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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2020

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number 001-37687

EDITAS MEDICINE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**46-4097528**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11 Hurley Street **Cambridge, Massachusetts**	**02141**
(Address of principal executive offices)	**(Zip Code)**

(617) 401-9000
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**EDIT**	**The Nasdaq Stock Market LLC**

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

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

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

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

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

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

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

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

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

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

As of June 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's Common Stock held by non-affiliates of the registrant was approximately $1,840,064,425 based upon the closing price of the registrant's Common Stock on June 30, 2020.

The number of shares of the registrant's Common Stock outstanding as of February 14, 2021 was 67,362,791.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2021 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A within 120 days of the end of the registrant's fiscal year ended December 31, 2020 are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

Editas Medicine, Inc.
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References to Editas

Throughout this Annual Report on Form 10-K, the "Company," "Editas," "Editas Medicine," "we," "us," and "our," except where the context requires otherwise, refer to Editas Medicine, Inc. and its consolidated subsidiary, and "our board of directors" refers to the board of directors of Editas Medicine, Inc.

Special Note Regarding Forward-Looking Statements and Industry Data

This Annual Report on Form 10-K contains forward-looking statements regarding, among other things, our future discovery and development efforts, our future operating results and financial position, our business strategy, and other objectives for our operations. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the section entitled "Risk Factors" in Part I that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make.

You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Annual Report on Form 10-K are made as of the date of this Annual Report on Form 10-K, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

This Annual Report on Form 10-K includes statistical and other industry and market data, which we obtained from our own internal estimates and research, as well as from industry and general publications and research, surveys, and studies conducted by third parties. Industry publications, studies, and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that each of these studies and publications is reliable, we have not independently verified market and industry data from third-party sources. While we believe our internal company research is reliable and the market definitions are appropriate, neither such research nor these definitions have been verified by any independent source.

Risk Factor Summary:

- *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, which may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.*
- *We have never generated revenue from product sales and may never be profitable.*
- *We intend to identify and develop product candidates based on a novel genome editing technology, which makes it difficult to predict the time and cost of product candidate development.*
- *Because genome editing is novel and the regulatory landscape that will govern any product candidates we 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 develop.*

- *Adverse public perception of genomic medicines, and genome editing in particular, may negatively impact regulatory approval of, or demand for, our potential products.*

- *The genome editing field is relatively new and is evolving rapidly. We are focusing our research and development efforts on CRISPR gene editing technology using Cas9 and Cas12a enzymes, but other genome editing technologies may be discovered that provide significant advantages over CRISPR/Cas9 or CRISPR/Cas12a.*

- *Except for EDIT-101 and EDIT-301, all of our product development programs are at the preclinical or research stage. Preclinical testing and clinical trials of product candidates may not be successful.*

- *If serious adverse events, undesirable side effects, or unexpected characteristics are identified during the development of any product candidates we develop, we may need to abandon or limit our further clinical development of those product candidates, and it may delay or prevent their regulatory approval, limit the commercial potential, or result in significant negative consequences following any potential marketing approval.*

- *We have not extensively tested any of our proposed delivery modes and product candidates in clinical trials.*

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

- *We face significant competition in an environment of rapid technological change, and our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours.*

- *Due to the novel nature of our technology and the potential for some of our product candidates 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.*

- *Genomic medicines are novel, and our product candidates may be complex and difficult to manufacture. We could experience production problems that result in delays in our development or commercialization programs, limit the supply of our products, or otherwise harm our business.*

- *We expect to depend on collaborations with third parties for the research, development, and commercialization of certain of the product candidates we develop, for development of certain of our research programs, and to conduct our clinical trials and some aspects of our research and preclinical testing.*

- *If we are unable to obtain and maintain patent protection for any products we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours.*

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

- *Some of our in-licensed patents are subject to priority and validity disputes. Our owned and in-licensed patents, patent applications and other intellectual property may be subject to further priority and validity disputes, and other similar intellectual property proceedings including inventorship disputes. 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 develop.*

- *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 of our product candidates.*

- *Our future success depends on our ability to attract and retain key executives and to attract, retain, and motivate qualified personnel.*

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

- *We do not expect to pay any dividends for the foreseeable future. Accordingly, stockholders must rely on capital appreciation, if any, for any return on their investments.*

PART I

Item 1. Business

We are a leading, clinical stage gene editing company dedicated to developing potentially transformative gene-editing medicines to treat a broad range of serious diseases. The promise of genomic medicines is supported by the advancing knowledge of the human genome and by harnessing the progress in technologies for cell therapy, gene therapy, and, most recently, gene editing. We believe this progress sets the stage for us to create medicines with the potential to have a durable benefit for patients. Our core capability in gene editing uses the technology known as CRISPR (clustered, regularly interspaced, short palindromic repeats) to allow us to create molecules that efficiently and specifically edit DNA. Our mission is to translate the promise of gene editing into a broad class of differentiated, transformational medicines for diseases with high unmet need.

We have developed a proprietary genome editing platform based on CRISPR technology and we continue to expand its capabilities. CRISPR uses a protein-RNA complex composed of an enzyme, including either Cas9 (CRISPR associated protein 9) or Cas12a (CRISPR from *Prevotella* and *Francisella* 1, also known as Cpf1), bound to a guide RNA molecule designed to recognize a particular DNA sequence. Once the complex binds to the DNA sequence it was designed to recognize, the complex makes a specific cut in the DNA. We believe we are the only human genome editing company with a platform that includes CRISPR/Cas9, CRISPR/Cas12a, and engineered forms of both of these CRISPR systems. Because of the broad nature of this platform, we believe we can create gene editing molecules for over 95% of the human genome.

Our Strategy

Our product development strategy is to target diseases of high unmet need where we aim to make differentiated, transformational medicines using our gene editing platform. We are advancing both *in vivo* gene-editing medicines, in which the medicine is injected or infused into the patient to edit the cells inside their body, and *ex vivo* gene-edited cell medicines, in which cells are edited with our technology and then administered to the patient. While our discovery efforts have ranged across several diseases and therapeutic areas, the two areas where our programs are more mature are our *in vivo* medicines to treat ocular diseases and *ex vivo* gene-edited cell medicines to treat hemoglobinopathies and cancer.

For our *in vivo* gene-editing medicines, we are leveraging an adeno-associated virus (“AAV”)-mediated editing platform with our proprietary *Staphylococcus aureus* Cas9 (“SaCas9”) to develop these medicines. In ocular diseases, our most advanced program is designed to address a specific genetic form of retinal degeneration called Leber congenital amaurosis 10 (“LCA10”), a disease that leads to blindness and for which we are not aware of any available therapies and only one other potential treatment is in clinical trials in the United States and Europe. In mid-2019, we initiated our Phase 1/2 BRILLIANCE clinical trial for EDIT-101, an experimental gene-editing medicine to treat LCA10. We plan to enroll up to 18 patients in the United States and Europe in up to five cohorts. We completed dosing of the first cohort, the adult low-dose cohort, in 2020. Due to an absence of severe adverse events or dose limited toxicity in adults treated in the first cohort, the inclusion criteria of the protocol was modified to allow inclusion of subjects with better than light perception vision only. Although we experienced slowed enrollment in 2020 for subsequent cohorts due to the ongoing impact of the COVID-19 pandemic, in the first quarter of 2021 we initiated dosing of the second cohort, the adult mid-dose cohort. We expect to announce initial clinical data in 2021.

We believe our preclinical results to date with EDIT-101 validate our platform technology, including its potential application to other ocular diseases, such as Usher syndrome 2A (“USH2A”), a form of retinitis pigmentosa that also includes hearing loss, and autosomal dominant retinitis pigmentosa 4 (“adRP4”), a progressive form of retinal degeneration characterized by initial night blindness early in life followed by loss of peripheral vision and eventual complete blindness, as well as diseases of other organs and tissues. In 2019, we achieved *in vivo* preclinical proof of concept and declared a development candidate, referred to as EDIT-102, for USH2A. We have also advanced preclinical studies for our adRP4 program, and expect to declare a development candidate for the treatment of adRP4 by the end of 2021.

We are leveraging our AAV-mediated editing platform and expertise in ocular therapies to pursue additional therapeutic areas to treat other organ and tissues that are accessible by AAV. For example, in 2019, we entered into a research collaboration with Asklepios BioPharmaceutical, Inc., a fully integrated AAV gene therapy company ("AskBio") that was acquired by Bayer AG in December 2020, to explore the use of our AAV-mediated editing platform to treat neurological diseases.

In addition to developing *in vivo* gene-editing medicines, the development of *ex vivo* gene-edited cell medicines is a core part of our research effort and product pipeline. We believe that advances in genome editing will both improve the characteristics of current cellular medicines and also expand the universe of cellular medicines that can be developed. To this end, we have established capabilities to efficiently and specifically edit hematopoietic stem cells ("HSCs"), natural killer ("NK") cells and T cells, which we believe can lead to best-in-class medicines for hemoglobinopathies and cancer.

For our *ex vivo* gene-edited cell medicines, our lead program is EDIT-301, an experimental medicine to treat sickle cell disease, a severe inherited blood disease that causes premature death, and beta-thalassemia, another inherited blood disorder characterized by severe anemia. In December 2020, we submitted an investigational new drug application ("IND") to the U.S. Food and Drug Administration ("FDA") for the initiation of a Phase 1/2 clinical trial of EDIT-301, which we refer to as our RUBY trial, for the treatment of sickle cell disease. In January 2021, the FDA cleared the start of enrollment and dosing of patients in the first phase of the study (which will validate the safety and beneficial effects of the cell editing process). Dosing of the first subject is expected to occur in 2021. In parallel, the FDA has imposed a partial clinical hold and requested we develop a potency assay to ensure that the characteristics of the product released are as expected and confirmed by clinical data collected in the first patients treated. We also aim to file an IND for EDIT-301 for the treatment of beta-thalassemia by the end of 2021. The CRISPR nuclease used in our EDIT-301 program is a proprietary engineered form of Cas12a for which we have exclusively licensed the foundational intellectual property to develop and commercialize human therapeutics. We believe our editing approach, including targeting the HBG1 and HBG2 promoters in the beta-globin locus where naturally occurring fetal hemoglobin inducing mutations reside ("HBG1/2") as well as the use of Cas12a, differentiates us from other genome editing companies with sickle cell disease programs and positions us to develop a potentially best-in-class medicine to treat sickle cell disease and beta-thalassemia.

We have also continued to develop our capabilities to generate cells from induced pluripotent stem cells ("iPSCs") to develop engineered cell medicines to treat cancer. For example, in 2019, we advanced development of engineered iPSC-derived NK ("iNK") cell medicines for solid tumors using technology from BlueRock Therapeutics LP ("BlueRock") and generated edited NK cells from iPSCs with significantly increased anti-cancer activity. We aim to accelerate the development of iNK cell medicines for the treatment of solid tumor cancers in 2021. We are also advancing alpha-beta T cell experimental medicines in collaboration with Juno Therapeutics, Inc., a wholly owned subsidiary of Bristol-Myers Squibb Company ("Juno Therapeutics"). For our allogeneic, off-the-shelf medicines, we edit cells from iPSCs that are subsequently differentiated into effector cells, such as NK cells or T cells. The engineered cells are then administered to the patient. We believe these approaches and expertise will allow us to develop allogeneic, off-the-shelf engineered cell medicines, as opposed to relying on obtaining cells directly from a patient. These allogeneic cell medicines have the potential to greatly reduce the costs and complexity of engineered cells and increase the number and type of cancers that we can potentially address.

Our Core Capability — Gene Editing

Gene editing is the process of revising, removing, or repairing defective DNA *in situ*. In general, gene editing corrects the defective DNA in its native genomic location, and consequently the repaired genetic region retains the cell's normal control and feedback mechanisms. Gene editing typically takes advantage of naturally occurring DNA repair mechanisms, including non-homologous end joining ("NHEJ") and homology directed repair ("HDR"), to achieve its desired therapeutic outcome. Edits that are repaired by NHEJ typically disrupt a gene or eliminate a disease-causing mutation. Edits that are repaired by HDR, including targeted insertion, aim to correct or replace aberrant DNA sequences. The diversity of genetic drivers of disease demands a variety of solutions. Gene editing has the potential to deliver a variety of types of genome modification to address a broad range of diseases.

CRISPR technology uses a protein-RNA complex composed of a type of enzyme, referred to as a DNA endonuclease, bound to an RNA molecule, referred to as a guide RNA, that has been designed to recognize a particular DNA sequence. A DNA endonuclease is an enzyme that cleaves DNA. This combination of a DNA endonuclease and a guide RNA only bind and cut DNA when two criteria are met: first, the protein recognizes a short DNA specific to the enzyme called the protospacer adjacent motif ("PAM"), and second, the appropriate portion of the guide RNA matches the adjacent DNA sequence. The PAM sequence that is recognized by the DNA endonuclease creates a second layer of recognition in addition to the guide RNA. We believe that CRISPR technology has three principal advantages for genome editing:

- *Rapid, comprehensive, and systematic identification of product candidates.* The key targeting mechanism for the endonuclease, whether it is Cas9 or Cas12a, is a guide RNA, which can be rapidly replaced with a different guide RNA or optimized by changes as small as a single nucleotide. This allows for the flexible design, synthesis, and testing of hundreds of guide RNA/endonuclease combinations for each genetic target in order to find those that cut the DNA target with the optimal efficiency and specificity. In contrast, other commonly used DNA nucleases for gene editing have inherently limited flexibility. For example, zinc finger nucleases, engineered meganucleases, and transcription activator-like effector nucleases use proteins for DNA sequence recognition to bring the endonuclease to the site of the genome where cleavage is desired, requiring the creation of an entirely new protein for each target site.

- *Simultaneous and efficient targeting of multiple sites.* In CRISPR technology, multiple guide RNAs can be provided along with the same endonuclease, enabling the simultaneous and efficient targeting of multiple sites. This ability to target multiple DNA sequences expands the applicability of CRISPR technology and also creates the potential for self-regulating systems that control exposure to the editing machinery. To address more than one target, other gene editing technologies require the engineering, characterization, manufacture, and delivery of distinct nuclease proteins for each target.

- *Ability to achieve a range of different types of edits.* The inherent differences in Cas9 and Cas12a and the availability of different engineered variants of both enzymes allow for different types of cuts for gene editing. We are able to make a blunt cut, cut either strand of the DNA, or create overhangs of differing length. This may be a critical component of improved HDR-driven approaches because the type of DNA cut can influence the type of repair mechanism used by a cell in response to that cut. We believe the ability to modify CRISPR technology to allow for different types of cuts will expand the potential of our gene editing platform.

Our Gene Editing Platform

We have developed a proprietary gene-editing platform that includes different natural and engineered variants of Cas9 and Cas12a. We have characterized different Cas9 and Cas12a enzymes for several reasons. Firstly, a lower molecular weight enzyme will have advantages for delivering the endonuclease using a viral vector due to the inherent size limitations of most such delivery systems. For example, the Cas9 enzyme from *Staphylococcus aureus* ("*S. aureus*" or "SaCas9") is significantly smaller than that from *Streptococcus pyogenes* ("*S. pyogenes*" or "SpCas9") (3,159 vs. 4,104 base pairs), and this decreased size is important when working with AAV as a delivery vector, which has an effective packaging limit of approximately 4,700 base pairs. Secondly, we have gained access to modified versions of Cas12a and Cas12a guide RNAs that increase Cas12a activity. This increased activity may allow us to use Cas12a editing in more indications where editing at a Cas12a susceptible site is desirable from a biological perspective but technically difficult with the wild-type Cas12a editing system. EDIT-301 for sickle cell disease and beta-thalassemia is one such example. Thirdly, identifying Cas9 and Cas12a enzymes with different editing properties will expand the number of potential editing sites in the human genome. The range of natural and engineered variants of Cas9 and Cas12a have significantly expanded the number of sites in the human genome that we can potentially target. As compared to the most commonly used, naturally occurring version of Cas9, from the bacterial species *S. pyogenes*, the range of endonucleases in our platform can target approximately ten times as many genomic sites. Thus, while the *S. pyogenes* Cas9 can target approximately 1 in 10 bases in the human genome, we have the potential to hit over 95% of all bases due to the wide range of endonucleases at our disposal.

The guide RNA molecule is another component of our gene editing platform. We have made substantial advances in the design, synthesis, modification, analysis, and characterization of guide RNAs. For example, in order to accelerate and standardize the selection of guide RNAs, we have created proprietary analytical software that supports guide RNA design through single nucleotide polymorphism analysis, specificity prediction, and assessment of relative importance of potential off target sites.

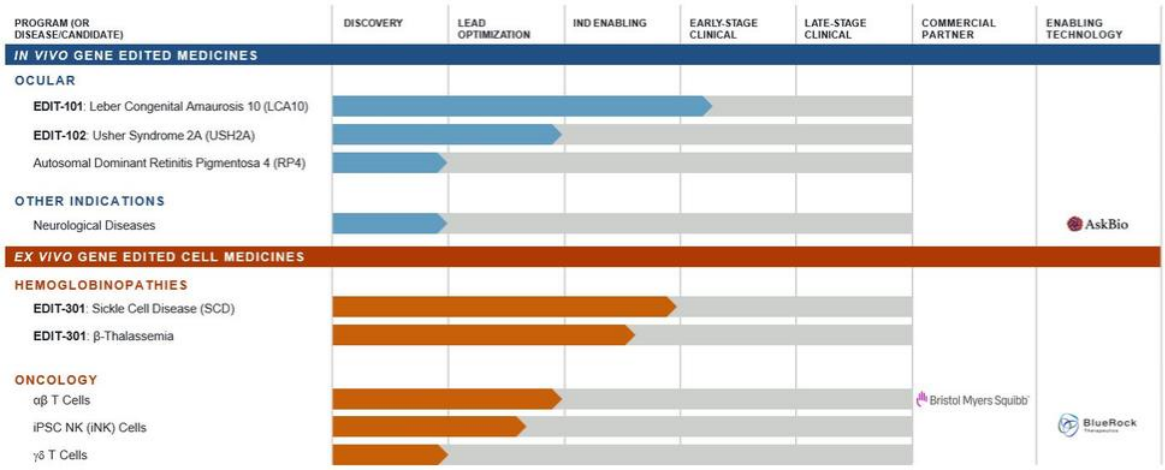
Of critical importance in determining the activity and specificity of an endonuclease-guide RNA complex is understanding the quality and composition of the guide RNA. The ability to understand the quality and composition of the guide RNA is an essential component to developing product candidates that have the potential to be safe and efficacious medicines. In addition to state-of-the-art mass spectrometry and sequencing methodologies to understand the absolute composition of our guide RNAs, we have developed two-step synthesis methods which results in guide RNAs which we believe are significantly superior to those generated by other approaches. This method allows us to independently synthesize and purify guide RNAs in multiple parts and covalently couple them using a proprietary catalyst-free chemistry. These covalently coupled, dual-guide RNAs retain the advantages afforded by a single guide RNA and we believe are of higher quality than a guide RNA made by a single synthesis reaction. We believe this method will lead to higher quality gene editing medicines.

Our gene editing platform includes multiple modular delivery modes that can be efficiently adapted to deliver different CRISPR gene editing components to address the specific needs of each disease targeted. Our strategy is to leverage existing delivery technologies to target cell types of interest while developing next generation capabilities as warranted. We are currently using, and will continue to use, a variety of delivery approaches, including AAVs and electroporation. For example, we have taken advantage of the smaller *S. aureus* Cas9 and existing AAV technology to construct an “all-in-one” viral vector that is able to deliver the DNA coding for the nuclease protein and one or two guide RNAs directly to cells. We believe our ability to configure all the components for gene editing in an “all-in-one” AAV vector has substantial advantages for manufacturing and delivery compared to approaches that rely on multiple vectors. In addition, we have also made substantial advances in the *ex vivo* delivery of CRISPR systems to a number of cell types. We have been able to demonstrate greater than 90% *ex vivo* editing on multiple genetic targets simultaneously in human T cells and greater than 90% *ex vivo* editing in hematopoietic stem cells using ribonucleoprotein complexes, which consist of the Cas9 or Cas12a endonuclease complexed with its guide RNA. These results are consistent across multiple cell donors and multiple target genes.

To optimize the specificity of our product candidates, there are a number of different aspects of the product configuration that we customize in addition to the sequence and quality of the guide RNA, including the length of the guide RNA, the type of Cas9 or Cas12a enzyme, including engineered forms, the delivery vector, the use of tissue-selective promoters, and the duration of exposure all contribute to overall specificity. For example, to reduce the potential persistence of gene editing activity, we are developing self-regulating gene editing systems designed to deliver not only the endonuclease-guide RNA complex, but also an “off switch” that reduces the presence of the endonuclease-guide RNA complex over time. We have completed studies of these systems that demonstrate the ability to both maintain on-target editing and also reduce levels of editing components once the on-target edit is expected to have been completed.

Our Gene Editing Medicine Programs

We have initiated a diversified range of research programs across multiple therapeutic and disease areas. Our product development strategy is to target diseases where gene editing can be used to enable or enhance therapeutic outcomes for patients. We believe the therapeutic programs and delivery technologies we have chosen to date will demonstrate the depth and breadth of our ability to deploy our genome editing platform to develop differentiated, transformational medicines for patients with high unmet need. The following summarizes our product candidates, research programs and disease areas:



In Vivo *Gene Editing Medicines - Ocular*

Our initial focus for our *in vivo* gene-edited medicines is ocular diseases. We estimate that over 5 million people worldwide suffer from autosomal recessive inherited retinal diseases. In ocular diseases, our most advanced *in vivo* gene-edited medicine, EDIT-101, is designed to treat LCA10. We are leveraging our experience with the LCA10 program to support the development of therapies for other eye diseases, including USH2A and adRP4.

Leber Congenital Amaurosis 10

Leber congenital amaurosis ("LCA") is a heterogeneous group of inherited retinal dystrophies caused by mutations in at least 18 different genes and is the most common cause of inherited childhood blindness, with an incidence of two to three per 100,000 live births worldwide. Symptoms of LCA appear within the first year of life with significant vision loss, rapid involuntary movements of the eyes, painful eye response to bright light, and absence of measurable electroretinogram recordings due to a lack of functional photoreceptor cells. The most common form of the disease is LCA10, a monogenic disorder that represents approximately 20-30% of all LCA subtypes. LCA10 is caused by autosomal recessive mutations in the CEP290 gene, which encodes a protein required for the survival and proper function of photoreceptor cells. The most frequently found mutation within the CEP290 gene, occurring in approximately 85% of north and west European patients with LCA10, is an A to G nucleotide change that disrupts normal splicing, or processing, of the gene message, ultimately resulting in a deficiency of functional CEP290 protein. Decreased CEP290 protein leads to loss of the outer segments of photoreceptor cells and function over time, which leads to blindness. We believe there are approximately 4,000 LCA10 patients in the United States and Europe and over 30,000 in the rest of the world.

EDIT-101 uses an AAV5 vector to deliver the DNA encoding SaCas9 and two guide RNAs to photoreceptor cells in the eye. EDIT-101 is designed to eliminate a disease-causing A to G nucleotide change in a non-coding region, or intron, of the CEP290 gene by cutting out that nucleotide and surrounding DNA. We believe this genome editing approach has the potential to restore normal protein expression and function of the remaining photoreceptor cells, which could improve vision or arrest the further loss of vision in LCA patients. Certain clinical research studies estimated that retention of 10% of photoreceptors can impart meaningful vision in humans. Based on these studies, we have prespecified a therapeutic target of 10% productive editing of photoreceptors with the assumption that each productively edited photoreceptor will be fully functional. We tested EDIT-101 in preclinical studies by delivering several dose quantities of EDIT-101 subretinally in mice that had a humanized CEP290 gene. Subretinal delivery of EDIT-101 in humanized CEP290 mice showed rapid and sustained CEP290 gene editing. These studies demonstrated that EDIT-101 edited the relevant cells at therapeutically relevant levels as early as a week following dosing and greater than 10% editing at AAV dose levels that have been safely administered to humans based on prior clinical studies.

To investigate genome editing *in vivo*, we conducted studies in non-human primates using subretinal injection of an AAV5 expressing SaCas9 and nonhuman primate specific guide RNAs. After either six or 13 weeks, animals were euthanized and retinal tissue from the injected region was removed for analysis. These studies showed that AAV genomes and Cas9 expression were limited to photoreceptors. In addition, we estimate that 12-22% and 50% of CEP-290 alleles were productively edited at six weeks and at 13 weeks, respectively. In these studies, productive editing is defined as the proportion of photoreceptor cells edited in a manner that we believe will restore CEP290 protein function. All of these values exceed our prespecified therapeutic target of 10% productive editing. Furthermore, these doses were shown in subsequent studies to be well tolerated in non-human primates based on visual and immunohistochemical analysis. Similar studies in mice showed that editing was rapid, achieving maximum levels by six weeks, and stable with changes maintained for the 26 weeks of the study at an AAV dose that has been safely administered to humans.

In mid-2019, we and our then-partner Allergan Pharmaceuticals International Limited (together with its affiliates, "Allergan") initiated an initial Phase 1/2 clinical trial which is an open-label, single ascending dose trial of EDIT-101 in adult and pediatric (i.e., ages 3 to 17 years) patients with retinal degeneration caused by a homozygous or compound heterozygous mutation of the CEP290 gene, which is referred to as an IVS26 mutation. Patients will receive a single dose of EDIT-101 administered via subretinal injection in one eye. Approximately 18 patients will be enrolled at approximately eight trial centers in the United States and Europe. Up to five cohorts across three doses will be enrolled in this clinical trial. The primary endpoint of the trial is an assessment of safety and tolerability, and the secondary endpoint is to evaluate and identify endpoints of efficacy of a single dose of EDIT-101 on change from baseline in various parameters. Efficacy will be evaluated at multiple timepoints, including core measures every three months for the first year and then less frequently thereafter. In March 2020, we announced the first patient in this clinical trial was dosed, and we completed dosing of the adult low-dose cohort by the end of 2020. To date, there have been no reported severe adverse events or dose limited toxicity with respect to the patients in the first cohort. We experienced slowed enrollment for subsequent cohorts due to the ongoing impact of the COVID-19 pandemic. However, we initiated dosing of the adult mid-dose cohort in the first quarter of 2021. We expect to announce initial clinical data in 2021. As a result of the termination of our collaboration with Allergan in August 2020, we have regained full responsibility for this clinical trial.

Other Eye Diseases

We are also pursuing the development of therapies for eye diseases other than LCA10, including USH2A and adRP4. We believe that our experience with the LCA10 program supports the development of therapies for these other eye diseases. For example, the successful construction and testing of the components of the AAV vector we are pursuing for EDIT-101 continue to inform our approach to treating the most common cause of USH2A.

Usher Syndrome 2A

USH2A gene mutations are the most common cause of Usher syndrome, a form of retinitis pigmentosa that also includes hearing loss. Loss of the usherin protein encoded by the USH2A gene leads to a degeneration of the retina and progressive vision loss. More than 200 mutations have been identified for this gene. Our initial goal in this research program is to address mutations within exon 13, which contains the highest percentage of USH2A gene mutations. We believe there are over 4,500 USH2A patients with the mutation we aim to correct in the United States and Europe and over 40,000 in the rest of the world. We have declared a development candidate, EDIT-102, to treat USH2A patients. EDIT-102 is comprised of the same proprietary enzyme, vector and promoter as EDIT-101.

We tested EDIT-102 in preclinical studies of human cell lines and demonstrated approximately 47% productive editing in the cells that resulted in such cells expressing 60% more USH2A messenger RNA as compared to the unedited cells. In other preclinical studies, we tested EDIT-102 in humanized retinal organoids, which are three-dimensional structures derived from human pluripotent stem cells and can serve as an in vitro model of retinas. These studies demonstrated noticeable increases in the proper localization of the usherin complex in the photoreceptor cells at 120-140 days, as compared to retinal organoids formed from cells that contained a patient-derived mutation in exon 13.

Retinitis Pigmentosa

Mutations in the human rhodopsin (“RHO”) gene account for 25% of all forms of adRP4, a progressive form of retinal degeneration characterized by initial night blindness early in life followed by loss of peripheral vision and eventual complete blindness. More than 150 mutations in the RHO gene have been identified, with the most prevalent allele in the United States representing approximately 10% of all patients with adRP4. We believe there are over 18,000 adRP4 patients with mutations in the RHO gene in the United States and Europe and over 15,000 in the rest of the world. Leveraging our EDIT-101 and EDIT-102 learnings, we are developing a novel approach to treat all forms of adRP4 resulting from mutations in the RHO gene and aim to declare a development candidate, potentially using the same enzyme and vector as EDIT-101, by the end of 2021.

In Vivo *Gene Editing Medicines – Early Discovery Programs*

We believe the curative potential for gene editing is significant in light of the over 6,000 human genetic disorders. In addition to our ocular programs, we hope to leverage our expertise in developing gene-editing medicines utilizing AAV delivery to expand our *in vivo* programs to treat additional diseases and therapeutic areas, including neuromuscular, liver, hematological, central nervous system and cardiological disorders. Under our research collaboration with AskBio, we are aiming to develop a therapy to treat a neurological disease.

Ex Vivo *Gene Editing Cell Medicines*

Our most advanced *ex vivo* gene-edited cell medicine, EDIT-301, is designed to treat sickle cell disease and beta-thalassemia. We are also developing multiple *ex vivo* gene-edited cell medicines for the potential treatment of different cancers, including solid tumors. In our collaboration with Juno Therapeutics, we are researching and developing engineered alpha-beta T cell therapies to treat cancer and autoimmune diseases. In our wholly owned oncology programs, we are further developing our capabilities to generate certain engineered NK cells from iPSCs that we edit to treat solid tumors. We are also collaborating with BlueRock to increase our technical capabilities in such programs.

Ex Vivo Gene *Editing* Cell Medicines – Hemoglobinopathies

We are developing an approach for gene editing in HSCs to support the advancement of research programs to treat non-malignant hematological diseases, including sickle cell disease and beta thalassemia.

There are over 165,000 sickle cell disease patients, and over 15,000 beta-thalassemia patients, in the United States and Europe. Patients suffering from sickle cell disease have a median life expectancy of 42-47 years, while those with beta-thalassemia typically suffer from chronic anemia, often requiring lifelong blood transfusions that can result in iron overload that requires separate treatment. We are actively pursuing a distinct gene editing approach to treating these hemoglobinopathies. Our primary criteria for a successful product candidate include high and pancellular fetal hemoglobin ("HbF") with a best-in-class safety profile. To this end, we have developed EDIT-301, an experimental, autologous cell therapy that targets the HBG1/2 promoter in the beta-globin gene to stimulate HbF production, to treat sickle cell disease. EDIT-301 is the first experimental medicine in development generated using CRISPR/Cas12a (also known as Cpf1) gene editing.

We have focused our efforts on editing a site within the beta-globin locus that we believe has the potential to create superior expression of fetal hemoglobin since patients with elevated fetal hemoglobin levels have better clinical outcomes. We believe that EDIT-301 has the potential to impact beta-globin expression by increasing HbF and decreasing sickle globin. In particular, our preclinical data shows that EDIT-301 induces more HbF than the approach of targeting the *BCL11A* erythroid enhancer (“BC11Ae”). Likewise, we believe our approach will reduce the sickle globin and, therefore, not have to compete for alpha globin in the same cell unlike lentiviral gene therapy approaches. Our preclinical studies identified the potential that BC11Ae might result in deleterious lineage skewing when editing the *BCL11Ae* locus. Finally, gene editing is more specific than lentiviral expression. To get the high levels of beta-globin required for an efficacious therapy, there will be cells in the CD34+ population, which are cells that contain the long-term stem cells that repopulate the hematopoietic lineages, that carry more than twenty copies of the viral genome. These random integration

events have the potential to inadvertently activate or inactivate genes involved in cell function and tumorigenesis. As such, we believe our approach to editing the beta-globin locus provides the highest likelihood of providing clinical benefit in patients while minimizing potential safety risks.

Using our approach in preclinical studies, we tested the ability of CD34+ cells obtained from healthy donors and edited at the beta-globin locus to induce fetal hemoglobin. As predicted from our preclinical *in vitro* studies, editing at the beta-globin site with Cas12a caused a robust, pancellular induction of HbF of approximately 45% above the background levels.

We also tested CD34+ cells obtained from sickle cell patients, which we edited at the beta-globin locus. These studies showed that editing was highly efficient and reproducible, with approximately 90% editing in multiple sickle patient donors. We found that EDIT-301 derived red blood cells had more than 50% HbF expression. Further, EDIT-301 derived red blood cells had a significant improvement in deformability, which could aid red blood cell transit without sickling, and a four-fold decrease in sickling, when subjected to reduced oxygen levels compared to unedited control cells. These data suggest EDIT-301 can provide potential clinical benefit for sickle patients. *In vivo* studies revealed editing was highly efficient with greater than 90% editing in bone marrow cells from mice infused with edited CD34+ cells 16 weeks post-infusion. In these mice, HbF expression was increased by approximately 50% in the red blood cells derived from these edited cells. We also observed that approximately 90% of these cells were HbF positive, demonstrating that HbF expression was pan-cellular, which we believe is likely a critical property for potential clinical benefit. For these reasons, we believe our approach of editing the hemoglobin locus to increase fetal hemoglobin has the potential to generate differentiated medicines to benefit patients with sickle cell disease and beta thalassemia.

In January 2021, the FDA cleared the initiation of the safety phase of our Phase 1/2 RUBY clinical trial for EDIT-301 for sickle cell disease, and permitted us to begin dosing patients, which we expect to occur in 2021. This trial is a single-arm, open-label, multi-center Phase 1/2 study designed to assess the safety and efficacy of EDIT-301 in patients with sickle cell disease. Enrolled patients will receive a single administration of EDIT-301. We are manufacturing components of the clinical trial materials. We also aim to file an IND for EDIT-301 for the treatment of beta-thalassemia by the end of 2021.

Our IND for EDIT-301 permits us to proceed with the safety portion of our Phase 1/2 RUBY clinical trial. Prior to commencing the efficacy portion of the RUBY clinical trial, we will be required to resolve the partial clinical hold on EDIT-301 related to developing a potency assay to ensure that the characteristics of the product released are as expected and confirmed by clinical data collected in the first patients treated. We do not expect that the overall timing for clinical development of EDIT-301 will be affected by the partial clinical hold. Further, the partial clinical hold does not impact our ability to conduct our clinical development activities of EDIT-301 for the safety portion of the trial. If the partial clinical hold is not lifted on the Phase 1/2 RUBY clinical trial, we will not be able to collect the efficacy data of EDIT-301 necessary to support an application for approval.

Ex Vivo Gene Edited Cell Medicines – Oncology

Natural Killer Cells

We are developing gene-edited NK cell medicines to treat solid tumors. The American Cancer Society estimates that there are over 1.3 million new cases of solid tumor cancers, linked to over 400,000 deaths, annually in the United States. NK cells are innate immune cells that can recognize tumor cells by a variety of mechanisms, including multiple innate receptors that recognize cells that do not express T cell antigens and cells that express stress ligands. NK cells are also part of a process known as antibody-directed cellular cytotoxicity (“ADCC”) by which therapeutic antibodies are directed to and kill tumor cells. Further, NK cells have a lower risk of causing graft versus host disease. If we are successful, genome-edited NK cells have the potential to increase the signaling power of ADCC pathways, improve the persistence of NK cells and/or increase tumor microenvironment resistance. Genome-edited NK cells may be further engineered with one or more chimeric antigen receptors (“CARs”) or innate receptors to further improve one or more of these properties. For example, gene-edited engineered NK cells could be used to improve recognition of tumor cells lacking T cell antigens, including PD-1 non-responding tumors.

We obtain NK cells by differentiating iPSCs into such cells. Once we have obtained the cells, we then edit them to increase certain of the natural properties of the cell to better enable them to treat solid tumors, such as the cells persistence in vivo, its ability to withstand the tumor micro-environment, improved ability to cause ADCC and improved recognition of tumor cells. In preclinical studies, we achieved 70-100% editing in five genes in iPSCs. For one such edited iPSC, the resulting edited iNKs killed 74% of cultured cells while unedited cells only killed 2% of cultured cells. We aim to accelerate the development of iNK cell medicines for the treatment of solid tumor cancers in 2021.

Alpha-Beta T Cells

Engineered T cells, including alpha-beta T cells, have shown encouraging clinical activity against multiple cancers, culminating in the recent approval of two such therapies in the United States. Because of these promising results, there is significant interest in the medical community in expanding the application of this technology across a broader range of cancers and patients. We believe that our genome editing technology has the potential to improve multiple properties of these alpha-beta T cell therapies. Alpha-beta cells are part of the adaptive immune system and recognize tumors with endogenous alpha-beta T cell receptors or CARs or engineered T cell receptors ("Engineered TCRs"). If we are successful, genome-edited engineered alpha-beta T cells have the potential to significantly expand the types of cancers treatable by CAR/ Engineered TCR alpha-beta T cells and to improve the outcomes of these therapies.

Through our collaboration with Juno Therapeutics, we have applied our genome editing technology to multiple gene targets in order to improve the efficacy and safety of CAR/ Engineered TCR alpha-beta T cells directed against a range of tumor types. In addition, we have optimized genome editing components and delivery methods compatible with engineered alpha-beta T cell manufacturing methods developed by Juno Therapeutics.

Gamma Delta T Cells

Like NK cells, gamma delta T cells are part of the innate immune system. We have retained rights to develop gamma delta T cell therapies to treat cancer, and we hope to leverage our capabilities and expertise in alpha-beta T cells and our NK cell programs to develop such therapies.

Our Collaborations and Licensing Strategy

Juno Therapeutics Collaboration and License Agreement

In May 2015, we entered into a collaboration and license agreement with Juno Therapeutics for the research and development of engineered T cells with CARs and Engineered TCRs that have been genetically modified to recognize and kill other cells. We and Juno Therapeutics amended and restated this agreement in May 2018 and November 2019 (the "Juno Collaboration Agreement") and, in connection with the amendment and restatement in November 2019, we entered into a license agreement with Juno Therapeutics (such agreement, the "Juno License Agreement," and together with the Juno Collaboration Agreement, the "Juno Agreements"). Under the terms of the Juno Collaboration Agreement, we received an upfront payment of $25.0 million, amendment fees totaling $75.0 million and have received five milestone payments totaling $15.0 million, in addition to certain opt-in fees.

The Juno Agreements relate to technology used to edit or modify the genome of a cell in connection with the research, development, manufacture, commercialization or other exploitation of T cells that express or have ever expressed T cell receptor dimers consisting of an alpha (α) chain and a beta (β) chain (such cells, "Alpha-beta T Cells"), and T cells derived from pluripotent stem cells or any other precursor cell (such cells, "Other Derived T Cells"), subject to certain exclusions for certain of our existing obligations. The exploitation of Alpha-beta T Cells and Other Derived T Cells specifically excludes the exploitation of T Cells that express a T cell receptor dimer consisting of a gamma (γ) chain and a delta (δ) chain, which we refer to as gamma-delta T Cells. As such, we may develop such gamma delta T Cells.

During the research term under the Juno Collaboration Agreement, we may research ribonucleoprotein complexes comprising an RNA-guided engineered nuclease paired with an oligonucleotide ("RNP Complexes") that

recognize or modulate the expression of up to twenty gene targets selected by Juno Therapeutics (each, a "Research Program") for the purpose of identifying the RNP Complexes that may be used in the creation of potential drug development candidates. The initial research term is five years from the effective date of the Juno Collaboration Agreement. Juno Therapeutics may extend the research term for up to two one-year periods upon written notice to us and payment to us of a mid to high single digit million-dollar payment upon each extension. Juno Therapeutics' right to extend the research term for the second one-year period is subject to our consent.

Under the Juno Collaboration Agreement, if Juno Therapeutics elects to opt-in with respect to a Research Program, it shall make a mid-six digit dollar payment to us and we shall amend the Juno License Agreement to include such Research Program by executing a licensed program addendum for such Research Program. Following Juno Therapeutic's opt-in for each program we shall grant to Juno Therapeutics an exclusive (even as to us), royalty-bearing worldwide right and license under specified intellectual property rights to research, develop, manufacture commercialize or otherwise exploit the RNP Complexes in such Research Program to create products containing, incorporating, comprising or containing Alpha-beta T Cells and/or Other Derived T Cells, in each case modified using the RNP Complexes in such Research Program (each, a "Juno Licensed Product").

We are entitled to receive high single-digit to low double-digit percentage royalties on net sales made by Juno Therapeutics, its affiliates and sublicensees of any Juno Licensed Products, subject to reductions in certain circumstances. We are also entitled to receive development milestones totaling up to $135.0 million in the aggregate upon achievement of certain clinical milestones and specified regulatory approvals and commercial milestone payments totaling up to $60.0 million in the aggregate for each of the first two Juno Licensed Products to achieve specified net sales milestones.

We have agreed during the term of the Juno Collaboration Agreement not to use (directly or indirectly), or license others to use, genome editing technology in connection with any research, development, manufacture, commercialization or other exploitation of any Alpha-beta T Cells or Other Derived T Cells. Our exclusivity obligation will not apply to activities related to (i) any identified RNP Complexes in a program for which Juno Therapeutics elects not to exercise its opt-in right, (ii) certain of our existing obligations to third parties, and (iii) certain existing programs of an acquiror of our company in a change of control.

We have agreed during the term of any licensed program addendum under the Juno License Agreement not to use (directly or indirectly), or license others to use, any genome editing technology that modulates or recognizes a gene target covered by such licensed program addendum for the conduct of any research, development, manufacture, commercialization or other exploitation with respect to any product that constitutes, incorporates, comprises or contains any Alpha-beta T Cell or Other Derived T Cells.

The Juno Collaboration Agreement continues in effect until the later of expiration of the research term or expiration of the last to expire of Juno Therapeutics' right to opt-in with respect to any Research Program. Juno Therapeutics may terminate the Juno Collaboration Agreement in its discretion upon six months' prior written notice to us. Either party may terminate the Juno Collaboration Agreement for uncured material breach of the other party, provided that the breaching party has had sixty days to cure such breach, or in the event of insolvency or bankruptcy of the other party.

The Juno License Agreement continues in effect on a Juno Licensed Product-by-Juno Licensed Product and country-by-country basis until the expiration of the royalty term with respect to such licensed product in such country and in its entirety upon the expiration of all royalty terms with respect to all Juno Licensed Products in all countries. Juno Therapeutics may terminate the Juno License Agreement in its entirety or on a Juno Licensed Product-by-Juno Licensed Product basis in its discretion upon ninety days' prior written notice to us. Either party may terminate the Juno License Agreement on a Juno Licensed Product-by-Juno Licensed Product basis in the event of an uncured material breach of the other party, provided that the breaching party has had sixty days to cure such breach, or in the event of insolvency or bankruptcy of the other party. We have the right to terminate the Juno License Agreement on a program-by-program basis in the event that Juno Therapeutics fails to make any undisputed payment to us and has not cured such payment breach within the cure period. Other than Juno Therapeutics' right to wind-down its operations with respect to

Juno Licensed Products during the twelve months following the date of effectiveness of termination, all licenses and other exclusive rights granted under the Juno License Agreement shall terminate.

Allergan Agreement

In March 2017, we entered into a strategic alliance and option agreement with Allergan to discover, develop, and commercialize new gene editing medicines for a range of ocular disorders. Pursuant to this agreement, we granted Allergan an exclusive option to exclusively license from us up to five collaboration development programs for the treatment of ocular disorders, including EDIT-101. In July 2018, Allergan exercised its option to develop and commercialize EDIT-101 and we subsequently entered into a co-development and commercialization agreement with Allergan under which we agreed to co-develop and equally split profits and losses for EDIT-101 in the United States. In connection with entering into this agreement, Allergan paid us a one-time up-front payment of $90.0 million. Allergan also paid us $15.0 million in connection with Allergan exercising its option for the LCA10 program and $25.0 million in connection with the acceptance of the IND for the LCA10 program.

Allergan was acquired by AbbVie Inc. in May 2020. On August 5, 2020, we entered into a termination agreement with Allergan pursuant to which, among other things, we and Allergan terminated the strategic alliance and option agreement and the co-development and commercialization agreement. As a result of the termination of our collaboration with Allergan, we regained full global rights to research, develop, manufacture, and commercialize our ocular product candidates, including EDIT-101 for the treatment of LCA10. Under the termination agreement, Allergan granted us a non-exclusive, royalty-bearing right and license, including the right to grant sublicenses (through multiple tiers), to certain Allergan know-how that is necessary to develop, manufacture and commercialize EDIT-101. In addition, we are obligated to use commercially reasonable efforts to develop and commercialize a product directed to each of four collaboration targets, one of which is LCA10. In connection with our entry into the termination agreement, we made a one-time aggregate payment of $20.0 million to Allergan. In addition, we will make certain payments on achievements of clinical and regulatory milestones up to $20.0 million for each target program and aggregated sales milestones for all products covered by the termination agreement up to $90.0 million. We are also obligated to pay royalties in a low-single digit percentage, subject to reduction under specified circumstances, on net sales of specified products. Our obligation to pay royalties will expire on a country-by-country and product-by-product basis upon the later of the expiration of regulatory-based exclusivity with respect to such product in such country and the tenth anniversary of the first commercial sale of such product.

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 genome 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.

The Broad Institute and President and Fellows of Harvard College License Agreement

In October 2014, we entered into a license agreement with The Broad Institute, Inc. (“Broad”) and the President and Fellows of Harvard College (“Harvard”), for specified patent rights. In December 2016, we amended and restated this license agreement and further amended the agreement in March 2017 (as amended, the “Cas9-I License Agreement”). Among other things, the Cas9-I License Agreement amended the original license agreement by excluding additional fields from the scope of the exclusive license granted to us; converting the exclusive license to three specified targets to a non-exclusive license, subject to specified limitations; revising certain provisions relating to the rights of Harvard and Broad to grant further licenses under specified circumstances to third parties that wish to develop and commercialize products that target a particular gene and that otherwise would fall within the scope of our exclusive license; and providing Harvard and Broad with certain rights to designate, and reserve all rights to, gene targets for which the designating institution has an interest in researching and developing products that would otherwise be covered by rights licensed to us. The licenses granted to us under the Cas9-I License Agreement include rights to certain patents solely owned by Harvard (the “Harvard Cas9-I Patent Rights”), certain patents co-owned by the Massachusetts Institute

of Technology ("MIT") and Broad, certain patents co-owned by MIT, The Rockefeller University ("Rockefeller"), and Broad, and certain patents co-owned by MIT, Broad and Harvard. We refer to all the patents and patent applications licensed to us under the Cas9-I License Agreement as the Harvard/Broad Cas9-I Patent Rights.

Certain patent applications in the Harvard/Broad Cas9-I Patent Rights are jointly owned by Rockefeller. In February 2017, Broad and Rockefeller entered into an inter-institutional agreement pursuant to which Rockefeller authorized Broad to act as its sole and exclusive agent for the purposes of licensing Rockefeller's rights in such Harvard/Broad Cas9-I Patent Rights and any additional related patents or patent applications that Rockefeller may jointly own with Broad. The March 2017 amendment to the Cas9-I License Agreement included a license to Rockefeller's rights in such patents and patent applications.

The Harvard/Broad Cas9-I Patent Rights are directed, in part, to certain CRISPR/Cas9 compositions of matter and their use for genome editing and to certain CRISPR/Cas9 related delivery technologies. Pursuant to the Cas9-I License Agreement, and as of December 31, 2020, we have certain rights under 54 U.S. patents, 56 pending U.S. patent applications, 30 European patents and related validations, 29 pending European patent applications, and other related patent applications in jurisdictions outside of the United States and Europe.

Pursuant to the Cas9-I License Agreement, Harvard and Broad granted us an exclusive, worldwide, royalty-bearing, sublicensable license to the Harvard/Broad Cas9-I Patent Rights to make, have made, use, sell, offer for sale, have sold, import, and export products and services in the field of the prevention and treatment of human disease, subject to certain limitations and retained rights. The exclusive license granted by Broad and Harvard excludes certain fields, including the modification of animals or animal cells for the creation and sale of organs suitable for xenotransplantation into humans; the research, development and commercialization of products or services in the field of livestock applications; plant-based agricultural products; and, subject to certain limitations, products providing nutritional benefits. Moreover, the license granted by Broad is non-exclusive with respect to the treatment of medullary cystic kidney disease 1 and three other specified targets, subject to the limitation that for such three targets, each of Broad and Harvard is only permitted to grant a non-exclusive license to one third party at a time with respect to each such target within the field of exclusive license granted to us. Harvard and Broad also granted us a non-exclusive, worldwide, royalty-bearing, sublicensable license to the Harvard/Broad Cas9-I Patent Rights for all purposes, with the exception that the non-exclusive license to certain Harvard Cas9-I Patent Rights excludes the modification of animals or animal cells for the creation and sale of organs suitable for xenotransplantation into humans and the development and commercialization of products or services in the field of livestock applications. In addition to the exclusions described above, the following are excluded from the scope of both the exclusive and non-exclusive licenses granted to us under the Cas9-I License Agreement: human germline modification; the stimulation of biased inheritance of particular genes or traits within a population of plants or animals; the research, development, manufacturing, or commercialization of sterile seeds; and the modification of the tobacco plant with specified exceptions.

We are obligated to use commercially reasonable efforts to research, develop, and commercialize products for the prevention or treatment of human disease under the Cas9-I License Agreement. Also, we are required to achieve certain development milestones within specified time periods for products incorporating the technologies covered by the Harvard/Broad Cas9-I Patent Rights. Harvard and Broad have the right to terminate our license with respect to the Harvard/Broad Cas9-I Patent Rights covering the technology or technologies with respect to which we fail to achieve these development milestones.

The licenses granted by Broad and Harvard to us under the Cas9-I License Agreement are subject to retained rights of the U.S. government in the Harvard/Broad Cas9-I Patent Rights and the rights retained by Broad, Harvard, MIT, and Rockefeller on behalf of themselves and other academic, government and non-profit entities, to practice the Harvard/Broad Cas9-I Patent Rights for research, educational, or teaching purposes. In addition, certain rights granted to us under the Cas9-I License Agreement are further subject to a non-exclusive license to the Howard Hughes Medical Institute for research purposes. Our exclusive license rights also are subject to rights retained by Broad, Harvard, MIT, and Rockefeller any third party to research, develop, make, have made, use, offer for sale, sell, have sold, import or otherwise exploit the Harvard/Broad Cas9-I Patent Rights and licensed products as research products or research tools, or for research purposes.

We have the right to sublicense our licensed rights provided that the sublicense agreement must be in compliance and consistent with the terms of the Cas9-I License Agreement. Any sublicense agreement cannot include the right to grant further sublicenses without the written consent of Broad and Harvard. In addition, any sublicense agreements must contain certain terms, including a provision requiring the sublicensee to indemnify Harvard, Broad, MIT, and Howard Hughes Medical Institute according to the same terms as are provided in the Cas9-I License Agreement and a statement that Broad, Harvard, MIT, and Howard Hughes Medical Institute are intended third party beneficiaries of the sublicense agreement for certain purposes.

Under the agreement, Harvard and Broad also retained rights to grant further licenses under specified circumstances to third parties, other than specified entities, that wish to develop and commercialize products that target a particular gene and that otherwise would fall within the scope of our exclusive license from Harvard and Broad. If a third party requests a license under the Harvard/Broad Cas9-I Patent Rights for the development and commercialization of a product that would be subject to our exclusive license grant from Harvard and Broad under the Cas9-I License Agreement, Harvard and Broad may notify us of the request (the "Cas9-I Third Party Proposed Product Requests"). Our process to address Cas9-I Third Party Proposed Product Requests has been conformed to the same process established in our Cpf1 license agreement described below.

The Cas9-I License Agreement also provides Broad with the right, after a specified period of time and subject to certain limitations, to designate gene targets for which Broad, whether alone or together with an affiliate or third party, has an interest in researching and developing products that would otherwise be covered by rights licensed to us under the Cas9-I License Agreement. Broad may not so designate any gene target for which we, directly or through any of our affiliates, sublicensees, or collaborators, are researching, developing, or commercializing a product, or for which we can demonstrate to Broad's reasonable satisfaction that we are interested in researching, developing, and commercializing a product, that we have a commercially reasonable research, development, and commercialization plan to do so, and we commence and continue reasonable commercial efforts under such plan. If we directly or through any of our affiliates, sublicensees, or collaborators, are not researching, developing, or commercializing a product directed toward the gene target designated by Broad and are not able to develop and implement a plan reasonably satisfactory to Broad, Broad is entitled to reserve all rights under the Cas9-I License Agreement, including the right to grant exclusive or non-exclusive licenses to third parties, to develop and commercialize products directed to such gene target and our license granted with respect to such gene target will terminate, and we will not be entitled under the Cas9-I License Agreement to develop and commercialize products directed to that gene target.

Under the Cas9-I License Agreement, we paid Broad and Harvard an upfront license fee in the low six figures and issued a single-digit percentage of shares of our common stock to Broad (with Broad holding a right to request re-issuance to its designees, including MIT or MIT's designee) and Harvard. We also must pay an annual license maintenance fee ranging from the low- to mid-five figures to the low-six figures, depending on the calendar year. This annual license maintenance fee is creditable against royalties owed on licensed products and services in the same year as the maintenance fee is paid. We are obligated to reimburse Broad and Harvard for expenses associated with the prosecution and maintenance of the Harvard/Broad Cas9-I Patent Rights, including expenses associated with any interference proceedings in the USPTO, any opposition proceedings in the EPO, or any other *inter partes* or other post grant proceedings in these or other jurisdictions where we are seeking patent protection. Therefore, we are obligated to reimburse Broad and/or Harvard for expenses associated with the interference and opposition proceedings involving patents licensed to us under this agreement (described in more detail under "Risk Factors—Risks Related to Our Intellectual Property—Some of Our In-Licensed Patents are Subject to Priority and Validity Disputes" in Part I, Item 1A of this Annual Report on Form 10-K).

Broad and Harvard are collectively entitled to receive clinical and regulatory milestone payments totaling up to $14.8 million in the aggregate per licensed product approved in the United States, the European Union and Japan for the prevention or treatment of a human disease that afflicts at least a specified number of patients in the aggregate in the United States. If we undergo a change of control during the term of the Cas9-I License Agreement, these clinical and regulatory milestone payments will be increased by a certain percentage in the mid double-digits. We are also obligated to make additional payments to Broad and Harvard, collectively, of up to an aggregate of $54.0 million upon the occurrence of certain sales milestones per licensed product for the prevention or treatment of a human disease that afflicts at least a specified number of patients in the aggregate in the United States. Broad and Harvard are collectively

entitled to receive clinical and regulatory milestone payments totaling up to $4.1 million in the aggregate per licensed product approved in the United States and at least one jurisdiction outside the United States for the prevention or treatment of a human disease that afflicts fewer than a specified number of patients in the aggregate in the United States or a specified number of patients per year in the United States, which we refer to as an ultra-orphan disease. We are also obligated to make additional payments to Broad and Harvard, collectively, of up to an aggregate of $36.0 million upon the occurrence of certain sales milestones per licensed product for the prevention or treatment of an ultra-orphan disease.

Broad and Harvard, collectively, are entitled to receive mid single-digit percentage royalties on net sales of licensed products for the prevention or treatment of human disease, and ranging from low single-digit to high single-digit percentage royalties on net sales of other licensed products and services, made by us, our affiliates, or our sublicensees. The royalty percentage depends on the licensed product and licensed service, and whether such licensed product or licensed service is covered by a valid claim within the Harvard/Broad Cas9-I Patent Rights. If we are legally required to pay royalties to a third party on net sales of our licensed products because such third party holds patent rights that cover such licensed product, then we can credit up to a mid double-digit percentage of the amount paid to such third party against the royalties due to Harvard and Broad in the same period. Our obligation to pay royalties will expire on a product-by-product and country-by-country basis upon the later of the expiration of the last to expire valid claim of the Harvard/Broad Cas9-I Patent Rights that cover the composition, manufacture, or use of each covered product or service in each country or the tenth anniversary of the date of the first commercial sale of the licensed product or licensed service. If we sublicense any of the Harvard/Broad Cas9-I Patent Rights to a third party pursuant to our exclusive license under the Cas9-I License Agreement, Broad and Harvard, collectively, had the right to receive a low to mid double-digit percentage of the sublicense income, which percentage decreased to a low double-digit percentage in 2018 and may still decrease to a low of a high single-digit percentage for licensed products for the prevention or treatment of human disease under sublicenses executed after we meet a certain clinical milestone.

Broad and Harvard retain control of the prosecution of their respective patent rights. If an interference is declared or a derivation proceeding is initiated, with respect to any Harvard/Broad Cas9-I Patent Rights, then our prosecution related rights, including our right to receive correspondence from a patent office, will be suspended with respect to the patent rights involved in the interference or derivation proceeding until, under some circumstances, we enter into a common interest agreement with that institution. Nevertheless, we remain responsible for the cost of such interference or derivation proceeding. We are responsible for the cost of the interference proceeding and appeal with respect to these patents and this patent application. Broad and Harvard are required to maintain any application or patent within the Harvard/Broad Patents Rights so long as we meet our obligation to reimburse Broad and Harvard for expenses related to prosecution and there is a good faith basis for doing so. If we cease payment for the prosecution of any Harvard/Broad Patent Right, then any license granted to us with respect to such Harvard/Broad Patent Right will terminate.

We have the first right, but not the obligation, to enforce the Harvard/Broad Cas9-I Patent Rights with respect to our licensed products so long as certain conditions are met, such as providing Broad and Harvard with evidence demonstrating a good faith basis for bringing suit against a third party. We are solely responsible for the costs of any lawsuits we elect to initiate and cannot enter into a settlement without the prior written consent of Broad and Harvard (and MIT and Rockefeller, if applicable). Any sums recovered in such lawsuits will be shared between us, Broad, and Harvard.

Unless terminated earlier, the term of the Cas9-I License Agreement will expire on a country-by-country basis, upon the expiration of the last to expire valid claim of the Harvard/Broad Cas9-I Patent Rights in such country. However, our royalty obligations, discussed above, may survive expiration or termination. We have the right to terminate the agreement at will upon four months' written notice to Broad and Harvard. Broad and Harvard may terminate the agreement upon a specified period of notice in the event of our uncured material breach, such notice period varying depending on the nature of the breach. Both Broad and Harvard may terminate the Cas9-I License Agreement immediately if we challenge the enforceability, validity, or scope of any Harvard/Broad Patent Right or assist a third party to do so, or in the event of our bankruptcy or insolvency. Neither Broad nor Harvard acting alone has the right to terminate the Cas9-I License Agreement. However, Broad and Harvard may separately terminate the licenses granted to us with respect to their respective patent rights upon the occurrence of the same events that would give rise to the right of both institutions acting collectively to terminate the Cas9-I License Agreement.

The Broad Institute—Cpf1 License Agreement

In December 2016, we entered into a license agreement with Broad, for specified patent rights ("Cpf1 Patent Rights") related primarily to Cas12a compositions of matter and their use for gene editing (as amended, the "Cpf1 License Agreement"). Pursuant to the Cpf1 License Agreement, Broad, on behalf of itself, Harvard, MIT, Wageningen University ("Wageningen"), and the University of Tokyo ("Tokyo" and collectively with the other institutions, the "Cpf1 Institutions") granted us an exclusive, worldwide, royalty-bearing, sublicensable license to the Cpf1 Patent Rights, to make, have made, use, have used, sell, offer for sale, have sold, export and import products solely in the field of the prevention or treatment of human disease using gene therapy, editing of genetic material, or targeting of genetic material, subject to certain limitations and retained rights (collectively, the "Exclusive Cpf1 Field"), as well as a non-exclusive, worldwide, royalty-bearing, sublicensable license to the Cpf1 Patent Rights for all other purposes, subject to certain limitations and retained rights. The licenses granted to us under the Cpf1 License Agreement exclude certain fields, including human germline modification; the stimulation of biased inheritance of particular genes or traits within a population of plants or animals; the research, development, manufacturing, or commercialization of sterile seeds; and the modification of the tobacco plant with specified exceptions.

Tokyo and the National Institute of Health ("NIH") are joint owners on certain Cpf1 Patent Rights. Broad has only granted a license to us with respect to its interests and to Tokyo's interests in these U.S. patent applications but not to any foreign equivalents thereof. Broad does not, and does not purport to, grant any rights in NIH's interest in these U.S. patent applications under our agreement. As a result, we may not have exclusive rights under any U.S. patents that issue from these U.S. patent applications and we may not have any rights under any foreign patents that issue from any foreign equivalents thereof.

Pursuant to the Cpf1 License Agreement, and as of December 31, 2020, we have certain rights under three U.S. patent, 12 pending U.S. patent applications, five European patents and related validations, six pending European patent applications, and other related patent applications in jurisdictions outside of the United States and Europe.

We are obligated to use commercially reasonable efforts to research, develop, and commercialize licensed products in the Exclusive Cpf1 Field. We are also required to achieve certain development milestones within specified time periods for products covered by the Cpf1 Patent Rights, with Broad having the right to terminate the Cpf1 License Agreement if we fail to achieve these milestones within the required time periods. We have the right to sublicense our licensed rights provided that the sublicense agreement must be in compliance and consistent with the terms of the Cpf1 License Agreement. Any sublicense agreement cannot include the right to grant further sublicenses without the written consent of Broad. In addition, any sublicense agreements must contain certain terms, including a provision requiring the sublicensee to indemnify the Cpf1 Institutions according to the same terms as are provided in the Cpf1 License Agreement and a statement that the Cpf1 Institutions are intended third party beneficiaries of the sublicense agreement for certain purposes.

The licenses granted to us under the Cpf1 License Agreement are subject to retained rights of the U.S. government in the Cpf1 Patent Rights and rights retained by the Cpf1 Institutions on behalf of themselves and other academic, government and non-profit entities, to practice the Cpf1 Patent Rights for research, teaching, or educational purposes. Our exclusive license rights also are subject to rights retained by the Cpf1 Institutions for themselves and any third party to research, develop, make, have made, use, offer for sale, sell, have sold, import or otherwise exploit the Cpf1 Patent Rights and licensed products as research products or research tools, or for research purposes.

Under the Cpf1 License Agreement, Broad also retained rights to grant further licenses under specified circumstances to third parties that wish to develop and commercialize products that target a particular gene and that otherwise would fall within the scope of our exclusive license from Broad. If a third party requests a license under the Cpf1 Patent Rights for the development and commercialization of a product that would be subject to our exclusive license grant from Broad (a "Cpf1 Third Party Proposed Product Request"), Broad may notify us of such request. A Cpf1 Third Party Proposed Product Request must be accompanied by a research, development and commercialization plan reasonably satisfactory to Broad, including evidence that the third party has, or reasonably expects to have, access to any necessary intellectual property and funding. Broad may not grant a Cpf1 Third Party Proposed Product Request

(i) if we, directly or through any of our affiliates, sublicensees, or collaborators are researching, developing, or commercializing a product directed to the same gene target that is the subject of the Cpf1Third Party Proposed Product Request ("Cpf1 Licensee Product") and we can demonstrate such ongoing efforts to Broad's reasonable satisfaction, or (ii) if we, directly or through any of our affiliates or sublicensees, wish to do so either alone or with a collaboration partner, and we can demonstrate to Broad's reasonable satisfaction that we are interested in researching, developing, and commercializing a Cpf1 Licensee Product, that we have a commercially reasonable research, development, and commercialization plan to do so, and we commence and continue reasonable commercial efforts under such plan. If we, directly or through any of our affiliates, sublicensees, or collaborators, are not researching, developing, or commercializing a Cpf1 Licensee Product nor able to develop and implement a plan reasonably satisfactory to Broad, Broad may grant an exclusive or non-exclusive license to the third party on a gene target-by-gene target basis.

The Cpf1 License Agreement also provides Broad with the right, subject to certain limitations, to designate gene targets for which Broad, whether alone or together with a Cpf1 Institution, affiliate or third party, has an interest in researching and developing products that would otherwise be covered by rights licensed to us under the Cpf1 License Agreement. Broad may not so designate any gene target for which we, directly or through any of our affiliates, sublicensees, or collaborators, are researching, developing, or commercializing a product, or for which we can demonstrate to Broad's reasonable satisfaction that we are interested in researching, developing, and commercializing a product, that we have a commercially reasonable research, development, and commercialization plan to do so, and we commence and continue reasonable commercial efforts under such plan. If we, directly or through any of our affiliates, sublicensees, or collaborators, are not researching, developing, or commercializing a product directed toward the gene target designated by Broad and are not able to develop and implement a plan reasonably satisfactory to Broad, Broad is entitled to reserve all rights under the Cpf1 License Agreement, including the right to grant exclusive or non-exclusive licenses to third parties, to develop and commercialize products directed to such gene target, our license with respect to such gene target will terminate, and we will not be entitled under the Cpf1 License Agreement to develop and commercialize products directed to such gene target.

Under the Cpf1 License Agreement, we paid Broad and Wageningen an aggregate upfront license fee in the mid seven digits and issued to Broad and Wageningen promissory notes (the "Initial Promissory Notes") in an aggregate principal amount of $10.0 million, which we settled in full in 2017. Broad and Wageningen are collectively entitled to receive clinical and regulatory milestone payments totaling up to $20.0 million in the aggregate per licensed product approved in the United States, the European Union and Japan for the prevention or treatment of a human disease that afflicts at least a specified number of patients in the aggregate in the United States. If we undergo a change of control during the term of the Cpf1 License Agreement, certain of these clinical and regulatory milestone payments will be increased by a certain percentage in the mid double-digits. We are also obligated to make additional payments to Broad and Wageningen, collectively, of up to an aggregate of $54.0 million upon the occurrence of certain sales milestones per licensed product for the prevention or treatment of a human disease that afflicts at least a specified number of patients in the aggregate in the United States. Broad and Wageningen are collectively entitled to receive clinical and regulatory milestone payments totaling up to $6.0 million in the aggregate per licensed product approved in the United States, the European Union and Japan for the prevention or treatment of an ultra-orphan disease. We are also obligated to make additional payments to Broad and Wageningen, collectively, of up to an aggregate of $36.0 million upon the occurrence of certain sales milestones per licensed product for the prevention or treatment of an ultra-orphan disease.

Broad and Wageningen, collectively, are entitled to receive mid single-digit percentage royalties on net sales of products for the prevention or treatment of human disease, and ranging from sub single-digit to high single-digit percentage royalties on net sales of other products and services, made by us, our affiliates, or our sublicensees. The royalty percentage depends on the product and service, and whether such licensed product or licensed service is covered by a valid claim within the Cpf1 Patent Rights. If we are legally required to pay royalties to a third party on net sales of our products because such third party holds patent rights that cover such licensed product, then we can credit up to a mid double-digit percentage of the amount paid to such third party against the royalties due to Broad and Wageningen in the same period. Our obligation to pay royalties will expire on a product-by-product and country-by-country basis upon the later of the expiration of the last to expire valid claim of the Cpf1 Patent Rights that covers each licensed product or licensed service in each country or the tenth anniversary of the date of the first commercial sale of the product or service. If we sublicense any of the Cpf1 Patent Rights to a third party, Broad and Wageningen, collectively, have the right to

receive high single-digit to low double-digit percentages of the sublicense income, depending on the stage of development of the products or services in question at the time of the sublicense.

Under the Cpf1 License Agreement, Broad and Wageningen are also entitled, collectively, to receive success payments in the event our market capitalization reaches specified thresholds ascending from a high nine digit dollar amount to $10.0 billion ("Market Cap Success Payments") or sale of our company for consideration in excess of those thresholds, ("Company Sale Success Payments," which with the Market Cap Success Payments, the "Success Payments"). Market Cap Success Payments are payable by us in cash, in shares of our common stock, with such shares being valued for such purpose at the closing price of our common stock as reported the Nasdaq Stock Market for the trading day immediately preceding the date of such payment if our common stock was then listed on the Nasdaq Stock Market, or in the form of promissory notes (the "Promissory Notes"). The Promissory Notes bear interest at 4.8% per annum. Principal and interest on the Promissory Notes are payable on, subject to certain exceptions, 150 days following issuance (or if earlier, a specified period of time following a sale of our company). We could elect to make any payment of amounts outstanding under the Promissory Notes either in the form of cash or, subject to certain conditions, in shares of our common stock of equal value, with such shares being valued for such purpose at the closing price of our common stock as reported the Nasdaq Stock Market for the trading day immediately preceding the date of such payment if our common stock was then listed on the Nasdaq Stock Market. In the event of a change of control of our company or a sale of our company, we are required to pay all remaining principal and accrued interest on the Promissory Notes in cash within a specified period following such event. Following a change in control of our company, Market Cap Success Payments are required to be made in cash. Company Sale Success Payments are payable solely in cash. In 2017, two Market Cap Success Payments of $5.0 million each became due and payable and we issued Promissory Notes in such amounts, which we fully settled by issuing shares of our common stock in 2017 and 2018. In December 2020, an additional Market Cap Success Payment of $15.0 million became due and payable, which we settled through the issuance of shares of our common stock in January 2021. The remaining Success Payments that may be paid to Broad and Wageningen range from a low-eight digit dollar amount to a mid-eight digit dollar amount, and collectively will not exceed, in aggregate, $100.0 million, which maximum would be payable only if we achieve a market capitalization threshold of $10.0 billion and have at least one product candidate covered by a claim of a patent right licensed to us under either the Cpf1 License Agreement or the Cas9-I License Agreement that is or was the subject of a clinical trial pursuant to development efforts by us or any of our affiliates or sublicensees.

In addition, in the event that a sale of our company or change of control has occurred and the maximum amount of potential Success Payments under the Cpf1 License Agreement has not been paid to Broad and Wageningen, Broad and Wageningen are entitled to receive, upon the subsequent achievement of specified regulatory milestones, percentages ranging from high single digits to mid-to-low double digits of the remaining unpaid maximum amount of Success Payments. Broad and Wageningen are further entitled to receive up to the full remaining unpaid maximum amount of Success Payments upon the subsequent achievement of specified sales milestones. All such post-sale or post-change of control milestone payments are required to be made in cash.

Broad retains control of the prosecution and maintenance of the Cpf1 Patent Rights. We have the right to provide input in the prosecution of the Cpf1 Patent Rights, including to direct Broad to file and prosecute patents in certain countries. We are also obligated to reimburse Broad and Wageningen for all unreimbursed expenses incurred by them in connection with the prosecution and maintenance of the Cpf1 Patent Rights prior to the date of the Cpf1 License Agreement, and to reimburse Broad for expenses associated with the prosecution and maintenance of the Cpf1 Patent Rights following the date of the Cpf1 License Agreement.

We have the first right, but not the obligation, to enforce the Cpf1 Patent Rights with respect to our licensed products in the Exclusive Cpf1 Field so long as certain conditions are met, such as providing Broad and the applicable Cpf1 Institutions with evidence demonstrating a good faith basis for bringing suit against a third party. We are solely responsible for the costs of any lawsuits we elect to initiate and cannot enter into a settlement without the prior written consent of Broad. Any sums recovered in such lawsuits will be shared between Broad, Wageningen, and us.

Unless terminated earlier, the term of the Cpf1 License Agreement will expire on a country-by-country basis, upon the expiration of the last to expire valid claim of the Cpf1 Patent Rights in such country. However, our royalty obligations, discussed above, may survive expiration or termination. We have the right to terminate the Cpf1 License

Agreement at will upon four months' written notice to Broad. Either party may terminate the Cpf1 License Agreement upon a specified period of notice in the event of the other party's uncured material breach of a material obligation, such notice period varying depending on the nature of the breach. Broad may terminate the Cpf1 License Agreement immediately if we challenge the enforceability, validity, or scope of any Cpf1 Patent Right or assist a third party to do so, or in the event of our bankruptcy or insolvency.

Other Broad Agreements

In addition to the Cas9-I License Agreement and the Cpf1 License Agreement, in December 2016, we entered into a license agreement with Broad for certain Cas9 compositions of matter and their use for gene editing (the "Cas9-II Agreement"), and, in December 2018, we entered into a Sponsored Research Agreement with Broad providing for Broad to conduct research useful or relevant to genome editing in the field of genomic medicines for the prevention of treatment of human diseases with funding from us (the "Sponsored Research Agreement"). Under the Cas9-II Agreement and the Sponsored Research Agreement, we have potential obligations with respect to success payments, which are described in Note 8 to the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our platform technology, 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 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. 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.

Our in-licensed patents and patent applications cover various aspects of our genome editing platform technology, including CRISPR systems that employ Cas9 including *S. aureus* Cas9, high-fidelity Cas9 nucleases and Cas9 PAM variants, self-inactivating forms of Cas9, Cas9 nickases, CRISPR systems that employ Cas12a including Cas12a nickases and other variants and self-inactivating forms of Cas12a, and also CRISPR systems that employ viral vectors for delivery, single guide RNAs, or modified guide RNAs, including guide nucleic acids containing both DNA and RNA components. We also have filed patent applications and have in-licensed rights to filed patent applications directed to each of the four components of our genome editing platform technology. We intend 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. We also intend to obtain rights to existing delivery technologies through one or more licenses from third parties.

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. Moreover, trade secrets can be difficult to protect. While we have confidence in the measures we take 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 "Risk Factors—Risks Related to Our Intellectual Property."

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. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. The Drug Price Competition and Patent Term Restoration Act of 1984 extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug or a method for using it may be extended.

CRISPR

As of December 31, 2020, we owned nine U.S. patents, 64 pending U.S. non-provisional patent applications, seven European patents and related validations, 56 pending European patent applications, five pending U.S. provisional patent applications, seven pending PCT patent applications, and other related patent applications in jurisdictions outside the United States and Europe that are related to our CRISPR technology and which include claims directed to our genome editing platform, including our directed editing component, as well as composition of matter and method of use claims for our therapeutic programs, including LCA10 and other genetic and infectious eye disorders, and engineered T cells. Three of these U.S. patents, one of these European patents and their U.S., European and foreign counterpart applications are co-owned with Broad and Iowa and we have obtained an exclusive license to such co-ownership rights from these third parties in the field of prevention or treatment of human disease using gene therapy or genome editing. In addition, one of these pending PCT patent applications and 12 of these pending U.S. non-provisional patent applications are co-owned with certain of our collaborators because they encompass inventions developed under our collaborations. Our current issued U.S. patents, 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. If issued as U.S. patents, and if the appropriate maintenance fees are paid, the U.S. patent applications would be expected to expire between 2035 and 2040, excluding any additional term for patent term adjustments or patent term extensions.

As of December 31, 2020, we in-licensed 88 U.S. patents, 44 European patents and related validations, and approximately 500 pending patent applications, including 92 pending U.S. non-provisional patent applications, 58 pending European patent applications, and other related patents and patent applications in jurisdictions outside the United States and Europe that are related to our CRISPR technology collectively from various universities and institutions. The patents and patent applications outside of the United States and Europe are held primarily in Canada, Japan, and Australia, although some of our in-licensed patent families were filed in a larger number of countries. The claims from our in-licensed portfolio include claims to compositions of matter, methods of use, and certain processes. These include claims directed to CRISPR systems that employ Cas9 including Cas9 nickases, *S. aureus* Cas9, high-fidelity Cas9 nucleases, Cas9 PAM variants and self-inactivating forms of Cas9, CRISPR systems that employ Cas12a including Cas12a nickases and other variants and self-inactivating forms of Cas12a, and also CRISPR systems that employ viral vectors for delivery, single guide RNAs, or modified guide RNAs. Our current in-licensed U.S. patents, if the appropriate maintenance fees are paid, are expected to expire between 2033 and 2039, excluding any additional term for patent term adjustments or patent term extensions. If issued as U.S. patents, and if the appropriate maintenance fees are paid, the U.S. patent applications would be expected to expire between 2034 and 2040, excluding any additional term for patent term adjustments or patent term extensions.

Our in-licensed patents and patent applications claim the inventions of investigators at various universities and institutions and the majority of these licensed patents and patent applications are licensed on an exclusive basis. The exclusive licenses are, in some cases, limited to certain technical fields. Certain U.S. patent applications licensed to us by Broad include Tokyo and NIH as joint applicants. Broad has only granted a license to us with respect to its interests and to Tokyo's interests in these U.S. patent applications but not to any foreign equivalents thereof. Broad does not and does not purport to grant any rights in NIH's interest in these U.S. patent applications under our agreement. As a result, we may not have exclusive rights under any U.S. patents that issue from these U.S. patent applications and we may not have any rights under any foreign patents that issue from any foreign equivalents thereof. For more information regarding these license agreements, please see the section of this Annual Report on Form 10-K titled "Business —Intellectual Property Licenses."

LCA10

As of December 31, 2020, we owned two U.S. patents, five pending U.S. non-provisional patent applications, one European patent and related validations, two pending European patent applications, and seven pending foreign patent applications, which are directed to compositions of matter, including guide RNAs directed to CEP290, and methods of use for the treatment of LCA10. Our current issued U.S. patents, if the appropriate maintenance fees are paid, are expected to expire in 2035, excluding any additional term for patent term extensions. If issued as a U.S. patent, and if the appropriate maintenance fees are paid, the U.S. patent applications would be expected to expire between 2035 and 2039, excluding any additional term for patent term adjustments or patent term extensions.

Trademarks

As of December 31, 2020, our registered trademark portfolio consisted of registrations in the United States for EDITAS, EDITAS in Stylized Letters and the Infinity Logo, registrations in Australia, China, the European Union, Japan and Switzerland for EDITAS, registrations in Australia, China, the European Union, Japan and Switzerland for the Infinity Logo and a registration in the European Union for UDITAS.

Competition

The biotechnology and pharmaceutical industries, including in the gene therapy, genome editing and cell therapy fields, are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on intellectual property and proprietary products. While we believe that our technology, development experience, and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical, biotechnology companies, governmental agencies, and public and private research institutions. Any product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies may become available in the future.

We compete in the segments of the pharmaceutical, biotechnology, and other related markets that utilize technologies encompassing genomic medicines to create therapies, including genome editing and gene therapy. There are additional companies that are working to develop therapies in areas related to our research programs. Our platform and product focus is the development of therapies using CRISPR technology. Other companies developing CRISPR technology or therapies using CRISPR technology include Arbor Biotechnologies, Caribou Biosciences, CRISPR Therapeutics, ERS Genomics, Intellia Therapeutics, Locus Biosciences, ToolGen Inc. TRACR Hematology and Vertex Pharmaceuticals. In addition, there have been and may continue to be discoveries of new CRISPR-based gene editing technologies. There are additional companies developing therapies using other genome editing technologies, including base editing, prime editing, transcription activator-like effector nucleases, meganucleases, Mega-TALs and zinc finger nucleases. The companies developing these other genome editing technologies include Beam Therapeutics, Prime Medicine, bluebird bio, Cellectis, Poseida Therapeutics, Precision Biosciences and Sangamo Therapeutics. Additional companies developing cell and gene therapy products include Abeona Therapeutics, Adverum Biotechnologies, AGTC Therapeutics, Audentes Therapeutics, Fate Therapeutics, Inc., Graphite Bio, Homology Medicines, Nkarta, Inc., REGENXBIO, Sarepta Therapeutics, Solid Biosciences, Spark Therapeutics, uniQure and Voyager Therapeutics. In addition to competition from other genome editing therapies, gene therapies or cell medicine therapies, any products that we may develop may also face competition from other types of therapies, such as small molecule, antibody, protein, oligonucleotide, or ribonucleic acid therapies. For example, ProQR Therapeutics N.V. is conducting a Phase I/II clinical trial for its experimental treatment using antisense oligonucleotide technology for LCA10.

In addition, many of our current or potential competitors, either alone or with their collaboration partners, may have greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, 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 products that are safer, more effective, 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.

If our current programs are approved for the indications for which we are currently planning clinical trials, they may compete with other products currently under development, including genome editing and gene therapy products. Competition with other related products currently under development may include competition for clinical trial sites, patient recruitment, and product sales.

Manufacturing

We currently perform some manufacturing activities such as the production of guide RNA for our various internal and partner programs and some pre-clinical and early-phase clinical production for our *ex vivo* gene edited cell medicines. These activities are performed on site at our existing facilities or, in the case of EDIT-301 for sickle cell disease, at current good manufacturing practice-compliant space leased by us and staffed by our employees. We contract with third parties for the manufacturing of all other materials for preclinical studies and our clinical trials. We have limited manufacturing operations and do not own or operate any substantial manufacturing facilities for the production of our program materials. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. The use of contracted manufacturing and reliance on collaboration partners is relatively cost-efficient and has eliminated the need for our direct investment in manufacturing facilities and additional staff early in development. Although we rely on contract manufacturers, we have personnel with manufacturing experience to oversee our contract manufacturers. We expect third-party manufacturers to be capable of providing sufficient quantities of our program materials to meet anticipated needs for preclinical studies and clinical trials. To meet our projected needs for commercial manufacturing, third parties with whom we currently work might need to increase their scale of production or we will need to secure alternate suppliers. We believe that there are alternate sources of supply that can satisfy our preclinical, clinical, and commercial requirements, although we cannot be certain that identifying and establishing relationships with such sources, if necessary, would not result in significant delay or material additional costs.

Commercialization

We currently intend to build the commercial infrastructure in the United States and Europe necessary to effectively support the commercialization of all of our programs, if and when we first believe a regulatory approval of a product candidate under one of our programs in a particular geographic market appears probable. The commercial infrastructure for orphan products typically consists of a targeted, specialty sales force that calls on a limited and focused group of physicians supported by sales management, medical liaisons, internal sales support, an internal marketing group, and distribution support.

Additional capabilities important to the orphan marketplace include the management of key accounts such as managed care organizations, group purchasing organizations, specialty pharmacies, and government accounts. To develop the appropriate commercial infrastructure, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that any product candidate we may develop will be approved.

Outside of the United States and Europe, where appropriate, we may elect in the future to utilize strategic partners, distributors, or contract sales forces to assist in the commercialization of our products. In certain instances, we may consider building our own commercial infrastructure.

As product candidates advance through our pipeline, our commercial plans may change. In particular, some of our research programs target potentially larger indications. Data, the size of the development programs, the size of the

target market, the size of a commercial infrastructure, and manufacturing needs may all influence our strategies in the United States, Europe, and the rest of the world.

Government Regulation and Licensure of Products

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, pricing, reimbursement, sales, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products, including biological products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Licensure and Regulation of Biologics in the United States

In the United States, our candidate products would be regulated as biological products, or biologics, under the Public Health Service Act (the "PHSA") and the Federal Food, Drug and Cosmetic Act (the "FDCA") and its implementing regulations and guidances. The failure to comply with the applicable U.S. requirements at any time during the product development process, including non-clinical testing, clinical testing, the approval process or post-approval process, may subject an applicant to delays in the conduct of the study, regulatory review and approval, and/or administrative or judicial sanctions.

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 ("GLP") regulations;
- completion of the manufacture, under current Good Manufacturing Practices ("cGMP") conditions, of the drug substance and drug product that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("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 ("GCP");
- preparation and submission to the FDA of a Biologic License Application ("BLA") for a biologic product requesting marketing for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development and proposed labelling;
- review of the product by an FDA advisory committee, where appropriate or if 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 cGMP requirements and 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 ("GTP") 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 GCPs and the integrity of clinical data in support of the BLA;

- payment of user Prescription Drug User Free Act ("PDUFA") securing FDA approval of the BLA and licensure of the new biologic product; and

- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy ("REMS") and any post-approval studies required by the FDA.

Preclinical Studies and Investigational New Drug Application

Before testing any biologic product candidate in humans, including a gene therapy 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. 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 product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational product to humans. The IND 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 or recommence.

As a result, submission of the IND may result in the FDA not allowing the trials to commence or allowing the trial to commence on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND process, it may choose to impose a partial or complete clinical hold. Clinical holds are imposed by the FDA whenever there is concern for patient safety and may be a result of new data, findings, or developments in clinical, nonclinical, and/or chemistry, manufacturing, and controls. This order issued by the FDA would delay either 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. This 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. The rules and regulations related to expanded access are intended to improve access to investigational products for patients who may benefit from investigational therapies. 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.

When considering an IND application for expanded access to an investigational product with the purpose of treating a patient or a group of patients, the sponsor and treating physicians or investigators will determine suitability 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 initiation, conduct, or completion of clinical investigations that could support marketing approval of the product or otherwise compromise the potential development of the product.

There is no obligation for a sponsor to make its drug products available for expanded access; however, as required by the 21st Century Cures Act (the "Cures Act"), passed in 2016, if a sponsor has a policy regarding how it responds to expanded access requests, it must make that policy publicly available. Although these requirements were rolled out over time, they have now come into full effect. 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 a federal framework for certain patients to access certain investigational products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a manufacturer to make its investigational products available to eligible patients as a result of 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 a qualified principal investigator in accordance with GCP requirements. 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 regulatory requirements of the FDA in order to use the trial as support for an IND or application for marketing approval. Specifically, the FDA requires that such trials be conducted in accordance with GCP, including review and approval by an independent ethics committee and informed consent from subjects. The GCP requirements encompass both ethical and data integrity standards for clinical trials. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign trials are conducted in a manner comparable to that required for clinical trials in the United States.

Further, 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. 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 or the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent.

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 ("DSMB"). This group may recommend continuation of the study as planned, changes in study conduct, or cessation of the study at designated check points based on certain available data from the study to which only the DSMB has access. 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 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 patients, such as patients suffering from LCA10, sickle cell disease or cancer.

- *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 may 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. Phase 3 clinical trials are undertaken within an expanded patient population to further evaluate dosage, provide substantial evidence of clinical efficacy, and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites. 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 and 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. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement or to request a change in the product labeling. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products.

Information about clinical trials must be submitted within specific timeframes to the NIH for public dissemination on its ClinicalTrials.gov website.

Pediatric Studies

Under the Pediatric Research Equity Act of 2003, 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 also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA’s internal review committee must then review the information submitted, consult with each other, 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. Additional requirements and procedures relating to deferral requests and requests for extension of

deferrals are contained in the Food and Drug Administration Safety and Innovation Act, or FDASIA. The FDA maintains a list of diseases that are exempt from PREA requirements due to low prevalence of disease in the pediatric population. Congress amended the FDA Reauthorization Act of 2017, or FDARA. Previously, drugs that had been granted orphan drug designation were exempt from the requirements of the Pediatric Research Equity Act. Under the amended section 505B, beginning on August 18, 2020, the submission of a pediatric assessment, waiver or deferral will be required for certain molecularly targeted cancer indications with the submission of an application or supplement to an application.

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 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 transferred to cells *ex vivo* prior to administration to the recipient.

Within the FDA, the Center for Biologics Evaluation and Research ("CBER") regulates gene therapy products. Within the CBER, the review of gene therapy and related products is consolidated in the Office of Cellular, Tissue and Gene Therapies, and the FDA has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its reviews. The NIH, including its Novel and Exceptional Technology Research Advisory Committee ("NExTRAC"), also advises the FDA on gene therapy issues and other issues related to emerging biotechnologies. The FDA and the NIH have published guidance documents with respect to the development and submission of gene therapy protocols.

The FDA has issued various guidance documents regarding gene therapies, including recent final guidance documents released in January 2020 relating to chemistry, manufacturing and controls information for gene therapy INDs, long-term follow-up after the administration of gene therapy products, gene therapies for rare diseases and gene therapies for retinal disorders, as well as draft guidance in January 2021 for Human Gene Therapy for Neurodegenerative Diseases. Although the FDA has indicated that these and other guidance documents it previously issued are not legally binding, compliance with them is likely necessary to gain approval for any gene therapy product candidate. The guidance documents provide additional factors that the FDA will consider at each of the above stages of development and relate to, among other things, the proper preclinical assessment of gene therapies; the chemistry, manufacturing, and control 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; and measures to observe delayed adverse effects in subjects who have been exposed to investigational gene therapies when the risk of such effects is high. 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.

Until 2019, most gene therapy clinical trials required pre-review by the predecessor of NExTRAC before being submitted for approval by the IRBs and any local biosafety boards. In 2019, the NIH eliminated the pre-review process and going forward, the review of future gene therapy clinical trial protocols would be largely handled by IRBs. Furthermore, in 2019, the NIH removed from public access the Genetic Modification Clinical Research Information System database, which previously contained substantial amounts of safety and other patient information regarding human gene therapy studies performed to date.

Compliance with cGMP and GTP 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.

For a gene therapy product, the FDA also will not approve the product if the manufacturer is not in compliance with GTP. These standards are found in FDA regulations and guidances 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 ("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. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Inspections must follow a "risk-based schedule" that may result in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

Review and Approval of a BLA

The results of product candidate development, preclinical testing, and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of a BLA requesting license to market the product. The BLA must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling as well as payment of a user fee. Under federal law, the submission of most BLAs is subject to an application user fee, which for federal fiscal year 2021 is $2,875,842 for an application requiring clinical data. The sponsor of a licensed BLA is also subject to an annual program fee, which for fiscal year 2021 is $336,432. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether it is sufficient to accept for filing based on the agency's threshold determination that 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 the PDUFA, the FDA has ten months in which to complete its initial review of a standard application and respond to the applicant, and six months for a priority review of the application. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs. The review process may often be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may be extended by three months if the FDA requests or if the applicant otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure, and potent and 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 GCPs, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information 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 final 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.

The FDA may also refer the application to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved. In particular, the FDA may refer applications for novel biologic products or biologic 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, that reviews, evaluates, and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

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 call for post-approval studies, including Phase 4 clinical trials, to further assess the product's safety 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 ("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 is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as fast track designation, breakthrough therapy designation, priority review designation and regenerative advanced therapy designation.

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a 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 application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, in 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act ("FDASIA"). This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, 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, such as substantial treatment effects observed early in clinical development. 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 design the clinical trials in an efficient manner.

Third, the 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. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

With passage of the Cures Act in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this 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 a regenerative advanced therapy designation include early interactions with FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

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 ("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. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

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.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Post-Approval Regulation

If regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with all regular post-approval regulatory requirements as well as any post-approval requirements that the FDA have imposed as part of the approval process. The sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling requirements. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon manufacturers. 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.

A product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency, and effectiveness of pharmaceutical products.

Once an approval is granted, the FDA may withdraw the 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 with manufacturing processes, or failure to comply with regulatory requirements, 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 risks; 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, complete withdrawal of the product from the market or product recalls;
- 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 seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved label. Although health care providers may prescribe products for off-label uses in their professional judgment, drug manufacturers are prohibited from soliciting, encouraging or promoting unapproved uses of a product. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products placed on the market. This regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the Internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the drug is approved. After approval, a drug product generally may not be promoted for uses that

are not approved by the FDA, as reflected in the product's prescribing information. In the United States, health care professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because the FDA does not regulate the practice of medicine. However, FDA regulations impose rigorous restrictions on manufacturers' communications, prohibiting the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, 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.

Orphan Drug Designation and Exclusivity

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for 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 available the biologic for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for tax credits and market exclusivity for seven years following the date of the product's marketing approval if granted by the FDA. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. A product becomes an orphan when it receives orphan drug designation from the Office of Orphan Products Development at the FDA based on acceptable confidential requests made under the regulatory provisions. The product must then go through the review and approval process like any other product.

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.

If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same product for the same indication for seven years, except in certain limited circumstances. In particular, the concept of what constitutes the "same drug" for purposes of orphan drug exclusivity remains in flux in the context of gene therapies, and the FDA has issued recent draft guidance suggesting that it would not consider two gene therapy products to be different drugs solely based on minor differences in the transgenes or vectors. If a product designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, 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.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. 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. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Biosimilars and Exclusivity

The 2010 Patient Protection and Affordable Care Act, which was signed into law in March 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"). The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. A biosimilar is a biological product that is highly similar to an existing FDA-licensed "reference product." As of January 1, 2021, the FDA has approved 29 biosimilar products for use in the United States. No interchangeable biosimilars, however, have been approved. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Additional guidances are expected to be finalized by the FDA in the near term.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic 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 BPCIA, 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 approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law. Since the passage of the BPCIA, many states have passed laws or amendments to laws, including laws governing pharmacy practices, which are state-regulated, to regulate the use of biosimilars.

Patent Term Restoration and Extension

A patent claiming a new biologic product, its method of use or its method of manufacture 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 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 of a clinical investigation involving human beings is begun and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. 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, 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.

The 2014 guidance also explains that a companion diagnostic device used to make treatment decisions in clinical trials of a biologic product candidate generally will be considered an investigational device, unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA's Investigational Device Exemption ("IDE") regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a product are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the study plan and subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE.

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 pre-market approval ("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. For federal fiscal year 2021, the standard fee 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. 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.

Regulation and Procedures Governing Approval of Medicinal Products in the European Union

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 European Union 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 for each proposed indication. It also requires the submission to the relevant competent authorities of a marketing authorization application ("MAA") and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union.

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 European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and further detailed in applicable guidance documents.

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. The new Clinical Trials Regulation will become directly applicable to and binding in all 28 EU Member States without the need for any national implementing legislation. It will overhaul the current system of approvals for clinical trials in the EU. Specifically, the new legislation aims at simplifying and streamlining the approval of clinical trials in the EU. Under the new coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial will be required to submit a single application for approval of a clinical trial to a reporting EU Member State (RMS) through an EU Portal. The submission procedure will be the same irrespective of whether the clinical trial is to be conducted in a single EU Member State or in more than one EU Member State.

The Regulation was published on June 16, 2014 but has not yet become effective. As of January 1, 2020, the website of the European Commission reported that the implementation of the Clinical Trials Regulation was dependent on the development of a fully functional clinical trials portal and database, which would be confirmed by an independent audit, and that the new legislation would come into effect six months after the European Commission publishes a notice of this confirmation. The website indicated that the audit was expected to commence in December 2020. In late 2020, the EMA indicated that it plans to focus on the findings of a system audit; improving the usability, quality and stability of the clinical trial information system; and knowledge transfer to prepare users and their organizations for the new clinical trial system. The EMA has indicated that the system will go live in December 2021.

Parties conducting certain clinical studies must, as in the U.S., post clinical trial information in the European Union at the EudraCT website: https://eudract.ema.europa.eu.

PRIME Designation in the EU

In March 2016, the European Medicines Agency ("EMA") launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIority Medicines ("PRIME") scheme 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. Importantly, a dedicated EMA contact and rapporteur from the Committee for Human Medicinal Products ("CHMP") or Committee for Advanced Therapies are appointed early in the PRIME scheme facilitating increased understanding of the product at the EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Pediatric Studies

Applicants developing a new medicinal product must agree upon a Pediatric Investigation Plan ("PIP") with the EMA's pediatric committee ("PDCO"), and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies (e.g., because the relevant disease or condition occurs only in adults). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted by the PDCO of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults, in which case the pediatric clinical trials must be completed at a later date.

Marketing Authorization

To obtain a marketing authorization for a product under the European Union regulatory system, an applicant must submit an MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in European Union Member States (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the European Union. Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the European Union, an applicant must demonstrate compliance with all measures included in an EMA-approved PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver, or a deferral for one or more of the measures included in the PIP.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU member states. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional. Manufacturers must demonstrate the quality, safety, and efficacy of their products to the EMA, which provides an opinion regarding the MAA. The European Commission grants or refuses marketing authorization in light of the opinion delivered by the EMA.

Specifically, the grant of marketing authorization in the European Union 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 EMA which provides an opinion regarding the

application for marketing authorization. The European Commission grants or refuses marketing authorization in light of the opinion delivered by EMA.

Under the centralized procedure, the CHMP established at the EMA is responsible for conducting an initial assessment of a product. Under the centralized procedure in the European Union, 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.

Specialized Procedures for Gene Therapies

The grant of marketing authorization in the European Union for gene therapy 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 includes specific rules concerning the authorization, supervision, and pharmacovigilance of gene therapy medicinal products. Manufacturers of advanced therapy medicinal products must demonstrate the quality, safety, and efficacy of their products to the EMA, which provides an opinion regarding the MAA. The European Commission grants or refuses marketing authorization in light of the opinion delivered by the EMA.

Regulatory Data Protection in the European Union

In the European Union, 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 European Union from referencing the innovator's data to assess a generic (abbreviated) application for a period of eight years. 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. Even if a compound is considered to be a new chemical 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.

Patent Term Extensions in the European Union and Other Jurisdictions

The European Union also provides for patent term extension through Supplementary Protection Certificates, or SPCs. The rules and requirements for obtaining an SPC are similar to those in the United States. An SPC may extend the term of a patent for up to five years after its originally scheduled expiration date and can provide up to a maximum of fifteen years of marketing exclusivity for a drug. These periods can be extended for six additional months if pediatric exclusivity is obtained, which is described in detail below. Although SPCs are available throughout the European Union, sponsors must apply on a country-by-country basis. Similar patent term extension rights exist in certain other foreign jurisdictions outside the European Union.

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 European Union'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, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's GMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities, and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. Finally, 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 European Union under Directive 2001/83EC, as amended.

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 European Union when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union 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 European Union or, if such method exists, the drug will be of significant benefit to those affected by that condition.

An orphan drug designation provides a number of benefits, including fee reductions, regulatory assistance, and the possibility to apply for a centralized European Union marketing authorization. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. During this market exclusivity period, neither the EMA nor the European Commission or the member states can accept an application or grant a marketing authorization for a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation because, for example, the product is sufficiently profitable not to justify market exclusivity.

Pediatric Exclusivity

Products that are granted a marketing authorization with the results of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) even where the trial results are negative. In the case of orphan medicinal products, a two year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the EU, commonly referred to as Brexit. Following protracted negotiations, the United Kingdom left the EU on January 31, 2020. Under the withdrawal agreement, there is a transitional period until December 31, 2020 (extendable by up to two years). On December 24, 2020, the United Kingdom and the European Union entered into a Trade and Cooperation Agreement. The agreement sets out certain procedures for approval and recognition of medical products in each jurisdiction. Since the regulatory framework for pharmaceutical products in the United Kingdom covering 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 could materially impact the future regulatory regime which applies to products and the approval of product candidates in the UK, as the UK legislation now has the potential to diverge from EU legislation. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the UK in the long-term. The MHRA has recently published detailed guidance for industry and organizations to follow from January 1, 2021 now the transition period is over, which will be updated as the UK's regulatory position on medicinal products evolves over time.

Furthermore, while the Data Protection Act of 2018 in the United Kingdom that "implements" and complements the European Union's General Data Protection Regulation, or GDPR, has achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is still unclear whether transfer of data from the European Economic Area, or EEA, to the United Kingdom will remain lawful under GDPR. The Trade and Cooperation Agreement provides for a transitional period during which the United Kingdom will be treated like an European Union member state in relation to processing and transfers of personal data for four months from January 1, 2021. This may be extended by two further months. After such period, the United Kingdom will be a "third country" under the GDPR unless the European Commission adopts an adequacy decision in respect of transfers of personal data to the United Kingdom. The United Kingdom has already determined that it considers all of the EU 27 and EEA member states to be adequate for the purposes of data protection, ensuring that data flows from the United Kingdom to the EU/EEA remain unaffected.

General Data Protection Regulation

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the EU General Data Protection Regulation ("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, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, 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 EU, 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 will be 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.

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. Even if any product candidates we may develop are approved, sales of such product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers, and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such product candidates. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party reimbursement and coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

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

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 European Union, pricing and reimbursement schemes vary widely from country to country. Some 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. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union 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. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union 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 European Union. The downward pressure on health care costs 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 European Union 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 physicians and teaching physicians and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent or knowingly making, using, or causing to made or used a false record or statement to avoid, decrease, or conceal an obligation to pay money to the federal government;

- the federal civil monetary penalty and false statement laws and regulations relating to pricing and submission of pricing information for government programs, including penalties for knowingly and intentionally overcharging 340b eligible entities and the submission of false or fraudulent pricing information to government entities;

- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information;

- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;

- the Foreign Corrupt Practices Act, which prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment;

- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act ("PPACA"), as amended by the Health Care Education Reconciliation Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services ("CMS") within the U.S. Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

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

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States.

By way of example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In March 2010, the United States Congress enacted the PPACA, which, among other things, includes changes to the coverage and payment for products under government health care programs. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2030 under the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by President Trump on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Court of Appeals for the Fifth Circuit court affirmed the lower court's ruling that the individual mandate

portion of the ACA is unconstitutional and it remanded the case to the district court for reconsideration of the severability question and additional analysis of the provisions of the ACA. Thereafter, the U.S. Supreme Court agreed to hear this case. Oral argument in the case took place on November 10, 2020. On February 10, 2021, the Biden Administration withdrew DOJ's support for this lawsuit. A ruling by the Court is expected sometime this year. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

The Trump Administration also took executive actions to undermine or delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden rescinded those orders and issued a new Executive Order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this Order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents.

The costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States To date, there have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. To those ends, President Trump issued five executive orders intended to lower the costs of prescription drug products but it is unclear whether, and to what extent, these orders will remain in force under the Biden Administration. Further, on September 24, 2020, the Trump Administration finalized a rulemaking allowing states or certain other non-federal government entities to submit importation program proposals to the FDA for review and approval. Applicants are required to demonstrate that their importation plans pose no additional risk to public health and safety and will result in significant cost savings for consumers. The FDA has issued draft guidance that would allow manufacturers to import their own FDA-approved drugs that are authorized for sale in other countries (multi-market approved products).

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Additional Regulations

In addition to the foregoing, state, and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act, and the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling, and disposal of various biologic, chemical, and radioactive substances used in, and wastes generated by, operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. Equivalent laws have been adopted in third countries that impose similar obligations.

Human Capital

As of February 1, 2021, we had 235 full-time employees, including 61 employees with M.D. or Ph.D. degrees. Of these full-time employees, 185 employees are engaged in research and development activities. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We experienced significant growth in the number of our employees in 2020, particularly in our research and development organization. We anticipate that we will continue to increase headcount in our clinical and development organization as we progress the clinical development of EDIT-101 to treat LCA10 and EDIT-301 to treat sickle cell disease, and further advance our current research programs and our preclinical development activities.

Our values – community, innovation, and results – are built on the foundation that our people and the way we treat one another promote creativity in all aspects of our work and drive us as a team to achieve our mission of translating the promise of gene editing into a broad class of differentiated, transformational medicines for diseases with high unmet need.

Our human capital is integral to our future success. For that reason, our human capital resources objectives include attracting, retaining, developing and motivating a diverse team of highly skilled employees at all levels. We value our employees and provide them with competitive salaries and bonuses, opportunities for equity ownership, including stock-based compensation awards and an employee stock purchase plan, development programs that enable continued learning and growth and an employment package that promotes well-being across all aspects of their lives, including health care, retirement planning and paid time off. We regularly benchmark these total rewards against our industry peers to ensure we remain competitive and attractive to potential new hires. In addition, we regularly conduct employee surveys to gauge employee engagement and solicit feedback, and enhance our understanding of the views of our employees, work environment and culture. The results from engagement surveys are used to implement programs and processes designed to enhance employee engagement and improve the employee experience.

Our Corporate Information

We were incorporated under the name Gengine, Inc. as a Delaware corporation in September 2013, and we changed our name to Editas Medicine, Inc. in November 2013. Our principal executive offices are located at 11 Hurley St., Cambridge, Massachusetts, 02141, and our telephone number is (617) 401-9000.

Available Information

We maintain an internet website at www.editasmedicine.com and make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act of 1934, or the Exchange Act. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the Securities and Exchange Commission, or the SEC. You can review our electronically filed reports and other information that we file with the SEC on the SEC's web site at http://www.sec.gov. We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. In addition, we regularly use our website to post information regarding our business, product development programs and governance, and we encourage investors to use our website, particularly the information in the section entitled "Investors & Media," as a source of information about us.

The information on our website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered to be a part of this Annual Report on Form 10-K. Our website address is included in this Annual Report on Form 10-K as an inactive technical reference only.

Item 1A. Risk Factors

Our business is subject to numerous risks. The following important factors, among others, could cause our actual results to differ materially from those expressed in forward-looking statements made by us or on our behalf in this Annual Report on Form 10-K and other filings with the Securities and Exchange Commission (the "SEC"), press releases, communications with investors, and oral statements. Actual future results may differ materially from those anticipated in our forward-looking statements. We undertake no obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise.

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 losses were $116.0 million, $133.7 million, and $110.0 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of $665.2 million. We have financed our operations primarily through public offerings of our common stock, private placements of our preferred stock, our collaboration with Juno Therapeutics, Inc., a wholly-owned subsidiary of Bristol-Myers Squibb Company ("Juno Therapeutics"), and payments under our strategic alliance with Allergan Pharmaceuticals International Limited (which was acquired by AbbVie Inc. in May 2020 and is referred to together with its affiliates as "Allergan"), which was terminated in August 2020. We have devoted substantially 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:

- progress the clinical development of EDIT-101 to treat Leber congenital amaurosis ("LCA") 10 ("LCA10");
- continue our current research programs and our preclinical and clinical development of product candidates from our current research programs, including EDIT-301, our experimental medicine to treat sickle cell disease and beta-thalassemia;
- 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, 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;
- ultimately establish a sales, marketing, and distribution infrastructure to commercialize any medicines for which we may obtain marketing approval;
- further develop our genome editing platform;
- hire additional clinical, quality control, and scientific personnel;
- add operational, financial, and management information systems and personnel, including personnel to support our product development;
- acquire or in-license other medicines and technologies;

- validate a commercial-scale current Good Manufacturing Practices ("cGMP") manufacturing facility; and
- continue to operate as a public company.

We are in the early stages of the clinical development of EDIT-101 and expect that it will be many years, if ever, before we have a product candidate ready for commercialization. As a result of the termination of our agreements with Allergan in August 2020, we are now obligated to fund all of the costs related to developing and commercializing the LCA10 program in the United States, including the costs of the clinical development of EDIT-101. To become and remain profitable, we must develop and 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. Other than EDIT-101 and EDIT-301, we are currently only in the preclinical testing stages for our most advanced research programs. 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. A decline in the value of our company could cause our stockholders to lose all or part of their investments in us.

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 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 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. 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.

We expect that our existing cash, cash equivalents, and marketable securities at December 31, 2020 and anticipated interest income will enable us to fund our operating expenses and capital expenditure requirements into 2023. Our future capital requirements will depend on many factors, including:

- the costs of progressing the clinical development of EDIT-101 to treat LCA10 and EDIT-301 to treat sickle cell disease;
- the scope, progress, results, and costs of drug discovery, preclinical development, laboratory testing, and clinical or natural history study trials for the product candidates we 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 develop;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, and distribution, for any product candidates for which we receive regulatory approval;
- the success of our collaboration with Juno Therapeutics;

- whether Juno Therapeutics exercises any of its options to extend the research program term and/or to certain of the research programs under our collaboration;
- our ability to establish and maintain additional collaborations on favorable terms, if at all;
- the extent to which we acquire or in-license other medicines and technologies;
- the costs of reimbursing our licensors for the prosecution and maintenance of the patent rights in-licensed by us; and
- the costs of operating as a public company.

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.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, and licensing arrangements. We do not have any significant committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders may be materially diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. 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.

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

We were founded and commenced operations in the second half of 2013. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential product candidates, undertaking preclinical studies and preparing to undertake clinical trials. Except for EDIT-101 and EDIT-301, all of our research programs are still in the preclinical or research stage of development, and the risk of failure of all of our research programs is high. We have not yet demonstrated an ability to 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. In addition, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors.

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

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

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with collaboration 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.

Even if one or more of the product candidates we develop is 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 U.S. Food and Drug Administration (the "FDA"), the European Medicines Agency (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 products, we may not become profitable and may need to obtain additional funding to continue operations.

Risks Related to Discovery, Development, and Commercialization

We intend to identify and develop product candidates based on a novel genome editing technology, which makes it difficult to predict the time and cost of product candidate development. No therapeutic products that utilize genome editing technology have been approved in the United States or in Europe, and there have only been a limited number of human clinical trials of a genome editing product candidate.

We have concentrated our research and development efforts on our genome editing platform, which uses CRISPR technology. Our future success depends on the successful development of this novel genome editing therapeutic approach. To date, no therapeutic product that utilizes genome editing, including CRISPR technology, has been approved in the United States or Europe and there have been only a limited number of clinical trials involving the use of a therapeutic utilizing genome editing technologies. It is difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our genome editing platform, or any similar or competitive genome editing platforms, will result in the identification, development, and regulatory approval of any medicines. There can be no assurance that any development problems we experience in the future related to our genome editing platform or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays in developing a sustainable, reproducible, and scalable manufacturing process or transferring that process to commercial partners. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or commercializing any product candidates we develop on a timely or profitable basis, if at all.

Because genome editing is novel and the regulatory landscape that will govern any product candidates we 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 develop.

The regulatory requirements that will govern any novel genome editing product candidates we develop are not entirely clear and may change. Within the broader genomic medicine field, we are aware of a limited number of 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 ("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 to review and oversight by an institutional biosafety committee ("IBC"), a committee that reviews and oversees the use of biological agents. 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 allowed its initiation. The same applies in the European Union. The EMA's Committee for Advanced Therapies ("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 EMA. 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.

Adverse developments in clinical trials conducted by others of gene therapy products, cell therapy products, or products developed through the application of a CRISPR or other genome editing technology may cause the FDA, the EMA, and other regulatory bodies to revise the requirements for approval of any product candidates we develop or limit the use of products utilizing genome editing technologies, either of which could materially harm our business. 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 ours 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 genome 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.

Adverse public perception of genomic medicines, and genome editing in particular, may negatively impact regulatory approval of, 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 genome editing therapy for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that genome editing is unsafe, unethical, or immoral, and, consequently, our products may not gain the acceptance of the public or the medical community. 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 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, genome editing technology is subject to public debate and heightened regulatory scrutiny due to ethical concerns relating to the application of genome 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 genome of human embryos as part of basic research and, 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, announced he had created the first human genetically edited babies, twin girls and helped create a second gene-edited pregnancy. The announcement was negatively received by the public, in particular by those in the scientific community. In the United States, germline editing for clinical application has been expressly prohibited since enactment of a December 2015 U.S. FDA ban on such activity. Prohibitions are also in place in the United Kingdom, across most of Europe, in China, and many other countries around the world. In the United States, the NIH has announced that it would not fund any use of genome editing technologies in human embryos, noting that there are multiple existing legislative and regulatory prohibitions against such work, including the Dickey-Wicker Amendment, which prohibits the use of appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed. Laws in the United Kingdom prohibit genetically modified embryos from being implanted into women, but embryos can be altered in research labs under license from the Human Fertilisation and Embryology Authority. Basic research on embryos is more tightly controlled in many other European countries.

Although we do not use our technologies to edit human embryos or the human germline, such public debate about the use of genome 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 products we may develop.

We may not be successful in our efforts to identify, develop, or commercialize potential product candidates.

The success of our business depends primarily upon our ability to identify, develop, and commercialize products based on our genome editing platform. Other than EDIT-101 to treat LCA10 and EDIT-301 to treat sickle cell disease, all of our product development programs are still in the preclinical or research stage of development. Our research programs, including those subject to our collaboration with Juno Therapeutics, 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, or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products impractical to manufacture, unmarketable, or unlikely to receive marketing approval.

If any of these events occur, we may be forced to abandon our 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.

The genome editing field is relatively new and is evolving rapidly. We are focusing our research and development efforts on CRISPR gene editing technology using Cas9 and Cas12a enzymes, but other genome editing technologies may be discovered that provide significant advantages over CRISPR/Cas9 or CRISPR/Cas12a, which could materially harm our business.

To date, we have focused our efforts on genome editing technologies using CRISPR and the Cas9 and Cas12a (also known as Cpf1) enzymes. Other companies have previously undertaken research and development of genome editing technologies using zinc finger nucleases, engineered meganucleases, and transcription activator-like effector nucleases, but to date none has obtained marketing approval for a product candidate. There can be no certainty that the CRISPR/Cas9 or CRISPR/Cas12a technology will lead to the development of genomic medicines, that other genome editing technologies will not be considered better or more attractive for the development of medicines or that either Cas9 or Cas12a, the two CRISPR associated proteins that we use, may be useful or successful in developing therapeutics. For example, Cas9 or Cas12a may be determined to be less attractive than other CRISPR enzymes, including CRISPR enzymes that have yet to be discovered. Similarly, a new genome editing technology that has not been discovered yet may be determined to be more attractive than CRISPR. Moreover, if we decide to develop genome technologies other than CRISPR technology using a Cas9 or Cas12a enzyme, we cannot be certain we will be able to obtain rights to such technologies. 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 depend heavily on the success of EDIT-101. Except for EDIT-101 and EDIT-301, all of our product development programs are at the preclinical or research stage. Preclinical testing and clinical trials of product candidates may not be successful. If we are unable to commercialize any product candidates we develop or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the identification and development of EDIT-101 to treat LCA10. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of EDIT-101 for the treatment of LCA10 and other product candidates that we may identify in the future. As a result of the termination of our collaboration with Allergan in August 2020, we are now obligated to fund all of the costs related to developing and commercializing the LCA10 program in the United States, including the costs of the clinical development of EDIT-101, and will need to expand our clinical development organization. Previously, we relied on Allergan to conduct the Phase 1/2 clinical trial of EDIT-101 and we do not have significant experience conducting Phase 1/2 clinical trials. The success of product candidates we identify and develop will depend on many factors, including the following:

- 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;
- 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 develop;
- 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 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 arrangements;
- maintain, protect, and expand our portfolio of intellectual property rights, including patents, trade secrets, and know-how;
- avoid and defend against third-party interference or infringement claims; and
- attract, hire, and retain qualified personnel.

The foregoing also applies to our collaborators to the extent we have partnered, sold or licensed any of our research programs to them. If we or our collaborators do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize any product candidates we develop, which would materially harm our business.

If serious adverse events, undesirable side effects, or unexpected characteristics are identified during the development of any product candidates we develop, we may need to abandon or limit our further clinical development of those product candidates.

Other than in connection with the EDIT-101 Phase 1/2 clinical trial, for which we began dosing patients in 2020 and is in the early stages of assessing safety, we have not evaluated any product candidates in human clinical trials, and our proposed delivery modes, combined with CRISPR technology, have a limited history, if any, of being tested clinically. It is impossible to predict when or if any product candidates we develop will ultimately prove safe in humans, including EDIT-101. In the genomic medicine field, there have been several significant adverse events from gene therapy treatments in the past, including reported cases of leukemia and death. There can be no assurance that genome editing technologies will not cause severe or undesirable side effects.

A significant risk in any genome editing product is that the edit will be “off-target” and cause serious adverse events, undesirable side effects, or unexpected characteristics. For example, off-target cuts could lead to disruption of a gene or a genetic regulatory sequence at an unintended site in the DNA. We cannot be certain that off-target editing will not occur in any of our clinical studies. There is also the potential risk of delayed adverse events following exposure to

genome editing therapy due to the potential for persistent biological activity of the genetic material or other components of products used to carry the genetic material.

If any product candidates we develop are associated with serious adverse events, or undesirable side effects, or have characteristics that are unexpected, 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.

If any of the product candidates we develop or the delivery modes we rely on cause undesirable side effects, it could delay or prevent their regulatory approval, limit the commercial potential, or result in significant negative consequences following any potential marketing approval.

Our product candidates that we are testing or may test in clinical trials, including EDIT-101, or that are developed may be associated with off-target editing or other serious adverse events, undesirable side effects, or unexpected characteristics. In addition to serious adverse events or side effects caused by any product candidate we develop and test, the administration process or related procedures also can cause undesirable side effects. If any such events occur, our clinical trials could be suspended or terminated. If we are unable to demonstrate that such 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 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.

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 (“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 of our product candidates, 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;
- we may be required to change the way a product candidate is administered or 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, results of operations, and prospects.

We have not extensively tested any of our proposed delivery modes and product candidates in clinical trials.

Our proposed delivery modes, combined with our product candidates, have a limited history of being evaluated in human clinical trials. Any of our product candidates may fail to show the desired safety and efficacy in later stages of clinical development despite having successfully advanced through 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.

Because we are developing product candidates for the treatment of diseases in which there is little clinical experience using new technologies, 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 our product candidates. As we are seeking to identify and develop product candidates to treat diseases in which there is little clinical experience 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. 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 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. The FDA 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. Any product candidates we 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 genome 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 of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy in humans of any such product candidates. 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.

We or our collaborators 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;

- regulators, institutional review boards ("IRBs") or independent ethics committees ("IECs") not authorizing 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 ("CROs") and clinical trial sites;
- clinical trials of any product candidates we develop producing negative or inconclusive results, and us deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development or research programs;
- the number of patients required for clinical trials of any product candidates we 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 failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators, IRBs, or IECs requiring that we or our investigators suspend or terminate clinical research or clinical trials of any product candidates we 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 supply or quality of any product candidates we develop or other materials necessary to conduct clinical trials of any product candidates we develop being insufficient or inadequate, including as a result of delays in the testing, validation, manufacturing, and delivery of any product candidates we develop to the clinical sites by us or by third parties with whom we have contracted to perform certain of those functions;
- occurrence of serious adverse events associated with any product candidates we develop that are viewed to outweigh their potential benefits; and
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

If we or our collaborators are required to conduct additional clinical trials or other testing of any product candidates we develop beyond those that we currently contemplate, if we or our collaborators are unable to successfully complete clinical trials or other tests of any product candidates we develop, or if the results of these trials or tests are not positive or 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 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 modified risk evaluation and mitigation strategy;
- be sued; or
- experience damage to our reputation.

Product development costs will also increase if we or our collaborators experience delays in testing or 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 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 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 of our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or analogous regulatory authorities outside the United States, or as needed to provide appropriate statistical power for a given trial. Enrollment may be challenging for the rare genetically defined diseases we are targeting. In addition, if patients are unwilling to participate in our genome editing trials because of negative publicity from adverse events related to the biotechnology, gene therapy, or genome 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 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 develop, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. For example, ProQR Therapeutics N.V. has already enrolled LCA10 patients in its clinical trial, which may limit the number of potential patients available to enroll in the ongoing Phase 1/2 clinical trial for EDIT-101.

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 genome 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;
- the ongoing COVID-19 pandemic; and
- proximity and availability of clinical trial sites for prospective patients.

In particular, EDIT-101 for the treatment of LCA10 has a limited patient pool from which to draw for enrollment in a clinical trial, as the global incidence of LCA10 is estimated to be two to three per 100,000 live births worldwide. The eligibility criteria of our clinical trials further limits the pool of available trial participants. Additionally, the process of finding and diagnosing patients may prove costly. We experienced slowed enrollment in the EDIT-101 clinical trial resulting from the impact of the COVID-19 pandemic, including international travel restrictions imposed in response to the pandemic. The ultimate impact of the COVID-19 pandemic on enrollment for our clinical trials, including our trial for EDIT-301, is highly uncertain and we do not yet know the full extent of the delays or impacts on these clinical trials.

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;
- inability to locate 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.

Enrollment delays in our clinical trials may result in increased development costs for any of our product candidates, 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.

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 our product candidates 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 medicines 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.

If we are unable to successfully identify patients who are likely to benefit from therapy with any medicines 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 of our medicines, which may require 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;
- any product candidates we develop may not receive marketing approval if safe and effective use of such product candidates depends on an in vitro diagnostic; 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.

As a result, 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.

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 develop, 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 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 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 develop. Any of the foregoing scenarios could materially harm the commercial prospects for any product candidates we develop and materially adversely affect our business, financial condition, results of operations, and prospects.

Even if any product candidates we 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 will depend upon its degree of market acceptance by physicians, patients, third-party payors, and others in the medical community. The degree of market acceptance of any of our product candidates, 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 European Commission, or other regulatory agencies;
- public attitudes regarding genomic medicine generally and genome editing technologies specifically;
- the willingness of the target patient population to try new 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 genome;
- 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.

If any of our product candidates do 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 of our product candidates, 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 no 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 if and when they are approved.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization

personnel.

Factors that may inhibit our efforts to commercialize our medicines on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future medicines;
- 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 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 face significant competition in an environment of rapid technological change, and our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours.

The development and commercialization of new drug products is highly competitive. Moreover, the biotechnology and pharmaceutical industries, including in the gene therapy, genome editing and cell therapy fields, are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on intellectual property and proprietary products. We will face competition with respect to any of our product candidates now and 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.

Our platform and product focus is the development of therapies using CRISPR technology. Other companies developing CRISPR technology or therapies using CRISPR technology include Arbor Biotechnologies, Caribou Biosciences, CRISPR Therapeutics, ERS Genomics, Intellia Therapeutics, Locus Biosciences, ToolGen Inc. (“ToolGen”), TRACR Hematology and Vertex Pharmaceuticals. In addition, there have been and may continue to be discoveries of new CRISPR-based gene editing technologies. There are additional companies developing therapies using other genome editing technologies, including base editing, prime editing, transcription activator-like effector nucleases, meganucleases, Mega-TALs, and zinc finger nucleases. These companies include Beam Therapeutics, Prime Medicine, bluebird bio, Cellectis, Poseida Therapeutics, Precision Biosciences and Sangamo Therapeutics. Additional companies developing gene therapy products include Abeona Therapeutics, Adverum Biotechnologies, AGTC Therapeutics, Audentes Therapeutics, Homology Medicines, REGENXBIO, Sarepta Therapeutics, Solid Biosciences, Spark Therapeutics, uniQure and Voyager Therapeutics. In addition to competition from other genome editing therapies, gene therapies or cell medicine therapies, any products that we may develop may also face competition from other types of therapies, such as small molecule, antibody, protein, oligonucleotide, or ribonucleic acid therapies. For example, ProQR Therapeutics N.V. is conducting a clinical trial for its experimental treatment using antisense oligonucleotide technology

for LCA10.

Many of our competitors 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 products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop or that would render any products that we may develop obsolete or non-competitive. 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. 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 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 products that we may develop and commercialize.

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. In the United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. 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 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, even if any of our product candidates 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 health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, 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 requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any medicine that we commercialize and, if reimbursement is available, the level of reimbursement. 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 or similar 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. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. 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 some of our product candidates 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 for some of our programs are relatively small, as a result of which the pricing and reimbursement of any of our product candidates, 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 of our product candidates, e.g., for administration of our product to patients, is also important. Inadequate reimbursement for such services may lead to physician resistance and adversely affect our ability to market or sell our products. In addition, it may be necessary for us 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 genomic medicine products 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 develop will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers, and other third-party payors. 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 of our product candidates. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell any product candidates we develop will be harmed.

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

Some of our most advanced programs, including EDIT-101, focus on treatments for rare genetically defined diseases. 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 our product candidates, 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 products, 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.

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 of our product candidates 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 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 commercial general liability and umbrella liability policies (under which we currently have an aggregate of $12.0 million in coverage) 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.

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.

Genomic medicines are novel, and our product candidates may be complex and difficult to manufacture. We could experience production problems that result in delays in our development or commercialization programs, limit the supply of our products, or otherwise harm our business.

Our product candidates 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 our product candidates generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product 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, or insufficient inventory. 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.

In addition, the FDA, the EMA, and other regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA, or other regulatory authorities may require that we not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay clinical trials, including the ongoing Phase 1/2 clinical trial for EDIT-101, or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations, and prospects.

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, 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 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 products we commercialize.

Risks Related to Our Dependence on Third Parties

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

We anticipate seeking third-party collaborators for the research, development, and commercialization of certain of the product candidates we develop or for development of certain of our research programs. Our likely collaborators include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, and biotechnology companies. 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 and, if applicable, whether they exercise any additional options to commercialize a product. 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 of our product candidates and alliance arrangements we may enter into under which our research programs or product candidates may be involved pose the following risks to us:

- Collaborators may 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 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 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.

- 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.

For example, in March 2017, we entered into a strategic alliance with Allergan focused on discovering, developing, and commercializing new gene editing medicines for a range of ocular disorders, which collaboration was terminated in August 2020. As a result of the termination of the collaboration and the related co-development and commercialization agreement, we are now obligated to fund all of the costs related to developing and commercializing the LCA10 program in the United States, including the costs of the clinical development of EDIT-101, which will increase our expenses significantly.

If our collaborations do not result in the successful development and commercialization of products, or if one of our collaborators terminates its agreement with us, we may not receive any milestone or royalty payments under such collaborations. 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.

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

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 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 conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators or allies. For example, under our amended and restated collaboration with Juno Therapeutics, we may not use directly or indirectly, or license others to use, genome editing technology in connection

with any research, development, manufacture, commercialization or other exploration of certain T cells, subject to certain exceptions, as more fully described in "Part I—Business—Our Collaborations and Licensing Strategy" of this Annual Report on Form 10-K. Collaborations are also complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue.

We expect to rely on third parties to 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 currently rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, 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. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities. Additionally, the activities performed by these third parties may be delayed or suspended in light of the ongoing COVID-19 pandemic, which may impact our ability to successfully develop and test our product candidates and research programs in a timely manner.

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 requires 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. 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.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates we develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any product candidates we develop or commercialization of our medicines, producing additional losses and depriving us of potential product revenue.

We contract with third parties for the manufacture of materials for our research programs, preclinical studies and clinical trials and expect to continue to do so and for commercialization of any product candidates that we 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 have a limited ability to manufacture materials for our research programs and preclinical studies and we do not operate any significant manufacturing facilities. We primarily rely on third-party contract manufacturing organizations ("CMOs") for the manufacture of our materials for preclinical and clinical studies and expect to continue to do so and for commercial supply of any product candidates that we develop and for which we or our collaborators obtain marketing approval. Additionally, the activities performed by our CMOs may be delayed or suspended in light of the ongoing COVID-19 pandemic, which may impact our ability to successfully develop and test our product candidates, including in clinical trials, and research programs in a timely manner.

Even though we have established 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; and
- reliance on the third party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting.

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. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

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

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for any products we develop and for our technology, or if the scope of the patent 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 of our product candidates, and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our CRISPR platform technology and any proprietary product candidates and technology we develop. 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 technologies and product candidates that are important to our business. If we or our licensors and/or collaborators are unable to obtain or maintain patent protection with respect to our CRISPR platform technology and any proprietary products and technology we develop, our business, financial condition, results of operations, and prospects could be materially harmed.

No consistent policy regarding the scope of claims allowable in the field of genome editing, including CRISPR 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, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. 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 provide sufficient protection from competitors.

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. 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.

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 issue 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 hold 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 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. For example, we are aware that third parties have suggested the use of the CRISPR technology in conjunction with a protein other than Cas9 or Cas12a. Our owned and in-licensed patents may not cover CRISPR technology in conjunction with a protein other than Cas9 or Cas12a. If our competitors commercialize the CRISPR technology in conjunction with a protein other than Cas9 or Cas12a, our business, financial condition, results of operations, and prospects could be materially adversely affected.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Our licensors are currently, and we or our licensors may in the future become, subject to a third party pre-issuance submission of prior art to the United States Patent and Trademark Office (the "USPTO") or opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceedings and other similar proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products 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 of 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 priority of invention or other features of patentability. 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. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. As discussed below, some of our in-licensed patents are subject to interference, opposition and *ex parte* re-examination proceedings and therefore subject to these risks.

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 with third parties. 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 or our licensors may need the cooperation of any such co-owners of our owned and in-licensed patents in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Furthermore, our owned and in-licensed patents and patent applications may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our owned and in-licensed patent rights and technology was funded in part by the U.S. government. As a result, the U.S. government has certain rights to such patent rights and technology. These rights may permit the U.S. government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. Any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations, and prospects.

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

We are heavily reliant upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our genome editing technology, including our CRISPR technology, and product candidates. 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 technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. For example, pursuant to our license agreements with The Broad Institute, Inc. (“Broad”), and Broad and the President and Fellows of Harvard College (“Harvard”), the licensors may, under certain circumstances, grant a license to the patents that are the subject of such license agreements to a third party. Such third party would have full rights to the patent rights that are the subject of such licenses, which could impact our competitive position and enable a third party to commercialize products similar to our future product candidates and technology. The terms of these license agreements are described more fully under “Part I—Business—Our Collaborations and Licensing Strategy” in this Annual Report.

In addition, we may not have the right to control 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 and Harvard, our licensors retain control of preparation, filing, prosecution, and maintenance, and, in certain circumstances, enforcement and defense of their patents and patent applications. Therefore, 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, and our right to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected. Additionally, we are required to reimburse our licensors for all of their expenses related to the prosecution, maintenance, enforcement and defense of patents and patent applications that we in-license from them, and we anticipate that our obligation to reimburse our licensors for expenses related to these matters will continue to be substantial.

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 and patent applications we in-license. For example, certain patent applications licensed to us by Broad are co-owned with NIH. Broad does not and does not purport to grant any rights in NIH’s interest in these patent applications under our agreement. If other third parties have ownership rights to our in-licensed patents and patent applications, they may be able to license such patents and patent applications to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Some of our in-licensed patents are subject to priority and validity disputes. In addition, our owned and in-licensed patents, patent applications and other intellectual property may be subject to further priority and validity disputes, and other similar intellectual property proceedings including inventorship disputes. 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 develop, which could have a material adverse impact on our business.

Certain U.S. patents and a U.S. patent application that are co-owned by Broad and the Massachusetts Institute of Technology ("MIT"), and in some cases Harvard, and in-licensed by us were involved in a first interference with a U.S. patent application that is co-owned by the University of California, the University of Vienna, and Emmanuelle Charpentier. An interference is a proceeding before the Patent Trial and Appeal Board of the USPTO ("PTAB") to determine priority of invention of the subject matter of patent claims filed by different parties. In this first interference, the PTAB made a judgment of no interference-in-fact in favor of the Broad, which was upheld on appeal. This decision was final and bars any further interference between the same parties for claims to the same invention that was considered in the interference. As a result of this decision, the U.S. patents and application that we in-license from the Broad and others were not modified or revoked.

On June 24, 2019, the PTAB declared a second interference between certain pending U.S. patent applications that are co-owned by the University of California, the University of Vienna, and Emmanuelle Charpentier and certain U.S. patents and a U.S. patent application that are co-owned by Broad and MIT, and in some cases Harvard, and in-licensed by us. Most of the Broad U.S. patents and the patent application that are involved in the second interference were also part of the first interference. The invention that was considered in the first interference was related to a method that involves contacting a target DNA in a eukaryotic cell with certain defined CRISPR/Cas9 components for the purpose of cleaving or editing a target DNA molecule or modulating transcription of at least one gene encoded thereon. The second interference is directed to a different invention, namely a eukaryotic cell that comprises a target DNA and certain defined CRISPR/Cas9 components including a single molecule guide RNA that are capable of cleaving or editing the target DNA molecule.

On September 10, 2020, the PTAB granted Broad's motion for priority benefit while denying the University of California, the University of Vienna, and Emmanuelle Charpentier priority benefit to their two earliest provisional patent applications. As a result, Broad entered the priority phase of the interference as "Senior Party" while the University of California, the University of Vienna, and Emmanuelle Charpentier remained the "Junior Party" for purposes of determining which entity was the first to invent the inventions at issue. We cannot predict with any certainty how long it will take before the PTAB issues a decision at the conclusion of the priority phase.

On December 14, 2020, the PTAB, declared a third interference between a pending U.S. patent application that is owned by ToolGen and certain U.S. patents and U.S. patent applications that are co-owned by Broad and MIT, and in some cases Harvard, and in-licensed by us. Most of the Broad U.S. patents and patent applications that are involved in the interference with ToolGen are also part of the second interference with the University of California, the University of Vienna, and Emmanuelle Charpentier. On the same day, the PTAB also declared a fourth interference between the same pending U.S. patent application that is owned by ToolGen and the U.S. patent applications that are co-owned by the University of California, the University of Vienna, and Emmanuelle Charpentier and involved in the second interference with Broad. These two declarations of interference involving ToolGen's patent application describe the interfering subject matter as related to a mammalian cell with a CRISPR/Cas system that comprises a codon optimized nucleic acid encoding a Cas9 polypeptide with a nuclear localization signal and a single-molecule guide RNA that are together capable of forming a Cas9/RNA complex that mediates double stranded cleavage of a target nucleic acid sequence.

As a result of these declarations of interference, parallel adversarial proceedings in the USPTO before the PTAB have been initiated. We cannot predict with any certainty how long each interference proceeding will actually take. It is also possible that other third parties may seek to become a party to these interferences.

Our owned and in-licensed patents and patent applications are, or may in the future become, subject to validity disputes in the USPTO and other foreign patent offices. For example, a request for *ex parte* re-examination was filed with the USPTO on February 16, 2016 against a U.S. patent that we have in-licensed from Broad, which is part of the second and third interferences . The request for *ex parte* re-examination was granted on May 9, 2016 thereby initiating a re-examination procedure between the USPTO and Broad, acting on behalf of itself and MIT. The PTAB has suspended the re-examination noting that it has jurisdiction over any file that involves a patent involved in an interference. It is uncertain when the PTAB will lift the suspension. If Broad is unsuccessful during the re-examination, the patent in question may be revoked or narrowed, which could have a material adverse effect on the scope of our rights under such patent.

We or our licensors may also be subject to claims that former employees, collaborators, or other third parties have an interest in our owned or in-licensed patents or patent applications, or other intellectual property rights 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 patents, patent applications or other intellectual property rights, 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, including any patents that issue from 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 the conduct of our business, financial condition, results of operations, and prospects.

We or our licensors are subject to and may in the future become a party to similar proceedings or priority disputes in Europe or other foreign jurisdictions. For example, certain European patents that we have in-licensed from Broad have been revoked in their entirety by the European Patent Office Opposition Division (the "Opposition Division"). Certain other European patents that we have in-licensed from Broad were maintained with amended patent claims. Certain of these decisions have been appealed by both Broad and the opposing party, and it is uncertain when or in what manner the Boards of Appeal will act on these appeals. The Opposition Division has also initiated opposition proceedings against certain other European patents that we have in-licensed from Broad. The EPO opposition proceedings may involve issues including, but not limited to, procedural formalities related to filing the European patent application, priority, and the patentability of the involved claims. In view of certain arguments made by the third parties against the revoked patents and similar arguments made by the third parties against other in-licensed European patents under opposition, the opposition proceedings may lead to the revocation of certain additional in-licensed European patents. The loss of priority for, or the loss of, these European patents could have a material adverse effect on the conduct of our business. One or more of the third parties that have filed oppositions against these European patents or other third parties may file future oppositions against other European patents that we in-license or own. There may be other oppositions against these European patents that have not yet been filed or that have not yet been made available to the public.

If we or our licensors are unsuccessful in any patent related disputes, including interference proceedings, patent oppositions, re-examinations, or other priority, inventorship, or validity disputes to which we or they are subject (including any of the proceedings discussed above), we may lose valuable intellectual property rights through the loss of one or more patents owned or licensed or our owned or licensed patent claims may be narrowed, invalidated, or held unenforceable. In addition, if we or our licensors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our owned or in-licensed patents and patent applications. If we or our licensors are unsuccessful in any interference proceeding or other priority or inventorship dispute, 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 develop. The loss of exclusivity or the narrowing of our owned and in-licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations, or prospects. Even if we are successful in any interference proceeding or other priority, inventorship, or validity disputes, it could result in substantial costs and be a distraction to our management and other employees.

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

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. In addition, our intellectual property license agreements may not always include worldwide rights. For example, certain U.S. patent applications licensed to us by Broad include The University of Tokyo ("Tokyo") and NIH as joint applicants. Broad has only granted a license to us with respect to its interests and to Tokyo's interests in these U.S. patent applications but not to any foreign equivalents thereof. 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 or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, 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 products, which could make it difficult for us to stop the infringement of our patents and our intellectual property rights or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary 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, could put 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. 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.

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 will be due to be paid to the USPTO and various government 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 various non-U.S. government 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. In some cases, 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 in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential 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.

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 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 that 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 CRISPR genome editing technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or sales, or, with respect to our 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, and we expect in our future agreements, we are 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. 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 under our collaborative development relationships;
- our diligence obligations under the license agreement 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 increase what we believe to be our financial or other obligations under the relevant agreement, including the amount, if any, that may become due and payable to our licensors in connection with sublicense income. If these events were to occur, they 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, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

We may not be successful in obtaining necessary rights to any product candidates we develop through acquisitions and in-licenses.

We currently have rights to intellectual property, through licenses from third parties, to identify and develop product candidates. Many pharmaceutical companies, biotechnology companies, and academic institutions are competing with us in the field of genome editing technology and filing patent applications potentially relevant to our business. For example, we are aware of third party patents and patent applications that may be construed to cover our CRISPR technology and product candidates. In order to avoid infringing these third party patents, or patents that issue from these third party patent applications, we may find it necessary or prudent to obtain licenses from such third party intellectual property holders. We may also require licenses from third parties for certain non-CRISPR technologies including certain delivery methods that we are evaluating for use with product candidates we develop. In addition, with respect to any patents we co-own with third parties, we may require licenses to such co-owners' interest in such patents. 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 our CRISPR technology and product candidates we develop. For example, certain methods for editing cells, guide RNA modifications and delivery modes, including certain adeno-associated virus vector technologies, that we are evaluating for us for use are covered by patents held by third parties. If we are unable to successfully obtain rights to required third party intellectual 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.

Issued patents covering our technology and product candidates could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

If we or one of our licensors or our collaborators were to initiate legal proceedings against a third party to enforce a patent covering a product candidate we develop or our technology, including CRISPR genome editing technology, the defendant could counterclaim that such patent is invalid or unenforceable. Third parties have raised challenges to the validity of certain of our in-licensed patent claims and may in the future raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. These and other proceedings could result in the revocation or cancellation of, or amendment to our patents in such a way that they no longer cover our technology or platform, or any product candidates that we develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates that we develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and prospects.

The intellectual property landscape around genome editing technology, including CRISPR, 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 could have a material adverse effect on the success of our business.

The field of genome editing, especially in the area of CRISPR technology, is still in its infancy, and no such products 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 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 to develop, manufacture, market, and sell any product candidates that we develop and use our proprietary technologies without infringing, misappropriating, or otherwise violating the intellectual property and proprietary rights of third parties. We are 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 technology and any product candidates we develop, including interference, re-examination, post-grant review, inter partes review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the EPO. Third parties may assert infringement claims

against us based on existing patents or patents that may be granted in the future, regardless of their merit. We are aware of certain third party patents and patent applications in this landscape that may be asserted to encompass our CRISPR/Cas9 technology. In particular, we are aware of several separate families of U.S. patents and/or U.S. patent applications and foreign counterparts which relate to CRISPR/Cas9 technology, where the earliest priority dates of each family pre-date the priority dates of our in-licensed patents and patent applications, including patent families filed by Vilnius University, by the University of California, the University of Vienna, and Emmanuelle Charpentier, by ToolGen, and by Sigma-Aldrich. Each of these patent families are owned by a different third party and contain claims that may be construed to cover components and uses of CRISPR/Cas9 technology. If we are not able to obtain or maintain a license on commercially reasonable terms to any third-party patents that cover our product candidates or activities, such third parties could potentially assert infringement claims against us, which could have a material adverse effect on the conduct of our business.

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 develop and any other product candidates or technologies covered by the asserted third party patents. 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 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. 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.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, it could have a material adverse effect on our business.

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 patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, an extension may not be granted because of, for example, failure to exercise due diligence during the testing phase or regulatory review process, failure to apply within applicable deadlines, failure to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Further, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or if the term of any such extension is less than we request, we will be unable to rely on our patent position to forestall the marketing of competing products following our patent expiration, and it could have a materially adverse effect on our business, financial condition, results of operations, and prospects.

We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants, and advisors are currently or were previously employed at universities 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 used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary 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 management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. 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. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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 some of our technology and product candidates, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. With respect to our technology platform, we consider trade secrets and know-how to be one of our primary sources of intellectual property. Trade secrets and know-how can be difficult to protect. In particular, we anticipate that with respect to our technology platform, these trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. 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. Despite these efforts, 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, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

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

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

Risks Related to Regulatory Approval 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 of our product candidates. 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, our product candidates, and our ability to generate revenue will be materially impaired.

Any of our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA 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-party CROs 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 biologic product candidate's safety, purity, and potency. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any of our product candidates 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 additional clinical trials are required, 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.

Finally, disruptions at the FDA and other agencies may prolong the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. The Trump Administration also took several executive actions that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities.

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

Fast track and Priority Review 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 our product candidates.

If a product candidate is intended for the treatment of a serious or life threatening condition and the product candidate demonstrates the potential to address unmet medical need for this condition, the sponsor may apply for FDA fast track designation. Further, if the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request fast track and priority review designations for certain of our product candidates.

The FDA has broad discretion with respect to whether or not to grant fast track and 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 decide not to grant it. Moreover, a fast track or 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. As a result, while we may seek and receive these designations for our product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw these designations if it believes that the designation is no longer supported by data from our clinical development program.

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 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 products by the EMA in the European Union. Generally, if a product candidate 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 the same product for the same therapeutic indication for that time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union 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.

In order for the FDA to grant orphan drug exclusivity to one of our products, the agency must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200,000 individuals annually 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, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. In particular, the concept of what constitutes the "same drug" for purposes of orphan drug exclusivity remains in flux in the context of gene therapies, and the FDA has issued recent draft guidance suggesting that it would not consider two gene therapy products to be different drugs solely based on minor differences in the transgenes or vectors. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. 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, Congress passed the FDA Reauthorization Act of 2017 (“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. 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.

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

In order to market and sell any of our product candidates in the European Union and many other foreign jurisdictions, we or our collaborators must obtain separate marketing approvals 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 be approved for reimbursement before the product 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.

Additionally, we could face heightened risks with respect to seeking marketing approval in the United Kingdom as a result of the recent withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom withdrew from the European Union, effective December 31, 2020. On December 24, 2020, the United Kingdom and European Union entered into a Trade and Cooperation Agreement. The agreement sets out certain procedures for approval and recognition of medical products in each jurisdiction. Since the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing any product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for any product candidates, which could significantly and materially harm our business.

Even if we, or any collaborators we may have, obtain marketing approvals for any of our product candidates, the terms of approvals and ongoing regulation of our products could require the substantial expenditure of resources and may limit how we, or they, manufacture and market our products, 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 and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and 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 of our product candidates, 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 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 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 and other regulatory agencies impose stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our medicines for their approved indications, 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, relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.

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 results, 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;
- 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 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, 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 of our product candidates 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 include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;

- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval from Medicare, Medicaid, or other government payors that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties;

- the federal Health Insurance Portability and Accountability Act of 1996, as further amended by the Health Information Technology for Economic and Clinical Health Act, which imposes certain requirements, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses, and health care providers;

- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services;

- the federal transparency requirements under the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and

- analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. 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 European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union 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 European Union Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs. Liabilities they incur pursuant to these laws 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.

Recently enacted and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved products.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare Modernization Act"), changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (the "PPACA"), which became law in 2010, contains provisions of importance to our business, including, without limitation, our ability to commercialize and the prices we may obtain for any of our product candidates and that are approved for sale, the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of federal healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program new requirements to report financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2029 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Since enactment of the PPACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017 (the "TCJA"), Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Court of Appeals for the Fifth Circuit court affirmed the lower court's ruling that the individual mandate portion of the ACA is unconstitutional and it remanded the case to the district court for reconsideration of the severability question and additional analysis of the provisions of the ACA. Thereafter, the U.S. Supreme Court agreed to hear this case. Oral argument in the case took place on November 10, 2020. On February 10, 2021, the Biden Administration withdrew the federal government's support for overturning the ACA. A ruling by the Court is expected sometime this year. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

The Trump Administration also took executive actions to undermine or delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden issued a new Executive Order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this Order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents. This Executive Order also directs the U.S. Department of Health and Human Services to create a special enrollment period for the Health Insurance Marketplace in response to the COVID-19 pandemic.

The prices of prescription pharmaceuticals in the United States and foreign jurisdictions is subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when licensed.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. To date, there have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for products. To those ends, President Trump issued several executive orders intended to lower the costs of prescription drug products. Certain of these orders are reflected in recently promulgated regulations, including an interim final rule implementing President Trump's most favored nation model, but such final rule is currently subject to a nationwide preliminary injunction. It remains to be seen whether these orders and resulting regulations will remain in force during the Biden Administration. Further, on September 24, 2020, the Trump Administration finalized a rulemaking allowing states or certain other non-federal government entities to submit importation program proposals to the FDA for review and approval. Applicants are required to demonstrate that their importation plans pose no additional risk to public health and safety and will result in significant cost savings for consumers. The FDA has issued draft guidance that would allow manufacturers to import their own FDA-approved drugs that are authorized for sale in other countries (multi-market approved products).

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

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, principal investigators, consultants, and partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the European Commission, 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 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 ("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 the company 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.

Compliance with the FCPA 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.

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.

Risks Related to Employee Matters, Managing Growth, Public Health and Information Technology

Our future success depends on our ability to attract and retain key executives and to attract, retain, and motivate qualified personnel.

We are highly dependent on the principal members of our management and scientific teams. Each of these individuals is employed "at will," meaning we or the individual may terminate the employment relationship at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development, and commercialization objectives. Additionally, we are actively trying to recruit a candidate for the role of Chief Scientific Officer. Any inability to fill this position in an expedient manner may have a material adverse effect on our business.

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 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.

We face risks related to health epidemics, pandemics and other widespread outbreaks of contagious disease, including the COVID-19 pandemic, which could significantly disrupt our operations, impact our financial results or otherwise adversely impact our business.

Significant outbreaks of contagious diseases, and other adverse public health developments, could have a material impact on our business operations and operating results. For example, the spread of COVID-19 has affected segments of the global economy and could affect our operations. We have taken steps in line with guidance from the U.S. Centers for Disease Control and Prevention, the Commonwealth of Massachusetts and the State of Colorado, the jurisdictions in which we primarily operate our business, to protect the health and safety of our employees and the community. In particular, we have implemented a work from home policy, and restricted on-site activities at our facilities in Massachusetts and Colorado to certain manufacturing, laboratory and related support activities. Under our return-to-work plans, we have resumed manufacturing, laboratory, and related support activities at our facilities in Massachusetts and Colorado using shifts and other capacity-limiting measures to comply with social distancing guidelines. We continue to assess the impact of the COVID-19 pandemic to best mitigate risk and continue the operations of our business.

As a result of the COVID-19 pandemic or similar public health crises that may arise, we may experience disruptions that could adversely impact our operations, research and development, including preclinical studies, clinical trials and manufacturing activities, including:

- delays or disruptions in clinical trials that we may be conducting, including patient screening, patient enrollment, patient dosing, clinical trial site activation, and study monitoring;
- delays or disruptions in preclinical experiments and IND- and clinical trial application-enabling studies due to restrictions related to our staff being on site;
- interruption or delays in the operations of the FDA, EMA and comparable foreign regulatory agencies;
- interruption of, or delays in, receiving, supplies of drug substance and drug product from our CMOs or delays or disruptions in our pre-clinical experiments or clinical trials performed by CROs due to staffing shortages, production and research slowdowns or stoppages and disruptions in delivery systems or research;

- limitations imposed on our business operations by local, state, or federal authorities to address such pandemics or similar public health crises could impact our ability to conduct preclinical or clinical activities, including conducting IND- and CTA-enabling studies or our ability to select future development candidates; and

- 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 shortages, 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 or clinical trial sites and other important agencies and contractors.

For example and in light of the ongoing COVID-19 pandemic, we previously delayed the development of our research program to treat autosomal dominant retinitis pigmentosa 4. We also experienced slowed enrollment in the EDIT-101 clinical trial as a result of the COVID-19 pandemic and may experience further slowdowns. In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising additional capital through sales of our common stock or such sales may be on unfavorable terms.

We cannot presently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operation and financial condition.

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

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs, clinical development, manufacturing, 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, 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.

Security breaches and other disruptions to our information technology structure could compromise our information, disrupt our business and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect, process and store sensitive data, including intellectual property, as well as our proprietary business information and that of our suppliers and business partners, employee data, and we may collect personally identifiable information of clinical trial participants in connection with clinical trials. We also rely to a large extent on information technology systems to operate our business, including our financial systems. We have outsourced elements of our confidential information processing and information technology structure, and as a result, we are managing independent vendor relationships with third parties who may or could have access to our confidential information. Similarly, our business partners and other third-party providers possess certain elements of our sensitive data. The secure maintenance of this information is important to our operations and business strategy. Despite our security measures, our information technology infrastructure (and those of our partners, vendors and third-party providers) may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. We, our partners, vendors, and other third-party providers could be susceptible to third party attacks on our, and their, information security systems, which attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including organized criminal groups, hacktivists,

nation states and others. We have invested in information technology security measures and the protection of confidential and sensitive information, but there can be no assurance that our efforts will prevent system failures, accidents or security breaches. While we believe we have not experienced any such material system failure, accident or security breach to date, any such event may substantially impair our ability to operate our business and would compromise our, and their, networks and the information stored could be accessed, publicly disclosed, lost, or stolen. Any such event, or other loss of information, could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, any of which could adversely affect our business.

Although we have general liability and cybersecurity insurance coverage, our insurance may not cover all claims, continue to be available on reasonable terms or be sufficient in amount to cover one or more large claims; additionally, the insurer may disclaim coverage as to any claim. The successful assertion of one or more large claims against us that exceed or are not covered by our insurance coverage or changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could materially harm our business, financial condition, results of operations and prospects.

Risks Related to Our Common Stock

An active trading market for our common stock may not be sustained.

Although our common stock is listed on The Nasdaq Global Select Market, an active trading market for our common stock may not be sustained. If an active market for our common stock does not continue, it may be difficult for our stockholders to sell their shares. An inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration..

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

Our stock price has been, and is likely to remain, volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the success of existing or new competitive products or technologies;
- the timing and results of clinical trials for EDIT-101 and any preclinical studies and clinical trials of any other product candidates that we develop;
- commencement or termination of collaborations for our product development and research programs;
- 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 genomic medicines, including those that involve genome editing;
- 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 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;
- 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, including the impact of the COVID-19 pandemic; 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. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management’s attention and resources from our business.

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

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

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

Sales of a significant number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

We have registered substantially all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

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

As a public company we have incurred, and will continue to incur, significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Select 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 had to hire additional accounting, finance, and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company, and our management and other personnel devote a substantial amount of time towards maintaining compliance with these requirements. These requirements increase our legal and financial compliance costs and make some activities more time-consuming and costly.

We have broad discretion in the use of our cash reserves and may not use them effectively.

Our management has broad discretion to use our cash reserves and could use our cash reserves in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline, and delay the development of our product candidates. Pending their use, we may invest our cash reserves in a manner that does not produce income or that loses value.

We do not expect to pay any dividends for the foreseeable future. Accordingly, stockholders must rely on capital appreciation, if any, for any return on their investments.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be stockholders' sole source of gain for the foreseeable future.

Provisions in our restated certificate of incorporation and amended and restated bylaws or Delaware law might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our restated certificate of incorporation and amended and restated bylaws or Delaware law may discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions include:

- limitations on the removal of directors;
- a classified board of directors so that not all members of our board of directors are elected at one time;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to act by written consent or to call special meetings;
- the requirement that at least 75% of the votes cast by all our stockholders approve the amendment or repeal of certain provisions of our amended and restated bylaws or restated certificate of incorporation;
- the ability of our board of directors to make, alter, or repeal our amended and restated bylaws; and
- the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could be used to institute a rights plan, or a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our board of directors.

In addition, Section 203 of the General Corporation Law of the State of Delaware prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions could deter potential acquirers of our company, thereby reducing the likelihood that our stockholders could receive a premium for their shares of common stock in an acquisition.

Our restated certificate of incorporation designates the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against the company and our directors and officers.

Our restated certificate of incorporation provides that, unless our board of directors otherwise determines, the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to our company or our stockholders, any action asserting a claim against us or any of our directors or officers arising pursuant to any provision of the General Corporation Law of the State of Delaware or our restated certificate of incorporation or amended and restated bylaws, or any action asserting a claim against us or any of our directors or officers governed by the internal affairs doctrine. This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors or officers, which may discourage such lawsuits against us and our directors and officers. This exclusive forum provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act of 1934, which provides for exclusive jurisdiction of the federal courts. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act of 1933, as amended (the “Securities Act”), inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder; provided, that with respect to claims under the Securities Act, our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties.

We lease 59,783 square feet of office and laboratory space in Cambridge, Massachusetts under a lease that expires in October 2023. 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.

From time to time, we may become involved in litigation or other legal proceedings relating to claims arising from the ordinary course of business. There can be no assurance that any proceedings that result from these third-party actions will be resolved in our favor. In addition, if they are not resolved in our favor, there can be no assurance that the result will not have a material adverse effect on our business, financial condition, results of operations, or prospects. Certain of our intellectual property rights, including ones licensed to us under our licensing agreements, are subject to, and from time to time may be subject to, priority and validity disputes. For additional information regarding these matters, see “Item 1A. Risk Factors—Risks Related to Our Intellectual Property.” Regardless of outcome, litigation or other legal proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock trades on the Nasdaq Global Select Market under the symbol "EDIT." Trading of our common stock commenced on February 3, 2016 in connection with our initial public offering. Prior to that time, there was no established public trading market for our common stock.

Holders

As of February 14, 2021, we had approximately 18 holders of record of our common stock. This number does not include beneficial owners whose shares were held in street name.

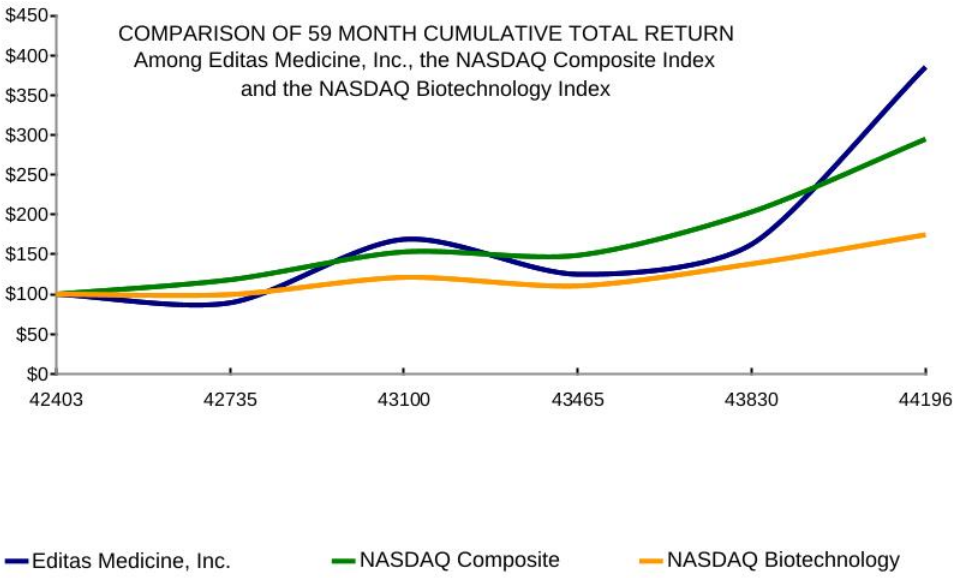
Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently intend to retain future earnings to fund the development and growth of our business. We do not expect to pay any cash dividends in the foreseeable future. In addition, the terms of any future debt agreements that we may enter into may preclude us from paying dividends without the lenders' consent or at all.

Performance Graph

The following performance graph and related information shall not be deemed to be "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities under that Section, nor shall such information be incorporated by reference into any future filing under the Exchange Act or the Securities Act of 1933, as amended (the "Securities Act"), except to the extent that we specifically incorporate it by reference into such filing.

The following graph compares the performance of our common stock to The Nasdaq Composite Index and to The Nasdaq Biotechnology Index from February 3, 2016 (the first date on which shares of our common stock were publicly traded) through December 31, 2020. The comparison assumes $100 was invested after the market closed on February 3, 2016 in our common stock and in each of the foregoing indices, and it assumes reinvestment of dividends, if any. The stock price performance included in this graph is not necessarily indicative of future stock price performance.



Recent Sales of Unregistered Securities

On November 9, 2020, we granted our Chief Medical Officer an option to purchase 120,000 shares of our common stock and a restricted stock unit award of 20,000 shares as an inducement to employment in accordance with Nasdaq Listing Rule 5635(c)(4). No underwriters were involved in the foregoing issuance of securities. The securities were issued pursuant to Section 4(a)(2) under the Securities Act of 1933, as amended, relating to transactions by an issuer not involving any public offering. The recipient either received adequate information about us or had access, through other relationships, to such information.

The stock option is scheduled to become exercisable as to 25% of the shares underlying the option on the first anniversary of the date of grant, and as to an additional 2.0833% of the shares underlying the option at the end of each successive month following such date, subject to the recipient's continued service. The option has an exercise price of $30.41 per share. The restricted stock unit award is scheduled to vest as to one-fourth of the shares on each anniversary of the date of grant until the fourth anniversary of the date of grant, subject to the recipient's continued service.

On January 22, 2021, we issued an aggregate of 303,599 shares of common stock to The Broad Institute, Inc. ("Broad") in satisfaction of payment obligations in an aggregate amount of $27.5 million to Broad under the Cpf1 License Agreement and the Sponsored Research Agreement. No underwriters were involved in the foregoing issuance of securities. The securities were issued pursuant to Section 4(a)(2) under the Securities Act, relating to transactions by an issuer not involving any public offering. Prior to receiving the shares, Broad represented to us that it was acquiring the shares for its own account for investment purposes, that it had received from us and our management all of the information that it considered appropriate to evaluate whether to accept the shares, that it was capable of evaluating and understanding the risks of the investment, and that it was an accredited investor as such term is defined in Rule 501 of Regulation D promulgated under the Securities Act.

Purchases of Equity Securities by the Issuer and Affiliates Purchasers

Neither we nor any affiliated purchaser or anyone acting on behalf of us or an affiliated purchaser made any purchases of shares of our common stock during the fourth quarter of 2020.

Item 6. Selected Consolidated Financial Data.

You should read the following selected consolidated financial data together with our consolidated financial statements and accompanying notes appearing elsewhere in this Annual Report on Form 10-K and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Annual Report on Form 10-K. The following selected consolidated financial data are derived from our audited consolidated financial statements. Our historical results for any prior period are not necessarily indicative of the results that may be expected in any future period. Our consolidated statements of operations are summarized as follows (in thousands, except share and per share amounts):

	Year Ended December 31,				
	2020	2019	2018	2017	2016
Consolidated Statements of Operations Data:					
Collaboration revenue	$ 90,732	$ 20,531	$ 31,937	$ 13,728	$ 6,053
Operating expenses:					
Research and development	157,996	96,898	90,654	83,159	56,979
General and administrative	67,576	64,555	55,010	50,502	46,262
Total operating expenses	225,572	161,453	145,664	133,661	103,241
Operating loss	(134,840)	(140,922)	(113,727)	(119,933)	(97,188)
Other income (expense), net	16,259	(137)	328	587	(57)
Interest income, net	2,605	7,313	3,445	-978	62
Total other income, net	18,864	7,176	3,773	(391)	5
Net loss and comprehensive loss	$ (115,976)	$ (133,746)	$ (109,954)	$ (120,324)	$ (97,183)
Reconciliation of net loss to net loss attributable to common stockholders:					
Net loss	$ (115,976)	$ (133,746)	$ (109,954)	$ (120,324)	$ (97,183)
Accretion of redeemable convertible preferred stock to redemption value [1]	—	—	—	—	(47)
Net loss attributable to common stockholders [1]	$ (115,976)	$ (133,746)	$ (109,954)	$ (120,324)	$ (97,230)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.98)	$ (2.68)	$ (2.33)	$ (2.98)	$ (3.02)
Weighted-average common shares outstanding, basic and diluted [1]	58,609,389	49,983,329	47,097,735	40,323,631	32,219,717

(1) See Note 15 to our consolidated financial statements for further details on the calculation of net loss per share, basic and diluted, attributable to common stockholders and the weighted-average number of shares used in the computation of the per share amounts.

Our consolidated balance sheets are summarized as follows (in thousands, except share and per share amounts):

	December 31,				
	2020	2019	2018	2017	2016
Consolidated Balance Sheet Data:					
Cash, cash equivalents, and marketable securities	$ 511,774	$ 457,140	$ 368,955	$ 329,139	$ 185,323
Working capital	360,879	403,881	338,876	295,492	154,100
Total assets	572,602	508,885	420,386	373,260	229,182
Deferred revenue, net of current portion	73,984	163,207	115,614	94,725	26,000
Construction financing lease obligation, net of current portion	—	—	32,417	33,431	35,096
Total stockholders' equity	393,586	262,437	236,162	208,080	134,607

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 together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K.

Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the section entitled "Risk Factors" in Part I, Item 1A that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make.

You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Annual Report on Form 10-K are made as of the date of this Annual Report on Form 10-K,and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

Overview

We are a leading, clinical stage gene editing company dedicated to developing potentially transformative gene-editing medicines to treat a broad range of serious diseases. We have developed a proprietary gene editing platform based on CRISPR technology and we continue to expand its capabilities. Our product development strategy is to target diseases of high unmet need where we aim to make differentiated, transformational medicines using our gene editing platform. We are advancing both *in vivo* gene editing medicines, in which the medicine is injected or infused into the patient to edit the cells inside their body, and *ex vivo* gene edited cell medicines, in which cells are edited with our technology and then administered to the patient. While our discovery efforts have ranged across several diseases and therapeutic areas, the two areas where our programs are more mature are our *in vivo* medicines to treat ocular diseases and *ex vivo* gene edited cell medicines to treat hemoglobinopathies and cancer.

In ocular diseases, our most advanced program is designed to address a specific genetic form of retinal degeneration called Leber congenital amaurosis 10 ("LCA10"), a disease for which we are not aware of any available therapies and only one other potential treatment is in clinical trials in the United States and Europe. In mid-2019, we initiated our Phase 1/2 BRILLIANCE clinical trial for EDIT-101, an experimental gene-editing medicine to treat LCA10. We plan to enroll approximately 18 patients in the United States and Europe in up to five cohorts. We completed dosing of the first cohort, the adult low-dose cohort, in 2020. Due to an absence of severe adverse events and dose limited toxicity in adults treated in the first cohort, the inclusion criteria of the protocol was modified to allow inclusion of subjects with better than light perception vision only. Although we experienced slowed enrollment in 2020 for subsequent cohorts due to the ongoing impact of the COVID-19 pandemic, in the first quarter of 2021 we initiated dosing of the second cohort, the adult mid-dose cohort. We expect to announce initial clinical data in 2021.

In May 2015, we entered into a collaboration with Juno Therapeutics, Inc., a wholly-owned subsidiary of Bristol-Myers Squibb Company ("Juno Therapeutics"), a leader in the emerging field of immuno-oncology, to develop novel engineered alpha-beta T cell therapies for cancer and autoimmune diseases, which was amended and restated in each of May 2018 and November 2019, at which time we also entered into a related license agreement with Juno Therapeutics, which we collectively refer to as our collaboration with them.

In March 2017, we entered into a strategic alliance and option agreement with Allergan Pharmaceuticals International Limited (together with its affiliates, "Allergan") to discover, develop, and commercialize new gene editing medicines for a range of ocular disorders. In July 2018, Allergan exercised its option to develop and commercialize EDIT-101 and paid us $15.0 million in connection with such exercise (the "EDIT-101 Option Exercise Payment"). We and Allergan subsequently entered into a co-development and commercialization agreement under which we agreed to co-develop and equally split profits and losses for EDIT-101 in the United States. In December 2018, we also received a $25.0 million payment from Allergan in connection with the acceptance of the IND for EDIT-101 (the "EDIT-101 Milestone Payment"). In August 2020, we and Allergan terminated the strategic alliance and option agreement and the co-development and commercialization agreement, and we assumed full rights to EDIT-101 and responsibility for conducting the clinical trial. In connection with such termination, we and Allergan entered into a termination agreement, pursuant to which we made a one-time aggregate payment of $20.0 million to Allergan during the second half of 2020.

Since our inception in September 2013, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio, assembling our core capabilities in gene editing, seeking to identify potential product candidates, and undertaking preclinical studies. Except for EDIT-101 and EDIT-301, all of our research programs are still in the preclinical or research stage of development and the risk of failure of all of our research programs is high. We have not generated any revenue from product sales. We have primarily financed our operations through various equity financings and payments received under our research collaboration with Juno Therapeutics and our strategic alliance with Allergan. From inception through December 31, 2020, we raised an aggregate of $1,104.2 million to fund our operations.

Since inception, we have incurred significant operating losses. Our net losses were $116.0 million, $133.7 million, and $110.0 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of $665.2 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and from year to year. We anticipate that our expenses will increase substantially as we continue our current research programs and our preclinical development activities; progress the clinical development of EDIT-101 and EDIT-301 for the treatment of sickle cell disease; seek to identify additional research programs and additional product candidates; initiate preclinical testing and clinical trials for other product candidates we identify and develop; maintain, expand, and protect our intellectual property portfolio, including reimbursing our licensors for such expenses related to the intellectual property that we in-license from such licensors; further develop our genome editing platform; hire additional clinical, quality control, and scientific personnel; and incur additional costs associated with operating as a public company. We do not expect to be profitable for the year ending December 31, 2021 or the foreseeable future.

Although we did not experience any significant impact on our financial condition, results of operations or liquidity due to the ongoing COVID-19 pandemic during the year ended December 31, 2020, we did experience slowed enrollment in the EDIT-101 clinical trial as a result of the COVID-19 pandemic. The ultimate impact of the COVID-19 pandemic is highly uncertain and we do not yet know the full extent of potential delays or impacts on our business, our ability to continue to raise additional capital, the EDIT-101 or EDIT-301 clinical trials, ongoing preclinical activities, or the global economy as a whole. In March 2020, we implemented a work from home policy, and restricted on-site activities at our facilities in Massachusetts and Colorado to certain manufacturing, laboratory and related support activities in light of the COVID-19 pandemic. Under our return to onsite work plans, we have resumed manufacturing, laboratory and related support activities at our facilities in Massachusetts and Colorado using shifts and other capacity-limiting measures to comply with social distancing guidelines. As such, it is uncertain as to the full magnitude that the pandemic will have directly or indirectly on our financial condition, liquidity and future results of operations.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales and we do not expect to generate any revenue from product sales for the foreseeable future. In connection with our collaboration with Juno Therapeutics, we have received an aggregate of $120.5 million in payments, which have primarily consisted of the initial upfront and amendment payments, development milestone payments and research funding support. We no longer receive research funding support. As of December 31, 2020, we recorded $90.7 million of deferred revenue, of which $73.7 million is classified as long-term on our consolidated balance sheet. During the year ended December 31, 2020, we recognized $5.7 million of previously deferred revenue related to Juno Therapeutics. Under this collaboration, we will recognize revenue upon delivery of option packages to Juno Therapeutics. We expect that our revenue will fluctuate from quarter-to-quarter and year-to-year as a result of the timing of when we deliver such option packages.

In connection with our strategic alliance with Allergan, we received an aggregate of $130.0 million in payments, which consisted of the initial upfront payment, an option exercise payment and a milestone payment. Prior to the termination of our agreements with Allergan, certain of these payments were deferred and were being recognized over the remaining contract term using the proportional performance method. During the third quarter of 2020, as a result of the termination of our agreements with Allergan, we recognized $63.2 million of previously deferred revenue related to Allergan.

For additional information about our revenue recognition policy related to the Juno Therapeutics collaboration or the Allergan strategic alliance, see "—Critical Accounting Policies and Estimates—Revenue Recognition" included in our Annual Report.

For the foreseeable future we expect substantially all of our revenue will be generated from our collaboration with Juno Therapeutics, and any other collaborations or agreements we may enter into.

Expenses

Research and Development Expenses

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

- employee-related expenses including salaries, benefits, and stock-based compensation expense;
- costs of funding research performed by third parties that conduct research and development and preclinical activities on our behalf;
- costs of purchasing lab supplies and non-capital equipment used in our preclinical activities and in manufacturing preclinical study materials;
- consultant fees;
- facility costs including rent, depreciation, and maintenance expenses; and
- fees for acquiring and maintaining licenses under our third-party licensing agreements, including any sublicensing or success payments made to our licensors.

Research and development costs are expensed as incurred. At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of any product

candidates we may identify and develop. This is due to the numerous risks and uncertainties associated with developing such product candidates, including the uncertainty of:

- successful completion of preclinical studies, IND-enabling studies and natural history studies;
- successful enrollment in, and completion of, clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity;
- launching commercial sales of a product, if and when approved, whether alone or in collaboration with others;
- acceptance of a product, 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 following approval;
- enforcing and defending intellectual property and proprietary rights and claims; and
- achieving desirable medicinal properties for the intended indications.

A change in the outcome of any of these variables with respect to the development of any product candidates we develop would significantly change the costs, timing, and viability associated with the development of that product candidate.

Research and development activities are central to our business model. We expect research and development costs to increase significantly for the foreseeable future as our development programs progress, including as we progress the clinical development of EDIT-101 and EDIT-301 as well as supporting preclinical studies for our other research programs.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation for personnel in executive, finance, investor relations, business development, legal, corporate affairs, information technology, facilities and human resource functions. Other significant costs include corporate facility costs not otherwise included in research and development expenses, legal fees related to intellectual property and corporate matters, and fees for accounting and consulting services.

We anticipate that our general and administrative expenses will increase in the future to support continued research and development activities and potential commercialization of any product candidates we identify and develop. These increases will include increased costs related to the hiring of additional personnel and fees to outside consultants. We also anticipate increased expenses related to reimbursement of third-party patent-related expenses and expenses associated with operating as a public company, including costs for audit, legal, regulatory, and tax-related services, director and officer insurance premiums, and investor relations costs. With respect to reimbursement of third-party intellectual property-related expenses specifically, given the ongoing nature of the opposition and interference proceedings involving the patents licensed to us under our license agreement with The Broad Institute, Inc. (“Broad”)

and the President and Fellows of Harvard College ("Harvard"), we anticipate general and administrative expenses will continue to be significant.

Other Income (Expense), Net

For the year ended December 31, 2020, other income (expense), net consisted primarily of changes in the fair value of equity securities, interest income and accretion of discounts associated with other marketable securities.

For the year ended December 31, 2019, other income (expense), net consisted primarily of interest income and accretion of discounts associated with marketable securities.

For the year ended December 31, 2018, other income (expense), net consisted primarily of interest income, accretion of discounts associated with marketable securities, and rental income from our former subtenant, partially offset by interest expense on our construction financing lease obligation.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of our consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues, and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts, and experience. The effects of material revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of change in estimates.

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

Revenue Recognition

We recognize revenue in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"), Topic 606, *Revenue Recognition* ("ASC 606"). Accordingly, we recognize revenue following the five step model prescribed under Accounting Standards Updates No. 2014-09, *Revenue from Contracts with Customers*: (i) identify contract(s) with a 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 revenues when (or as) we satisfy the performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. A significant portion of revenue recognized from our strategic alliance with Allergan, prior to termination, was related to research services performed for each clinical development program whereby revenue was recognized as the underlying services were performed using a proportional performance model. Prior to the termination of the arrangement with Allergan, we measured proportional performance based on full time employee hours incurred relative to projected full time employee hours to complete the research services for each clinical development program. We evaluated the measure of progress each reporting period and, if necessary, adjusted the measure of performance and related revenue recognition.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in our consolidated balance sheets.

Accrued research and development expenses

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:

- CROs in connection with clinical studies;
- vendors in connection with preclinical development activities; and
- vendors related to development, manufacturing and distribution of clinical trial materials.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical 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 clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical study milestones. 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.

Results of Operations

Comparison of Years ended December 31, 2020 and 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019, together with the changes in those items in dollars (in thousands) and the respective percentages of change:

	Year Ended December 31,			
	2020	2019	Dollar Change	Percentage Change
Collaboration and other research and development revenues	$ 90,732	$ 20,531	$ 70,201	n/m
Operating expenses:				
Research and development	157,996	96,898	61,098	63 %
General and administrative	67,576	64,555	3,021	5 %
Total operating expenses	225,572	161,453	64,119	40 %
Other income, net				
Other income (expense), net	16,259	(137)	16,396	n/m
Interest income, net	2,605	7,313	(4,708)	(64) %
Total other income, net	18,864	7,176	11,688	n/m
Net loss	$ (115,976)	$ (133,746)	$ 17,770	(13) %

For our results of operations, we have included the respective percentage of changes, unless greater than 100% or less than (100)%, in which case we have denoted such changes as not meaningful (n/m).

Collaboration and Other Research and Development Revenues

Collaboration and other research and development revenues increased by $70.2 million, to $90.7 million for the year ended December 31, 2020 from $20.5 million for the year ended December 31, 2019. This increase was primarily attributable to a $57.1 million increase in the revenue recognized as a result of the termination of our strategic alliance with Allergan, a $5.1 million increase in revenue recognized pursuant to our collaboration with Juno Therapeutics, and a $8.0 million increase in revenue recognized in connection with other out-license agreements that are individually insignificant.

Research and Development Expenses

Research and development expenses increased by $61.1 million, to $158.0 million for the year ended December 31, 2020 from $96.9 million for the year ended December 31, 2019. The following table summarizes our research and development expenses for the years ended December 31, 2020 and December 31, 2019, together with the changes in those items in dollars (in thousands) and the respective percentages of change:

	Year Ended December 31,			
	2020	2019	Dollar Change	Percentage Change
External research and development expenses	$ 63,807	$ 33,242	$ 30,565	92 %
Employee related expenses	32,349	24,249	8,100	33 %
Facility expenses	13,372	9,131	4,241	46 %
Stock-based compensation expenses	11,580	13,538	(1,958)	(14) %
Sublicense and license fees	32,888	11,731	21,157	n/m
Other expenses	4,000	5,007	(1,007)	(20) %
Total research and development expenses	$ 157,996	$ 96,898	$ 61,098	63 %

The increase in research and development expenses for the year ended December 31, 2020 compared to the year ended December 31, 2019 was primarily attributable to:

- approximately $30.6 million in increased external research and development expenses due to increased research activity, mostly relating to external research and development costs that we expect will increase further as we progress the clinical development of EDIT-101 and EDIT-301 and further advance our current research programs and our preclinical development activities;
- approximately $27.5 million in increased sublicense and license fees resulting from success payments that were triggered during the fourth quarter of 2020 in connection to the Cpf1 license agreement and the sponsored research agreement with Broad;
- approximately $8.1 million in increased employee related expenses due to an increase in the size of our workforce; and
- approximately $4.2 million in increased facility and other related expenses due to increased office space and increased professional service expenses.

These increases were partially offset by the following decreases in research and development expenses:

- approximately $6.3 million in decreased sublicense and license expenses resulting from sublicense expense recorded during the fourth quarter of 2019 in connection with receiving $70.0 million related to our amended and restated collaboration agreement with Juno Therapeutics compared to sublicense expense

recorded during 2020 in connection with receiving $13.0 million related to upfront and milestone payments for our collaboration agreement with Juno and our other individually insignificant out-license agreements;

- approximately $2.0 million in decreased stock-based compensation expenses resulting from forfeitures; and
- approximately $1.0 million in decreased other expenses.

General and Administrative Expenses

General and administrative expenses increased by approximately $3.0 million, to $67.6 million for the year ended December 31, 2020 from $64.6 million for the year ended December 31, 2019. The following table summarizes our general and administrative expenses for the years ended December 31, 2020 and December 31, 2019, together with the changes in those items in dollars (in thousands) and the respective percentages of change:

	Year Ended December 31,			
	2020	2019	Dollar Change	Percentage Change
Intellectual property and patent related fees	$ 18,654	$ 18,103	$ 551	3 %
Employee related expenses	15,758	12,781	2,977	23 %
Professional service expenses	13,666	14,462	(796)	(6) %
Stock-based compensation expenses	11,576	13,705	(2,129)	(16) %
Facility and other expenses	7,922	5,504	2,418	44 %
Total general and administrative expenses	$ 67,576	$ 64,555	$ 3,021	5 %

The increase in general and administrative expenses for the year ended December 31, 2020 compared to the year ended December 31, 2019 was primarily attributable to:

- approximately $3.0 million in increased employee related expenses primarily due to an increase in the size of our workforce and the timing of hiring key executives;
- approximately $2.4 million in increased facility and other expenses resulting from additional office space leased in 2020; and
- approximately $0.6 million in intellectual property and patent related fees.

These increases were partially offset by approximately $2.1 million in decreased stock-based compensation expenses resulting from a modification that occurred in 2019 with respect to which there was no similar activity in 2020 and approximately $0.8 million in decreased professional service expenses.

Total Other Income, Net

For the year ended December 31, 2020, total other income, net was $18.9 million, which was primarily attributable to the realized gains related to the sale of corporate equity securities, interest income and accretion of discounts associated with marketable securities.

For the year ended December 31, 2019, total other income, net was $7.2 million, which was primarily attributable to interest income and accretion of discounts associated with marketable securities.

Comparison of Years Ended December 31, 2019 and 2018

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018, together with the changes in those items in dollars (in thousands) and the respective percentages of change:

	Year Ended December 31, 2019	2018	Dollar Change	Percentage Change
Collaboration revenue	$ 20,531	$ 31,937	$ (11,406)	(36) %
Operating expenses:				
Research and development	96,898	90,654	6,244	7 %
General and administrative	64,555	55,010	9,545	17 %
Total operating expenses	161,453	145,664	15,789	11 %
Other expense, net:				
Other expense, net	(137)	328	(465)	n/m
Interest expense	7,313	3,445	3,868	n/m
Total other expense, net	7,176	3,773	3,403	90 %
Net loss	$ (133,746)	$ (109,954)	$ (23,792)	22 %

For our results of operations, we have included the respective percentage of changes, unless greater than 100% or less than (100)%, in which case we have denoted such changes as not meaningful (n/m).

Collaboration and Other Research and Development Revenues

Collaboration and other research and development revenues decreased by $11.4 million, to $20.5 million for the year ended December 31, 2019 from $31.9 million for the year ended December 31, 2018. This decrease was primarily attributable to a $7.9 million decrease in revenue recognized pursuant to our strategic alliance with Allergan, $3.9 million in revenue recognized during the second quarter of 2018 related to a one time upfront payment in connection with an out-license arrangement and a $0.2 million decrease in revenue recognized pursuant to our collaboration with Juno Therapeutics.

Research and Development Expenses

Research and development expenses increased by $6.2 million, to $96.9 million for the year ended December 31, 2019 from $90.7 million for the year ended December 31, 2018. The following table summarizes our research and development expenses for the years ended December 31, 2019 and December 31, 2018, together with the changes in those items in dollars (in thousands) and the respective percentages of change:

	Year Ended December 31, 2019	2018	Dollar Change	Percentage Change
External research and development expenses	$ 33,242	25,466	$ 7,776	$ 31 %
Employee and contractor related expenses	24,249	$ 19,771	4,478	23 %
Stock-based compensation expenses	13,538	14,734	(1,196)	(8) %
Sublicense and license fees	11,731	8,707	3,024	35 %
Facility expenses	9,131	6,058	3,073	51 %
Other expenses	5,007	3,418	1,589	46 %
Success payment expenses	—	12,500	(12,500)	n/m
Total research and development expenses	$ 96,898	$ 90,654	$ 6,244	$ 7 %

The increase in research and development expenses for the year ended December 31, 2019 compared to the year ended December 31, 2018 was primarily attributable to:

- approximately $7.8 million in increased external research and development expenses due to increased research activity, mostly relating to external research and development costs that we expect will increase further as we continue to progress the clinical development of EDIT-101;
- approximately $4.5 million in increased employee related expenses due to an increase in the size of our workforce;
- approximately $4.7 million in increased facility and other related expenses due to increased office and professional service expenses; and
- approximately $3.0 million in increased licensing and sublicensing payment expenses, primarily due to sublicense expense recorded during the fourth quarter of 2019 in connection with receiving $70.0 million related to our amended and restated collaboration agreement with Juno Therapeutics, partially offset by sublicense fees owed to certain of our licensors in 2018 in connection with receiving milestone and other payments from our licensees.

These increases were partially offset by the following decreases in research and development expenses:

- approximately $12.5 million in decreased success payment expenses resulting from notes payable that were issued to Broad and settled during the second quarter of 2018 in connection with us entering into a sponsored research agreement with Broad; and
- approximately $1.2 million in decreased stock-based compensation expenses mostly due to a decrease in nonemployee stock option expense.

General and Administrative Expenses

General and administrative expenses increased by approximately $9.5 million, to $64.6 million for the year ended December 31, 2019 from $55.0 million for the year ended December 31, 2018. The following table summarizes our general and administrative expenses for the years ended December 31, 2019 and December 31, 2018, together with the changes in those items in dollars (in thousands) and the respective percentages of change:

	Year Ended December 31,			
	2019	2018	Dollar Change	Percentage Change
Intellectual property and patent related fees	$ 18,103	$ 20,442	$ (2,339)	(11) %
Professional service expenses	14,462	6,875	7,587	n/m
Stock-based compensation expenses	13,705	11,864	1,841	16 %
Employee related expenses	12,781	11,502	1,279	11 %
Other expenses	5,504	4,327	1,177	27 %
Total general and administrative expenses	$ 64,555	$ 55,010	$ 9,545	17 %

The increase in general and administrative expenses for the year ended December 31, 2019 compared to the year ended December 31, 2018 was primarily attributable to:

- approximately $7.6 million in increased professional services expenses primarily related to an increase in our use of consulting services;
- approximately $1.8 million in increased stock-based compensation expenses due to an increase in employee stock option expense and employee headcount;

- approximately $1.3 million in increased employee related expenses due to an increase in the size of our workforce; and

- approximately $1.2 million in increased other expenses including facility-related expenses.

These increases were partially offset by an approximate $2.3 million in decreased intellectual property and patent related fees, including expenses associated with the prosecution and maintenance of patents and patent applications.

Other Income, Net

For the year ended December 31, 2019, other income, net was $7.2 million, which was primarily attributable to interest income and accretion of discounts associated with marketable securities.

For the year ended December 31, 2018, other income, net was $3.8 million, which was primarily attributable to interest income, accretion of discounts associated with marketable securities, and rental income from our former subtenant, partially offset by interest expense on our construction financing lease obligation.

Liquidity and Capital Resources

Sources of Liquidity

In May 2020, we entered into a sales agreement with Cowen and Company, LLC ("Cowen") under which we are able from time to time to issue and sell shares of our common stock through Cowen for aggregate gross sales proceeds of up to $150.0 million (the "ATM Facility"). We have not sold any shares of our common stock under this ATM Facility as of the date of this Annual Report on Form 10-K. In June 2020, we completed a public offering in which we sold 6,900,000 shares of our common stock, inclusive of 900,000 shares of common stock sold by us pursuant to the full exercise of an option granted to the underwriters in connection with the offering and received net proceeds of approximately $203.7 million. As of December 31, 2020, we have raised an aggregate of $648.7 million in net proceeds through the sale of shares of our common stock in public offerings and at-the-market offerings. We also have funded our business from payments received under our research collaboration with Juno Therapeutics, our strategic alliance with Allergan, which was terminated in August 2020, and our license agreement with Beam Therapeutics, from which we received $20.0 million from the sale of our shares of common stock in October 2020. As of December 31, 2020, we had cash, cash equivalents and marketable securities of $511.8 million.

In January 2021, we completed a public offering in which we sold 3,500,000 shares of our common stock and received net proceeds of approximately $216.9 million. In February 2021, the underwriters in the public offering exercised their option to purchase an additional 525,000 shares, resulting in additional net proceeds to us of approximately $32.6 million.

In addition to our existing cash, cash equivalents and marketable securities we are eligible to earn milestone and other payments under our collaboration agreement with Juno Therapeutics. Our ability to earn the milestone payments and the timing of earning these amounts are dependent upon the timing and outcome of our development, regulatory and commercial activities and, as such, are uncertain at this time. As of December 31, 2020, our right to contingent payments under our collaboration agreement with Juno Therapeutics is our only significant committed potential external source of funds.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2020, 2019 and 2018, respectively (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Net cash (used in) provided by:			
Operating activities	$ (179,843)	$ (40,669)	$ (45,707)
Investing activities	(140,522)	12,252	(53,087)
Financing activities	224,122	131,824	86,940
Net (decrease) increase in cash and cash equivalents	$ (96,243)	$ 103,407	$ (11,854)

Net Cash Used in Operating Activities

The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital.

Net cash used in operating activities was approximately $179.8 million for the year ended December 31, 2020, which primarily consisted of operating expenses that relate to our on-going preclinical and clinical activities, patent costs and license fees, and increased costs as a result of staffing needs due to our expanding operations. These expenses were partially offset by the recognition of deferred revenue relating to the Allergan termination and Celgene milestone payment.

Net cash used in operating activities was approximately $40.7 million for the year ended December 31, 2019. During the year ended December 31, 2019, we received $70.0 million related to our amended and restated collaboration agreement with Juno Therapeutics, which was partially recognized in revenue during the fourth quarter of 2019, partially offset by revenue recognized related to our strategic alliance with Allergan. This amount was offset by operating expenses that related to our on-going preclinical and clinical activities, sublicense expense, intellectual property costs and increased employee related expenses due to an increase in the size of our workforce.

Net cash used in operating activities was approximately $45.7 million for the year ended December 31, 2018. During the year ended December 31, 2018, we received $25.0 million related to the EDIT-101 Milestone Payment which was partially recognized as revenue during the fourth quarter of 2018 and $15.0 million related to the EDIT-101 Option Exercise Payment which was fully recognized as revenue during the third quarter of 2018, both related to our strategic alliance with Allergan. We received $10.0 million related to our amended and restated collaboration agreement with Juno Therapeutics which was partially recognized during 2018. Additionally, we issued $12.5 million in notes payable to Broad and settled in shares of common stock during the second quarter of 2018 in connection with our entry into a sponsored research agreement with Broad. This amount was offset by operating expenses that related to our on-going preclinical activities, sublicensing and success payments, intellectual property costs and increased employee related expenses due to an increase in the size of our workforce.

Net Cash (Used in) Provided by Investing Activities

Net cash used in investing activities was approximately $140.5 million for the year ended December 31, 2020, primarily related to the costs to acquire marketable securities of $458.4 million and costs to acquire property, plant and

equipment of $7.2 million, partially offset by proceeds from maturities of marketable securities of $305.0 million and proceeds from the sale of corporate equity securities of $20.0 million.

Net cash provided by investing activities was approximately $12.3 million for the year ended December 31, 2019, primarily related to proceeds from maturities of marketable securities of $360.5 million, partially offset by costs to acquire marketable securities of $342.2 million and costs to acquire property plant and equipment of $6.2 million.

Net cash used in investing activities was approximately $53.1 million for the year ended December 31, 2018, primarily related to costs to acquire marketable securities of $459.4 million and costs to acquire property plant and equipment of $4.8 million, partially offset by proceeds from maturities of marketable securities of $411.0 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was approximately $224.1 million for the year ended December 31, 2020, primarily related to $203.7 million in net proceeds received from offering of common stock, and $19.5 million in proceeds received from exercises of options for our common stock.

Net cash provided by financing activities was approximately $131.8 million for the year ended December 31, 2019, primarily related to $116.3 million in proceeds received from at-the-market offerings of our common stock, net of issuance costs that were paid as of December 31, 2019, $14.9 million in proceeds from exercises of options for our common stock and $0.6 million from issuances of our common stock under equity benefit plans.

Net cash provided by financing activities was approximately $86.9 million for the year ended December 31, 2018, primarily related to $76.8 million in proceeds received from at-the-market offerings of our common stock, net of issuance costs that were paid as of December 31, 2018, $10.3 million in proceeds from exercises of options for our common stock and $0.7 million from issuances of our common stock under equity benefit plans, partially offset by payments on our construction financing lease obligation of $0.9 million.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we progress the clinical development of EDIT-101 and EDIT-301; further advance our current research programs and our preclinical development activities; seek to identify product candidates and additional research programs; initiate preclinical testing and clinical trials for other product candidates we identify and develop; maintain, expand, and protect our intellectual property portfolio, including reimbursing our licensors for expenses related to the intellectual property that we in-license from such licensors; hire additional clinical, quality control, and scientific personnel; and incur costs associated with operating as a public company. In addition, if we obtain marketing approval for any product candidate that we identify and develop, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution to the extent that such sales, marketing, and distribution are not the responsibility of a collaborator. We do not expect to generate significant recurring revenue unless and until we obtain regulatory approval for and commercialize a product candidate. Furthermore, since 2016 we have incurred, and in future years we expect to continue to incur, significant 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 development programs or future commercialization efforts.

We expect that our existing cash, cash equivalents and marketable securities at December 31, 2020 and anticipated interest income will enable us to fund our operating expenses and capital expenditure requirements into 2023. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including: the scope, progress, results, and costs of drug discovery, preclinical development, laboratory testing, and clinical or natural history study trials for the product candidates we develop;

- the scope, progress, results, and costs of drug discovery, preclinical development, laboratory testing, and

clinical or natural history study trials for the product candidates we develop;

- the costs of progressing the clinical development of EDIT-101 to treat LCA10;
- the costs of progressing the clinical development of EDIT-301 to treat sickle cell disease;
- the costs of IND-enabling studies for EDIT-301 to treat beta-thalassemia;
- 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 develop;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, and distribution, for any product candidates for which we receive regulatory approval;
- the success of our collaboration with Juno Therapeutics;
- whether Juno Therapeutics exercises any of its options to extend the research program term and/or to certain of the research programs under our collaboration;
- our ability to establish and maintain additional collaborations on favorable terms, if at all;
- the extent to which we acquire or in-license other medicines and technologies;
- the costs of reimbursing our licensors for the prosecution and maintenance of the patent rights in-licensed by us; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive, and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, any product candidate that we identify and develop, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of genomic 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. Further, our ability to continue to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

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. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. 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 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.

Contractual Obligations

The following table summarizes our significant contractual obligations as of payment due date by period at December 31, 2020 (in thousands):

	Total	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
Operating lease obligations [1]	$ 30,206	$ 8,778	$ 17,149	$ 4,169	$ 110
Total	$ 30,206	$ 8,778	$ 17,149	$ 4,169	$ 110

(1) Represents future minimum lease payments under our non-cancelable operating leases. The minimum lease payments above exclude our share of the facility operating expenses and other costs that are reimbursable to the landlord under the leases.

The table above 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 development or regulatory approval milestones, as well as commercial 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. For further information regarding these agreements, please see "Business—Our Collaborations and Licensing Strategy."

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 we do not currently have, any off-balance sheet arrangements, as defined under applicable Securities and Exchange Commission rules.

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 and cash equivalents of $139.7 million, primarily held in money market mutual funds consisting of U.S. government-backed securities, and marketable securities of $372.1 million, primarily consisting of U.S. government-backed securities, corporate equity securities and corporate debt 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, including cash equivalents, are in the form, or may be in the form of, money market funds or marketable securities and are or may be invested in U.S. Treasury and U.S. government agency obligations. Due to the short-term maturities and low risk profiles of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our investments.

While we contract with certain vendors and institutions internationally, substantially all of our total liabilities as of December 31, 2020 were denominated in the United States dollar and we believe that we do not have any material exposure to foreign currency exchange rate risk.

Item 8. Financial Statement and Other Supplementary Information.

EDITAS MEDICINE, INC.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Editas Medicine, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Editas Medicine, Inc. (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, stockholders' equity , and cash flows for each of the three years in the period ended December 31, 2020 and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 26, 2021 expressed an unqualified opinion thereon.

Adoption of ASU No. 2016-02

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for leases in year ended December 31, 2019 due to the adoption of ASU No. 2016-02, *Leases (Topic 842)*.

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

Critical Audit Matters

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

Accrued Research and Development Expense

Description of the Matter	The Company's accrual for research and development expenses totaled $10.2 million at December 31, 2020. As discussed in Note 2 to the consolidated financial statements, the Company expenses research and development costs as incurred. The Company's determination of costs incurred to conduct research and development on the Company's product candidates, as well as the related accrued expenses at each reporting period incorporates judgment and utilizes various assumptions, including an evaluation of the information provided to the Company by third parties on actual costs incurred but not yet billed, estimated project timelines and patient enrollment. Payments for these activities are based on the terms of the individual arrangements, which often differ from the pattern of costs incurred. Auditing the Company's research and development accruals is especially complex due to the judgments and estimations of the research and development expenses. The Company uses judgment and estimation to estimate costs incurred and not yet billed at each reporting period as a result of the volume of pre-clinical and clinical trials and the related manufacturing activities, as well as the extent of third-party vendors utilized. Additionally, due to the timing of invoices received from third parties, actual amounts incurred are not always known as of the audit report date.
How We Addressed the Matter in Our Audit	We obtained an understanding of the Company's process, evaluated and tested the design and operating effectiveness of internal controls that address the risks related to the completeness and valuation of accrued research and development expenses. To test the research and development accrual, our audit procedures included, among others, testing the accuracy and completeness of the underlying data used in the estimates and evaluating and testing the significant assumptions that are used by management to estimate the accruals. To test the significant assumptions, we inspected the contracts and any amendments to the contracts with third-party service providers, corroborated the progress of pre-clinical and clinical trials and other research and development projects with the Company's research and development personnel that oversee the clinical trials and the related manufacturing activities, and obtained information received directly from third parties, which included the third parties' estimate of costs incurred to date. We also tested subsequent invoicing received from third parties.

/s/ *Ernst & Young LLP*

We have served as the Company's auditor since 2015.

Boston, Massachusetts

February 26, 2021

Editas Medicine, Inc.
Consolidated Balance Sheets
(amounts in thousands, except share and per share data)

	December 31,	
	2020	2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 139,682	$ 238,183
Marketable securities	262,428	218,957
Accounts receivable	6,048	418
Prepaid expenses and other current assets	10,929	6,286
Total current assets	419,087	463,844
Marketable securities	109,664	—
Property and equipment, net	14,020	10,887
Right-of-use assets	25,128	28,761
Restricted cash and other non-current assets	4,703	5,393
Total assets	$ 572,602	$ 508,885
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,408	$ 5,843
Accrued expenses	24,046	22,120
Deferred revenue, current	20,943	23,514
Operating lease liabilities	6,811	5,804
Other current liabilities	—	2,682
Total current liabilities	58,208	59,963
Operating lease liabilities, net of current portion	19,324	23,277
Deferred revenue, net of current portion	73,984	163,207
Other non-current liabilities	27,500	1
Total liabilities	179,016	246,448
Stockholders' equity		
Preferred stock, $0.0001 par value per share: 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.0001 par value per share: 195,000,000 shares authorized; 62,689,457 and 54,533,798 shares issued, and 62,563,457 and 54,355,798 shares outstanding at December 31, 2020 and December 31, 2019, respectively	6	5
Additional paid-in capital	1,058,823	811,546
Accumulated other comprehensive (loss) income	(46)	107
Accumulated deficit	(665,197)	(549,221)
Total stockholders' equity	393,586	262,437
Total liabilities and stockholders' equity	$ 572,602	$ 508,885

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

Editas Medicine, Inc.
Consolidated Statements of Operations
(amounts in thousands, except per share and share data)

	Year Ended December 31,		
	2020	2019	2018
Collaboration and other research and development revenues	$ 90,732	$ 20,531	$ 31,937
Operating expenses:			
Research and development	157,996	96,898	90,654
General and administrative	67,576	64,555	55,010
Total operating expenses	225,572	161,453	145,664
Operating loss	(134,840)	(140,922)	(113,727)
Other income (expense), net:			
Other income (expense), net	16,259	(137)	328
Interest income, net	2,605	7,313	3,445
Total other income, net	18,864	7,176	3,773
Net Loss	$ (115,976)	$ (133,746)	$ (109,954)
Reconciliation of net loss to net loss attributable to common stockholders:			
Net loss	$ (115,976)	$ (133,746)	$ (109,954)
Net loss per share, basic and diluted	$ (1.98)	$ (2.68)	$ (2.33)
Weighted-average common shares outstanding, basic and diluted	58,609,389	49,983,329	47,097,735

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

Editas Medicine, Inc.
Consolidated Statements of Comprehensive Loss
(amounts in thousands)

	Year Ended December 31,		
	2020	2019	2018
Net loss	$ (115,976)	$ (133,746)	$ (109,954)
Other comprehensive (loss) income:			
Unrealized (loss) gain on marketable debt securities	(153)	136	47
Comprehensive loss	$ (116,129)	$ (133,610)	(109,907)

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

Editas Medicine, Inc.
Consolidated Statements of Stockholders' Equity
(amounts in thousands except share data)

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Income (Loss)	Equity
Balance at December 31, 2017	44,507,960	$ 4	$ 514,002	$ (305,850)	$ (76)	$ 208,080
Cumulative effect adjustment for adoption of new accounting guidance	—	—	—	(474)	—	(474)
Issuance of common stock for repayment of notes payable	636,526	—	22,030	—	—	22,030
Issuance of common stock from at-the-market offering, net of issuance costs of $0.1 million	1,429,205	1	48,493	—	—	48,494
Issuance of common stock from at-the-market offering, net of issuance costs of $0.6 million	1,107,000	—	28,387	—	—	28,387
Issuance of common stock for asset purchase agreement	56,099	—	1,942	—	—	1,942
Exercise of stock options	749,294	—	10,328	—	—	10,328
Stock-based compensation expense	0	0	26,598	0	0	26,598
Purchase of common stock under benefits plans	26,272	—	680	—	—	680
Vesting of restricted common stock awards	72,000	—	—	—	—	—
Vesting of employee restricted common stock and common stock subject to repurchase	174,595	—	4	—	47	4
Unrealized gain on marketable securities	—	—	—	—	—	47
Net loss	—	—	—	(109,954)	—	(109,954)
Balance at December 31, 2018	48,758,951	$ 5	$ 652,464	$ (416,278)	$ (29)	$ 236,162
Cumulative effect adjustment for adoption of new accounting guidance	—	—	—	803	—	803
Issuance of common stock from at-the-market offering, net of issuance costs of $0.2 million	4,341,428	—	116,356	—	—	116,356
Exercise of stock options	1,120,186	—	14,863	—	—	14,863
Stock-based compensation expense	—	—	27,243	—	—	27,243
Purchase of common stock under benefits plans	35,314	—	620	—	—	620
Vesting of restricted common stock and awards	99,919	—	—	—	—	—
Unrealized gain on marketable securities	—	—	—	—	136	136
Net loss	—	0	—	(133,746)	$ —	$ (133,746)
Balance at December 31, 2019	54,355,798	$ 5	$ 811,546	$ (549,221)	$ 107	$ 262,437
Exercise of stock options	964,412	—	19,500	—	—	19,500
Vesting of restricted common stock awards	304,638	—	—	—	—	—
Purchase of common stock under benefit plan	38,609	—	896	—	—	896
Issuance of common stock from public offering, net of issuance costs of $0.1 million	6,900,000	1	203,725	—	—	203,726
Stock-based compensation expense	—	—	23,156	—	—	23,156
Unrealized loss on marketable debt securities	—	—	—	—	(153)	(153)
Net loss	—	—	—	(115,976)	—	(115,976)
Balance at December 31, 2020	62,563,457	$ 6	$ 1,058,823	$ (665,197)	$ (46)	$ 393,586

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

Editas Medicine, Inc.
Consolidated Statements of Cash Flows
(amounts in thousands)

	Year Ended December 31,		
	2020	2019	2018
Cash flow from operating activities			
Net loss	$ (115,976)	$ (133,746)	$ (109,954)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	23,156	27,243	26,598
Depreciation	3,959	2,830	3,254
Realized gain on corporate equity securities	(16,366)	—	—
Non-cash investment in equity securities		—	(3,667)
Other non-cash items, net	104	(2,928)	(3,268)
Changes in operating assets and liabilities:			
Accounts receivable	(5,630)	(388)	649
Prepaid expenses and other current assets	(4,643)	(495)	(3,410)
Right-of-use assets	3,633	(9,300)	—
Other non-current assets	(719)	(15)	(92)
Accounts payable	855	274	1,780
Accrued expenses	1,707	9,485	4,042
Deferred revenue	(91,794)	55,395	22,889
Operating lease liabilities	(2,946)	9,324	—
Other current and non-current liabilities	(2,683)	1,652	1,030
Non-cash research and development expenses	27,500	—	14,442
Net cash used in operating activities	(179,843)	(40,669)	(45,707)
Cash flow from investing activities			
Purchases of property and equipment	(7,162)	(6,167)	(4,754)
Proceeds from the sale of equipment	12	102	37
Purchases of marketable securities	(458,404)	(342,183)	(459,370)
Proceeds from maturities of marketable securities	305,000	360,500	411,000
Proceeds from sale of corporate equity securities	20,032	—	—
Net cash (used in) provided by investing activities	(140,522)	12,252	(53,087)
Cash flow from financing activities			
Proceeds from offering of common stock, net of issuance costs	203,726	116,341	76,789
Proceeds from exercise of stock options	19,501	14,863	10,328
Payments on construction financing lease obligation	—	—	(857)
Issuance of common stock under benefit plans	895	620	680
Net cash provided by financing activities	224,122	131,824	86,940
Net increase (decrease) in cash, cash equivalents, and restricted cash	(96,243)	103,407	(11,854)
Cash, cash equivalents, and restricted cash, beginning of period	239,802	136,395	148,249
Cash, cash equivalents, and restricted cash, end of period	$ 143,559	$ 239,802	$ 136,395
Supplemental disclosure of cash and non-cash activities:			
Fixed asset additions included in accounts payable and accrued expenses	$ 656	$ 728	$ 659
Cash paid in connection with operating lease liabilities	9,760	5,970	—
Offering costs included in accounts payable and accrued expenses	—	15	92
Right-of-use assets obtained in exchange of operating lease obligations	—	19,461	—
Reclassification of liability for common stock subject to repurchase	—	—	4
Issuance of common stock for repayment of notes payable	—	—	22,030
Issuance of common stock for asset acquisition	—	—	1,942

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

Editas Medicine, Inc.
Notes to Consolidated Financial Statements

1. Nature of Business

Editas Medicine, Inc. (the "Company") is a leading, clinical stage genome editing company dedicated to developing potentially transformative genomic medicines to treat a broad range of serious diseases. The Company was incorporated in the state of Delaware in September 2013. Its principal offices are in Cambridge, Massachusetts.

Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and raising capital. The Company has primarily financed its operations through various equity financings, payments received under a research collaboration with Juno Therapeutics, a wholly-owned subsidiary of the Bristol-Myers Squibb Company ("Juno Therapeutics"), and payments received under a strategic alliance and option agreement with Allergan Pharmaceuticals International Limited (together with its affiliates, "Allergan").

The Company is subject to risks common to companies in the biotechnology industry, including but not limited to, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval for any drug product candidate that it may identify and develop, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development by competitors of technological innovations and ability to transition from pilot-scale manufacturing to large-scale production of products.

Liquidity

In May 2020, the Company entered into a sales agreement with Cowen and Company, LLC ("Cowen"), under which the Company from time to time can issue and sell shares of its common stock through Cowen in at-the-market offerings for aggregate gross sale proceeds of up to $150.0 million (the "ATM Facility"). As of December 31, 2020, the Company has not sold any shares of its common stock under the ATM Facility. In June 2020, the Company completed a public offering whereby the Company sold 6,900,000 shares of its common stock, inclusive of 900,000 shares of common stock sold by the Company pursuant to the full exercise of an option granted to the underwriters in connection with the offering and received net proceeds of approximately $203.7 million. As of December 31, 2020, the Company has raised an aggregate of $648.7 million in net proceeds through the sale of shares of its common stock in public offerings and at-the-market offerings.

The Company has incurred annual net operating losses in every year since its inception. The Company has an accumulated deficit of $665.2 million at December 31, 2020. The Company expects that its existing cash, cash equivalents and marketable securities on December 31, 2020, anticipated interest income, and the proceeds of its subsequent public offering described in Note 18, will enable it to fund its operating expenses and capital expenditure requirements for at least 36 months following the date of this Annual Report on Form 10-K. The Company will require substantial additional capital to fund its operations. The Company has never generated any product revenue. There can be no assurance that the Company will be able to obtain additional debt or equity financing or generate product revenue or revenues from collaborative partners, on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations, and financial condition.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Editas Medicine, Inc. and its wholly owned subsidiary, Editas Securities Corporation, which is a Delaware subsidiary created to buy, sell and hold securities. All intercompany transactions and balances have been eliminated.

Basis of Presentation

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

Reclassification

Certain prior period amounts have been reclassified for consistency with the current period presentation. These reclassifications had no effect on previously reported results of operations.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. On an ongoing basis, the Company's management evaluates its estimates, which include, but are not limited to, estimates related to revenue recognition, accrued expenses, stock-based compensation expense, research and development expenses and deferred tax valuation allowances. The Company bases its estimates on historical experience and other market-specific or relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Fair Value of Financial Instruments

ASC Topic 820, *Fair Value Measurement* ("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 sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances.

ASC 820 identifies fair value as the exchange price representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair 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 developed using estimates of assumptions developed by the Company, which reflect those that a market participant would use.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in 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.

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, restricted cash, marketable securities, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses, and other current liabilities approximate their fair values, due to their short-term nature.

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. Cash and cash equivalents include cash held in banks and amounts held in money market funds and U.S. government-backed securities.

The Company has restricted cash of $3.9 million held as collateral for the Company's corporate headquarters and credit card program. The restricted funds are maintained in a traditional bank account.

The following table presents cash, cash equivalents, and restricted cash as reported on the consolidated balance sheets that equal the total amounts on the consolidated statements of cash flows (in thousands):

	Year Ended December 31,	
	2020	2019
Cash and cash equivalents	$ 511,774	$ 238,183
Restricted cash included in "Restricted cash and other non-current assets"	3,877	1,619
Total cash, cash equivalents, and restricted cash	$ 515,651	$ 239,802

Marketable Securities

The Company classifies marketable securities with a remaining maturity when purchased of greater than three months and less than one year from the balance sheet date as current. Marketable securities are classified as long-term assets on the consolidated balance sheets if the contractual maturity exceeds one year and the Company does not intend to utilize the marketable securities to fund current operations. The Company classifies all of its marketable securities as available-for-sale securities. Available-for-sale debt securities are carried at fair value with the unrealized gains and losses included in other comprehensive loss 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 of the underlying security. Realized gains and losses are included in other income (expense). The Company adopted Accounting Standards Update ("ASU") 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13") as of January 1, 2020, which did not have a significant impact on its consolidated financial statements. For available-for-sale debt securities in unrealized loss positions, ASU 2016-13 requires the Company to record an allowance for credit losses using an expected loss model, which replaces the incurred loss model required under the previous guidance. A credit loss is limited to the amount by which the amortized cost of an investment exceeds its fair value. A previously recognized credit loss may be decreased in subsequent periods if the Company's estimate of fair value for the investment increases. To determine whether to record a credit loss, the Company considers issuer specific credit ratings and historical losses as well as current economic conditions and its expectations for future economic conditions.

Corporate Equity Securities

The Company classifies investments in equity securities that have a readily determinable fair value as marketable securities in the Company's consolidated balance sheets. The Company's marketable securities are stated at fair value. Typically, the fair value of these securities is based on a quoted price for an identical equity security. If the equity security has a restriction that is determined to be an attribute of the security that would transfer to a market participant, the fair value of the security is measured based on the quoted price for an otherwise identical unrestricted equity security, adjusted for the effect of the restriction. The adjustment reflects the discount that a market participant would demand for the risk relating to the inability to dispose of the security for a specified period of time. That adjustment is based on the nature and duration of the restriction and the limitations imposed by the restriction to a buyer.

The Company records changes in the fair value of its equity securities in “Other Income (Expense), net” in the Company’s condensed consolidated statement of operations.

Accounts Receivable

The Company makes judgments as to its ability to collect outstanding receivables and provides an allowance for receivables when collection becomes doubtful. The Company’s estimates for its allowance for credit losses, which has not been significant to date, is determined based on existing contractual payment terms, historical payment patterns, current economic conditions and the Company’s expectation for future economic conditions. The Company's receivables primarily relate to amounts reimbursed under its collaboration agreements. The Company believes that credit risk associated with its collaborations partners is not significant. To date, the Company has not had any write-offs of bad debt, and the Company did not have an allowance for doubtful accounts as of December 31, 2020 and 2019.

Property and Equipment

Property and equipment consists of computers, laboratory equipment, furniture and office equipment, and leasehold improvements and is stated at cost, less accumulated depreciation. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred, while costs of major additions and betterments are capitalized. Depreciation is calculated over the estimated useful lives of the assets using the straight-line method. The Company capitalizes laboratory equipment used for research and development if it has alternative future use in research and development or otherwise.

Asset:	Estimated Useful life
Lab equipment	5 years
Computer equipment and software	3 years
Furniture and equipment	5 years
Leasehold improvements	Shorter of useful life or remaining lease term

Impairment of Long-lived Assets

The Company evaluates long-lived assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book values of the assets to the expected future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book values of the assets exceed their fair value. The Company has not recognized any impairment losses from inception through December 31, 2020.

Profit-Sharing Arrangements

The Company considers the nature and contractual terms of the arrangements and assesses whether such arrangements involve a joint operating activity pursuant to which the Company is an active participant and is exposed to significant risks and rewards with respect to such arrangement. If the Company is an active participant and is exposed to significant risks and rewards with respect to such arrangement, the Company accounts for such arrangement as a collaboration under ASC Topic 808, *Collaborative Arrangements* (“ASC 808”). ASC 808 describes arrangements within its scope and considerations surrounding presentation and disclosure, with recognition matters subjected to other authoritative guidance, in certain cases by analogy.

Payments received from a collaboration partner to which this policy applies are recorded as contra-expense in the applicable period and may include development costs or patent expense reimbursements. The Company classifies payments made under the cost sharing provisions of such arrangements as a component of research and development expenses to reflect the joint risk sharing nature of such profit-sharing arrangements. The Company classifies payments owed or receivables recorded as other current liabilities or prepaid expenses and other current assets, respectively, in the

Company's consolidated balance sheets. At December 31, 2020, the Company no longer had any agreements considered under ASC 808.

Revenue Recognition

To date, the Company has primarily earned revenue under the collaboration and license agreement with Juno Therapeutics and the strategic alliance with Allergan, which was terminated on August 5, 2020.

The Company recognizes revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). The Company enters into collaboration agreements and certain other agreements that are within the scope of ASC 606, under which the Company licenses, may license or grants an option to license rights to certain of the Company's product candidates and performs research and development services in connection with such arrangements. The terms of these arrangements typically include payment of one or more of the following: non-refundable, up-front fees; reimbursement of research and development costs; development, clinical, regulatory and commercial sales milestone payments; and royalties on net sales of licensed products.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The promised goods or services in the Company's arrangements typically consist of a license, or option to license, rights to the Company's intellectual property or research and development services. The Company provides options to additional items in such arrangements, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer and are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised good or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on its own or whether the required expertise is readily available and whether the goods or services are integral or dependent to other goods or services in the contract.

The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration or variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of potential payment and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected value method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration that is included in the transaction price may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

The Company's contracts often include development and regulatory milestone payments that are as assessed under the most likely amount method and constrained if it is probable that a significant revenue reversal would occur. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of such development and clinical 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 collaboration and other research and development revenues in the period of adjustment.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes 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 the Company's collaboration or strategic alliance arrangements.

The Company allocates the transaction price based on the estimated standalone selling price. The Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the stand-alone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs. Variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated are consistent with the amounts the Company would expect to receive for the satisfaction of each performance obligation.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations which consist of licenses and 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. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company receives payments from its customers based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional.

Research and Development Expenses

Research and development expenses are charged to expense as incurred in performing research and development activities. The costs include employee-related expenses including salaries, benefits, and stock-based compensation expense, costs of funding research performed by third parties that conduct research and development and preclinical and clinical activities on the Company's behalf, the cost of purchasing lab supplies and non-capital equipment used in preclinical and clinical activities and in manufacturing preclinical and clinical study materials, consultant fees, facility costs including rent, depreciation, and maintenance expenses, and fees for acquiring and maintaining licenses under third party licensing agreements, including any sublicensing or success payments made to the Company's licensors. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the Company's estimate, the accrual or prepaid is adjusted accordingly. The Company defers and capitalizes non-refundable advance payments made by the Company for research and development activities until the related goods are received or the related services are performed. In circumstances where amounts have been paid in excess of costs incurred, the Company records a prepaid expense.

In-process Research and Development Assets

In-process research and development assets that are acquired in a transaction that does not qualify as a business combination under GAAP and that do not have an alternative future use are expensed in the period in which the assets are acquired.

Patent Costs

The Company expenses patent and patent application costs and related legal costs for the prosecution and maintenance of such patents and patent applications, including patents and patent applications the Company in-licenses, as incurred and classifies such costs as general and administrative expenses in the accompanying consolidated statements of operations.

Construction Financing Lease Obligation

Beginning in 2016, the Company began recording certain estimated construction costs incurred and reported to the Company by a landlord as an asset and corresponding construction financing lease obligation on the Company's consolidated balance sheets because the Company was deemed to be the owner of the building during the construction period for accounting purposes. In each reporting period, the landlord estimated and reported to the Company the costs incurred to date and provided supporting invoices for the Company to review. The Company periodically met with the landlord and its construction manager to review the estimates and observe construction progress prior to recording such amounts. Construction was completed in October 2016 and the Company considered the requirements for sale-leaseback accounting treatment, which included an evaluation of whether all risks of ownership had transferred back to the landlord as evidenced by a lack of continuing involvement in the lease property. The Company determined that the arrangement did not qualify for sale lease-back accounting treatment, the building asset will remain on the Company's consolidated balance sheet at its historical cost, and such asset would be depreciated over its estimated useful life of thirty years.

Effective January 1, 2019, the Company adopted Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842) ("ASC 842") and derecognized the balances relating to the building, accumulated depreciation and the corresponding construction financing lease as summarized in the table below (in thousands). In applying the ASC 842 transition guidance, the Company determined that the lease should be classified as an operating lease and recorded a right-of-use asset and lease liability on the effective date, accordingly.

		As of January 1, 2019
Property and equipment, net	$	32,627
Other current liabilities	$	(1,014)
Construction financing lease obligation, net of current portion	$	(32,417)
Accumulated deficit	$	803

Leases

The Company accounts for leases in accordance with ASC 842. At the inception of an arrangement the Company determines whether the arrangement contains a lease. If a lease is identified in an arrangement, the Company recognizes a right-of-use asset and liability on its balance sheet and determines whether the lease should be classified as a finance or operating lease. The Company does not recognize assets or liabilities for leases with lease terms of less than 12 months. Lease payments for short-term leases are recorded to operating expense on a straight-line basis over the lease term and variable lease payments are recorded in the period in which the obligation for those payments is incurred.

A lease qualifies as a finance lease if any of the following criteria are met at the inception of the lease: (i) there is a transfer of ownership of the leased asset to the Company by the end of the lease term, (ii) the Company holds an option to purchase the leased asset that it is reasonably certain to exercise, (iii) the lease term is for a major part of the remaining economic life of the leased asset, (iv) the present value of the sum of lease payments equals or exceeds substantially all of the fair value of the leased asset, and (v) the nature of the leased asset is specialized to the point that it is expected to provide the lessor no alternative use at the end of the lease term. All other leases are recorded as operating leases.

Finance and operating lease assets and liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term using the discount rate implicit in the lease. If the rate is not readily determinable, the Company utilizes its incremental borrowing rate at the lease commencement date. Operating lease assets are further adjusted for prepaid or accrued lease payments. Operating lease payments are expensed using the straight-line method as an operating expense over the lease term. Finance lease assets are amortized to depreciation expense using the straight-line method over the shorter of the useful life of the related asset or the lease term. Finance lease payments are bifurcated into (i) a portion that is recorded as imputed interest expense and (ii) a portion that reduces the finance liability associated with the lease.

The Company does not separate lease and non-lease components when determining which lease payments to include in the calculation of its lease assets and liabilities. Variable lease payments are expensed as incurred. If a lease includes an option to extend or terminate the lease, the Company reflects the option in the lease term if it is reasonably certain it will exercise the option.

Stock-based Compensation Expense

The Company's stock-based compensation program grant awards which have included stock options, restricted stock awards ("RSAs"), restricted stock unit awards ("RSUs"), a market-based option award, and shares issued under the Company's 2015 employee stock purchase plan ("ESPP"). The Company accounts for stock-based compensation awards in accordance with ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718"). ASC 718 requires all stock-based payments to employees, directors and non-employees to be recognized as expense in the consolidated statements of operations based on their grant date fair values. The Company estimates the grant date fair value of each option award using the Black-Scholes option-pricing model. The fair value of the Company's RSAs and RSUs is based on market value of the Company's common stock on the date of grant. For awards subject to service-based vesting conditions, the Company recognizes the stock-based compensation expense on a straight-line basis over the requisite service period. If an employee or non-employee service requirement is concluded to be non-substantive, the stock-based compensation expense would be expensed immediately. Forfeitures are recorded as they occur.

Prior to 2019, the Company accounted for stock-based payments issued to non-employees in accordance with ASC Topic 505-50, *Equity Based Payments to Non-Employees*. Stock-based payments issued to non-employees were initially recorded at their fair value, and were revalued at each reporting date and as the equity instruments vest and were recognized as expense over the related service period.

The Company estimates the grant date fair value of each option award using the Black-Scholes option-pricing model. The Black-Scholes option pricing model requires the input of certain subjective assumptions, including (1) the expected stock price volatility, (2) the calculation of expected term of the award, (3) the risk-free interest rate, and (4) the expected dividend yield. Because there had been no public market for the Company's common stock prior to its initial public offering, there was a lack of company-specific historical and implied volatility data. Accordingly, the Company based its estimates of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The Company calculates historical volatility based on a period of time commensurate with the expected term. The Company computes expected volatility based on the historical volatility of a representative group of companies with similar characteristics to the Company, including their stages of product development and focus on the life science industry. The Company uses the simplified method as prescribed by the Securities and Exchange Commission's Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term for options granted to employees as the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. For options granted to non-employees, the Company utilizes the contractual term of the arrangement as the basis for the expected term. The Company determines the risk-free interest rate based on a treasury instrument whose term is consistent with the expected term of the stock options. The Company uses an assumed dividend yield of zero as the Company has never paid dividends and does not have current plans to pay any dividends on its common stock.

RSAs are subject to repurchase rights. Accordingly, the Company has recorded the proceeds from the issuance of restricted stock as a liability in the consolidated balance sheets. The restricted stock liability is reclassified into stockholders' equity as the restricted stock vests.

For market-based awards, the Company recognizes the fair value of the market-based options over the earlier of the derived service period, pursuant to a Monte-Carlo simulation model, or when the market-based vesting conditions are met. The Company estimates an award's derived service period based on the best estimate of the period over which an award's vesting condition(s) will be achieved. If the market-based vesting conditions are met ahead of the derived service period, the expense will be accelerated. If the market-based vesting conditions are not met and the market-based award is cancelled, the expense will not be reversed unless the market-based award is forfeited.

If factors change or different assumptions are used, the Company's stock-based compensation expense could be materially different in the future.

Success Payments, Research Funding Payments and Notes Payables

Certain arrangements require the Company to make payments, if and when, the Company's market capitalization reaches specified thresholds for a specific period of time or upon a sale of the Company for consideration in excess of those thresholds or above a specific amount. The payments were historically accounted for under the provisions of ASC Topic 505-50 and as of January 1, 2019, are accounted for under the provisions of ASC 718, whereby the Company recognizes the expense and liability when it becomes probable that the amounts will become due. The Company records this expense as a research and development expense in its consolidated statements of operations. The arrangements and payments are described more fully in Note 8.

The payments are payable in either cash, common stock or promissory notes payable, depending upon the licensor and the Company's election. If the Company elects to issue a promissory note relating to contractual obligations, the promissory note bears interest at 4.8% per annum. Outstanding principal and accrued interest on the promissory notes are typically payable on the earlier of five months or a specified period of time following a Company sale or change of control event, subject to certain exceptions.

Income taxes

Income taxes are recorded in accordance with ASC Topic 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial reporting and the tax reporting basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the weight of available evidence, it is more likely than not that the deferred tax assets will be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances.

Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income or loss. Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. Comprehensive loss currently consists of net loss and changes in unrealized gains and losses on marketable securities.

Concentrations of Credit Risk and Off-Balance Sheet Risk

The Company has no financial instruments with off-balance sheet risk such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Financial instruments that potentially subject the Company to a concentration of credit risk are cash, cash equivalents, marketable securities and receivables owed to the Company from collaboration partners. The Company's cash, cash equivalents and marketable securities are held in accounts at a financial institution that may exceed federally insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision maker, the Company's Chief Executive Officer, view the Company's operations and manage the Company's business as a single operating segment, which is the business of developing and commercializing genome editing technology.

Recent Accounting Pronouncements –Adopted

Financial Instruments- Credit Losses

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses* ("ASU 2016-13") which was clarified and amended by the issuances of ASUs 2018-19, 2019-04, 2019-05 and 2019-11 in November 2018, April 2019, May 2019 and November 2019, respectively. The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis to be measured using an expected-loss model, replacing the current incurred-loss model, and recorded through an allowance for credit losses which is a valuation account that is deducted from the amortized cost basis of the financial asset. ASU 2016-13 requires evaluation of credit loss based on historical experience, current conditions and reasonable and supportable forecasts. The Company's estimate of expected credit losses includes a measure of the expected risk of credit loss even if the risk is remote. When assessing financial assets for credit losses, the Company pools financial assets with similar risk characteristics and performs a collective evaluation. However, the Company is not required to measure expected credit losses in which historical credit loss information adjusted for current conditions and reasonable and supportable forecasts results in an expectation that nonpayment of the amortized cost basis is zero. At each reporting date, the Company will record an allowance for credit losses and reports it as credit loss expense which is included in "Other income (expense), net" in the Company's condensed consolidated statement of operations. However subsequent increases or decreases in the fair value of available-for-sale securities that do not result in recognition or reversal of an allowance for credit loss or write-down will continue to be recorded in other comprehensive loss. The Company adopted the new standard and the related amendments on January 1, 2020 using a modified retrospective approach. The modified retrospective approach requires the Company to record a one-time adjustment to opening accumulated deficit as of the effective date. At adoption, the Company concluded that there are no indicators of credit loss with respect to its available-for-sale debt securities which consist of U.S Treasury securities and government-agency bonds. The Company therefore did not record an allowance for credit losses or doubtful accounts upon adoption or during the first quarter of 2020. The adoption of ASU 2016-13 had no impact on the Company's condensed consolidated financial statements.

Intangibles and Goodwill

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal Use Software: Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* ("ASU 2018-15"). ASU 2018-15 aligns the requirements for capitalizing implementation costs incurred in a cloud computing arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. *ASU 2018-15 was* effective on January 1, 2020. The Company adopted ASU 2018-15 using the prospective transition approach, which allows the Company to change the accounting method without restating prior periods or recording cumulative adjustments. The adoption of ASU 2018-15 did not have a material impact on the Company's condensed consolidated financial statements.

Fair Value Measurement

In 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which eliminates, adds, and modifies the disclosure requirements for fair value measurements. ASU 2018-13 was effective on January 1, 2020. The adoption of ASU 2018-13 results in additional disclosures related to the Company's assets and liabilities that are valued based on Level 3 inputs and transfers between Level 1 and Level 2 fair value measurements. The adoption of ASU 2018-13 did not have a material impact on the Company's financial statement footnote disclosures.

3. Cash Equivalents and Marketable Securities

Cash equivalents and marketable securities consisted of the following at December 31, 2020 (in thousands):

December 31, 2020	Amortized Cost	Allowance for Credit Losses	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents and marketable securities:					
Money market funds	$ 139,682	$ —	$ —	$ —	$ 139,682
U.S. Treasuries	180,376	—	8	(11)	180,373
Government agency securities	107,665	—	—	(20)	107,645
Commercial paper	41,912	—	—	(8)	41,904
Corporate notes/bonds	42,185	—	10	(25)	42,170
Total	$ 511,820	$ —	$ 18	$ (64)	$ 511,774

Cash equivalents and marketable securities consisted of the following at December 31, 2019 (in thousands):

December 31, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents and marketable securities:				
Money market funds	$ 230,201	$ —	$ —	$ 230,201
U.S. Treasuries	71,348	20	—	71,368
Government agency securities	155,484	87	—	155,571
Equity securities included in other non-current assets:				
Corporate equity securities	3,667	—	—	3,667
Total	$ 460,700	$ 107	$ —	$ 460,807

As of December 31, 2020, the Company did not hold any marketable securities that had been in an unrealized loss position for more than twelve months. Furthermore, the Company has determined that there were no material changes in the credit risk of the debt securities. As of December 31, 2020, the Company holds 62 securities with an aggregate fair value of $109.7 million that had remaining maturities between one and two years.

4. Fair Value Measurements

Assets measured at fair value on a recurring basis as of December 31, 2020 were as follows (in thousands):

Financial Assets	December 31, 2020	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents:				
Money market funds	$ 139,682	$ 139,682	$ —	$ —
Marketable securities:				
U.S. Treasuries	180,373	180,373	—	—
Government agency securities	107,645	—	107,645	—
Commercial paper	41,904	—	41,904	—
Corporate bonds	42,170	—	42,170	—
Restricted cash and other non-current assets:				
Money market funds	3,877	3,877	—	—
Total financial assets	$ 515,651	$ 323,932	$ 191,719	$ —

Assets measured at fair value on a recurring basis as of December 31, 2019 were as follows (in thousands):

Financial Assets	December 31, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents:				
Money market funds	$ 230,201	$ 230,201	$ —	$ —
U.S. Treasuries	7,982	7,982	—	—
Marketable securities:				
U.S. Treasuries	63,386	63,386	—	—
Government agency securities	155,571	155,571	—	—
Restricted cash and other non-current assets:				
Corporate equity securities	3,667	—	3,667	—
Money market funds	1,619	1,619	—	—
Total financial assets	$ 462,426	$ 458,759	$ 3,667	$ —

During the year ended December 31, 2020, the Company held an investment in Beam Therapeutics Inc. (“Beam Therapeutics”) consisting of shares of Beam Therapeutics’ common stock. Prior to Beam Therapeutics’ initial public offering in February 2020, the Company valued such investment based on the cost of the equity securities adjusted for any observable market transactions. Following the initial public offering, the equity securities had a readily determinable fair value, and were included in marketable securities on the consolidated balance sheet. The Company sold this investment in October 2020, resulting in a realized gain of $16.4 million recorded in other income (expense), net on the consolidated statements of operations.

5. Property and Equipment, Net

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

	As of	
	December 31, 2020	December 31, 2019
Laboratory equipment	$ 18,433	$ 14,571
Leasehold improvements	4,967	1,042
Computer equipment	858	858
Construction-in-progress	500	1,336
Furniture and office equipment	239	166
Software	118	118
Total property and equipment	25,115	18,091
Less: accumulated depreciation	(11,095)	(7,204)
Property and equipment, net	$ 14,020	$ 10,887

The Company recorded $4.0 million, $2.8 million, and $3.3 million in depreciation expense during the years ended December 31, 2020, 2019 and 2018, respectively.

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	As of December 31,	
	2020	2019
External research and development expenses	$ 12,820	$ 735
Employee related expenses	5,323	4,971
Intellectual property and patent related fees	4,240	3,725
Sublicensing expenses	771	11,416
Professional service expenses	533	674
Other expenses	359	599
Total accrued expenses	$ 24,046	$ 22,120

7. Leases

The Company has multiple lease agreements for office, laboratory and manufacturing space with varying contractual terms set to expire between 2021 and 2025. Typically, base rent payments commence at the beginning of each lease term and continue through the term of the respective lease. Additionality, base rent is also subject to increases over the term of the lease. The Company has two significant leases for office and laboratory space located in Cambridge, Massachusetts that are summarized below. Prior to January 1, 2019, the Company accounted for leases as operating leases under ASC 840, *Leases* (“ASC 840”) and recognized straight-line rent expense over the remaining non-cancellable lease terms. As part of its adoption of ASC 842, the Company elected to apply the package of practical expedients which, among other things, allowed the Company to carry forward its existing operating lease classification under ASC 840. Additionally, the Company recorded right-of-use assets and lease liabilities for these operating leases on the effective date.

The Company's leases are included on its consolidated balance sheet as follows (in thousands):

	As of	
	December 31, 2020	January 1, 2019
Right-of-use assets	$ 25,128	$ 19,461
Operating lease liabilities, current	$ (6,811)	$ (3,848)
Operating lease liabilities, noncurrent	$ (19,324)	$ (15,909)

During the years ended December 31, 2020 and 2019, the Company recorded $10.5 million and $5.6 million related to operating lease costs and $1.1 million and $1.0 million related to variable costs associated with the Company's operating leases under ASC 842, respectively. Under ASC 840, the Company incurred rent expense of approximately $1.8 million during the year ended December 31, 2018.

Maturities of the Company's lease liabilities in accordance with ASC 842 as of December 31, 2020 were as follows (in thousands):

Maturity of lease liabilities:	Year Ended December 31, 2020
2021	$ 8,778
2022	$ 9,342
2023	$ 7,807
2024	$ 3,695
2025	$ 474
Thereafter	$ 110
Total minimum lease payments	$ 30,206
Less: imputed interest	$ (4,071)
Total operating lease liabilities at December 31, 2020	$ 26,135

The weighted-average remaining lease term is 3.4 years and the weighted-average discount rate is 8.8%.

Hurley Street

In 2016, the Company entered into a lease agreement for 59,783 square feet of office and laboratory space located on Hurley Street in Cambridge, Massachusetts. The term of the lease began on October 1, 2016 and continues until October 2023. In connection with the lease and as a security deposit, the Company deposited with the landlord a letter of credit in the amount of approximately $1.6 million. Subject to the terms of the lease and certain reduction requirements specified therein, the $1.6 million security deposit may decrease over time. The letter of credit, which is collateralized by the Company, is recorded in restricted cash and other non-current assets in the accompanying consolidated balance sheets as of December 31, 2020 and December 31, 2019.

The Company has the option to extend the lease for an additional five-year term at market-based rates. The base rent payments commenced in November 2016 and continue through the term of the lease and are subject to increases over the term of the lease.

One Main Street

In December 2019, the Company entered into a lease agreement for 31,571 square feet of office space located on One Main Street in Cambridge, Massachusetts. The term of the lease began on January 15, 2020 and continues until January 2025. In connection with the lease and as a security deposit, the Company issued a letter of credit in the amount of approximately $0.8 million in January 2020.

The Company has the option to extend the lease for an additional five-year term at market-based rates. The base rent payments commenced in January 2020 and continue through the term of the lease and are subject to increases over

the term of the lease.

8. Commitments and Contingencies

The Company is a party to a number of license agreements under which the Company licenses patents, patent applications and other intellectual property from third parties. As such, the Company is obligated to reimburse licensors for various costs including upfront licenses fees, annual license fees, certain licensor expense reimbursements, success payments, research funding payments, and milestones triggerable upon certain development, regulatory, and commercial events as well as royalties on future products. These contracts are generally cancellable, with notice, at the Company's option and do not have significant cancellation penalties.

Broad Sponsored Research Agreement

In June 2018, the Company entered into a sponsored research agreement (the "Sponsored Research Agreement") with The Broad Institute, Inc. ("Broad"). The Sponsored Research Agreement provides for Broad to conduct research useful or relevant to genome editing in the field of genomic medicines for the prevention or treatment of human disease with funding from the Company. Under the Sponsored Research Agreement, Broad granted to the Company an exclusive right of first negotiation for licenses from Broad with respect to patentable inventions developed by Broad in the course of the sponsored research, subject to certain limitations and retained rights ("Sponsored Invention Licenses").

Under the Sponsored Research Agreement, the Company is obligated to make Market Cap Research Funding payments in the event the Company's market capitalization reaches specified thresholds ranging from a mid-nine digit dollar amount to a low-eleven digit dollar amount or Company Sale Research Funding payments in the event of a Company sale for consideration ranging from a mid-nine digit dollar amount to a low-eleven digit dollar amount. In connection with entering into the Sponsored Research Agreement, the Company confirmed that the first two research payments of $5.0 million and $7.5 million, respectively, were due and payable to Broad. In connection with the Initial Research Payments, the Company issued promissory notes to Broad that it settled in common stock in June 2018. The $12.5 million in research funding expense was recorded to research and development expenses during the year ended December 31, 2018. The Company fully settled the outstanding principal and accrued interest on the Initial Research Notes by issuing 330,617 shares of common stock to Broad in June 2018.

The Company triggered a Success Payment under the Broad Sponsored Research Agreement during the fourth quarter of 2020 when the Company's average market capitalization (as determined pursuant to the agreement) reached $2.5 billion. The Company accrued $12.5 million related to the Success Payment in the consolidated balance sheet at December 31, 2020. In January 2021, the Company settled this liability through the issuance of shares of its common stock.

Other than the Initial Research Payments, the Company is not required to make additional Research Funding Payments if the Company, whether directly or through its affiliates or sublicensees, is not researching, developing, or commercializing products based on or incorporating inventions exclusively licensed to the Company from Broad under Sponsored Invention Licenses or based on or incorporating CRISPR technology owned, co-owned, or controlled by Broad and otherwise licensed to the Company, subject to certain exclusions (an "Applicable Product" and such exemption from payment, the "Funding Exemption"). In the event that the Company, whether directly or through its affiliates or sublicensees, later resumes research, development, or commercialization of an Applicable Product within a specified period of time, any Research Funding Payment that was not paid to Broad as a result of the Funding Exemption shall become payable. Under the Sponsored Research Agreement, the Company is obligated to pay up to $125.0 million to Broad in Research Funding, inclusive of the Initial Research Payments, and in no event shall the aggregate amount of all Research Funding Payments exceed such amount.

Unless the Company has undergone a change in control, Market Cap Research Funding is payable by the Company in cash, common stock, or in the form of promissory notes, which may be settled in shares of common stock at the election of the Company. Following a change in control of the Company, Company Sale Research Funding is

required to be made in cash. The Sponsored Research Agreement is terminable by each party upon the occurrence of specified bankruptcy events of the other party and otherwise will continue in effect until the later of the expenditure of all Research Funding Payments by Broad and such time as the Company has no further rights of first negotiation for Sponsored Invention Licenses, unless otherwise mutually agreed between the parties.

Cas9-I License Agreement

In October 2014, the Company entered into an agreement (the "Cas9-I License Agreement") with Broad and the President and Fellows of Harvard College ("Harvard") to license certain patent rights owned or co-owned by, or among, Broad, the Massachusetts Institute of Technology ("MIT"), and Harvard (collectively, the "Institutions"). Consideration for the granting of the license included the payment of an upfront license issuance fee of $0.2 million and the issuance of 561,531 shares of the Company's common stock. The Institutions are collectively entitled to receive clinical and regulatory milestone payments totaling up to $14.8 million in the aggregate per licensed product approved in the United States, European Union, and Japan for the treatment of a human disease that afflicts at least a specified number of patients in the aggregate in the United States. If the Company undergoes a change of control during the term of the license agreement, the clinical and regulatory milestone payments will be increased by a certain percentage in the mid-double digits. The Company is also obligated to make additional payments to the Institutions, collectively, of up to an aggregate of $54.0 million upon the occurrence of certain sales milestones per licensed product for the treatment of a human disease that afflicts at least a specified number of patients in the aggregate in the United States. The Institutions are collectively entitled to receive clinical and regulatory milestone payments totaling up to $4.1 million in the aggregate per licensed product approved in the U.S. and at least one jurisdiction outside the U.S. for the treatment of a human disease based on certain criteria. The Company is also obligated to make additional payments to the Institutions, collectively, of up to an aggregate of $36.0 million upon the occurrence of certain sales milestones per licensed product for the treatment of a rare disease meeting certain criteria. The Institutions are entitled to receive from the Company nominal annual license fees and a mid-single digit percentage royalties on net sales of products for the prevention or treatment of human disease and ranging from low single digit to high single digit percentage royalties on net sales of other products and services, made by the Company, its affiliates, or its sublicensees. The royalty percentage depends on the product and service, and whether such licensed product or licensed service is covered by a valid claim within the certain patent rights that the Company licenses from the Institutions.

Cpf1 License Agreement

In December 2016, the Company entered into the Cpf1 License Agreement with Broad, for specified patent rights (the "Cpf1 Patent Rights") related primarily to Cas12a (formerly known as Cpf1) compositions of matter and their use for gene editing. Concurrently with entering into the Cpf1 License Agreement, the Company, Broad, and Harvard amended and restated the Cas9-I License Agreement as described below and the Company and Broad entered into the Cas9-II License Agreement for specified patent rights (the "Cas9-II Patent Rights") related primarily to certain Cas9 compositions of matter and their use for genome editing. The Company paid an upfront fee in aggregate of $16.5 million under these agreements which was recorded in research and development expenses during 2016. The upfront fee was fully settled in 2017, partially by issuing 479,270 shares of common stock.

Pursuant to the Cpf1 License Agreement, Broad, on behalf of itself, Harvard, MIT, Wageningen, and the University of Tokyo ("UTokyo" and, together with Broad, Harvard, Massachusetts Institute of Technology ("MIT"), and Wageningen University ("Wageningen"), (the "Cpf1 Institutions") granted the Company an exclusive, worldwide, royalty-bearing, sublicensable license to the Cpf1 Patent Rights, to make, have made, use, have used, sell, offer for sale, have sold, export and import products in the field of the prevention or treatment of human disease using gene therapy, editing of genetic material, or targeting of genetic material, subject to certain limitations and retained rights (collectively, the "Cpf1 Exclusive Field"), as well as a non-exclusive, worldwide, royalty-bearing sublicensable license to the Cpf1 Patent Rights for all other purposes, subject to certain limitations and retained rights. The Company is obligated to use commercially reasonable efforts to research, develop, and commercialize products in the Cpf1 Exclusive Field. The Company is also required to achieve certain development milestones within specified time periods for products covered by the Cpf1 Patent Rights, with Broad having the right to terminate the Cpf1 License Agreement if the Company fails to achieve these milestones within the required time periods.

Broad and Wageningen are collectively entitled to receive clinical and regulatory milestone payments totaling up to $20.0 million in the aggregate per licensed product approved in the United States, European Union, and Japan for the prevention or treatment of a human disease that afflicts at least a specified number of patients in the aggregate in the United States. The Company is also obligated to make additional payments to Broad and Wageningen, collectively, of up to an aggregate of $54.0 million upon the occurrence of certain sales milestones per licensed product for the prevention or treatment of a human disease that afflicts at least a specified number of patients in the aggregate in the United States. Broad and Wageningen are collectively entitled to receive clinical and regulatory milestone payments totaling up to $6.0 million in the aggregate per licensed product approved in the United States, European Union and Japan for the prevention or treatment of a human disease that afflicts fewer than a specified number of patients in the aggregate in the United States or a specified number of patients per year in the United States (an "Ultra-Orphan Disease"). The Company is also obligated to make additional payments to Broad and Wageningen, collectively, of up to an aggregate of $36.0 million upon the occurrence of certain sales milestones per licensed product for the prevention or treatment of an Ultra-Orphan Disease.

Broad and Wageningen, collectively, are entitled to receive, on a product-by-product and country-by-country basis, mid single-digit percentage royalty on net sales of licensed products for the prevention or treatment of human disease, and royalties on net sales of other licensed products and licensed services, made by the Company, its affiliates, or its sublicensees. The royalty percentage depends on the product and service, and whether such licensed product or licensed service is covered by a valid claim within the Cpf1 Patent Rights. If the Company is legally required to pay royalties to a third party on net sales of the Company's products because such third party holds patent rights that cover such licensed product, then the Company can credit up to a specified percentage of the amount paid to such third party against the royalties due to Broad and Wageningen in the same period. Such credit may not exceed 50% of the applicable royalties paid by the Company to the applicable third party. The Company's obligation to pay royalties will expire on a product-by-product and country-by-country basis upon the later of the expiration of the last to expire valid claim of the Cpf1 Patent Rights that covers each licensed product or service in each country or the tenth anniversary of the date of the first commercial sale of the licensed product or licensed service. If the Company sublicenses any of the Cpf1 Patent Rights to a third party, Broad and Wageningen, collectively, have the right to receive sublicense income, depending on the stage of development of the products or services in question at the time of the sublicense.

Under the Cpf1 License Agreement, Broad and Wageningen are also entitled, collectively, to receive success payments in the event the Company's market capitalization reaches specified thresholds (the "Cpf1 Market Cap Success Payments") or a Company sale for consideration in excess of those thresholds (the "Cpf1 Company Sale Success Payments" and, collectively with the Cpf1 Market Cap Success Payments, the "Cpf1 Success Payments"). The Cpf1 Success Payments payable to Broad and Wageningen are triggered when the Company's market capitalization reaches certain amounts ranging from $750.0 million to $10.0 billion for a specified period of time, and collectively the Cpf1 Success Payments will not exceed, in aggregate, $125.0 million, which maximum amount would be payable only if the Company reaches a market capitalization threshold of $10.0 billion and has at least one product candidate covered by a claim of a patent right licensed to the Company under either the Cpf1 License Agreement or the Cas9-I License Agreement that is or was the subject of a clinical trial pursuant to development efforts by the Company or any Company affiliate or sublicensee. The Cpf1 Market Cap Success Payments are payable by the Company in cash or in the form of promissory notes. Following a change in control of the Company, Cpf1 Market Cap Success Payments are required to be made in cash. Cpf1 Company Sale Success Payments are payable solely in cash. The Company triggered the first and second Cpf1 Success Payments during 2017 when the Company's market capitalization reached $750 million and $1.0 billion, respectively. The Company issued promissory notes for both Success Payments that were settled in 271,347 shares and 150,606 shares of common stock in August 2017 and January 2018, respectively.

The Company triggered the third Cpf1 Success Payment during the fourth quarter of 2020 when the Company's average market capitalization (as determined pursuant to the agreement) reached $2.5 billion. The Company accrued $15.0 million related to the Success Payment in the consolidated balance sheet for the year ended December 31, 2020. In January 2021, the Company settled this liability through the issuance of shares of its common stock.

Unless terminated earlier, the term of the Cpf1 License Agreement will expire on a country-by-country basis, upon the expiration of the last to expire valid claim of the Cpf1 Patent Rights in such country. The Company has the right to terminate the Cpf1 License Agreement at will upon four months' written notice to Broad. Either party may

terminate the Cpf1 License Agreement upon a specified period of notice in the event of the other party's uncured material breach of a material obligation, such notice period varying depending on the nature of the breach. Broad may terminate the Cpf1 License Agreement immediately if the Company challenges the enforceability, validity, or scope of any Cpf1 Patent Right or assist a third party to do so, or in the event of the Company's bankruptcy or insolvency.

Amendment and Restatement of Cas9-I License Agreement

In December 2016, the Company amended and restated the Cas9-I License Agreement (such agreement, as amended, the "Amended and Restated Cas9-I License Agreement") to exclude additional fields from the scope of the exclusive license previously granted to the Company, to make the exclusive license to three targets become non-exclusive, subject to the limitation that each of Broad and Harvard would only be permitted to grant a license to only one third party at a time with respect to each such target within the field of the exclusive license, and to revise certain provisions relating to the rights of Harvard and Broad to grant further licenses under specified circumstances to third parties that wish to develop and commercialize products that target a particular gene and that otherwise would fall within the scope of the exclusive license under this agreement, so that Harvard and Broad together would have rights substantially similar to the equivalent rights possessed by Broad under the Cpf1 License Agreement to designate gene targets for which the designating institution, whether alone or together with an affiliate or third party, has an interest in researching and developing products that would otherwise be covered by rights licensed by Harvard and/or Broad to the Company under this agreement, the Cpf1 License Agreement or the Cas9-II License Agreement. In March 2017, the Company and Harvard and Broad further amended the Amended and Restated Cas9-I License Agreement to (i) grant an exclusive license from Broad to the Company with respect to certain patent rights that The Rockefeller University ("Rockefeller") has or may have rights in and to and for which Rockefeller has, under a certain inter-institutional agreement that Broad and Rockefeller entered into in February 2017, appointed Broad as sole and exclusive agent for the purposes of licensing and (ii) provide to Rockefeller certain rights, including with respect to patent enforcement, indemnification, insurance, confidentiality, reservation of certain rights, and publicity, that are generally consistent with those granted to Broad, Harvard, MIT and the Howard Hughes Medical Institute under the Amended and Restated Cas9-I License Agreement.

Cas9-II License Agreement

Pursuant to the Cas9-II License Agreement, Broad, on behalf of itself, MIT, Harvard, and the University of Iowa Research Foundation, granted the Company an exclusive, worldwide, royalty bearing sublicensable license to certain of the Cas9-II Patent Rights as well as a non-exclusive, worldwide, royalty-bearing sublicensable license to all of the Cas9-II Patent Rights, in each case on terms substantially similar to the licenses granted to the Company under the Cpf1 License Agreement except, among other things, for the following commitment amounts. Under the Cas9-II License Agreement, the Company will pay an upfront license fee in a low seven digit dollar amount and will have to pay an annual license maintenance fee. The Company is obligated to pay clinical and regulatory milestone payments per licensed product approved in the United States, European Union and Japan for the prevention or treatment of a human disease that afflicts at least a specified number of patients in the aggregate in the United States totaling up to $3.7 million in the aggregate, and sales milestone payments for any such licensed product totaling up to $13.5 million in the aggregate. In addition, the Company is obligated to pay clinical and regulatory milestone payments totaling up to $1.1 million in the aggregate per licensed product approved in the United States and the European Union or Japan for the prevention or treatment of a human disease that afflicts fewer than a specified number of patients in the United States, plus sales milestone payments of up to $9.0 million for any such licensed product. Consistent with the Cpf1 License Agreement, the licensors are entitled to royalties on net sales of products for the prevention or treatment of human disease and other products and services made by the Company, its affiliates, or its sublicensees. Royalties due under other license agreements are creditable against these royalties up to a specified amount in the same period. Lastly, Broad is entitled to receive success payments if the Company's market capitalization reaches specified thresholds ascending from $1.0 billion to $9.0 billion or upon a sale of the Company for consideration in excess of those thresholds. The potential success payments range from a low seven digit dollar amount to a low eight digit dollar amount and will not exceed, in aggregate, $30.0 million, which maximum amount would be owed only if the Company reaches a market capitalization threshold of $9.0 billion and has at least one product candidate covered by a claim of a patent right licensed to the Company under either the Cas9-I License Agreement or the Cas9-II License Agreement that is or was the subject of a clinical trial pursuant to development efforts by the Company or any Company affiliate or sublicensee. The

Company triggered the first Success Payment under the Cas9-II License Agreement during the fourth quarter of 2017 when the Company's market capitalization reached $1.0 billion, which the Company settled by issuing 75,303 shares of its common stock in January 2018.

Licensor Expense Reimbursement

The Company is obligated to reimburse to Broad and Harvard for expenses incurred by each of them associated with the prosecution and maintenance of the patent rights that the Company licenses from them pursuant to the license agreement by and among the Company, Broad and Harvard, including the interference and opposition proceedings involving patents licensed to the Company under the license agreement, and other license agreements between the Company and Broad. As such, the Company anticipates that it has a substantial commitment in connection with these proceedings until such time as these proceedings have been resolved, but the amount of such commitment is not determinable. The Company incurred an aggregate of $13.1 million, $13.5 million, and $14.2 million in expense during the years ended December 31, 2020, 2019 and 2018, respectively, for such reimbursement.

Litigation

The Company is not a party to any litigation and did not have contingency reserves established for any litigation liabilities as of December 31, 2020 or 2019.

9. Collaboration and Profit-Sharing Agreements

The Company has entered into multiple collaboration and strategic alliances with third parties that typically involve research and development services in exchange for upfront fees, option payments, milestone payments and royalty payments to or from the Company.

Collaboration Revenue

As of December 31, 2020, the Company's contract liabilities were primarily related to the Company's collaboration with Juno Therapeutics as well as other out-license agreements that are individually insignificant. The following table presents changes in the Company's accounts receivable and contract liabilities for the year ended December 31, 2020 (in thousands):

For the year ended December 31, 2020	Balance at December 31, 2019	Additions	Deductions	Balance at December 31, 2020
Accounts receivable	$ 418	$ 6,097	$ (467)	$ 6,048
Contract liabilities:				
Deferred revenue	$ 186,721	$ 508	$ (92,302)	$ 94,927

During the three and twelve months ended December 31, 2020, the Company recognized the following collaboration revenue (in thousands):

Revenue recognized in the period from:	Three Months Ended December 31, 2020	Year Ended December 31, 2020
Amounts included in deferred revenue at the beginning of the period	$ 5,767	$ 92,302
Performance obligations satisfied in previous periods	$ —	$ 60

Juno Therapeutics Collaboration Agreement

In May 2015, the Company entered into a collaboration and license agreement (the "Collaboration Agreement") with Juno Therapeutics and in May 2018 the Company and Juno Therapeutics entered into an amended and restated collaboration and license agreement (the Collaboration Agreement, as amended and restated, the "2018 Amended Collaboration Agreement"). The collaboration was initially focused on the research and development of engineered T cells with chimeric antigen receptors and T cell receptors that have been genetically modified to recognize and kill other

cells. In November 2019 (the "Amendment Date"), the Company amended and restated the 2018 Amended Collaboration and entered into a license agreement (the 2018 Amended Collaboration Agreement, as amended and restated, and collectively with the license agreement, the "2019 Amended Collaboration Agreement") to focus on the research, development, and commercialization of autologous and allogenic alpha-beta T cell medicines for the treatment of all diseases, subject to certain exceptions.

2018 Amended Collaboration Agreement

Pursuant to the 2018 Amended Collaboration Agreement, the Company and Juno Therapeutics were pursuing research in accordance with a mutually agreed upon research plan across four research areas. The 2018 Amended Collaboration Agreement increased the scope of the research plan from three to four research areas. The Company's research and development responsibilities under the research plan were related to generating genome editing reagents that modify gene targets selected by Juno Therapeutics. Except with respect to the Company's obligations under the mutually agreed upon research plan, Juno Therapeutics had sole responsibility, at its own cost, for the worldwide research, development, manufacturing and commercialization of products within each of the four research areas for the diagnosis, treatment or prevention of any cancer in humans through the use of engineered T-cells, excluding the diagnosis, treatment or prevention of medullary cystic kidney disease 1 (the "Exclusive Field"). The initial term of the research program commenced on May 26, 2015 and continued for five years ending on May 26, 2020 (the "Initial Research Program Term").

Under the terms of the Collaboration Agreement, the Company granted to Juno Therapeutics during the Initial Research Program Term a nonexclusive research license solely for the purpose of conducting specific research related activities as defined by the research plan. Pursuant to the terms of the 2018 Amended Collaboration Agreement, the license rights granted to Juno Therapeutics were expanded to incorporate the fourth research area (together, the initial research license granted per the terms of the Collaboration Agreement and the incremental research license granted per the terms of the 2018 Amended Collaboration Agreement, the "Research License").

The Company granted to Juno Therapeutics exclusive worldwide development and commercialization licenses in the Exclusive Field, specifically as it relates to certain targets or products selected by Juno Therapeutics in each of the four research areas. Furthermore, for two of the original research areas under the terms of the Collaboration Agreement, the Company granted to Juno Therapeutics a non-exclusive worldwide license to use certain genome editing reagents that were created under the agreement in all fields outside the Exclusive Field ("the Non-Exclusive Field") specifically as it relates to certain targets selected by Juno Therapeutics, if the genome editing reagents were previously incorporated into an investigational new drug application filed by Juno Therapeutics in the Exclusive Field (together, the license in the Exclusive Field and the license in the Non-Exclusive Field are referred to as the "Development and Commercialization License" for each particular research area).

Under the terms of the Collaboration Agreement, the Company received a $25.0 million up-front, non-refundable, non-creditable cash payment. In connection with the entry into the 2018 Amended Collaboration Agreement, the Company received an additional $5.0 million up-front, non-refundable, non-creditable cash payment. In addition, Juno Therapeutics was obligated to pay to the Company research and development funding over the Initial Research Program Term across the four research areas consisting primarily of funding for up to a specified maximum number of full-time equivalents personnel each year. Consistent with the terms of the Collaboration Agreement, under the terms of the 2018 Amended Collaboration Agreement, there was no incremental compensation due to the Company with respect to the Development and Commercialization License granted to Juno Therapeutics associated with the first target or product, as applicable, designated by Juno Therapeutics within each of the four research areas. However, for two of the research areas Juno Therapeutics had the option to purchase up to three additional Development and Commercialization Licenses associated with other gene targets for an additional fee of $2.5 million per target. In addition, Juno Therapeutics would have been required to make certain milestone payments to the Company upon the achievement of specified development, regulatory and commercial events. Royalties would have been paid on a licensed product-by-product and country-by-country basis from the date of the first commercial sale of each product in a country until the expiration date.

The Company achieved two $2.5 million development milestones under the Collaboration Agreement resulting

from technical progress in a research program in each of May 2016 and July 2017. The Company also achieved two additional $2.5 million development milestones under the 2018 Amended Collaboration Agreement resulting from technical progress in a research program in May 2018.

The Company evaluated the 2018 Amended Collaboration Agreement in accordance with the provisions of ASC 606. The Company accounted for the amendment resulting from the 2018 Amended Collaboration Agreement as a modification to the original contract and not as a separate contract. The Company identified the following performance obligations under the modified arrangement: (i) Research License and the related research and development services during the Initial Research Program Term (the "Research License and Related Services"), (ii) four material rights related to the first Development and Commercialization Licenses related to each of the four research areas (each, a "First Development and Commercialization License Material Right") and (iii) six material rights related to the option to purchase up to three additional Development and Commercialization Licenses for two of the research areas (each, an "Additional Development and Commercialization License Material Right"). The rights to be conveyed to Juno Therapeutics pursuant to each of the Development and Commercialization Licenses extend exclusively to an individual target or product, as applicable; therefore, control is deemed to be transferred upon the designation by Juno Therapeutics of the specific target or product, as applicable, whereupon the license becomes effective upon Juno Therapeutics exercising their option.

Through the date of the 2018 Amended Collaboration Agreement, the Company had recognized approximately $12.3 million of revenue associated with the Research License and Related Services which was excluded from the modification date transaction price. The total transaction price associated with the remaining consideration based on the 2018 Amended Collaboration Agreement was determined to be $40.7 million, consisting of: (i) $30.0 million in upfront payments (ii) $2.9 million of remaining research and development funding and (iii) $7.7 million of milestones payments received by the Company that were not yet recognized as revenue. The Company utilized the most likely amount method to determine the amount of research and development funding to be received. The outstanding milestones payments were fully constrained.

The transaction price was allocated to the performance obligations based on the relative estimated standalone selling prices of each performance obligation or, in the case of certain variable consideration, to one or more performance obligations. The transaction price allocated to the Research License and Related Services was $10.7 million. The Company recognized revenue related to amounts allocated to the Research License and Related Services as the underlying services were performed using a proportional performance model. The Company measured proportional performance based on full time employee hours relative to projected full time employee hours to complete the research services which best reflects the progress towards satisfaction of the performance obligation. The remaining transaction price of $30.0 million was allocated to the material rights. Revenue related to each of the material rights would have been recognized upon the earlier of when the respective options were exercised or when the respective options lapse. None of the options associated with the material rights had been exercised or had lapsed prior to the execution of the 2019 Amended Collaboration Agreement.

2019 Amended Collaboration Agreement

The 2019 Amended Collaboration Agreement replaced the 2018 Amended Collaboration Agreement and, at the Company's discretion, it may develop non-alpha-beta T-cell therapies, while expanding Juno Therapeutics' permitted uses of gene edited alpha-beta T-cells beyond oncology. Pursuant to the 2019 Amended Collaboration Agreement, the Company may develop genome editing tools that, following the exercise of its option and the Company's grant of a license, Juno Therapeutics may use in its development of gene edited alpha-beta T-cell therapies and certain other T-cells derived from pluripotent stem cells or any other precursor cells for the treatment of all diseases, subject to certain exceptions (the "Juno Field"). The initial term of the 2019 Amended Collaboration Agreement is five years, which is subject to two one-year extension periods. During the term, including the extension periods, the Company may not alone, or with a third party, research, develop, manufacture, or commercialize a product in the Juno Field.

At the Company's discretion it can develop genome editing tools specific to a gene target and enzyme combination (or a "Program"). The Company may then present a Program to Juno Therapeutics for Juno Therapeutics to evaluate against predefined criteria. To assess the Programs prior to opt-in, the Company granted Juno Therapeutics a

non-exclusive perpetual research license in the Juno Field. Juno Therapeutics has the option to obtain an exclusive, worldwide, development and commercialization license to each of the Programs in the Juno Field for a nominal option exercise fee. If Juno Therapeutics fails to exercise its option during the contractually defined option period, the Company will retain all rights to such Program. Upon exercising an option, Juno Therapeutics has sole responsibility, at its own cost, for the worldwide research, development, manufacturing and commercialization of its products. Juno Therapeutics has the right to terminate the 2019 Amended Collaboration Agreement at any time upon no less than six months prior written notice.

The development and commercialization licenses granted to Juno Therapeutics are subject to the terms and conditions of a license agreement that was entered into on the same day as the 2019 Amended Collaboration Agreement. Pursuant to the license agreement, Juno Therapeutics must use commercially reasonable efforts and meet certain regulatory and commercial diligence requirements. The license agreement provided that the Company would manufacture clinical grade materials through a Phase 1 clinical trial if requested by Juno Therapeutics at an incremental cost to be negotiated by the parties. Per the termination provisions of the license agreement, Juno Therapeutics has the right to terminate the agreement either on a licensed product-by-product basis or in its entirety for any reason at any time upon ninety days prior written notice. If Juno Therapeutics terminates the license agreement without cause, the exclusive licenses granted to Juno Therapeutics automatically revert back to the Company.

On a product-by-product basis, the Company is eligible to receive up to $27.5 million in development milestones and $107.5 million in regulatory milestones. The Company is also eligible to receive up to an aggregate of $60.0 million for the first two licensed products to reach certain sales milestones. The Company is entitled to a high-single digit to low double-digit percentage of royalties on net sales of licensed products, subject to reductions in certain circumstances, through the later of the expiration of the patent(s) related to the licensed products or six years post-first commercial sale of such licensed products.

The Company received a $70.0 million up-front, non-refundable, non-creditable cash payment in connection with the execution of the 2019 Amended Collaboration Agreement. The Company also received an additional $0.5 million for the first development and commercialization license (the “First 2019 Development and Commercialization License”) which was delivered to Juno Therapeutics at the onset of the arrangement.

The Company evaluated the 2019 Amended Collaboration Agreement and concluded that the collaboration agreement and licensing agreement qualify as a contract with a customer under ASC 606 as one combined arrangement. The contract modification was accounted for on a prospective basis as if it were a termination of the existing contract and the creation of a new contract since the promised goods and services were distinct from the goods and services that were transferred on or before the effective date of the amendment.

The Company identified the following performance obligations under the 2019 Amended Collaboration Agreement: (i) First 2019 Development and Commercialization License and (ii) seventeen material rights for additional development and commercialization licenses for other Programs. The Company also evaluated the (i) the research license, (ii) contract term extensions, (iii) clinical supply arrangement, (iv) participation by employees on the oversight committee, alliance and technology transfer teams and (v) certain intellectual property rights and concluded that none of these met the definition of a performance obligation as a result of the promise being quantitively and qualitatively immaterial in the context of the arrangement or the promise did not convey a material right to Juno Therapeutics. The Company also concluded that there was not an implicit promise to perform research and development services.

As of Amendment Date and December 31, 2019, the total transaction price was approximately $102.5 million comprised of the following: (i) $70.0 million amendment fee, (ii) $0.5 million related to the exercise fee for the First 2019 Development and Commercialization License and (iii) $32.0 million in remaining deferred revenue balance that was not recognized pursuant to the 2018 Amended Collaboration Agreement. The Company utilizes the most likely amount method to estimate any development and regulatory milestone payments to be received as well as extension term fees. As of December 31, 2019, there were no milestones or extension term fees included in the transaction price. The Company considers the stage of development and the risks associated with the remaining development required to achieve the milestone, as well as whether the achievement of the milestone is outside the control of the Company or Juno Therapeutics. The outstanding milestone payments and extension term fees were fully constrained as of December 31,

2019, as a result of the uncertainty of whether any of the milestones will be achieved or the term would be extended. The Company has determined that any commercial milestones and sales-based royalties will be recognized when the related sales occurs. The Company reevaluates the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The Company concluded that rights and attributes of each of the development and commercialization licenses are identical for both the license granted at inception and the licenses that may be issued in the future upon exercise of the associated option. Each development and commercialization license is differentiated only by the Program to which it relates. The Company has considered the early stage of the science and the uncertainty of success and concluded that the probability of scientific success and opt-in is equal amongst all Programs. In addition, each Program is multi-functional, and a combination of Programs can be utilized in the development of a product candidate. As such, the Company concluded that the standalone selling price of each material right is the same. The Company will recognize the transaction price allocated to each material right when the material right is exercised, lapsed or expired.

During the year ended December 31, 2020 and 2019, the Company recognized $11.3 million and $6.2 million of revenue related to Juno Therapeutics. As of December 31, 2020, the Company recorded $90.7 million of deferred revenue, of which $73.7 million is classified as long-term on our condensed consolidated balance sheet. As of December 31, 2019, the $96.3 million was classified as long-term in the accompanying consolidated balance sheets.

During the year ended December 31, 2020, 2019 and 2018, the Company incurred $0.8 million, $11.3 million and $1.7 million in sublicense fees owed to certain of the Company's licensors in connection with certain exercise and milestone payments triggered in 2020, and the 2019 Amended Collaboration Agreement, respectively, which the Company recorded as research and development expenses during such periods. The sublicense fee owed in connection with the milestone payment is fully accrued in the consolidated balance sheet as of December 31, 2020.

Allergan Pharmaceuticals Strategic Alliance and Profit-Sharing Agreement

In March 2017, the Company entered into a Strategic Alliance and Option Agreement with Allergan to discover, develop, and commercialize new gene editing medicines for a range of ocular disorders (the "Allergan Agreement"). Pursuant to the Allergan Agreement, the Company granted Allergan an exclusive option (each, an "Option") to exclusively license from the Company up to five collaboration development programs for the treatment of ocular disorders (each, a "CDP"), including the Company's Leber congenital amaurosis 10 ("LCA10") program and the related experimental therapeutic EDIT-101 to treat LCA10 (the "LCA10 Program").

In July 2018, Allergan exercised its Option with respect to the LCA10 Program. In connection with such exercise, Allergan paid the Company $15.0 million. Following such exercise, the Company exercised its profit-share election with respect to the LCA10 Program, following which the Company and an affiliate of Allergan entered into a separate Profit-Sharing Agreement with respect to the LCA10 Program in February 2019. On August 5, 2020, the Company and Allergan terminated the Allergan Agreement and the Profit-Sharing Agreement.

Under the terms of the Allergan Agreement, the Company received a $90.0 million up-front, non-refundable, non-creditable cash payment related to the Company's research and development costs for option packages for at least five CDPs and for reimbursement of the Company's past out-of-pocket costs with respect to the prosecution and defense of patents that it owns and in-licenses.

Following the exercise by Allergan of its Option with respect to the LCA10 Program, Allergan was required to make certain milestone payments to the Company upon the achievement of specified development, product approval and launch and commercial events. In December 2018, the Company received a $25.0 million payment from Allergan in connection with the acceptance of the IND for the LCA10 Program, the Company's experimental therapeutic generated under the LCA10 Program (the "LCA-10 Program Milestone Payment").

Following the exercise by Allergan of its Option with respect to the LCA10 Program, the Company elected to participate in a profit-sharing arrangement with Allergan in the United States, under which the Company and Allergan agreed to share equally in net profits and losses, in lieu of Allergan paying royalties on net sales of any gene editing

therapy products that results from the LCA10 Program in the United States, and Allergan's applicable milestone payment obligations were reduced (the "Profit-Sharing Agreement"). Pursuant to the Profit-Sharing Agreement, the Company was obligated to reimburse Allergan for half of the United States development costs incurred by Allergan with respect to the LCA10 Program, and Allergan retained control of all development and commercialization activities.

Termination Agreements

Allergan was acquired by AbbVie Inc. in May 2020. On August 5, 2020, the Company and Allergan agreed to terminate the strategic alliance and option agreement (the "Collaboration Agreement") that was entered into in May 2017 and the profit-sharing arrangement (together with the Collaboration Agreement, the "Initial Agreements") to equally split U.S. profit and losses of EDIT-101, an experimental medicine for Leber congenital amaurosis 10 ("LCA10") that was originally licensed to Allergan under the Collaboration Agreement (the "Termination Agreement"). In addition, in connection with the termination, the Company entered into a transition services agreement with Allergan (together with the Termination Agreement, the "Termination Agreements"), primarily to facilitate the transfer of EDIT-101 back to the Company.

Pursuant to the Termination Agreements, the Company regained full global rights to research, develop, manufacture, and commercialize its ocular medicines, including EDIT-101. Allergan has no further obligations pursuant to the Initial Agreements, all unexercised options and contingent payments contemplated under the Initial Agreements have terminated, which includes Allergan's worldwide developmental and commercialization rights to EDIT-101. Under the Termination Agreements, Allergan granted the Company a non-exclusive license to certain know-how that is necessary to develop, manufacture and commercialize EDIT-101 and will transfer to the Company certain materials produced under the Collaboration Agreement. The Company will use commercially reasonable efforts to develop and commercialize products directed at four collaboration targets, one of which is LCA10.

In connection with the Termination Agreements, the Company agreed to make a $20.0 million payment to Allergan, $17.5 million of which was paid as of December 31, 2020. In addition, the Company will make certain payments on achievements of clinical and regulatory milestones up to $20.0 million for each target program and aggregated sales milestones for all products covered by the Termination Agreement up to $90.0 million. Allergan is also entitled to royalties in a low-single digit percentage, subject to reduction under specified circumstances, on net sales of specified products. The Company's obligation to pay royalties will expire on a country-by-country and product-by-product basis upon the later of the expiration of regulatory-based exclusivity with respect to such product in such country and the tenth anniversary of the first commercial sale of such product. Lastly, the Company is obligated to pay for a portion of the transition services.

Accounting Assessment

The Company evaluated the Termination Agreements in accordance with the provisions of Accounting Standards Codification ("ASC") 606 and concluded that they resulted in a modification followed by a termination of the Initial Agreements. Upon execution of the Termination Agreements, the Company is no longer obligated to transfer control of any goods or services to Allergan, and therefore there are no remaining performance obligations. As part of this assessment, the Company considered that Allergan relinquished its right to the remaining exclusive license options under the Collaboration Agreement and the Company reacquired the development and commercialization rights to EDIT-101. Allergan no longer has any involvement in the development activities of the collaboration targets. Since there are no remaining performance obligations, the Company accounted for the modification as part of the existing contract with a cumulative catch-up adjustment. The Company applied the vendor consideration to a customer guidance pursuant to ASC 606 in accounting for the $20 million payment due to Allergan and concluded that the worldwide rights to EDIT-101 represent a distinct good or service. The Company therefore recorded the fair value of the rights to EDIT-101 of $5 million as in-process Research and Development expense as of December 31, 2020 as the rights had no alternative future use. The remainder of the $20 million was recorded as a reduction to the contract liability that was recognized as revenue upon termination. The contingent payments associated with the collaboration targets not previously licensed by Allergan under the Collaboration Agreement did not impact the amount of deferred revenue recognized upon termination because it is not probable that a significant reversal of revenue will occur. The contingent milestone and royalty payments associated with EDIT-101 qualify for scope exceptions from derivative accounting, and therefore there is no accounting

for the contingent payments upon termination.

On the termination date, the Company recognized $62.1 million of previously deferred revenue related to the Collaboration Agreement. This amount consisted of $77.1 million of revenues that were previously deferred related to the collaboration agreement, partially offset by $15.0 million of the fee paid to Allergan that was determined to exceed the fair value of the re-acquired rights to EDIT-101.

During the year ended December 31, 2020, the Company recognized revenue of $70.6 million related to the Allergan arrangement. During the years ended December 31, 2019 and 2018, the Company recognized revenue of $13.6 million and $21.5 million, respectively, under the Allergan Agreement. At December 31, 2020 there was no remaining contract liability related to the Allergan arrangement.

Beam Therapeutics License Agreement

In May 2018, the Company entered into a license agreement with Beam Therapeutics Inc. (“Beam,” and such agreement, the “Beam License Agreement”). Beam is a biotechnology company focused on developing precision genetic medicines using technology that converts a single nucleobase into a different nucleobase (“Base Editing”). Pursuant to the Beam License Agreement, the Company granted to Beam licenses and options to acquire licenses to certain intellectual property rights owned or controlled by the Company, for specified uses. More specifically, the Company granted to Beam a worldwide, exclusive (subject to certain exceptions), sublicensable (subject to certain conditions), license under certain intellectual property controlled by the Company for the use of Base Editing therapies for the treatment of any field of human diseases and conditions, subject to certain exceptions (the “Beam Field,” and the licenses granted or to be granted under the Beam License Agreement, the “Beam Development and Commercialization License”). Additionally, the Company granted to Beam a royalty-free, non-exclusive license under certain intellectual property owned or controlled by the Company to perform research activities in the Beam Field (the “Beam Research License”). The Company provided Beam with an exclusive option to obtain a Beam Development and Commercialization License to three additional groups of intellectual property owned or controlled by the Company, on a group by group basis, during the specified option period, subject to certain exceptions. Pursuant to the Beam License Agreement, Beam will use commercially reasonable efforts to develop a product that includes the rights licensed to Beam within a specified period of time and to commercialize any such product that have received regulatory approval in certain specified countries.

As consideration for the license and option rights granted to Beam, the Company received a nominal one-time, non-refundable, non-creditable upfront cash payment. The Company also received non-cash consideration, consisting of a low to mid-single digit million number of shares of Beam Series A-1 and A-2 preferred stock, having an aggregate fair value of approximately $3.6 million. The Company is eligible to receive additional consideration if Beam elects to exercise its option to obtain a Beam Development and Commercialization License to the three categories of intellectual property underlying the Research License, for a fee ranging from a mid-teen million dollar amount to a low to mid-eight digit dollar amount per group, depending on the timing of the option exercise. Additionally, Beam is required to reimburse the Company for certain payments the Company may be obligated to make under the Company’s existing license agreements related to the intellectual property being licensed to Beam, including (i) development, regulatory and commercial milestone payments and certain sublicense income payments due as a result of the Beam License Agreement and (ii) a percentage of the annual maintenance fees and patent fees due to certain of the Company’s licensors. In addition, to the extent any products are commercialized under a Beam Development and Commercialization License, the Company would be entitled to receive royalty payments equivalent to the royalties that would be due from the Company to any applicable licensors of the Company related to the sales of such licensed products, plus an additional low single-digit percentage royalty. Additionally, if Beam exercises its right to obtain a Beam Development and Commercialization License to one of the categories of optioned intellectual property comprising Company-owned intellectual property and any related licensed products that are commercialized, the Company would be entitled to tiered low single-digit royalty payments related to sales of such licensed products.

The license rights and option rights granted to Beam are subject to the terms and conditions of the underlying license agreements that the Company is a party to and under which the Company licensed rights or option rights to Beam and the termination of such in-licenses, as applicable. Unless earlier terminated by either party pursuant to the terms of

the agreement, the Beam 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 expiration of the royalty term with respect to such licensed product in such country. Beam has the right, at its sole discretion, at any time to terminate the Beam License Agreement in its entirety or on a group-by-group of intellectual property basis, upon ninety days written notice to the Company. Upon termination of the Beam License Agreement, all rights and licenses granted by the Company to Beam (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 Beam 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 Company has identified the following performance obligations (i) the Beam Development and Commercialization License and (ii) the Beam Research License. In addition, the Company has concluded the option to obtain additional Beam Development and Commercialization Licenses to up to three additional groups of patents in the future is considered a marketing offer as the options did not provide any discounts or other rights that would be considered a material right in the arrangement.

As of December 31, 2019, the total transaction price at the inception of the arrangement was determined to be approximately $3.8 million, consisting of the upfront cash payment and non-cash consideration related to the shares of Beam preferred stock. The Company determined the fair value based on the price paid by other unrelated investors for such shares. The consideration associated with the exercise of the option(s) will be accounted for if and when Beam elects to purchase the additional licenses. The other forms of consideration, including the development and regulatory milestone reimbursement, the sublicense income reimbursement, the maintenance fee reimbursement and the patent costs reimbursement were estimated based on the most-likely amount and were excluded from the initial transaction price as the most-likely amount was estimated to be zero or the amount was otherwise fully constrained due to the significant uncertainties surrounding such payments. The commercial-based milestone reimbursement and the sales-based royalty payments will be recognized when the related sales occur as they were determined to relate predominantly to the licenses granted and therefore have also been excluded from the transaction price.

The total transaction price at the inception of the arrangement was allocated to the performance obligations in the aggregate, as the Beam Development and Commercialization License and the Beam Research License were delivered simultaneously with one another, at inception of the arrangement, when the licenses were made available for Beam’s use and benefit. Accordingly, the satisfaction of each performance obligation occurs at inception of the arrangement and the transaction price at the inception of the arrangement is recognized in its entirety at such time.

Following the initial public offering of Beam Therapeutics in 2020, the Company held equity securities that had a readily determinable fair value, and were included in marketable securities on the condensed consolidated balance sheet. The Company sold this investment in October 2020, resulting in a realized gain of $16.4 million recorded in other income (expense), net on the consolidated statements of operations.

During the year ended December 31, 2020 and 2019, the Company recognized revenue under the Beam License Agreement of approximately $0.2 million and $0.2 million, respectively.

10. Preferred Stock

The Company’s amended and restated certificate of incorporation authorized 5,000,000 shares of undesignated preferred stock that may be issued from time to time by the Company’s board of directors in one or more series. As of December 31, 2020, the Company had no shares of preferred stock issued or outstanding.

11. Common Stock

The voting, dividend, and liquidation rights of the holders of the common stock are subject to and qualified by the rights, powers, and preferences of holders of the preferred stock that may be issued from time to time. The common stock had the following characteristics as of December 31, 2020:

Voting

The holders of shares of common stock are entitled to one vote for each share of common stock held at any meeting of stockholders and at the time of any written action in lieu of a meeting.

Dividends

The holders of shares of common stock are entitled to receive dividends, if and when declared by the Company's board of directors. Cash dividends may not be declared or paid to holders of shares of common stock until all unpaid dividends on the redeemable convertible preferred stock have been paid in accordance with their terms. No dividends have been declared or paid by the Company since its inception.

2013 Stock Incentive Plan

In September 2013, the board of directors adopted the 2013 Stock Incentive Plan, which was subsequently amended (as amended, the "2013 Plan"), which provides for the grant of incentive stock options and nonqualified stock options or other awards including restricted stock awards, unrestricted stock awards, and restricted stock units to the Company's employees, officers, directors, advisors, and consultants for the purchase of up to 1,057,692 shares of the Company's common stock, which has been amended several times, and as of July 2015, a total of 6,317,769 shares were reserved.

The terms of stock awards agreements, including vesting requirements, are determined by the board of directors and are subject to the provisions of the 2013 Plan. The stock options granted to employees generally vest over a four-year period and expire ten years from the date of grant. Certain awards contain performance based vesting criteria. There has only been one such award to date. Certain options provide for accelerated vesting in the event of a change in control, as defined in the applicable options. Awards granted to non-employee consultants generally vest monthly over a period of one to four years. In connection with the Company's initial public offering ("IPO"), the Company's board of directors determined to grant no further awards under the 2013 Plan.

2015 Stock Incentive Plan

The Company's board of directors adopted and the Company's stockholders approved the 2015 stock incentive plan (the "2015 Plan"). The 2015 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock-based awards. The Company's employees, officers, directors and consultants and advisors are eligible to receive awards under the 2015 Plan.

The number of shares reserved for issuance under the 2015 Plan is subject to further increases for (a) any additional shares of the Company's common stock subject to outstanding awards under the 2013 Plan that expire, terminate, or are otherwise surrendered, cancelled, forfeited, or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right and (b) annual increases, to be added as of the first day of each fiscal year, from January 1, 2017 until, and including, January 1, 2026, equal to the lowest of 2,923,076 shares of common stock, 4% of the number of shares of common stock outstanding on such first day of the fiscal year in question and an amount determined by the Company's board of directors. In January 2021, the shares under the 2015 Plan were increased by 2,507,552 shares pursuant to the annual increase described in the prior sentence.

2015 Employee Stock Purchase Plan

The Company's board of directors adopted and the Company's stockholders approved the 2015 employee stock purchase plan (the "2015 ESPP"). The number of shares reserved for issuance under the 2015 ESPP is subject to annual increases, to be added as of the first day of each fiscal year, from January 1, 2017 until, and including, January 1, 2026, in an amount equal to the least of (a) 769,230 shares of common stock, (b) 1% of the total number of shares of common stock outstanding on the first day of the applicable year, and (c) an amount determined by the board of directors. The first offering under the 2015 ESPP opened on December 1, 2017. In January 2021, the shares under the 2015 ESPP Plan were increased by 626,888 shares pursuant to the annual increase described in the prior sentence.

Inducement Awards

From time to time the Company's board of directors approves inducement awards to certain employees outside of the existing equity compensation plans in connection with such employees commencing employment with the Company. Inducement awards are typically a service-based option or a restricted stock unit and are subject to the Company's typical vesting terms and the employee's continued service relationship with the Company through the applicable vesting dates. In November 2020, the Company's board of directors approved an inducement grant to the Company's recently hired Chief Medical Officer, including an option to purchase up to 120,000 shares of the Company's common stock and an award of 20,000 restricted stock units.

Shares Reserved for Future Issuance

	As of December 31,	
	2020	2019
Shares reserved for outstanding stock option awards under the 2013 Stock Incentive Plan, as amended	174,362	312,342
Shares reserved for outstanding stock option awards and restricted stock units under the 2015 Stock Incentive Plan	3,839,345	4,254,357
Shares reserved for outstanding inducement stock option award	280,000	175,000
Remaining shares reserved, but unissued, for future awards under the 2015 Stock Incentive Plan	5,599,450	4,061,357
Remaining shares reserved, but unissued, for future awards under the 2015 Employee Stock Purchase Plan	2,137,127	1,630,199
	12,030,284	10,433,255

12. Stock-Based Compensation

Total compensation cost recognized for all stock-based compensation awards in the consolidated statements of operations was as follows (in thousands):

	Year Ended December 31,	
	2020	2019
Research and development	$ 11,580	$ 13,538
General and administrative	11,576	13,705
Total stock-based compensation expense	$ 23,156	$ 27,243

Restricted Stock and Restricted Stock Unit Awards

The following table summarizes restricted stock and restricted stock unit awards activity for the instruments discussed above as of December 31, 2019 and 2020 is as follows:

	Shares	Weighted Average Grant Date Fair Value Per Share
Unvested restricted stock and restricted stock unit awards as of December 31, 2019	581,408	$ 24.03
Issued	364,549	$ 29.57
Vested	(304,638)	$ 23.37
Forfeited	(133,869)	$ 24.72
Unvested restricted stock and restricted stock unit awards as of December 31, 2020	507,450	$ 27.35

The expense related to restricted stock and restricted stock unit awards granted to employees and non-employees was $2.8 million and $1.6 million, respectively, for the year ended December 31, 2020. The expense related to restricted stock and restricted stock unit awards granted to employees and non-employees was $4.7 million and $1.6 million, respectively, for the year ended December 31, 2019. The expense related to restricted stock and restricted stock unit awards granted to employees and non-employees was $0 million and $2.4 million, respectively, for the year ended December 31, 2018.

As of December 31, 2020, total unrecognized compensation expense related to unvested restricted stock and restricted stock unit awards was $11.9 million, which the Company expects to recognize over a remaining weighted-average period of 2.7 years.

Stock Options

The following is a summary of stock option activity for the year ended December 31, 2020:

	Shares	Weighted Average Exercise Price	Remaining Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2019	4,358,291	$ 25.40	7.4	$ 26,060
Granted	1,721,748	$ 30.44		
Exercised	(964,412)	$ 20.22		
Cancelled	(1,203,370)	$ 30.72		
Outstanding at December 31, 2020	3,912,257	$ 27.26	7.9	$ 167,640
Exercisable at December 31, 2020	1,463,668	$ 24.05	6.8	$ 67,413

The total intrinsic value of options exercised for the years ended December 31, 2020, 2019 and 2018 was $15.6 million, $14.6 million, and $15.9 million, respectively.

Using the Black-Scholes option pricing model, the weighted average fair value of options containing service-based vesting granted to employees and directors during the years ended December 31, 2020, 2019, and 2018 was $16.60, $15.67, and $24.91, respectively. The expense related to options containing service-based vesting granted to employees and directors was $16.1 million, $18.1 million, and $19.9 million for the years ended December 31, 2020, 2019, and 2018, respectively.

The fair value of each service-based vesting option issued to employees and directors was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Year Ended December 31,		
	2020	2019	2018
Expected volatility	60.0 %	73.8 %	77.5 %
Expected option term (in years)	6.25	6.25	6.25
Risk free interest rate	1.5 %	2.0 %	2.9 %
Expected dividend yield	—	—	—

As of December 31, 2020, total unrecognized compensation expense related to stock options was $40.4 million, which the Company expects to recognize over a remaining weighted-average period of 2.7 years.

13. 401(k) Savings Plan

The Company has a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code of 1986, as amended (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 pretax basis. Effective in 2017, the Company will provide a 200% match of employee contributions up to a limit on the Company's contributions of the lesser of $6,000 and 3% of the employee's salary. The Company made $1.1 million, $0.8 million, and $0.7 million in contributions to the 401(k) Plan for the years ended December 31, 2020, 2019 and 2018, respectively.

14. Income Taxes

The Company had no income tax expense due to operating losses incurred for the years ended December 31, 2020, 2019 and 2018.

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:

	Year Ended December 31,		
	2020	2019	2018
Income tax computed at federal statutory tax rate	21 %	21 %	21 %
State taxes, net of federal benefit	5.20 %	5.20 %	6.4 %
General business credit carryovers	4.80 %	2.80 %	4.4 %
Stock Options	(1.8)%	(2.2)%	0.7 %
Non-deductible expenses	(0.1)%	(0.1)%	(0.1)%
Change in valuation allowance	(29.10)%	(26.70)%	(32.4)%
	— %	— %	— %

The principal components of the Company's deferred tax assets and liabilities consist of the following at December 31, 2020 and 2019 (in thousands):

	Year Ended December 31, 2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 70,751	$ 50,511
Tax credit carryforwards	19,353	13,767
Accrued expenses	11,372	2,219
Capitalized patent costs	46,197	39,070
Lease Liabilities	7,083	7,879
Deferred revenue	25,724	31,880
Construction financing lease obligation	—	—
Other	5,204	7,865
Total deferred tax assets	185,684	153,191
Less valuation allowance	(178,307)	(144,540)
Net deferred tax assets	7,377	8,651
Deferred tax liabilities	(7,377)	(8,651)
Depreciation and amortization	(567)	(859)
Right-of-use assets	(6,810)	(7,792)
Net deferred taxes	$ —	$ —

The Company has incurred net operating losses ("NOL") since inception. At December 31, 2020 and 2019, the Company had federal net operating loss carryforwards of $261.9 million and $185.4 million, respectively. Of the amount as of December 31, 2020, $186.4 million will carryforward indefinitely while $75.5 million will expire beginning in 2033 and will continue to expire through 2037. As of December 31, 2020, and 2019, the Company also had state net operating loss carryforwards of approximately $258.4 million and $183.3 million, respectively, which may be available to offset future income tax liabilities and will expire beginning in 2035 and will continue to expire through 2039. Loss generated in 2020 expires in 2040.

Under the provisions of the Internal Revenue Code of 1986, as amended (the "Code"), the NOL and tax credit carryforward are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Code, respectively, as well as other similar state provisions. The Company conducted an analysis under Section 382 to determine if historical changes in ownership through December 31, 2019 would limit or otherwise restrict its ability to utilize its NOL and research and development credit carryforwards. As a result of this analysis, the Company does not believe there are any significant limitations on its ability to utilize these carryforwards. However, future changes in ownership occurring after December 31, 2019 could affect the limitation in future years, and any limitation may result in expiration of a portion of the NOL or research and development credit carryforwards before utilization.

Management has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which principally comprise of NOL carryforwards, research and development credit carryforwards and capitalized license and patent costs. The Company's management has determined that it is more likely than not that the Company will not recognize the benefits of its federal and state deferred tax assets, and as a result, a valuation allowance of $178.3 million and $144.5 million has been established at December 31, 2020 and 2019, respectively. The increase in the valuation allowance of $33.8 million for the year ended December 31, 2020 was primarily due to current period pre-tax losses incurred and research tax credits generated.

The Company applies ASC 740 related to accounting for uncertainty in income taxes. The Company's reserves related to income taxes are based on a determination of whether, and how much of, a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized following resolution of any potential contingencies

present related to the tax benefit. At December 31, 2020 and 2019, the Company had no unrecognized tax benefits. Interest and penalty charges, if any, related to unrecognized tax benefits would be classified as income tax expense in the accompanying statements of operations.

The Company has not as yet conducted a study of its research and development credit carry forwards. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheets or statements of operations if an adjustment were required.

The Company files income tax returns in the U.S. federal tax jurisdiction, the Massachusetts state jurisdiction, the California state jurisdiction and the Colorado state jurisdiction. Since the Company is in a loss carryforward position, the Company is generally subject to examination by the U.S. federal, state and local income tax authorities for all tax years in which a loss carryforward is available. The Company did not have any international operations as of December 31, 2020. There is a 2018 IRS audit in process.

15. Net Loss per Share

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock and potentially dilutive securities outstanding for the period determined using the treasury stock and if converted methods. Contingently issuable shares are included in the calculation of basic loss per share as of the beginning of the period in which all the necessary conditions have been satisfied. Contingently issuable shares are included in diluted loss per share based on the number of shares, if any, that would be issuable under the terms of the arrangement if the end of the reporting period was the end of the contingency period, if the results are dilutive.

For purposes of the diluted net loss per share calculation, stock options are considered to be common stock equivalents, but they were excluded from the Company's calculation of diluted net loss per share allocable to common stockholders because their inclusion would have been anti-dilutive. Therefore, basic and diluted net loss per share applicable to common stockholders was the same for all periods presented.

The following common stock equivalents were excluded from the calculation of diluted net loss per share allocable to common stockholders because their inclusion would have been anti-dilutive:

	As of December 31,	
	2020	2019
Unvested restricted stock and restricted stock unit awards	507,450	581,408
Outstanding stock options	3,912,257	4,358,291
Estimated number of shares issuable for convertible notes [1]	392,240	—
Total	4,811,947	4,939,699

(1) Represents the number of shares that would have been issued if the Company had elected to pay the December Success Payment Notes, as discussed in Note 8, in shares of the Company's common stock, based on the closing price of the common stock on December 31, 2020. The number of shares issued, for purposes of this presentation, is calculated by dividing the principal of the notes payable, including accrued interest, by the stock price per share

The table above reflects restricted stock issued upon exercise of unvested stock options as exercised on the dates that the shares are no longer subject to repurchase.

16. Related-Party Transactions

The Company received $0.4 million in rent and facility-related fees from a related party during the year ended December 31, 2018 in connection with subleasing a portion of its headquarters and no rent or facility-related payments were received from this related party during the years ended December 31, 2020 and 2019. During the year ended December 31, 2018, the Company paid a related party $0.8 million in connection with certain research and development expenses. The Company did not make any payments to this related party during the years ended December 31, 2020 and 2019.

17. Selected Quarterly Financial Data (unaudited) –

The following table contains selected quarterly financial information from 2020 and 2019. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair statement of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

	Three months ended			
	March 31, 2020	June 30, 2020	September 30, 2020	December 31, 2020
	(in thousands, except per share data)			
Total collaboration and other research and development revenues	$ 5,723	$ 10,749	$ 62,841	$ 11,419
Total operating expenses	52,339	42,088	53,852	77,293
Total other income (expense), net	8,892	7,767	(1,170)	3,375
Net (loss) income	$ (37,724)	$ (23,572)	$ 7,819	$ (62,499)
Net (loss) income applicable to common stockholders	$ (37,724)	$ (23,572)	$ 7,819	$ (62,499)
Net (loss) income per share attributable to common shareholders:				
Basic	$ (0.69)	$ (0.43)	$ 0.13	$ (1.00)
Diluted	$ (0.69)	$ (0.43)	$ 0.12	$ (1.00)

	Three months ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
	(in thousands, except per share data)			
Total collaboration and other research and development revenues	$ 2,069	$ 2,330	$ 3,848	$ 12,284
Total operating expenses	33,331	37,979	38,436	51,707
Total other income (expense), net	2,013	1,863	1,647	1,653
Net loss	$ (29,249)	$ (33,786)	$ (32,941)	$ (37,770)
Net loss applicable to common stockholders	$ (29,249)	$ (33,786)	$ (32,941)	$ (37,770)
Net loss per share applicable to common stockholders — basic and diluted	$ (0.60)	$ (0.69)	$ (0.66)	$ (0.74)

18. Subsequent Events

In January 2021, the Company issued an aggregate of 303,599 shares of its common stock to Broad in connection with settling the third Cpfl Success Payment and the third research payment under the Sponsored Research Agreement (see Note 8).

In January 2021, the Company triggered the second Success Payment under the Cas9-II License Agreement when the Company's market capitalization reached $3.0 billion, which the Company settled in cash for a mid-seven digit dollar amount (see Note 8). Upon achieving a market capitalization of $3.0 billion, the Company also triggered a mid-seven digit dollar amount success payment under another license agreement, which remains due and payable.

In January 2021, the Company completed a public offering whereby the Company sold 3,500,000 shares of its common stock and received net proceeds of approximately $216.9 million. In February 2021, the underwriters in the public offering exercised their option to purchase an additional 525,000 shares, resulting in additional net proceeds to the Company of approximately $32.6 million.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (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 Securities and Exchange Commission'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. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2020, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. 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 for external purposes in accordance with general accepted accounting principles. 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.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial

reporting based on the 2013 framework in Internal Control–Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under that framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2020.

The effectiveness of our internal control over financial reporting as of December 31, 2020, has been audited by Ernst & Young LLP, an independent registered public accounting firm, and has issued an attestation report on such audit, which is included herein.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during our fiscal quarter ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Editas Medicine, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Editas Medicine Inc.'s internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Editas Medicine Inc. (the "Company") maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Editas Medicine Inc. as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes and our report dated February 26, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 of the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's 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 for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, 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.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 26, 2021

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except to the extent provided below, the information required by this Item 10 will be included in the section captioned "Corporate Governance" and the subsections thereof, "Nominees for Election as Class I Directors," "Directors Continuing in Office," "Executive Officers Who Are Not Directors," and "Delinquent Section 16(a) Reports," if applicable, in our definitive proxy statement to be filed with the Securities and Exchange Commission ("SEC") with respect to our 2021 Annual Meeting of Stockholders, which information is incorporated herein by reference.

We have adopted a written code of business conduct and ethics that applies to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code is posted on the Corporate Governance section of our website, which is located at www.editasmedicine.com. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K. We will provide any person, without charge, a copy of such Code of Business Conduct and Ethics upon written request, which may be mailed to 11 Hurley Street, Cambridge, MA 02141, Attn: Corporate Secretary.

Item 11. Executive Compensation.

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

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be included in the sections captioned "Principal Stockholders" and "Securities Authorized for Issuance under Equity Compensation Plans" in our definitive proxy statement to be filed

with the SEC with respect to our 2021 Annual Meeting of Stockholders, which information 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 the sections captioned "Transactions with Related Persons" and "Director Independence" in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders, which information is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 will be included in the sections captioned "Audit Fees" and "Audit Committee Pre-Approval Policies and Procedures" in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders, which information is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(1) Financial Statements

Our consolidated financial statements are set forth in Part II, Item 8 of this Annual Report on Form 10-K and are incorporated herein by reference.

(2) Financial Statement Schedules

Schedules have been omitted since they are either not required or not applicable or the information is otherwise included herein.

(3) Exhibits

The exhibits filed as part of this Annual Report on Form 10-K are listed in the following Exhibit Index.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Date of Filing	Exhibit Number	
3.1	Restated Certificate of Incorporation of the Registrant	8-K	001-37687	2/8/2016	3.1	
3.2	Amended and Restated By-laws of the Registrant	8-K	001-37687	2/8/2016	3.2	
4.1	Specimen Stock Certificate evidencing the shares of common stock	S-1	333-208856	1/4/2016	4.1	
4.2	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	10-K	001-37687	2/26/2020	4.2	
10.1+	2013 Stock Incentive Plan, as amended	S-1	333-208856	1/4/2016	10.5	
10.2+	Form of Incentive Stock Option Agreement under 2013 Stock Incentive Plan, as amended	S-1	333-208856	1/4/2016	10.6	
10.3+	Form of Nonstatutory Stock Option Agreement under 2013 Stock Incentive Plan, as amended	S-1	333-208856	1/4/2016	10.7	

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Date of Filing	Exhibit Number	
10.4+	Form of Early Exercise Nonstatutory Stock Option Agreement under 2013 Stock Incentive Plan, as amended	S-1	333-208856	1/4/2016	10.8	
10.5+	Form of Restricted Stock Agreement under 2013 Stock Incentive Plan, as amended	S-1	333-208856	1/4/2016	10.9	
10.6+	2015 Stock Incentive Plan	S-1	333-208856	1/4/2016	10.10	
10.7+	Form of Incentive Stock Option Agreement under 2015 Stock Incentive Plan	S-1	333-208856	1/4/2016	10.11	
10.8+	Form of Nonstatutory Stock Option Agreement under 2015 Stock Incentive Plan	S-1	333-208856	1/4/2016	10.12	
10.9+	Form of Restricted Stock Agreement under 2015 Stock Incentive Plan	10-Q	001-37687	11/8/2017	10.1	
10.10+	Form of Restricted Stock Unit Award Agreement under the 2015 Stock Incentive Plan	8-K	001-37687	1/22/2019	10.1	
10.11+	Amended and Restated Offer of Employment, dated July 24, 2016, between the Registrant and Charles Albright, Ph.D.	10-K	001-37687	3/3/2017	10.11	
10.12+	Employment Offer Letter, dated August 6, 2019, between the Registrant and Cynthia Collins	10-Q	001-37687	11/12/2019	10.1	
10.13+	Letter Agreement, dated February 15, 2021, by and between the Registrant and Cynthia Collins					X
10.14+	Employment Offer Letter, dated February 14, 2021, between the Registrant and James C. Mullen					X
10.15+	Employment Offer Letter, dated December 27, 2019, between the Registrant and Michelle Robertson	10-K	001-37687	2/26/2020	10.14	
10.16+	Form of Inducement Stock Option Agreement for the Registrant's executive officers	10-K	001-37687	2/26/2020	10.15	
10.17+	Form of Inducement Restricted Stock Unit Award Agreement for the Registrant's executive officers	10-K	001-37687	2/26/2020	10.16	
10.18+	Employment Offer Letter, dated September 25, 2020, between the Registrant and Lisa A. Michaels, M.D.					X
10.19†	Amended and Restated Cas9-I License Agreement, dated December 16, 2016, among the Registrant, the President and Fellows of Harvard College ("Harvard"), and the Broad Institute, Inc. (the "Broad")	8-K	001-37687	1/23/2017	99.2	
10.20	Amendment No.1 to Amended and Restated Cas9-I License Agreement, by and among Editas Medicine, Inc., Harvard, and Broad, dated March 3, 2017	8-K	001-37687	3/7/2017	99.1	
10.21*	Second Amended and Restated License and Collaboration Agreement, dated November 11, 2019, between the Registrant and Juno Therapeutics, Inc. ("Juno")	10-K	001-37687	2/26/2020	10.20	
10.22*	License and Agreement, dated November 11, 2019, between the Registrant and Juno	10-K	001-37687	2/26/2020	10.21	
10.23†	Sponsored Research Agreement, dated June 7, 2018, between the Registrant and Broad	10-Q/A	001-37687	10/23/2018	10.2	

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Date of Filing	Exhibit Number	
10.24*	First Amendment to Sponsored Research Agreement, dated January 11, 2021, between the Registrant and Broad					X
10.25+	Summary of Director Compensation Program					X
10.26+	2015 Employee Stock Purchase Plan	S-1	333-208856	1/4/2016	10.25	
10.27+	Amended Severance Benefits Plan	10-K	001-37687	2/26/2020	10.25	
10.28	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers	S-1	333-208856	1/4/2016	10.28	
10.29	Lease Agreement, dated February 12, 2016, between Registrant and ARE-MA Region No. 55 Exchange Holding LLC	8-K	001-37687	2/19/2016	99.1	
10.30†	Cpf1 License Agreement, dated as of December 16, 2016, by and between the Registrant and Broad	8-K	001-37687	1/23/2017	99.1	
10.31†	Cas9-II License Agreement, dated as of December 16, 2016, by and between the Registrant and Broad	8-K	001-37687	1/23/2017	99.3	
10.32*	Omnibus Amendment, dated as of January 11, 2021, by and between the Registrant and Broad					X
10.33*	Letter Agreement, dated as of November 18, 2019, by and among, the Registrant, Broad and Harvard	10-K	001-37687	2/26/2020	10.30	
10.34*	Letter Agreement, dated as of December 16, 2019, by and among, the Registrant, Broad and Harvard	10-K	001-37687	2/26/2020	10.31	
10.35	Common Stock Sales Agreement, dated as of May 15, 2020, by and between the Company and Cowen and Company, LLC	8-K	001-37687	5/15/2020	1.1	
10.36*	Termination Agreement, dated August 5, 2020, by and between the Registrant and Allergan Sales, LLC	10-Q	001-37687	11/6/2020	10.1	
21.1	Subsidiaries of the Registrant	10-K	001-37687	3/30/2016	21.1	
23.1	Consent of Ernst & Young					X
31.1	Rule 13a-14(a) Certification of Principal Executive Officer					X
31.2	Rule 13a-14(a) Certification of Principal Financial Officer					X
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. §1350					X
101	The following financial statements from the Company's Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Loss, (iv) Consolidated Statement of Stockholders' Equity, (v) Consolidated Statements of Cash Flows and (vi) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text and including detailed tags.					
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Inline XBRL.					

† Confidential treatment has been granted as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

* Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K. Certain portions of this exhibit have been omitted because they are not material and would likely cause competitive harm to the Registrant if disclosed.

\+ Management contract or compensatory plan or arrangement.

Item 16. Form 10-K Summary.

None.

SIGNATURES

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

EDITAS MEDICINE, INC.

Dated: February 26, 2021

By: /s/ James C. Mullen
James C. Mullen
Principal Executive Officer

SIGNATURES

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

Signature	Title	Date
/s/ James C. Mullen James C. Mullen	President and Chief Executive Officer, Chairman of the Board (principal executive officer)	February 26, 2021
/s/ Michelle Robertson Michelle Robertson	Chief Financial Officer (principal financial and accounting officer)	February 26, 2021
/s/ Meeta Chatterjee Meeta Chatterjee, Ph.D.	Director	February 26, 2021
/s/ Andrew Hirsch Andrew Hirsch	Director	February 26, 2021
/s/ Jessica Hopfield Jessica Hopfield, Ph.D.	Director	February 26, 2021
/s/ David Scadden David Scadden, M.D.	Director	February 26, 2021
/s/ Akshay K. Vaishnaw Akshay K. Vaishnaw, M.D., Ph.D.	Director	February 26, 2021

11 Hurley Street
Cambridge, MA 02141
P 617-401-9000
F 617-494-0985

VIA ELECTRONIC MAIL

February 4, 2021 (revised)

Cynthia Collins

Dear Cindy:

As we discussed, your employment with Editas Medicine, Inc. (the "Company") will end effective February 15, 2021 (the "Separation Date"). As we also discussed, you will be eligible to receive the severance benefits described in paragraph 1 below if you sign and return this letter agreement to me by February 26, 2021 (but no earlier than the Separation Date) and do not revoke your agreement (as described below). By signing and returning this letter agreement and not revoking your acceptance, you will be entering into a binding agreement with the Company and will be agreeing to the terms and conditions set forth in the numbered paragraphs below, including the release of claims set forth in paragraph 2. Therefore, you are advised to consult with an attorney before signing this letter agreement and you have been given at least twenty-one (21) days to do so. If you sign this letter agreement, you may change your mind and revoke your agreement during the seven (7) business day period after you have signed it (the "Revocation Period") by notifying me in writing. If you do not so revoke, this letter agreement will become a binding agreement between you and the Company upon the expiration of the Revocation Period.

Although your receipt of the severance benefits is expressly conditioned on your entering into this letter agreement, the following will apply regardless of whether or not you timely enter into this letter agreement:

- As of the Separation Date, all salary payments from the Company will cease and any benefits you had as of the Separation Date under Company-provided benefit plans, programs, or practices will terminate, except as required by federal or state law.

- You will receive on the Separation Date payment for your final wages and any unused vacation time accrued through the Separation Date.

- You may, if eligible and at your own cost, elect to continue receiving group medical insurance pursuant to the "COBRA" law. Please consult the COBRA materials to be provided under separate cover for details regarding these benefits.

- You are obligated to keep confidential and not to use or disclose any and all non-public information concerning the Company that you acquired during the course of your employment with the Company, including any non-public information concerning the Company's business affairs, business prospects, and financial condition, except as otherwise permitted by paragraph 9 below. Further, you remain subject to your continuing confidentiality, non-competition, and non-solicitation obligations to the Company as set forth in the Invention and Non-Disclosure Agreement and the Non-Competition and Non-Solicitation Agreement

(the "Restrictive Covenant Agreements") you previously executed in connection with your commencement of employment with the Company, which obligations remain in full force and effect.

- You must return to the Company on the Separation Date (or within ten (10) business days thereafter) all Company property.

- You will have three (3) months following the Separation Date to exercise any stock options under the Company's 2015 Stock Incentive Plan that were vested as of the Separation Date. After that three (3) month period, your stock options will expire and you will no longer have any rights with respect thereto. Any Company-imposed blackout restrictions arising because of your service for the Company, whether as an employee, officer, and/or director, will terminate on the Separation Date. In accordance with Section 9(b) of your Employment Agreement dated August 6, 2019, the Time-Vesting Option and RSU Award (each as defined in your Employment Agreement) shall become fully vested and exercisable as of the Separation Date. Your stock options and restricted stock units which are or will become vested as of the Separation Date are summarized on the attached Schedule II.

If you elect to timely sign and return this letter agreement and do not revoke your acceptance within the Revocation Period, the following terms and conditions will also apply:

1. **Severance Benefits** –The Company will provide you with the following severance benefits (the "severance benefits") pursuant to the Company's Severance Benefits Plan:

a. Severance Pay. The Company will pay to you an amount equivalent to twelve (12) months of your current base salary, less all applicable taxes and withholdings. This separation pay will be paid in installments in accordance with the Company's regular payroll practices, but in no event shall payments begin earlier than the Company's first payroll date following expiration of the Revocation Period.

b. COBRA Benefits. Should you timely elect and be eligible to continue receiving group health insurance pursuant to the "COBRA" law, the Company will, until the earlier of (x) the date that is twelve (12) months following the Separation Date, and (y) the date on which you are eligible to obtain alternative coverage with a subsequent employer (as applicable, the "COBRA Contribution Period"), continue to pay the share of the premiums for such coverage to the same extent it was paying such premiums on your behalf immediately prior to the Separation Date. The remaining balance of any premium costs during the COBRA Contribution Period, and all premium costs thereafter, shall be paid by you on a monthly basis for as long as, and to the extent that, you remain eligible for COBRA continuation. You agree that, should you become eligible to obtain alternative medical and/or dental insurance coverage with a subsequent employer prior to the date that is twelve (12) months following the Separation Date, you will so inform the Company in writing within five (5) business days of obtaining such coverage.

c. 2020 Annual Bonus. You will be eligible to receive a bonus for 2020 equal to your target bonus times the percentage achievement of the Company's 2020 goals as assessed by the Board of Directors of the Company in connection with the determination of bonuses for the executive team, with any such bonus paid less applicable taxes and withholdings and at the same time as annual bonuses are paid to other executives of the Company or, if later, immediately upon the expiration of the Revocation Period.

You will not be eligible for, nor shall you have a right to receive, any payments or benefits from the Company following the Separation Date other than as set forth in this paragraph.

2. **Release of Claims** – In consideration of the severance benefits, which you acknowledge you would not otherwise be entitled to receive, you hereby fully, forever, irrevocably and unconditionally release, remise and discharge the Company, its affiliates, subsidiaries, parent companies, predecessors, and successors, and all of their respective past and present officers, directors, stockholders, partners, members, employees, agents, representatives, plan administrators, attorneys, insurers and fiduciaries (each in their individual and corporate capacities) (collectively, the "Released Parties") from any and all claims, charges, complaints, demands, actions, causes of action, suits, rights, debts, sums of money, costs, accounts, reckonings, covenants, contracts, agreements, promises, doings, omissions, damages, executions, obligations, liabilities, and expenses (including attorneys' fees and costs), of every kind and nature that you ever had or now have against any or all of the Released Parties, whether known or unknown, including, but not limited to, any and all claims arising out of or relating to your employment with and/or separation from the Company, including, but not limited to, all claims under Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., the Americans With Disabilities Act of 1990, 42 U.S.C. § 12101 et seq., the Age Discrimination in Employment Act, 29 U.S.C. § 621 et seq., the Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. § 2000ff et seq., the Family and Medical Leave Act, 29 U.S.C. § 2601 et seq., the Worker Adjustment and Retraining Notification Act ("WARN"), 29 U.S.C. § 2101 et seq., the Rehabilitation Act of 1973, 29 U.S.C. § 701 et seq., Executive Order 11246, Executive Order 11141, the Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq., and the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 et seq., all as amended; all claims arising out of the Massachusetts Fair Employment Practices Act, Mass. Gen. Laws ch. 151B, § 1 et seq., the Massachusetts Wage Act, Mass. Gen. Laws ch. 149, § 148 et seq. (Massachusetts law regarding payment of wages and overtime), the Massachusetts Civil Rights Act, Mass. Gen. Laws ch. 12, §§ 11H and 11I, the Massachusetts Equal Rights Act, Mass. Gen. Laws. ch. 93, § 102, Mass. Gen. Laws ch. 214, § 1C (Massachusetts right to be free from sexual harassment law), the Massachusetts Labor and Industries Act, Mass. Gen. Laws ch. 149, § 1 et seq., Mass. Gen. Laws ch. 214, § 1B (Massachusetts right of privacy law), the Massachusetts Maternity Leave Act, Mass. Gen. Laws ch. 149, § 105D, and the Massachusetts Small Necessities Leave Act, Mass. Gen. Laws ch. 149, § 52D, all as amended; all claims arising out of the South Carolina Human Affairs Law, S.C. Code Ann. § 1-13-10 et seq., S.C. Code Ann. § 1-13-10 (bone marrow donation leave law), S.C. Code Ann. § 25-1-2310 et seq. (South Carolina military leave law), S.C. Code Ann. § 41-1-10 et seq. (South Carolina wage payment law), and S.C. Code Ann. § 41-15-510 et seq. (South Carolina whistleblower protection law), all as amended; all claims arising out of the Florida Civil Rights Act of 1992, Fla. Stat. § 760.01 et seq., Fla. Stat.

§§ 448.07 and 725.07 (Florida equal pay laws), Fla. Stat. § 741.313 (Florida domestic violence or sexual violence leave law), Fla. Stat. § 250.481 (Florida military leave law), Fla. Stat. § 760.50 (Florida AIDS discrimination law), Fla. Stat. § 448.075 et seq. (Florida sickle cell trait discrimination law), Fla. Stat. § 760.40 (Florida genetic testing law), and Fla. Stat. § 448.101 et seq. (Florida anti-retaliation law), all as amended; all common law claims including, but not limited to, actions in defamation, intentional infliction of emotional distress, misrepresentation, fraud, wrongful discharge, and breach of contract; all claims to any non-vested ownership interest in the Company, contractual or otherwise; all state and federal whistleblower claims to the maximum extent permitted by law; and any claim or damage arising out of your employment with and/or separation from the Company (including a claim for retaliation) under any common law theory or any federal, state or local statute or ordinance not expressly referenced above; *provided, however, that this release of claims does not prevent you from filing a charge with, cooperating with, or participating in any investigation or proceeding before, the Equal Employment Opportunity Commission or a state fair employment practices agency (except that you acknowledge that you may not recover any monetary benefits in connection with any such charge, investigation, or proceeding, and you further waive any rights or claims to any payment, benefit, attorneys' fees or other remedial relief in connection with any such charge, investigation or proceeding).*

3. **Continuing Obligations** – You acknowledge and reaffirm your confidentiality and non-disclosure obligations discussed on the first page of this letter agreement, as well as the obligations set forth in the Restrictive Covenant Agreements, which obligations survive your separation from employment with the Company. In addition, as an express condition of your receipt of the severance benefits, you agree that, for a period of one (1) year following the Separation Date, you will not, in the Applicable Territory (as defined in your existing Non-Competition and Non-Solicitation Agreement), directly or indirectly, whether as an owner, partner, officer, director, employee, consultant, investor, lender or otherwise, except as the passive holder of not more than 1% of the outstanding stock of a publicly-held company, engage or assist others in engaging in any Competitive Company (as defined below), if you would be performing job duties or services that are of a similar type that you performed for the Company as President and Chief Executive Officer. Without limiting the foregoing, you acknowledge and agree that undertaking an executive leadership role in a Competitive Company would constitute performing job duties or services of a similar type that you performed for the Company. If any restriction set forth in this paragraph is found by any court of competent jurisdiction to be unenforceable because it extends for too long a period of time or over too great a range of activities or in too broad a geographic area, it shall be interpreted to extend only over the maximum period of time, range or activities or geographic area as to which it may be enforceable. If you violate the non-competition provisions set forth in this paragraph, you shall continue to be bound by such restrictions until a period of one (1) year has expired without any violation of such provisions. You acknowledge that the Company has given you seven (7) business days to revoke your acceptance of this letter agreement, including the non-competition restrictions set forth in this paragraph 3. For purposes herein, Competitive Company shall mean any business or enterprise that is (i) engaged in the discovery and/or development of gene-editing or gene therapies for the treatment of indications covered by any of the Company's ocular (including LCA10 and USH2A), sickle cell and Beta thalassemia programs, and oncology programs involving ex vivo gene edited cells for administration as a therapeutic, in each case as such programs exist as of the Separation Date (collectively, the "Field"), or that develops, manufactures, markets, licenses, sells or provides, or plans to develop,

manufacture, market, license, sell or provide any product or service in the Field; or (ii) set forth on Schedule I hereto. Nothing in this agreement or in any other agreement with the Company prohibits or restricts your service as a member of the board of directors of companies and organizations, including but not limited to DermTech, Triumvira Immunologics, Biocare Medical, and the Alliance for Regenerative Medicine (but excluding those companies listed on Schedule I hereto), as long as you continue to adhere to your non-solicitation and confidentiality obligations to the Company.

4. **Non-Disparagement** – You understand and agree that, to the extent permitted by law and except as otherwise permitted by paragraph 9 below, you will not, in public or private, make any false, disparaging, derogatory or defamatory statements, online (including, without limitation, on any social media, networking, or employer review site) or otherwise, to any person or entity, including, but not limited to, any media outlet, industry group, financial institution or current or former employee, board member, consultant, client or customer of the Company, regarding the Company or any of the other Released Parties, or regarding the Company's business affairs, business prospects, or financial condition. In return, the Company will instruct its directors and officers not to make any false, disparaging, derogatory or defamatory statements, online or otherwise, to any third party regarding you.

5. **Company Affiliation** – You agree that, following the Separation Date, you will not hold yourself out as an officer, employee, or otherwise as a representative of the Company, and you agree to update any directory information that indicates you are currently affiliated with the Company. Without limiting the foregoing, you confirm that, within five (5) days following the Separation Date, you will update any and all social media accounts (including, without limitation, LinkedIn, Facebook, Twitter and Four Square) to reflect that you are no longer employed by or associated with the Company.

6. **Return of Company Property** – You confirm that you have returned (or will return, within 10 business days of the Separation Date) to the Company all keys, files, records (and copies thereof), equipment (including, but not limited to, computer hardware, software, printers, flash drives and other storage devices, wireless handheld devices, cellular phones, tablets, etc.), Company identification, and any other Company owned property in your possession or control, and that you have left intact all, and have otherwise not destroyed, deleted, or made inaccessible to the Company any, electronic Company documents, including, but not limited to, those that you developed or helped to develop during your employment, and that you have not (a) retained any copies in any form or media; (b) maintained access to any copies in any form, media, or location; (c) stored any copies in any physical or electronic locations that are not readily accessible or not known to the Company or that remain accessible to you; or (d) sent, given, or made accessible any copies to any persons or entities that the Company has not authorized to receive such electronic or hard copies. You further confirm that you have cancelled all accounts for your benefit, if any, in the Company's name, including but not limited to, credit cards, telephone charge cards, cellular phone accounts, and computer accounts.

7. **Business Expenses and Final Compensation** – You acknowledge that you have been reimbursed by the Company for all business expenses incurred in conjunction with the performance of your employment and that no other reimbursements are owed to you. You further acknowledge that you have received payment in full for all services rendered in conjunction with your employment by the Company, including

payment for all wages, bonuses, commissions, and accrued, unused vacation time, and that no other compensation is owed to you except as provided herein.

8. **Confidentiality** – You understand and agree that, to the extent permitted by law and except as otherwise permitted by paragraph 9 below, the contents of the negotiations and discussions resulting in this letter agreement, shall be maintained as confidential by you and your agents and representatives and shall not be disclosed except as otherwise agreed to in writing by the Company.

9. **Scope of Disclosure Restrictions** – Nothing in this letter agreement prohibits you from communicating with government agencies about possible violations of federal, state, or local laws or otherwise providing information to government agencies, filing a complaint with government agencies, or participating in government agency investigations or proceedings. You are not required to notify the Company of any such communications; provided, however, that nothing herein authorizes the disclosure of information you obtained through a communication that was subject to the attorney-client privilege. Further, notwithstanding your confidentiality and nondisclosure obligations, you are hereby advised as follows pursuant to the Defend Trade Secrets Act: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order."

10. **Cooperation** – You agree that, to the extent permitted by law, you shall cooperate fully with the Company in the investigation, defense or prosecution of any claims or actions which already have been brought, are currently pending, or which may be brought in the future against the Company by a third party or by or on behalf of the Company against any third party, whether before a state or federal court, any state or federal government agency, or a mediator or arbitrator related to events about which you have relevant knowledge. Your full cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with the Company's counsel, at reasonable times and locations designated by the Company, to investigate or prepare the Company's claims or defenses, to prepare for trial or discovery or an administrative hearing, mediation, arbitration or other proceeding and to act as a witness when requested by the Company. You further agree that, to the extent permitted by law, you will notify the Company promptly in the event that you are served with a subpoena (other than a subpoena issued by a government agency), or in the event that you are asked to provide a third party (other than a government agency) with information concerning any actual or potential complaint or claim against the Company. The Company agrees to pay you for any travel expenses you incur in connection with your cooperation. The Company also agrees to pay you a reasonable rate for your time if it requests that you spend more than *de minimis* time cooperating pursuant to this provision; provided, however, that Company will not at any time pay you any fee for time spent providing testimony.

11. **Amendment and Waiver** – This letter agreement shall be binding upon the parties and may not be modified in any manner, except by an instrument in writing of concurrent or subsequent date signed by duly authorized representatives of the parties hereto. This letter agreement is binding upon and shall inure to the benefit of the parties and their respective agents, assigns, heirs, executors, successors and administrators. No delay or omission by the Company in exercising any right under this letter agreement shall operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.

12. **Validity** – Should any provision of this letter agreement be declared or be determined by any court of competent jurisdiction to be illegal or invalid, the validity of the remaining parts, terms or provisions shall not be affected thereby and said illegal or invalid part, term or provision shall be deemed not to be a part of this letter agreement.

13. **Nature of Agreement –** You understand and agree that this letter agreement is a severance agreement and does not constitute an admission of liability or wrongdoing on the part of the Company.

14. **Acknowledgments –** You acknowledge that you have been given at least twenty-one (21) days to consider this letter agreement, and that the Company is hereby advising you to consult with an attorney of your own choosing prior to signing this letter agreement. You understand that you may revoke this letter agreement for a period of seven (7) business days after you sign this letter agreement by notifying me in writing, and the letter agreement shall not be effective or enforceable until the expiration of this seven (7) business day revocation period. You understand and agree that by entering into this letter agreement, you are waiving any and all rights or claims you might have under the Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act, and that you have received consideration beyond that to which you were previously entitled.

15. **Voluntary Assent –** You affirm that no other promises or agreements of any kind have been made to or with you by any person or entity whatsoever to cause you to sign this letter agreement, and that you fully understand the meaning and intent of this letter agreement. You further state and represent that you have carefully read this letter agreement, understand the contents herein, freely and voluntarily assent to all of the terms and conditions hereof, and sign your name of your own free act.

16. **Applicable Law** – This letter agreement shall be interpreted and construed by the laws of the Commonwealth of Massachusetts, without regard to conflict of laws provisions. You hereby irrevocably submit to and acknowledge and recognize the jurisdiction of the courts of the Commonwealth of Massachusetts, or if appropriate, a federal court located in the Commonwealth of Massachusetts (which courts, for purposes of this letter agreement, are the only courts of competent jurisdiction), over any suit, action or other proceeding arising out of, under or in connection with this letter agreement or the subject matter hereof.

17. **Entire Agreement** – This letter agreement contains and constitutes the entire understanding and agreement between the parties hereto with respect to your severance benefits and the settlement of claims against the Company and cancels all

previous oral and written negotiations, agreements, and commitments in connection therewith.

18. **Tax Acknowledgement** – In connection with the severance benefits provided to you pursuant to this letter agreement, the Company shall withhold and remit to the tax authorities the amounts required under applicable law, and you shall be responsible for all applicable taxes with respect to such severance benefits under applicable law. You acknowledge that you are not relying upon the advice or representation of the Company with respect to the tax treatment of any of the severance benefits set forth in paragraph 1 of this letter agreement.

[*signature page follows*]

Very truly yours,

By: /s/ Akshay Vaishnaw
Akshay Vaishnaw
Chairman of the Organization,
Leadership and Compensation
Committee

I hereby agree to the terms and conditions set forth above. I have been given at least twenty-one (21) days to consider this letter agreement, and I have chosen to execute this on the date below. I intend that this letter agreement will become a binding agreement between me and the Company if I do not revoke my acceptance in seven (7) days.

/s/ Cynthia Collins
Cynthia Collins

February 15, 2021
Date

To be returned in a timely manner as set forth on the first page of this letter agreement.

SCHEDULE I

CERTAIN COMPETITIVE COMPANIES

SCHEDULE II

Equity Awards

11 Hurley Street
Cambridge, MA 02141
617-401-9000
617-494-0985

February 13, 2021

By Electronic Mail

James C. Mullen

Dear Jim:

On behalf of Editas Medicine, Inc., a Delaware corporation (the "**Company**"), I am pleased to offer you employment with the Company. The purpose of this letter is to summarize the terms of your employment with the Company, should you accept our offer:

1. You will be employed to serve as President and Chief Executive Officer ("**CEO**"), effective February 15, 2021 (the "**Effective Date**"). As CEO, you will be responsible for such duties as are consistent with such position. You shall report to the Company's Board of Directors (the "**Board**"). During your employment as CEO, you will remain a member of the Board. Upon the ending of your employment as CEO, if so requested in writing by the Company, you shall immediately resign from the Board as well as from your position as CEO and any other position(s) with the Company to which you were elected or appointed in connection with your employment or Board membership.

2. Your base salary will be at the rate of $26,041.67 per semi-monthly pay period (equivalent to an annualized base salary of $625,000), subject to tax and other withholdings as required by law. Beginning in 2022, such base salary may be increased from time to time in accordance with normal business practice and in the sole discretion of the Company. In addition, the Company will provide you with a benefits allowance of $2,750 per month, less applicable taxes and withholdings, payable in accordance with the Company's normal payroll cycle. Such benefits allowance may be modified from time to time in the sole discretion of the Company.

3. Following the end of each fiscal year and subject to the approval of the Board (or a duly authorized committee thereof), you will be eligible for a retention and performance bonus, targeted at 60% of your annualized base salary (and payable from between 0% and 150% in accordance with bonus plan), based solely on the Company's performance during the applicable fiscal year, as determined by the Board (or such committee) in its sole discretion in accordance with certain corporate goals determined by the Board (or such committee) in its sole discretion each year; provided, however, that, for 2021, any bonus will be pro-rated based on the number of days employed in 2021 divided by 365. Provided that you are still employed on December 31 of any calendar year, your bonus will be payable by the Company for that calendar year even if you are no longer CEO at the time of payment. The Company will award and pay any bonus for the prior calendar year before March 15th of the next succeeding calendar year. Notwithstanding the foregoing, if you die or become disabled (as defined under the Company's long-term disability plan) prior to the date of payment of the bonus, you will be entitled to receive a pro-rata portion of the bonus to which you would otherwise have been

entitled (based on the number of days in the year to which the bonus relates prior to your death or disability divided by 365). You will also be eligible to participate in the Company's long-term incentive plan which provides for annual equity awards, as determined in the sole discretion of the Board (or a duly authorized committee thereof) after consideration of individual employee performance and Company performance benchmarked against the Company's peer group, and such other factors as the Board (or a duly authorized committee thereof) determines to be relevant in its discretion; provided, however, that you will not be eligible for long-term incentive awards in 2021 or 2022.

4. You may participate in any and all benefit programs that the Company establishes and makes available to its employees from time to time, provided you are eligible under (and subject to all provisions of) the plan documents governing those programs. The benefit programs made available by the Company, and the rules, terms and conditions for participation in such benefit plans, may be changed by the Company at any time without advance notice.

5. You will be eligible for paid vacation and holidays in accordance with Company policy.

6. The Company shall reimburse you for all reasonable and necessary documented out of pocket expenses incurred or paid by you in connection with, or related to, the performance of your services to the Company, including without limitation all travel (first or business class) and hotel and ancillary expenses. You shall abide by the Company's expense reimbursement policy, except as otherwise set forth herein or with the prior written approval of the Chairman of the Board.

7. Subject to approval of the Company's Board of Directors, the Company will grant to you:

(a) an option to acquire that number of shares of Company common stock having an aggregate Black-Scholes value of $10,000,000 (the "**New Hire Option**") as of the date of grant as determined by the Organization, Leadership and Compensation Committee (the "**OLC Committee**"), which will have an exercise price equal to the fair market value of the Company's common stock on the date of grant and will vest upon the achievement of specified organizational milestones to be determined by the OLC Committee at the time of grant;

(b) an option to purchase that number of shares of the Company's common stock having an aggregate Black-Scholes value, inclusive of a performance premium, of $5,000,000 (the "**Performance-Vesting Option**") as of the date of grant as determined by the OLC Committee, which will have an exercise price equal to the fair market value of the Company's common stock on the date of grant and will vest as to 1/3 of the shares underlying the option as of the date on which the closing price of the Company's common stock, as reported on Nasdaq, has for 15 consecutive trading days (in the five-year period following grant) equaled or exceeded $80.00, $100.00, and $120.00, respectively; and

8. a performance-based restricted stock unit award for Company common stock having a value of $5,000,000 (the "**PRSU Award**" and, collectively with the New Hire Option and the Performance-Vesting Option, the "**Equity Awards**") based on the fair market value of the Company's common stock on the date of grant, which PRSU Award will vest in thirds based on research and

development milestones to be determined by the OLC Committee at the time of grant. The Equity Awards will be granted under and subject to the terms of the Company's 2015 Stock Incentive Plan and evidenced in writing by, and subject to the terms of a stock option agreement (pursuant to which, unless your employment is terminated for Cause (as defined below) by the Company, the New Hire Option and the Performance-Vesting Option will remain exercisable until the expiration date of the option) and a restricted stock unit agreement, as applicable, thereunder. As set forth in and subject to the terms of the Severance Benefits Plan, the vesting of the Equity Awards shall accelerate upon a Change in Control Termination (as defined in the Severance Benefits Plan).

9. You may be eligible to receive such future equity awards as the Board of Directors of the Company shall deem appropriate.

10. You will be eligible to participate in the Company's Severance Benefits Plan at the Chief Executive Officer level. Your eligibility under the Severance Benefits Plan is subject to the terms and conditions thereof. In addition, in accordance with and subject to the terms of the Severance Benefits Plan, you will receive twelve months' Severance Pay (as defined in the Severance Benefits Plan) from the Company upon a Covered Termination.

11. You will work out of the Company's office in Cambridge, Massachusetts, with the understanding that you may be required to travel to other locations in connection with the performance of your duties, at the expense of the Company. The Company further acknowledges and agrees that you may work remotely as you deem reasonable, subject to your fulfillment of the functions of your position.

12. The Company shall also reimburse you for your attorneys' fees incurred in connection with the negotiation of this offer letter.

13. You will be required to execute an Amended and Restated Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement in the forms attached as Exhibit A, as a condition of employment. You acknowledge that your receipt of the grants of equity set forth in Paragraph 7 of this offer letter is contingent upon your agreement to the non-competition provisions set forth in the Amended and Restated Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement. You further acknowledge that such consideration was mutually agreed upon by you and the Company is fair and reasonable in exchange for your compliance with such non-competition obligations. The Company (i) is aware that you have existing commitments, including as a member of the board of several companies and industry organizations, all of which have been disclosed to the Board of Directors of the Company, and nothing in this letter agreement or any other agreement with the Company or Company policy is intended to prohibit or prevent your continued service with those roles and, subject to your compliance with applicable Company policies for approval by the Board (or a committee thereof), similar board and consulting assignments in the future entered into during the period of your employment and (ii) acknowledges that matters, transactions or interests that are presented to, or acquired, created or developed by you in the conduct of such existing commitments or future assignments shall not be deemed to relate to the Company unless such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into your possession in your capacity as an employee and director of the Company.

14. You agree to provide to the Company, within three days of your hire date, documentation of your eligibility to work in the United States, as required by the Immigration Reform and Control Act of 1986. You may need to obtain a work visa in order to be eligible to work in the United States. If that is the case, your employment with the Company will be conditioned upon your obtaining a work visa in a timely manner as determined by the Company.

15. This letter shall not be construed as an agreement, either express or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at will, under which both you and the Company remain free to terminate the employment relationship, with or without cause, at any time, with or without notice. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at-will" nature of your employment may only be changed by a written agreement signed by you and the Chairman of the Board**,** which expressly states the intention to modify the at-will nature of your employment.

16. As an employee of the Company, you will be required to comply with all Company policies and procedures. Violations of the Company's policies may lead to immediate termination of your employment. Further, the Company's premises, including all workspaces, furniture, documents, and other tangible materials, and all information technology resources of the Company (including computers, data and other electronic files, and all internet and email) are subject to oversight and inspection by the Company at any time. Company employees should have no expectation of privacy with regard to any Company premises, materials, resources, or information.

17. For the duration of your employment, the Company agrees to maintain directors and officers liability insurance at its expense, and agrees to indemnify you to the fullest extent permitted by law, the Company's Bylaws, or any other applicable statute, rule of law, contract, or insurance policy.

18. This offer letter is your formal offer of employment and supersedes any and all prior or contemporaneous agreements, discussions and understandings, whether written or oral, relating to the subject matter of this letter or your employment with the Company. The resolution of any disputes under this letter will be governed by the laws of the Commonwealth of Massachusetts.

If you agree with the provisions of this letter, please sign the enclosed duplicate of this letter in the space provided below and return it to the undersigned, by February 15, 2021. If you do not accept this offer by February 15, 2021, this offer will be revoked.

Very Truly Yours,

EDITAS MEDICINE, INC.

By: /s/ Akshay Vaishnaw
Name: Akshay Vaishnaw
Title: Chairman of the Organization, Leadership and Compensation Committee

The foregoing correctly sets forth the terms of my employment by Editas Medicine, Inc. I am not relying on any other representation, except as set forth in this letter.

Date: 2/14/2021

/s/ James Mullen
James C. Mullen

EXHIBIT A

AMENDED AND RESTATED EMPLOYEE NON-COMPETITION, NON-SOLICITATION, CONFIDENTIALITY AND ASSIGNMENT AGREEMENT

Exhibit 10.18

11 Hurley Street
Cambridge, MA 02141

P 617-401-9000
F 617-494-0985

September 25, 2020

Lisa A. Michaels, MD

Re: Offer of Employment

Dear Lisa,

On behalf of Editas Medicine, Inc. (the "**Company**"), I am pleased to offer you employment with the Company. The purpose of this letter (the "**Offer Letter**") is to set forth the terms of your employment with the Company, should you accept our offer.

I am pleased to offer you the position of Executive Vice President, Chief Medical Officer at the Company, reporting to the Chief Executive Officer. Your base salary will be at the rate of $18,076.92 per biweekly pay period (equivalent to an annualized base salary of $470,000.00), subject to tax and other withholdings as required by law. Such base salary may be adjusted from time to time in accordance with normal business practice and in the sole discretion of the Company. You will be employed on a full-time basis. Your effective date of hire as an employee (the "**Start Date**") will be November 9th, 2020. You shall work out of the Company's office at One Main Street, 8th Floor, Cambridge, MA 02142 and shall travel as required by your job duties.

Following the end of each fiscal year and subject to the approval of the Company's Board of Directors (the "**Board**"), or a duly authorized committee thereof, you will be eligible for a retention and performance bonus, targeted at 45% of your annualized base salary, based on your and the Company's performance during the applicable fiscal year as determined by the Board (or such committee) and in accordance with certain corporate goals determined by the Board (or such committee), in each case, in its sole discretion. Such bonus shall be pro-rated for any partial year and shall not be payable if your Start Date is within the last quarter of the fiscal year. You shall not be entitled to any bonus if you voluntarily terminate your employment with the Company, other than for Good Reason, as such term is defined in the Company's Severance Benefits Plan (as amended and/or restated from time to time, the "**Severance Benefits Plan**"), prior to the date such bonus is distributed, as it also serves as an incentive to remain employed by the Company, provided, that the Company will award and pay any bonus for the prior calendar year no later than March 15th of the next succeeding fiscal year.

You will receive a one-time sign on bonus of $150,000.00, less applicable taxes and withholdings (the "**Signing Bonus**"), which will be paid to you in the first regular payroll following your Start Date. If, within one (1) year after your Start Date, either (i) you voluntarily terminate your employment with the Company for any reason other than for Good Reason or (ii) if the Company terminates your employment because it has determined in its sole discretion that you have (a) engaged in fraud, misappropriation, or embezzlement, (b) materially breached any Company policy or any agreement by and between you and the Company; (c) committed one or more acts constituting either a felony or any crime involving dishonesty or moral turpitude; or (d) failed to perform your duties and/or responsibilities to the Company's satisfaction, you agree to repay the Company within thirty (30) days of your separation from employment with the Company, the entire Signing Bonus paid by the Company. You further acknowledge and agree that the Company may deduct from any amounts due to you from the Company (including without limitation any salary, bonuses, severance or separation pay, and expense reimbursements) up to the full amount of the Signing Bonus owed to the Company, subject to applicable law. If such deduction does not fully satisfy the amount of reimbursement due, or if the Company elects not to take such deduction, you agree to repay the remaining unpaid balance to the Company within thirty (30) days of your separation from employment with the Company. By signing and returning this Offer Letter, you agree to repayment of the Signing Bonus as provided for in this paragraph, and you further agree to execute any documents that may be requested by the Company to memorialize any deductions that you have authorized herein.

You will be eligible for six (6) months of temporary living costs at a rate of $7,000.00 per month less applicable taxes and withholdings (the "**Housing Allowance**").

In addition, you will also be eligible to receive up to $125,000.00 less applicable taxes and withholdings (the "**Relocation Amount**") to support you in your relocation to the Cambridge, MA area You must submit an expense summary and adequate supporting documentation for all qualified expenses no later than the end of the month following the month in which the expense was incurred, to include by way of example:

- Packing and shipping your household goods and personal effects to Massachusetts*;*
- Travel, excluding meals, to your new home in Massachusetts*;*
- Disconnecting and connecting utilities; and
- Up to 30 days of storage and insurance expenses for household goods and personal effects.

The applicable portion of the Relocation Amount will be paid to you no later than the end of the month following your provision of supporting documentation.

All reimbursements and in-kind benefits provided hereunder shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in- kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses incurred during your lifetime (or during a shorter period of time specified herein), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year.

If, within twelve (12) months after the Company's final payment of the Relocation Amount, either (a) you voluntarily terminate your employment with the Company for any reason, other than for Good Reason, or (b) if the Company terminates your employment for Cause, you agree to repay the Company within thirty (30) days of your separation from employment with the Company, the entire Housing Allowance and Relocation Amount paid by the Company. If, after twelve (12) months but before twenty- four (24) months after the Company's final payment of the Relocation Amount, you voluntarily terminate your employment with the Company for any reason, other than for Good Reason, or if the Company terminates your employment for Cause, you agree to repay the Company within thirty (30) days of your separation from employment with the Company, an amount prorated starting at fifty percent (50%) of the Housing Allowance and Relocation Amount paid by the Company. You further acknowledge and agree that the Company may deduct from any amounts due to you from the Company (including without limitation any salary, bonuses, severance or separation pay, and expense reimbursements) up to the full amount of the Housing Allowance and Relocation Amount owed to the Company, subject to applicable law. If such deduction does not fully satisfy the amount of reimbursement due, or if the Company elects not to take such deduction, you agree to repay the remaining unpaid balance to the Company within thirty (30) days of your separation from employment with the Company. By signing and returning this Offer Letter, you agree to repayment of the Housing Allowance and Relocation Amount as provided for in this paragraph, and you further agree to execute any documents that may be requested by the Company to memorialize any deductions that you have authorized herein. For purposes of this Offer Letter, "**Cause**" shall have the respective definitions presently set forth in the Company's Severance Benefits Plan (as amended and/or restated from time to time, the "**Severance Benefits Plan**").

Subject to approval of the Board or a duly authorized committee thereof, you shall be granted (i) a stock option to purchase 120,000 shares of the Company's common stock (the "**Option**") at an exercise or purchase price equal to the fair market value of the Company's common stock on the date of grant and (ii) restricted stock units ("**RSU**," together with the Option, the "**Equity Awards**") in the amount of 20,000 units. The Option will vest over four (4) years at the rate of 25% on the first anniversary of the Start Date, and an additional 2.0833% of the original number of shares at the end of each successive month following the first anniversary of the Start Date until the fourth anniversary of such date, provided you remain employed by the Company on the vesting dates. The RSU will vest over four (4) years at the rate of 25% of the original number of RSUs on the first anniversary of the Start Date, and an additional 25% of the original number of RSUs will vest at the end of each successive anniversary date of your Start Date until the fourth anniversary of such date, provided you remain employed with the Company on the vesting dates. The Equity Awards are being granted pursuant to Nasdaq Listing Rule 5635(c)(4) as an inducement for you to enter into employment with the Company. The Equity Awards will be brought to the Board of Directors (or a duly authorized committee thereof) for approval on or after the date you begin employment with the Company. The Equity Awards will be evidenced in writing by, and subject to the terms of an inducement stock option agreement and an inducement restricted stock unit agreement, as applicable.

You may participate in any benefit programs that the Company establishes and makes available to its employees from time to time, provided you are eligible under (and subject to all provisions of) the plan documents governing those programs. Additionally, you will be eligible for paid vacation

and holidays in accordance with Company policy. Please see the enclosed "2020 Benefits Overview" for detailed information on our benefits and related policies, which currently include 13 paid holidays and a flexible time-off program. The benefit programs made available by the Company, and the rules, terms and conditions for participation in such benefit plans, may be changed by the Company at any time without advance notice. For clarification purposes, under the "Severance Benefits Plan", as an Executive Vice President, you are eligible to receive benefits as defined for the role of "Other C Level Officer".

You will be required to execute a Non-Solicitation, Non-Competition, Confidentiality and Assignment Agreement in the form attached hereto as Exhibit A (the "**Agreement**") and, prior to your Start Date, a Durable Automatic Sale Instruction Letter in the form attached hereto as Exhibit B. You acknowledge that your eligibility for the Housing Allowance and Relocation Amount Equity Awards referenced herein are contingent upon your agreement to the non- competition provisions set forth in the Agreement. You further acknowledge that such consideration was mutually agreed upon by you and the Company, is fair and reasonable, and is in exchange for your compliance with such non-competition obligations.

In making this offer, the Company understands, based on representations made by you, that you are not under any obligation to any former employer or any person or entity which would prevent, limit, or impair in any way your acceptance of this offer or employment or the performance by you of your duties as an employee of the Company. In accepting this offer you represent and warrant the foregoing to be true and correct (i) that in connection with providing services to the Company you will not use any confidential and/or proprietary information of any third party, including, without limitation, any former employer, or bring any biological or other materials to the Company and (ii) the Agreement was provided to you by the earlier of (A) the date we sent you this Offer Letter or (B) ten (10) business days before your Start Date.

You agree to provide to the Company, within three days of your hire date, documentation of your eligibility to work in the United States, as required by the Immigration Reform and Control Act of 1986. You may need to obtain a work visa in order to be eligible to work in the United States.

If that is the case, your employment with the Company will be conditioned upon your obtaining a work visa in a timely manner as determined by the Company.

It is understood that you are an "at-will" employee. You are not being offered employment for a definite period of time or pursuant to an employment contract, and either you or the Company may terminate the employment relationship at any time and for any reason, with or without cause, or prior notice and without additional compensation to you, except as provided in the

You will be eligible to participate in the Company's Severance Benefits Plan, as amended, a copy of which is attached hereto as Exhibit C (the "**Severance Benefits Plan**"), at the applicable level referenced in such plan. Your eligibility under the Severance Benefits Plan is subject to the terms and conditions thereof.

This Offer Letter and the Agreement referenced above constitute the complete agreement between you and the Company, contain all of the terms of your employment with the Company and supersede any prior agreements, representations or understandings (formal or informal, whether written, oral or implied) between you and the Company. This Offer Letter may not be amended or modified except by an express written agreement signed by both you and a duly authorized officer of the Company, although your job duties, title, reporting relationship, compensation and benefits may change from time to time in the Company's sole discretion and provided that the "at-will" nature of your employment may only be changed by a written agreement signed by you and the Company's Chief Executive Officer, which expressly states the intention to modify the at-will nature of your employment. Nothing in this Offer Letter shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company, except to the extent you are eligible for post-employment benefits under the Severance Benefits Plan.

As an employee of the Company, you will be required to familiarize yourself and comply with all Company policies and procedures. Violations of the Company's policies may lead to immediate termination of your employment. Further, the Company's premises, including all workspaces, furniture, documents and other tangible materials, together with all information technology resources of the Company (including computers, portable devices, data and other electronic files (whether in hard copy or electronic form), and all internet and email communications) are subject to oversight and inspection by the Company at any time. Company employees shall have no expectation of privacy with regard to any Company premises, materials, resources or information.

The Company's offer of at-will employment is contingent upon your authorization and successful completion of background and reference checks as may be requested by the Company. If requested by the Company, you will be required to execute authorizations for the Company to obtain consumer reports and/or investigative consumer reports and use them in conducting background checks as a condition to your employment. The Company may obtain background reports both pre-employment and from time to time during your employment with the Company, as necessary.

Please indicate your acceptance of this offer by signing the enclosed copy of this Offer Letter and the Agreement via the electronic signature tool, no later than October 1, 2020.

Please know that we are truly excited at the prospect of your becoming part of the Editas team and your leadership in helping to build what we hope will be an exceptional organization, one that is both a scientific pioneer and that delivers transformative medicines to many patients. We believe that you will be a fundamental part of turning that aspiration into reality.

Very truly yours,
Editas Medicine, Inc.

/s/ Clare Carmichael
Signature: Clare Carmichael
Chief Human Resources Officer

The foregoing correctly sets forth the terms of my employment by the Company. I am not relying on any other representation, except as set forth in this Offer Letter.

/s/ Lisa A. Michaels
Signature: Lisa Michaels
Chief Human Resources Officer

Exhibit 10.24

Certain identified information has been excluded from this exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

FIRST AMENDMENT TO SPONSORED RESEARCH AGREEMENT

This Amendment (the "**SRA Amendment**") is entered into as of January 11, 2021 (the "**SRA Amendment Effective Date**"), by and between **The Broad Institute, Inc.**, a non-profit Massachusetts corporation, with a principal office at 415 Maine Street, Cambridge, MA 02142 ("**Broad**") and **Editas Medicine, Inc.**, a Delaware corporation, located at 11 Hurley Street, Cambridge, MA 02141 ("**Editas**"), and amends that certain Sponsored Research Agreement, dated as of June 7, 2018 (the "**Sponsored Research Agreement**"). Broad and Editas may be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

Whereas, Broad and Editas are party to the Sponsored Research Agreement; and

Whereas, the Parties wish to amend the Sponsored Research Agreement as follows;

Now, Therefore, in consideration of the mutual covenants and agreements herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. **Section 3.5.1** of the Sponsored Research Agreement is amended by adding the following to the end of such section:

   "Notwithstanding the foregoing, in the event that the Company qualifies as a Well-Known Seasoned Issuer as defined in the Securities Act, then the Company may, upon notice to Broad, issue such number of shares of Common Stock that are Public Securities as calculated in accordance with the immediately preceding sentence (which shares, for the avoidance of doubt, shall not be registered under the Securities Act at issuance) no later than [**] after the applicable Trigger Date in full or partial satisfaction of a Research Payment, so long as the Company uses its commercially reasonable efforts to file a prospectus supplement that constitutes a Resale Registration Statement on the Trading Day on which such shares are issued and such prospectus supplement is filed no later than [**] following such issuance. Any shares issued pursuant to the prior sentence shall be deemed Note Shares for purposes of this Agreement."

2. **Effect of Amendment**. Except as specifically amended herein, the Sponsored Research Agreement is hereby ratified and confirmed and shall remain in full force and effect. Upon the effectiveness of this SRA Amendment, on and after the date hereof, each reference in the Sponsored Research Agreement to "this Agreement," "hereunder," "hereof," "herein" or words of like import, and each reference in the other documents entered into in connection with each such agreement, shall mean and be a reference to such agreement, as amended hereby.

3. **Governing Law**. This SRA Amendment shall be construed in accordance with, the substantive laws of the Commonwealth of Massachusetts, without giving effect to any choice or conflict of law provision.

4. **Counterparts**. This SRA Amendment may be executed and delivered by electronic signature and in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the Parties hereto have caused this **SRA AMENDMENT** to be executed and entered into by their duly authorized representatives as of the SRA Amendment Effective Date.

THE BROAD INSTITUTE, INC.		**EDITAS MEDICINE, INC.**	
By:	/s/ Issi Rozen	By:	/s/ Cynthia Collins
Name:	Issi Rozen	Name:	Cynthia Collins
Title:	Chief Business Officer	Title:	President and Chief Executive Officer

Exhibit 10.25

SUMMARY OF NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

Effective: February 16, 2021

The board of directors (the "Board") of Editas Medicine, Inc. (the "Company") has approved a non-employee director compensation program. Under this non-employee director compensation program, the Company pays its non-employee directors retainers in cash. Each non-employee director receives a cash retainer for service on the Board and for service on each committee of which the director is a member. The chairmen of the Board and of each committee receives higher retainers for such service. The amounts of the fees paid to each non-employee director for service on the board of directors and for service on each committee of the board of directors on which the director is a member are as follows:

	Member Annual Fee	Chairman Annual Fee
Board of Directors	$ 35,000	$ 75,000
Audit Committee	$ 7,500	$ 15,000
Organization, Leadership and Compensation Committee	$ 5,000	$ 10,000
Nominating and Corporate Governance Committee	$ 4,000	$ 8,000
Science and Technology Committee	$ 5,000	$ 10,000

Any non-employee director serving as the Board-appointed lead independent director also receives an annual fee of $25,000, in addition to any fees such director receives for his or her service on the Board or any committees thereof.

These fees are payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment shall be prorated for any portion of such quarter during which the director was not serving. The Company also reimburses its non-employee directors for reasonable travel and other expenses incurred in connection with attending Board and committee meetings. Additionally, the Board may establish other committees from time to time that include fees for both members and chairpersons, as well as per meeting fees.

Under the Company's non-employee director compensation program, each non-employee director receives, under the Company's 2015 Stock Incentive Plan, upon his or her initial election to the Board, an option to purchase 23,076 shares of the Company's common stock. Each of these options vests as to one-third of the shares of the Company's common stock underlying such option on each anniversary of the grant date until the third anniversary of the grant date, subject to the non-employee director's continued service as a director. Further, on the date of the first Board meeting held after each annual meeting of stockholders, each non-employee director that has served on the Board for at least four months receives, under the 2015 Stock Incentive Plan, an option to purchase 11,538 shares of the Company's common stock; these options vest in full on the one-year anniversary of the grant date unless otherwise provided at the time of grant, subject to the non-employee director's continued service as a director. All options issued to the Company's non-employee directors under the non-employee director compensation program are issued at exercise prices equal to the fair market value of the Company's common stock on the date of grant and become exercisable in full upon a change in control of the Company.

Exhibit 10.32

Certain identified information has been excluded from this exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

OMNIBUS AMENDMENT

This Omnibus Amendment (the "**Amendment**") is entered into as of January 11, 2021 (the "**Amendment Effective Date**"), by and between **The Broad Institute, Inc.**, a non-profit Massachusetts corporation, with a principal office at 415 Maine Street, Cambridge, MA 02142 ("**Broad**") and **Editas Medicine, Inc.**, a Delaware corporation, located at 11 Hurley Street, Cambridge, MA 02141 ("**Editas**"), and amends (i) that certain Cpf1 License Agreement, dated as of December 16, 2016 (the "**Cpf1 Agreement**") and (ii) that certain Cas9-II License Agreement, dated as of December 16, 2016 (the "**Cas9-II Agreement**" and together with the Cpf1 Agreement, the "**Agreements**"). Broad and Editas may be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

Whereas, Broad and Editas are party to the Agreements; and

Whereas, the Parties wish to amend the Agreements as follows;

Now, Therefore, in consideration of the mutual covenants and agreements herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Each of **Section 4.7.4.1** of the Cpf1 Agreement and **Section 4.8.3.1** of the Cas9-II Agreement are amended by adding the following to the end of such section:

   "Notwithstanding the foregoing, in the event that the Company qualifies as a Well-Known Seasoned Issuer as defined in the Securities Act, then the Company may, upon notice to Broad, issue such number of shares of Common Stock that are Public Securities as calculated in accordance with the immediately preceding sentence (which shares, for the avoidance of doubt, shall not be registered under the Securities Act at issuance) no later than [**] after the applicable Trigger Date in full or partial satisfaction of a Success Payment, so long as the Company uses its commercially reasonable efforts to file a prospectus supplement that constitutes a Resale Registration Statement on the Trading Day on which such shares are issued and such prospectus supplement is filed no later than [**] following such issuance. Any shares issued pursuant to the prior sentence shall be deemed Note Shares for purposes of this Agreement."

2. **Effect of Amendment**. Except as specifically amended herein, the Agreements are hereby ratified and confirmed and shall remain in full force and effect. Upon the effectiveness of this Amendment, on and after the date hereof, each reference in each of the Cpf1 Agreement and the Cas9-II Agreement to "this Agreement," "hereunder," "hereof," "herein" or words of like import, and each reference in the other documents entered into in

connection with each such agreement, shall mean and be a reference to such agreement, as amended hereby.

3. **Governing Law**. This Amendment shall be construed in accordance with, the substantive laws of the Commonwealth of Massachusetts, without giving effect to any choice or conflict of law provision.

4. **Counterparts**. This Amendment may be executed and delivered by electronic signature and in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Remainder of Page Intentionally Left Blank]

In Witness Whereof, the Parties hereto have caused this **Omnibus Amendment** to be executed and entered into by their duly authorized representatives as of the Amendment Effective Date.

The Broad Institute, Inc.		**Editas Medicine, Inc.**	
By:	/s/ Issi Rozen	By:	/s/ Cynthia Collins
Name:	Issi Rozen	Name:	Cynthia Collins
Title:	Chief Business Officer	Title:	President and Chief Executive Officer

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-3 No. 333-216528, 333-222266, 333-223596, and 333-239389) of Editas Medicine Inc.,

(2) Registration Statement (Form S-8 No. 333-209351) pertaining to the Editas Medicine Inc. 2013 Stock Incentive Plan, 2015 Stock Incentive Plan and 2015 Employee Stock Purchase Plan of Editas Medicine Inc., and

(3) Registration Statements (Form S-8 Nos. 333-216445, 333-223529, 333-230266, and 333-236662) pertaining to the 2015 Stock Incentive Plan and 2015 Employee Stock Purchase Plan of Editas Medicine, Inc.;

of our reports dated February 26, 2021, with respect to the consolidated financial statements of Editas Medicine, Inc. and the effectiveness of internal control over financial reporting of Editas Medicine, Inc., included in this Annual Report (Form 10-K) of Editas Medicine, Inc. for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 26, 2021

Exhibit 31.1

CERTIFICATIONS

I, James C. Mullen, certify that:

1. I have reviewed this Annual Report on Form 10-K of Editas Medicine, 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 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 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: February 26, 2021

By: /s/ James C. Mullen
James C. Mullen
Chief Executive Officer
Principal Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Michelle Robertson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Editas Medicine, 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 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 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: February 26, 2021

By: /s/ Michelle Robertson
Michelle Robertson
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

**CERTIFICATIONS OF CEO AND CFO 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 on Form 10-K of Editas Medicine, Inc. (the "Company") for the year ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. (section) 1350, as adopted pursuant to (section) 906 of the Sarbanes-Oxley Act of 2002, that to the best of her or his knowledge:

(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 results of operations of the Company.

Dated: February 26, 2021

By: /s/ James C. Mullen
James C. Mullen
President and Chief Executive Officer

By: /s/ Michelle Robertson
Michelle Robertson
Chief Financial Officer