settlement of this Award and to allow the Agent (as defined below) to remit the cash proceeds of such sale to the
Company (“Sell to Cover”) to satisfy the statutory minimum amount of the withholding obligations relating to this Award (the “Withholding Obligation”).

(i) The Participant hereby irrevocably appoints E*Trade, or such other registered broker-dealer that is a member of the Financial Industry Regulatory Authority as the Company may select, as the Participant’s agent (the “Agent”), and the Participant authorizes and directs the Agent to (A) sell on the open market at the then-prevailing market price(s), on the Participant’s behalf, as soon as practicable on or after the date on which the Shares are delivered to the Participant pursuant to Section 3 in connection with the vesting of the Restricted Stock Units, the number (rounded up to the nearest whole number) of Shares sufficient to cover (x) the satisfaction of the Withholding Obligation arising from the vesting of the Restricted Stock Units and the related issuance and delivery of Shares to the Participant and (y) all applicable fees and commissions due, or required to be collected by, the Agent with respect thereto; (B) remit directly to the Company the proceeds from the sale of the Shares referred to in clause (A) above necessary to satisfy the Withholding Obligation; (C) retain the amount required to cover all applicable fees and commissions due to, or required to be collected by, the Agent, relating directly to the sale of the Shares referred to in clause (A) above; and (D) maintain any remaining funds from the sale of the Shares referred to in clause (A) above in the Participant’s account with the Agent. The Participant hereby authorizes the Company and the Agent to cooperate and communicate with one another to determine the number of Shares that must be sold to satisfy the Participant’s obligations hereunder and to otherwise effect the purpose and intent of this Agreement and satisfy the rights and obligations hereunder.

(ii) The Participant acknowledges that the Agent is under no obligation to arrange for the sale of Shares at any particular price under a Sell to Cover and that the Agent may affect sales under any Sell to Cover in one or more sales and that the average price for executions resulting from bunched orders may be assigned to the Participant’s account. The Participant further acknowledges that he or she will be responsible for all brokerage fees and other costs of sale associated with any Sell to Cover or transaction contemplated by this Section 7 and agrees to indemnify and hold the Company harmless from any losses, costs, damages, or expenses relating to any such sale. In addition, the Participant acknowledges that it may not be possible to sell Shares as provided for in this Section 7 due to various circumstances. If it is not possible to sell Shares in a Sell to Cover, the Company will assist the Participant in determining alternatives available to the Participant. In the event of the Agent’s inability to sell Shares, the Company will continue to be responsible for the timely payment to the Company of all federal, state, local and foreign taxes that are required by applicable laws and regulations to be paid or withheld with respect to the Restricted Stock Units or this Award. In such event, or in
the event that the Company determines that the cash proceeds from a Sell to Cover are insufficient to meet the Withholding Obligation, the Participant authorizes the Company and its subsidiaries to withhold such amounts from any amounts otherwise owed to the Participant, but nothing in this sentence shall be construed as relieving the Participant of any liability for satisfying his or her obligations under the preceding provisions of this Section 7.

(iii) The Participant hereby agrees to execute and deliver to the Agent or the Company any other agreements or documents as the Agent or the Company reasonably deem necessary or appropriate to carry out the purposes and intent of this Agreement, including without limitation, any agreement intended to ensure the Sell to Cover and the corresponding authorization and instruction to the Agent set forth in this Section 7 to sell Common Stock to satisfy the Withholding Obligation comply with the requirements of Rule 10b5-1(c) under the Exchange Act. The Agent is a third-party beneficiary of this Section 7.

(iv) The Participant acknowledges that, unless otherwise determined by the Administrator, an order to Sell to Cover to satisfy the Withholding Obligation will be placed automatically and that it is mandatory, binding, irrevocable and non-discretionary on the part of the Participant. Upon acceptance of this Award, the Participant has elected to Sell to Cover to satisfy the Withholding Obligation, and the Participant acknowledges that he or she may not change this election at any time in the future.

(c) This Award is intended to be exempt from Section 409A of the Code as a short-term deferral thereunder and shall be construed and administered in accordance with that intent. Notwithstanding the foregoing, in no event will the Company have any liability relating to the failure or alleged failure of any payment or benefit under this Agreement to comply with, or be exempt from, the requirements of Section 409A.

8. Provisions of the Plan. This Agreement is subject in its entirety to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the Date of Grant has been made available to the Participant. By accepting, or being deemed to have accepted, this Award, the Participant agrees to be bound by the terms of the Plan and this Agreement. In the event of any conflict between the terms of this Agreement and the Plan, the terms of the Plan will control.

9. Acknowledgements. The Participant acknowledges and agrees that (i) this Agreement may be executed in two or more counterparts, each of which will be an original and all of which together will constitute one and the same instrument, (ii) this Agreement may be executed and exchanged using facsimile, portable document format (PDF) or electronic signature, which, in each case, will constitute an original signature for all purposes hereunder, and (iii) such signature by the Company will be binding against the Company. THE PARTICIPANT WILL BE DEEMED TO HAVE ACCEPTED THE TERMS AND
CONDITIONS OF THIS AGREEMENT UNLESS THE PARTICIPANT LOGS ON TO THE COMPANY’S ADMINISTRATIVE AGENT’S WEBSITE FOR THE PLAN WITHIN NINETY (90) DAYS FOLLOWING THE GRANT DATE AND AFFIRMATIVELY REJECTS THIS AWARD.

[Signature page follows.]
The Company, by its duly authorized officer, and the Participant have executed this Agreement as of the Date of Grant.

BEAM THERAPEUTICS INC.

By: ______________________________

Name: ______________________________

Title: ______________________________

Agreed and Accepted:

By ______________________________

[Participant’s Name]
This agreement (this “Agreement”), is made effective as of [  ], 2020 (the “Date of Grant”), by and between Beam Therapeutics Inc. (the “Company”) and [] (the “Participant”). Except as otherwise defined herein, all capitalized terms used herein have the same meaning as in the Beam Therapeutics Inc. 2019 Equity Incentive Plan (as from time to time amended and in effect, the “Plan”).

1. **Grant of the Award.** The Company hereby grants to the Participant an Award of [] shares of Restricted Stock, on the terms and conditions set forth in the Plan and this Agreement, subject to adjustment pursuant to Section 7 of the Plan in respect of transactions occurring after the date hereof.

2. **Vesting of the Restricted Stock.** The term “vest” as used herein with respect to any share of Restricted Stock means the lapsing of the restrictions described herein with respect to such share. The Restricted Stock shall vest as to [%] of the shares of Restricted Stock on [] and as to the remaining [%] of the shares in [] equal [] installments thereafter (with the number of shares of Restricted Stock that vest on any date being rounded down to the nearest whole share and the Award becoming vested as to 100% of the shares on []), subject, in each case, to the Participant’s continued Employment through the applicable vesting date. At any time, any portion of the Restricted Stock that is not vested is hereinafter referred to as the “Unvested Portion”.

3. **Cessation of Employment.** If the Participant’s Employment ceases, any Unvested Portion of the Restricted Stock will be forfeited automatically without consideration.

4. **Forfeiture; Recovery of Compensation.** By accepting, or being deemed to have accepted, the Restricted Stock, the Participant expressly acknowledges and agrees that his or her rights, and those of any permitted transferee, with respect to the Restricted Stock, including the right to any proceeds from the disposition of any shares of Stock acquired hereunder, are subject to Section 6(a)(5) of the Plan (including any successor provision). The Participant further agrees to be bound by the terms of any clawback or recoupment policy of the Company that applies to incentive compensation that includes Awards such as the Restricted Stock. Nothing in the preceding sentence will be construed as limiting the general application of Section 8 of this Agreement.

5. **No Right to Continued Employment.** The granting of the Restricted Stock shall impose no obligation on the Company or any of its subsidiaries to continue the Employment of the Participant and shall not lessen or affect any right that the Company or any subsidiary may have to terminate the Employment of the Participant.

6. **Tax Matters.**
   a. As a condition to the granting of the Restricted Stock and the vesting thereof, the Participant acknowledges and agrees that he or she is responsible for the payment of all income and employment taxes (and any other taxes required to be withheld) payable in connection with
the grant or vesting of, or otherwise in connection with, the Restricted Stock. The Company shall have the power and the right to require the Participant to remit to the Company (including through the delivery of irrevocable instructions to a broker to sell shares of Restricted Stock that have vested pursuant to this Agreement and to deliver promptly to the Company an amount out of the proceeds of such sale equal to an amount as determined by the Company, consistent with the terms of the Plan), such amount as is determined by the Company, consistent with the terms of the Plan, to satisfy all applicable federal, state, and local taxes required by law or regulation to be withheld with respect to any taxable event arising as a result of this Agreement. The Participant authorizes the Company and its Subsidiaries to withhold such amounts due hereunder from any payments otherwise owed to the Participant, but nothing in this sentence shall be construed as relieving the Participant of any liability for satisfying his or her obligation under the preceding provisions of this Section 6(a).

b. Unless the Company notifies the Participant in writing before a vesting date hereunder, the Participant shall be deemed to have forfeited to the Company that number of shares of Stock vesting on such date having a Fair Market Value equal to the amount of the minimum statutory withholding tax obligations with respect to the Restricted Stock that so vests in order to satisfy his or her tax obligations hereunder.

c. **Dividends.** The Restricted Stock shall have such rights with respect to dividends declared by the Company as are carried by other shares of Stock, provided that any dividends payable with respect to the Unvested Portion shall be subject to the same vesting conditions as the underlying shares of Restricted Stock and shall only be paid if, when and to the extent such underlying shares vest. The foregoing shall not prohibit or otherwise limit the adjustment of the terms of this Agreement in accordance with the terms of the Plan.

7. **Restrictions on Transfer.** Except as expressly permitted under Section 6(a)(3) of the Plan, the shares of Restricted Stock may not be transferred until they have vested in accordance with the terms of this Agreement.

8. **Provisions of the Plan.** This Agreement is subject in its entirety to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the Date of Grant has been made available to the Participant. By accepting, or being deemed to have accepted, the Restricted Stock, the Participant agrees to be bound by the terms of the Plan and this Agreement. In the event of any conflict between the terms of this Agreement and the Plan, the terms of the Plan will control.

9. **Acknowledgements.** The Participant acknowledges and agrees that (i) this Agreement may be executed in two or more counterparts, each of which will be an original and all of which together will constitute one and the same instrument, (ii) this Agreement may be executed and exchanged using facsimile, portable document format (PDF) or electronic signature, which, in each case, will constitute an original signature for all purposes hereunder, and (iii) such signature by the Company will be binding against the Company and will create a legally binding agreement when this Agreement is countersigned by the Participant.

[Signature page follows.]
The Company, by its duly authorized officer, and the Participant have executed this Agreement as of the Date of Grant.

BEAM THERAPEUTICS INC.

By: ________________________________

Name: ______________________________

Title: _______________________________

Agreed and Accepted:

By ________________________________

[]
Effective as of the date set forth above, each individual who provides services to Beam Therapeutics Inc. (the “Company”) as a director, other than a director who is employed by the Company or a subsidiary or a director who is affiliated with ARCH Venture Partners or F-Prime Capital (a “Non-Employee Director”), shall be entitled to receive the following amounts of compensation, subject to the limitations on annual Non-Employee Director compensation set forth in the Company’s 2019 Equity Incentive Plan:

<table>
<thead>
<tr>
<th>Type of Compensation</th>
<th>Amount and Form of Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual cash fee</td>
<td>$40,000 ($70,000 for the chairman of the Board of Directors (the “Board”))</td>
</tr>
<tr>
<td>Additional annual cash fee for members of the Audit Committee</td>
<td>$7,500 ($15,000 for the Audit Committee chairman)</td>
</tr>
<tr>
<td>Additional annual cash fee for members of the Compensation Committee</td>
<td>$5,000 ($10,000 for the Compensation Committee chairman)</td>
</tr>
<tr>
<td>Additional annual cash fee for members of the Nominating and Corporate Governance Committee</td>
<td>$4,000 ($8,000 for the Nominating and Corporate Governance Committee chairman)</td>
</tr>
<tr>
<td>Equity compensation</td>
<td>Each Non-Employee Director who is first elected or appointed to the Board shall, upon his or her initial election or appointment to the Board, be granted an option to purchase shares of the Company’s common stock having a grant date fair value, determined in accordance with FASB ASC Topic 718 (or any successor provision) (“ASC Topic 718”), approximately equal to $770,000 (the “Initial Option”), such option to vest as to one-third of the shares subject to the option on the first anniversary of the date of grant and in equal monthly installments as to the remainder of the shares for two years thereafter, subject to the Non-Employee Director’s continued service to the Board through each applicable vesting date. On the date of the first meeting of the Board following each annual meeting of stockholders of the Company, each Non-Employee Director who has been serving on the Board as a Non-Employee Director for at least three (3) months as of the date of such annual meeting shall be granted an option to purchase shares of the Company’s common stock having a grant date fair value, determined in accordance with ASC Topic 718, approximately equal to $385,000 (the “Annual Option”), such option to vest in full on the first anniversary of the date of grant, subject to the Non-Employee Director’s continued service to the Board through the applicable vesting date. Each option granted to any Non-Employee Director will have a per share exercise price equal to the fair market value of a share of the Company’s common stock on the date of grant, have a term of no more than ten (10) years and will be subject to the terms and conditions of the Company’s 2019 Equity Incentive Plan (or any successor plan).</td>
</tr>
</tbody>
</table>
All cash fees shall be payable in arrears on a quarterly basis or upon the earlier resignation or removal of the Non-Employee Director and shall be prorated for any calendar quarter of partial service, based on the number of calendar days the Non-Employee Director was a member of the Board.

In addition, Non-Employee Directors will be reimbursed by the Company for reasonable travel and other expenses incurred in connection with the Non-Employee Director’s attendance at Board and committee meetings, in accordance with the Company’s policies as in effect from time to time.

For the avoidance of doubt, directors who are employees of the Company or one of its subsidiaries and directors who are affiliated with ARCH Venture Partners or F-Prime Capital will not receive compensation for their service as a director, other than, with respect to directors who are so affiliated with an investor fund, reimbursement for reasonable travel and other expenses as described in the paragraph above.

The Board (or the compensation committee thereof) may amend this Non-Employee Director Compensation Policy at any time.
<table>
<thead>
<tr>
<th>Entity</th>
<th>State or other Jurisdiction of Incorporation or Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blink Therapeutics, Inc.</td>
<td>Delaware</td>
</tr>
<tr>
<td>Beam Therapeutics Securities Corporation</td>
<td>Massachusetts</td>
</tr>
<tr>
<td>Guide Therapeutics, LLC</td>
<td>Delaware</td>
</tr>
</tbody>
</table>
CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-236582 on Form S-8 of our report dated March 15, 2021, relating to the financial statements of Beam Therapeutics Inc. and subsidiaries appearing in this Annual Report on Form 10-K for the year ended December 31, 2020.

/s/ Deloitte & Touche LLP
Boston, Massachusetts
March 15, 2021
CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John Evans, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 15, 2021

By: /s/ John Evans

John Evans
Chief Executive Officer
(Principal executive officer)
CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Terry-Ann Burrell, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 15, 2021

By: /s/ Terry-Ann Burrell
Terry-Ann Burrell
Chief Financial Officer
(Principal financial and accounting officer)
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

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

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

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

Date: March 15, 2021

By: /s/ John Evans

John Evans
Chief Executive Officer
(Principal executive officer)
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

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

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

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

Date: March 15, 2021

By: /s/ Terry-Ann Burrell
Terry-Ann Burrell
Chief Financial Officer
(Principal financial and accounting officer)